



WELLFLEET

RX PLAN

Prior Authorization Guidelines

Please visit <https://wellfleetrx.com/electronic-prior-authorization/>
for information on submitting a prior authorization request.

PRIOR AUTHORIZATION GUIDELINES

ARIPIRAZOLE SENSOR TABS

Generic	Brand	HICL	GCN	Exception/Other
ARIPIRAZOLE TABLETS WITH SENSOR	ABILIFY MYCITE		44437 44438 44439 44441 44442 44443	

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Abilify MyCite is prescribed by or in consultation with a psychiatrist
- Physician attestation that the patient has a medical necessity for tracking medication ingestion

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ONE** of the following diagnoses?

- Diagnosis of schizophrenia
- Diagnosis of major depressive disorder (MDD) **AND** the request is for use as an adjunctive treatment

If yes, **approve for 12 months by GPID as follows:**

- **Abilify MyCite 2mg (GPID 44437): 1 kit per 30 days.**
- **Abilify MyCite 5mg (GPID 44438): 1 kit per 30 days.**
- **Abilify MyCite 10mg (GPID 44439): 1 kit per 30 days.**
- **Abilify MyCite 15mg (GPID 44441): 1 kit per 30 days.**
- **Abilify MyCite 20mg (GPID 44442): 1 kit per 30 days.**
- **Abilify MyCite 30mg (GPID 44443): 1 kit per 30 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of bipolar I disorder?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**ARIPIPRAZOLE SENSOR TABS****GUIDELINES FOR USE (CONTINUED)**4. Does the patient meet **ONE** of the following criteria?

- The request is for acute treatment of manic and mixed episodes as monotherapy, **OR** as an adjunct to lithium or valproate
- The request is for maintenance treatment as monotherapy, **OR** as an adjunct to lithium or valproate

If yes, **approve for 12 months by GPID as follows:**

- **Abilify MyCite 2mg (GPID 44437): 1 kit per 30 days.**
- **Abilify MyCite 5mg (GPID 44438): 1 kit per 30 days.**
- **Abilify MyCite 10mg (GPID 44439): 1 kit per 30 days.**
- **Abilify MyCite 15mg (GPID 44441): 1 kit per 30 days.**
- **Abilify MyCite 20mg (GPID 44442): 1 kit per 30 days.**
- **Abilify MyCite 30mg (GPID 44443): 1 kit per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ARIPIPRAZOLE SENSOR TABS (Abilify MyCite)** requires a diagnosis of schizophrenia, bipolar I disorder, or major depressive disorder. The patient must be 18 years of age or older, and the prescription must be prescribed by or in consultation with a psychiatrist, with physician attestation of medical necessity for medication ingestion tracking. In addition, the following criteria must be met:

For the diagnosis of major depressive disorder (MDD), approval requires:

- The request is for use as an adjunctive treatment

For the diagnosis of bipolar I disorder, approval requires ONE of the following:

- The request is for acute treatment of manic and mixed episodes as monotherapy, **OR** as an adjunct to lithium or valproate
- The request is for maintenance treatment as monotherapy, **OR** as an adjunct to lithium or valproate

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Abilify MyCite.

REFERENCES

- Abilify MyCite [Prescribing Information]. Redwood City, CA: Proteus Digital Health, Inc.: November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 02/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

CENEGERMIN-BKBJ

Generic	Brand	HICL	GCN	Exception/Other
CENEGERMIN-BKBJ	OXERVATE	45258		

GUIDELINES FOR USE

- Does the patient have a diagnosis of neurotrophic keratitis (NK) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with an ophthalmologist
 - The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
 - Physician attestation that patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
 - The patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

If yes, **approve for 8 weeks by HICL as follows:**

- If treatment is for 1 eye: #28 vials per 28 days per lifetime.**
- If treatment is for 2 eyes: #56 vials per 28 days per lifetime.**

If no, do not approve.

DENIAL TEXT: The guideline named **CENEGERMIN-BKBJ (Oxervate)** requires a diagnosis of neurotrophic keratitis. In addition, the following criteria must be met:

- Therapy is prescribed by or in consultation with an ophthalmologist
- The patient has a medical history supportive of causative etiology for trigeminal nerve damage (e.g., herpes zoster infection, multiple sclerosis, diabetes, ocular surgical damage)
- Physician attestation that patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
- The patient is refractory to conservative management (i.e., artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Oxervate.

REFERENCES

- Oxervate [Prescribing Information]. Boston, MA: Dompe U.S., Inc., August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 02/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR

Generic	Brand	HICL	GCN	Exception/Other
ELAPEGADEMASE-LVLR	REVCovi	45340		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as manifested by **ONE** of the following?

- Confirmatory genetic test
- Suggestive laboratory findings (e.g. elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) **AND** hallmark signs/symptoms (e.g. recurrent infections, failure to thrive, persistent diarrhea)

If yes, continue to #2.

If no, do not approve

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the requested medication prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders?

If yes, continue to #3.

If no, do not approve

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is there physician attestation that the patient meets **ONE** of the following criteria?

- The patient has failed or is not a candidate for hematopoietic cell transplantation (HCT)
- The requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires 1) documentation of trough plasma ADA activity greater than or equal to 30 mmol/hr/L and trough dAXP levels less than 0.02 mmol/L, **AND** 2) physician attestation of improvement in/maintenance of immune function from baseline, and patient has not received successful hematopoietic cell transplant (HCT) or gene therapy.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as manifested by ONE of the following:

- Confirmatory generic test, or
- Suggestive laboratory findings (e.g. elevated deoxyadenosine nucleotide [dAXP] levels, lymphopenia) AND hallmark signs/symptoms (e.g. recurrent infections, failure to thrive, persistent diarrhea)
- In addition, the following criteria must be met:
 - The requested medication is prescribed by or in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders
 - Physician attestation that the patient has failed or is not a candidate for hematopoietic cell transplant (HCT), OR the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant (HCT) or gene therapy

RENEWAL CRITERIA

1. Does the patient have a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) and meet **ALL** of the following criteria?
 - Documentation of trough plasma ADA activity ≥ 30 mmol/hr/L **AND** trough dAXP levels < 0.02 mmol/L
 - Physician attestation of improvement in/maintenance of immune function from baseline (e.g. decrease in number and severity of infections), **AND** patient has not received successful hematopoietic cell transplant (HCT) or gene therapy

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID). In addition, the following criteria must be met:

- Documentation of trough plasma ADA activity greater than or equal to 30 mmol/hr/L AND trough dAXP levels less than 0.02 mmol/L
- Physician attestation of improvement in/maintenance of immune function from baseline (e.g. decrease in number and severity of infections), AND patient has not received successful hematopoietic cell transplantation (HCT) or gene therapy

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PRIOR AUTHORIZATION GUIDELINES

ELAPEGADEMASE-LVLR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revcovi.

REFERENCES

- Revcovi [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences Inc., October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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PRIOR AUTHORIZATION GUIDELINES

GILTERITINIB

Generic	Brand	HICL	GCN	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		

GUIDELINES FOR USE

- Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **GILTERITINIB (Xospata)** requires a diagnosis of relapsed or refractory acute myeloid leukemia (AML). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES

- Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

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PRIOR AUTHORIZATION GUIDELINES

GLASDEGIB

Generic	Brand	HICL	GCN	Exception/Other
GLASDEGIB MALEATE	DAURISMO	45502		

GUIDELINES FOR USE

- Does the patient have a diagnosis of newly-diagnosed acute myeloid leukemia (AML) **AND** meet the following criterion?

- The requested medication will be used in combination with low-dose cytarabine

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Does the patient meet **ONE** of the following criteria?

- The patient is 75 years of age or older
- The patient has comorbidities that prevent use of intensive induction chemotherapy

If yes, **approve for 12 months by GPID as follows:**

- Daurismo 25mg (GPID 45797): #2 tablets per day.**
- Daurismo 100mg (GPID 45798): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **GLASDEGIB (Daurismo)** requires a diagnosis of newly-diagnosed acute myeloid leukemia (AML). In addition, the following criteria must be met:

- The requested medication will be used in combination with low-dose cytarabine
- The patient is 75 years of age or older, OR the patient has comorbidities that prevent use of intensive induction chemotherapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Daurismo.

REFERENCES

- Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

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P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Exception/Other
ITRACONAZOLE	TOLSURA		45848	

GUIDELINES FOR USE

- Is the patient 18 years of age or older and meets **ALL** of the following criteria?
 - The patient is diagnosed with **ONE** of the following types of fungal infections:
 - Blastomycosis, pulmonary and extrapulmonary
 - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
 - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy
 - Tolsura is prescribed by or in consultation with an Infectious Disease Specialist
 - The patient has had a previous trial of a generic itraconazole formulation
 - Physician attestation that Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

If yes, **approve for a total of 12 months by GPID (45848) as follows:**

- For requests that require a loading dose, enter both of the following approvals:**
 - FIRST APPROVAL:** approve for 1 month with a quantity limit of #126 capsules per 30 days for 1 fill.
 - SECOND APPROVAL:** approve for 11 months with a quantity limit of #120 capsules per 30 days (Please enter a start date of one day after the END date of the first approval).
- For requests that do NOT require a loading dose: approve for 12 months with a quantity limit of #120 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ITRACONAZOLE (Tolsura)** requires that the patient is 18 years of age or older. In addition, the following criteria must be met:

- The patient is diagnosed with **ONE** of the following fungal infections:
 - Blastomycosis, pulmonary and extrapulmonary
 - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
 - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy
- Tolsura is prescribed by or in consultation with an Infectious Disease Specialist
- The patient has had a previous trial of a generic itraconazole formulation
- Physician attestation that Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

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PRIOR AUTHORIZATION GUIDELINES**ITRACONAZOLE - TOLSURA****RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

REFERENCES

- Tolsura [Prescribing Information]. Greenville, NC: Mayne Pharma; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

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P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

LAROTRECTINIB

Generic	Brand	HICL	GCN	Exception/Other
LAROTRECTINIB	VITRAKVI	45494		

GUIDELINES FOR USE

- Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
 - The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
 - The tumor is metastatic or surgical resection is likely to result in severe morbidity
 - There are no satisfactory alternative treatments, or the patient has progressed following treatment

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Is the request for Vitrakvi oral capsules?

If yes, **approve for 12 months by GPID for all strengths as follows:**

- Vitrakvi 25mg (GPID 45793): #6 capsules per day.**
- Vitrakvi 100mg (GPID 45794): #2 capsules per day.**

If no, continue to #3.

- Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
 - The request is for a pediatric patient
 - Physician attestation that the patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
 - Physician attestation that the patient has other medical need for the oral solution

If yes, **approve for 12 months by GPID as follows:**

- Vitrakvi 20mg/mL oral solution (GPID 45789): #10mL per day.**

If no, do not approve Vitrakvi oral suspension. **Please enter a proactive PA for Vitrakvi capsules and approve for 12 months by GPID for all strengths as follows:**

- Vitrakvi 25mg (GPID 45793): #6 capsules per day.**
- Vitrakvi 100mg (GPID 45794): #2 capsules per day.**

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PRIOR AUTHORIZATION GUIDELINES**LAROTRECTINIB****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: The guideline named **LAROTRECTINIB (Vitrakvi)** requires a diagnosis of a solid tumor. In addition, the following criteria must be met:

- The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
- The tumor is metastatic or surgical resection is likely to result in severe morbidity
- There are no satisfactory alternative treatments, or the patient has progressed following treatment
- **Requests for Vitrakvi oral solution also requires that ONE of the following is met:**
 - The request is for a pediatric patient
 - Physician attestation that the patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
 - Physician attestation that the patient has other medical need for the oral solution

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

- Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

LORLATINIB

Generic	Brand	HICL	GCN	Exception/Other
LORLATINIB	LORBRENA	45448		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?

- Presence of anaplastic lymphoma kinase (ALK-) positive tumors

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Has the patient experienced disease progression on at least **ONE** of the following regimens?

- Crizotinib and at least one other ALK inhibitor for metastatic disease
- Alectinib as the first ALK inhibitor therapy for metastatic disease
- Ceritinib as the first ALK inhibitor therapy for metastatic disease

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

- Lorbrena 25 mg tablet (GPID 45687): #3 tablets per day.**
- Lorbrena 100mg tablet (GPID 45688): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **LORLATINIB (Lorbrena)** requires a diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC). In addition, approval requires that the patient has experienced disease progression on at least ONE of the following regimens:

- Crizotinib and at least one other ALK inhibitor for metastatic disease
- Alectinib as the first ALK inhibitor therapy for metastatic disease
- Ceritinib as the first ALK inhibitor therapy for metastatic disease

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lorbrena.

REFERENCES

- Lorbrena [Prescribing Information]. New York, NY : Pfizer, Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

Generic	Brand	HICL	GCN	Exception/Other
RIBOCICLIB	KISQALI	44151		
RIBOCICLIB LETROZOLE	KISQALI FEMARA CO- PACK	44246		

GUIDELINES FOR USE

1. Is the request for Kisqali-Femara Co-Pack?

If yes, continue to #2.

If no, continue to #5.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?

- The patient is female
- The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
- The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient pre/perimenopausal?

If yes, **approve Kisqali-Femara Co-Pack for 12 months by GPID for all daily dosage strengths with the following quantity limits:**

- **200mg daily dose (Co-Pack) (GPID 43366): #49 tablets per 28 days.**
- **400mg daily dose (Co-Pack) (GPID 43368): #70 tablets per 28 days.**
- **600mg daily dose (Co-Pack) (GPID 43369): #91 tablets per 28 days.**

If no, continue to #4.

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PRIOR AUTHORIZATION GUIDELINES**RIBOCICLIB****GUIDELINES FOR USE (CONTINUED)**

4. Is the patient post-menopausal **AND** meets the following criterion?
- The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

If yes, **approve Kisqali-Femara Co-Pack for 12 months by GPID for all daily dosage strengths with the following quantity limits:**

- **200mg daily dose (Co-Pack) (GPID 43366): #49 tablets per 28 days.**
- **400mg daily dose (Co-Pack) (GPID 43368): #70 tablets per 28 days.**
- **600mg daily dose (Co-Pack) (GPID 43369): #91 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for Kisqali?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline

6. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?
- The patient is female
 - The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
 - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
 - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

If yes, continue to #7.

If no, continue to #9.

7. Is the patient pre/perimenopausal?

If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**

- **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
- **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
- **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

If no, continue to #8.

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PRIOR AUTHORIZATION GUIDELINES**RIBOCICLIB****GUIDELINES FOR USE (CONTINUED)**

8. Is the patient post-menopausal **AND** meets the following criterion?

- The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**

- **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
- **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
- **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?

- The patient is female and postmenopausal
- The requested medication will be used in combination with Faslodex (fulvestrant)
- The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy

If yes, continue to #10.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

10. Is the request for a patient that has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)?

If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**

- **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
- **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
- **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

If no, continue to #11.

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PRIOR AUTHORIZATION GUIDELINES

RIBOCICLIB

GUIDELINES FOR USE (CONTINUED)

11. Is the request for a patient that has experienced disease progression on endocrine therapy **AND** meets the following criterion?

- The patient had a trial of Ibrance (palbociclib) **OR** Verzenio (abemaciclib)

If yes, **approve Kisqali for 12 months by GPID for all daily dosage strengths with the following quantity limits:**

- **200mg daily dose (GPID 43162): #21 tablets per 28 days.**
- **400mg daily dose (GPID 43166): #42 tablets per 28 days.**
- **600mg daily dose (GPID 43167): #63 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative. In addition, the following criteria must be met:

For Kisqali-Femara Co-Pack request, approval requires:

- The patient is female
- The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
- The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
- The patient meets **ONE** of the following:
 - The patient is pre/perimenopausal
 - The patient is post-menopausal and has had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

For Kisqali request, approval requires ONE of the following:

- **Kisqali will be used in combination with an aromatase inhibitor and meet all of the following:**
 - The patient is female
 - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
 - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
 - The patient meets **ONE** of the following:
 - The patient is pre/perimenopausal
 - The patient is post-menopausal and has had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

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PRIOR AUTHORIZATION GUIDELINES**RIBOCICLIB****GUIDELINES FOR USE (CONTINUED)**

- **Kisqali will be used in combination with Faslodex (fulvestrant) and meet all of the following:**
 - The patient is female and post-menopausal
 - The patient has **NOT** experienced disease progression following prior CDK inhibitor therapy
 - The patient meets **ONE** of the following:
 - The patient has **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
 - The patient has experienced disease progression on endocrine therapy **AND** has had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kisqali or Kisqali/Femara Co-Pack.

REFERENCES

- Kisqali [Prescribing Information]. East Hanover, NJ. Novartis; July 2018.
- Kisqali/Femara Co-Pack [Prescribing Information]. East Hanover, NJ. Novartis; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 05/17

Client Approval: 03/19

P&T Approval: 01/19

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ABALOPARATIDE

Generic	Brand	HICL	GCN	Exception/Other
ABALOPARATIDE	TYMLOS	44231		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis AND meet **ONE** of the following criteria?

-) High risk for fractures defined as ONE of the following:
 - o History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - o 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
 - o No prior treatment for osteoporosis AND FRAX score 20% for any major fracture OR 3% for hip fracture
-) Unable to use oral therapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
-) The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received a total of 24 months of parathyroid hormone therapy (e.g., Tymlos, Forteo)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 12 months by HICL with a quantity limit of #1.56 mL (#1 - 3120 mcg/1.56 mL prefilled pen) per 30 days.**

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ABALOPARATIDE****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: The guideline named **ABALOPARATIDE (Tymlos)** requires that the patient has a diagnosis of postmenopausal osteoporosis and has not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo. In addition, one of the following criteria must be met:

-) High risk for fractures defined as ONE of the following:
 - o History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - o 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
 - o No prior treatment for osteoporosis AND FRAX score 20% for any major fracture OR 3% for hip fracture
-) Unable to use oral therapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
-) The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

RATIONALE

To ensure safe and appropriate use of abaloparatide per approved indication and dosing and national treatment guidelines.

FDA APPROVED INDICATIONS

Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.

DOSAGE AND ADMINISTRATION

The recommended dosage of Tymlos is 80 mcg subcutaneously once daily. Cumulative use of Tymlos and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended. Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ABALOPARATIDE****REFERENCES**

-) Tymlos [Prescribing Information]. Waltham, MA: Radius Health, Inc.; 2017.
-) Miller PD, Hattersley G, Riis BJ, et al. Effect of abaloparatide vs placebo on new vertebral fractures in postmenopausal women with osteoporosis: a randomized clinical trial. *JAMA*. 2016;316:722-33.
-) American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Accessed online April 13, 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/19/18

Created: 04/17

Client Approval: 02/18

P&T Approval: 04/17

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ABEMACICLIB

Generic	Brand	HICL	GCN	Exception/Other
ABEMACICLIB	VERZENIO	44537		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) and meet **ALL** of the following criteria?

- ☐ The patient is female
- ☐ The medication will be used in combination with fulvestrant
- ☐ The patient has had disease progression following endocrine therapy
- ☐ The patient has NOT experienced disease progression following prior CDK inhibitor therapy (e.g., Ibrance)

If yes, **approve for 12 months by HICL with a quantity limit of #56 tablets (four 7-day dose packs) per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) and meet **ALL** of the following criteria?

- ☐ The medication will be used as monotherapy
- ☐ The patient is 18 years of age or older
- ☐ The patient has had disease progression following endocrine therapy AND prior chemotherapy in the metastatic setting
- ☐ The patient has NOT experienced disease progression following prior CDK inhibitor therapy (e.g., Ibrance)

If yes, **approve for 12 months by HICL with a quantity limit of #56 tablets (four 7-day dose packs) per 28 days.**

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) and meet **ALL** of the following criteria?

- ☐ The patient is a female and postmenopausal
- ☐ The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
- ☐ The patient has NOT received prior endocrine therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
- ☐ The patient has NOT experienced disease progression following prior CDK inhibitor therapy

If yes, **approve for 12 months by HICL with a quantity limit of #56 tablets (four 7-day dose packs) per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ABEMACICLIB (Verzenio)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-). In addition, **ONE** of the following criteria must be met:

The medication will be used in combination with fulvestrant and meet ALL of the following:

- ☐ The patient is female
- ☐ The patient has had disease progression following endocrine therapy
- ☐ The patient has NOT experienced disease progression following prior CDK inhibitor therapy

The medication will be used as monotherapy and meet ALL of the following:

- ☐ The patient is 18 years of age or older
- ☐ The patient has had disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
- ☐ The patient has NOT experienced disease progression following prior CDK inhibitor therapy

The medication will be used in combination with an aromatase inhibitor and meet ALL of the following:

- ☐ The patient is a female and postmenopausal
- ☐ The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
- ☐ The patient has NOT received prior endocrine therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
- ☐ The patient has NOT experienced disease progression following prior CDK inhibitor therapy

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ABEMACICLIB****RATIONALE**

Promote appropriate utilization of **ABEMACICLIB** (Verzenio) based on FDA approved indications.

FDA APPROVED INDICATIONS

Verzenio is a kinase inhibitor indicated:

-) In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy
-) As monotherapy for the treatment of adult patients with HR positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.
-) In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

DOSAGE AND ADMINISTRATION

When used in combination with fulvestrant or an aromatase inhibitor, the recommended dose of Verzenio is 150 mg taken orally twice daily. When given with Verzenio, the recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29; and once monthly thereafter.

Pre/perimenopausal women treated with the combination of Verzenio plus fulvestrant should be treated with a gonadotropin-releasing hormone agonist according to current clinical practice standards.

When used as monotherapy, the recommended dose of Verzenio is 200 mg taken orally twice daily.

When given with VERZENIO, refer to the Full Prescribing Information for the recommended dose of the aromatase inhibitor being used.

Continue treatment until disease progression or unacceptable toxicity. Verzenio may be taken with or without food. Instruct patients to take their doses of Verzenio at approximately the same times every day. If the patient vomits after taking the dose, or misses a dose, no additional dose should be taken that day. The next prescribed dose should be taken at the usual time. Verzenio tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing). No tablet should be ingested if it is broken, cracked, or otherwise not intact.

The recommended Verzenio dose modifications for adverse reactions are provided in the table below.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ABEMACICLIB****FDA APPROVED INDICATIONS (CONTINUED)****DOSAGE AND ADMINISTRATION**

Dose Level	Verzenio Dose in Combination with Fulvestrant or an Aromatase Inhibitor	Verzenio Dose for Monotherapy
Recommended starting dose	150 mg twice daily	200 mg twice daily
First dose reduction	100 mg twice daily	150 mg twice daily
Second dose reduction	50 mg twice daily	100 mg twice daily
Third dose reduction	Not applicable	50 mg twice daily*

*If further dose reduction below 50 mg twice daily is required, discontinue the treatment.

Avoid concomitant use of the strong CYP3A inhibitor ketoconazole.

AVAILABLE STRENGTHS

Tablets: 50 mg, 100 mg, 150 mg, and 200 mg

REFERENCES

) Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 10/17

Client Approval: 03/16

P&T Approval: 04/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ACALABRUTINIB**

Generic	Brand	HICL	GCN	Exception/Other
ACALABRUTINIB	CALQUENCE	44607		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mantle cell lymphoma (MCL) and meet **ALL** of the following criteria?

-) The patient is 18 years of age or older
-) The patient has received at least one prior therapy for mantle cell lymphoma (MCL)

If yes, **approve for 12 months by HICL with a quantity limit of #60 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ACALABRUTINIB (Calquence)** requires a diagnosis of mantle cell lymphoma (MCL) and the following criteria must also be met:

-) The patient is 18 years of age or older
-) The patient has received at least one prior therapy for mantle cell lymphoma (MCL)

RATIONALE

To promote appropriate utilization of Calquence based on FDA approved indication.

FDA APPROVED INDICATIONS

Calquence is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSING AND ADMINISTRATION

The recommended dose of Calquence is 100 mg taken orally approximately every twelve hours until disease progression or unacceptable toxicity.

Patients should swallow capsule whole with water. Patients should not open, break or chew the capsules. Calquence may be taken with or without food. If a dose of Calquence is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra capsules of Calquence should not be taken to make up for a missed dose.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ACALABRUTINIB

REFERENCES

) Calquence [Prescribing Information]. AstraZeneca Pharmaceuticals: Wilmington, DE; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 02/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ACETAMINOPHEN DAILY LIMIT OVERRIDE**

Generic	Brand	HICL	GCN	Exception/other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the patient taking a dose of the requested drug in an amount exceeding 4000mg of acetaminophen per day?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Is the requested medication being taken together with other acetaminophen containing product(s) and the combination will exceed 4000mg of acetaminophen per day?

If yes, continue to #3.

If no, **approve for ONE FILL count by GPID for the requested medication and set override type MAXINGREDIENTDOSE to a value of "Y"**.

3. Will the patient discontinue the concurrent acetaminophen containing drug(s) that place the patient over 4000mg of acetaminophen per day?

If yes, **approve for ONE FILL count by GPID for the requested medication and set override type MAXINGREDIENTDOSE to a value of "Y"**.

If no, do not approve.

DENIAL TEXT: The guideline named **ACETAMINOPHEN DAILY LIMIT OVERRIDE** will cause a claim for acetaminophen to deny when the dose of 4000mg of acetaminophen per day is exceeded. The claim will also deny if the requested drug is being used concurrently with other acetaminophen containing product(s) that exceed 4000mg of acetaminophen per day limit. An approval will be provided if the patient will discontinue the concurrent acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ACETAMINOPHEN DAILY LIMIT OVERRIDE****RATIONALE**

To ensure appropriate use of acetaminophen products and address overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. The maximum daily dose for an adult is 4000 mg. However, in some people, taking the maximum daily dose or more for an extended period of time can lead to serious liver damage.

A claim may reject at POS due to exceeding the acetaminophen daily limit as a result of concurrent use with other acetaminophen products. An approval is granted if the the concurrent acetaminophen containing product will be discontinued. In some cases, the member's history claim may have an incorrect day supply due to a pharmacy error. This will cause the new claim to reject at POS for exceeding the acetaminophen daily limit. This is addressed in question #2.

REFERENCES

-) "FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure". January 13, 2011. Available at <https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm> [Accessed 12/3/18].
-) "Medicare Part D Overutilization Monitoring System – Updates". October 25, 2013. Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoMedicare-Part-D-OMS-Updates-10-25-13.pdf> [Accessed 12/3/18].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 12/18

Client Approval: 12/18

P&T Approval: 01/19

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ADHD AGE RESTRICTION OVERRIDE

Generic	Brand	HICL	GCN	Exception/Other
AMPHET ASP/AMPHET/D-AMPHET (AMPHETAMINE SALTS)	ADDERALL XR		14635	
			14636	
			14637	
			17459	
			17468	
			17469	
DEXMETHYLPHENIDATE HCL	FOCALIN XR		24733	
			24734	
			24735	
			28035	
			28933	
			30305	
			30306	
			97111	
METHYLPHENIDATE HCL	CONCERTA		12248	
			12567	
			12568	
			17123	
	METADATE CD		13176	
			26734	
			26735	
			26736	
			20384	
	RITALIN LA		21763	
			20387	
			20388	
			20391	
			36195	
	METADATE ER RITALIN-SR		16180	
	METHYLIN ER		93075	
	METHYLPHENIDATE ER		44239	

GUIDELINES FOR USE

1. Is the request for an age restriction override?

If yes, continue to #2.

If no, guideline does not apply.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ADHD AGE RESTRICTION OVERRIDE

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have a diagnosis of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD)?

If yes, continue to #4.

If no, continue to #3.

3. Does the patient have a diagnosis of narcolepsy?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient previously been on **ONE** of these extended release stimulants (Adderall XR, Concerta, Focalin XR, Metadate CD, Metadate ER, Methylin ER, Ritalin-SR, or Ritalin LA) as a pediatric patient (i.e., the patient was on the product when the patient was under 18 years of age)?

If yes, **approve for 12 months by GPID with quantity limits. Do not override quantity limits.** (NOTE: Please analyze claim to verify allowable quantity limits per coding. If the request is for a quantity limit override, please defer to a pharmacist for further review. Quantity Exception overrides must be reviewed by a pharmacist.)

If no, continue to #5.

5. Has the patient had a previous trial of or contraindication to a generic immediate release stimulant (e.g., dextroamphetamine, methylphenidate or amphetamine/dextroamphetamine mixture)?

If yes, **approve for 12 months by GPID with quantity limits. Do not override quantity limits.** (NOTE: Please analyze claim to verify allowable quantity limits per coding. If the request is for a quantity limit override, please defer to a pharmacist for further review. Quantity Exception overrides must be reviewed by a pharmacist.)

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ADHD AGE RESTRICTION OVERRIDE****GUIDELINES FOR USE (CONTINUED)**

6. Is the request for methylphenidate 20mg ER tablet (Ritalin-SR, Metadate ER, Methylin ER) or methylphenidate 10mg ER tablet (Methylin ER)?

If yes, **approve for 12 months by GPID with quantity limits. Do not override quantity limits.** (NOTE: Please analyze claim to verify allowable quantity limits per coding. If the request is for a quantity limit override, please defer to a pharmacist for further review. Quantity Exception overrides must be reviewed by a pharmacist.)

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: This medication is available on the formulary for the treatment of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) in patients who are age 18 years and older who have been receiving the medication as a pediatric patient or had a previous trial or contraindication to a generic immediate-release stimulant. Additionally, Metadate ER, Ritalin-SR, and Methylin ER may be approved for the treatment of narcolepsy.

RATIONALE

Ensure appropriate use of CNS stimulants.

FDA APPROVED INDICATIONS

All medications on this guideline have FDA approval for ADHD. Metadate ER, Ritalin-SR, and Methylin ER have FDA approval for narcolepsy.

REFERENCES

-) Micromedex Vol 126.
-) Pliszka S. Practice parameter for the assessment and treatment of children and adolescents with attention deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry 2007; 46 (7): 894-921.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/01/18

Created: 08/11

Client Approval: 01/18

P&T Approval: 02/16

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AFATINIB

Generic	Brand	HICL	GCN	Exception/Other
AFATINIB DIMALATE	GILOTRIF	40478		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
) Disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

 If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
 If no, continue to #2.
- Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
) The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test

 If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
 If no, do not approve.
DENIAL TEXT: The guideline named **AFATINIB (Gilotrif)** requires a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) or metastatic non-small cell lung cancer (NSCLC). The following criteria must also be met:
For the diagnosis of metastatic squamous non-small cell lung cancer (NSCLC), approval requires:
) Disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin).
For the diagnosis of metastatic non-small cell lung cancer, approval requires:
) Patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****AFATINIB****RATIONALE**

Promote appropriate utilization of **Afatinib** based on FDA approved indications.

FDA APPROVED INDICATIONS

Gilotrif is a kinase inhibitor indicated for:

- J First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.
 - o Limitation of Use: The safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant EGFR mutations.
- J Treatment of patients with metastatic, squamous NSCLC progressing after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION

The recommended dose of Gilotrif is 40 mg orally once daily until disease progression or no longer tolerated by the patient. Take Gilotrif at least 1 hour before or 2 hours after a meal.

For patients who require therapy with a P-glycoprotein (P-gp) inhibitor, *reduce* Gilotrif daily dose by 10 mg if not tolerated. Resume the previous dose after discontinuation of the P-gp inhibitor as tolerated.

For patients who require chronic therapy with a P-gp inducer, *increase* Gilotrif daily dose by 10 mg as tolerated. Resume the previous dose 2 to 3 days after discontinuation of the P-gp inducer.

Reduce dose to 30mg daily in patients with severe renal impairment (eGFR 15 to 29 ml/min).

Withhold Gilotrif in patients with NCI CTCAE Grade 3 or higher, diarrhea of Grade 2 or higher persisting for 2 or more consecutive days while taking anti-diarrheal medication, cutaneous reactions of Grade 2 that are prolonged (lasting more than 7 days) or intolerable, or renal impairment of Grade 2 or higher. Resume treatment when the adverse reaction fully resolves, returns to baseline, or improves to Grade 1, and resume at a reduced dose of 10mg per day less than the dose at which the adverse reaction occurred.

Permanently discontinue for life-threatening bullous, blistering, or exfoliative skin lesions, confirmed interstitial lung disease, severe drug-induced hepatic impairment, persistent ulcerative keratitis, symptomatic left ventricular dysfunction, and severe or intolerable adverse reaction occurring at a dose of 20 mg per day.

HOW SUPPLIED

Tablets: 40 mg, 30 mg, and 20 mg

CONTINUED ON NEXT PAGE

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AFATINIB

REFERENCES

) Gilotrif (afatinib) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.; Ridgefield, CT. January 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/05/18

Created: 10/13

Client Approval: 01/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ALECTINIB**

Generic	Brand	HICL	GCN	Exception/Other
ALECTINIB	ALECENSA	42895		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
 -) Patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test

If yes, **approve for 12 months by HICL with a quantity limit of #240 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ALECTINIB (Alecensa)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA-approved test.

RATIONALE

Promote appropriate utilization of ALECTINIB based on its FDA approved indication.

FDA APPROVED INDICATIONS

Alecensa is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION

The recommended dose of Alecensa is 600 mg orally twice daily with food. Alecensa therapy is continued until disease progression or unacceptable toxicity.

The dose of Alecensa can be modified if certain adverse reactions or laboratory abnormalities occur (e.g., elevated hepatic transaminases, bradycardia, elevated CPK). The dose should be reduced first to 450 mg twice daily, then to 300 mg twice daily, and discontinued if intolerability persists thereafter. If treatment-related ILD/pneumonitis, elevated ALT or AST greater than 3 times ULN with total bilirubin greater than 2 times ULN in the absence of cholestasis or hemolysis, grade 4 renal impairment, or life-threatening bradycardia occurs, Alecensa should be permanently discontinued.

The contents of the capsule should not be opened or dissolved. If a dose is missed or vomiting occurs after taking a dose, the next dose should be taken at the scheduled time.

REFERENCES

-) Alecensa [Prescribing Information]. South San Francisco, CA: Genentech, Inc. November 2017.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALECTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/18

Created: 12/15
Client Approval: 12/17

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALISKIREN AND ALISKIREN COMBINATION AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ALISKIREN HEMIFUMARATE	TEKTURNA		98076 98077	
ALISKIREN/AMLOD IPINE	TEKAMLO		28974 28975 28976 28977	
ALISKIREN/AMLOD IPINE/HCTZ	AMTURNIDE		29393 29394 29395 29396 29397	
ALISKIREN/HYDRO CHLOROTHIAZIDE	TEKTURNA HCT		99310 99311 99312 99313	
ALISKIREN/VALSA RTAN	VALTURNA		27642 27643	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of diabetes mellitus?

If yes, continue to #2.

If no, **approve for 12 months by GPID for #1 tablet per day.**

2. Is the patient currently taking an ACE inhibitor (e.g., benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, or trandolapril) or an angiotensin receptor blocker (ARB) (e.g., azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan, or an ARB-HCTZ combination)?

If yes, do not approve.

DENIAL TEXT: Approval requires that patients with a diagnosis of diabetes mellitus are not currently taking an angiotensin converting enzyme inhibitor (ACE) or an angiotensin receptor blocker (ARB) medication.

If no, **approve for 12 months by GPID for #1 tablet per day.**

RATIONALE

To Promote use of Aliskiren in accordance with the FDA safety warning and package insert contraindications.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ALISKIREN AND ALISKIREN COMBINATION AGENTS****FDA APPROVED INDICATIONS**

Tekturna, Tekamlo, Amturnide, and Tekturna HCT are indicated to treat hypertension.

OTHER INFORMATION

On April 20, 2012 the U.S. Food and Drug Administration (FDA) released a safety announcement regarding medications containing aliskiren when used in combination with angiotensin converting enzyme inhibitors (ACE) or angiotensin receptor blocker (ARB) therapy in diabetics or those with renal impairment.

A randomized, double-blind, placebo controlled, parallel-group clinical trial (Aliskiren Trial in Type 2 diabetes using Cardio-renal Endpoints (ALTITUDE)) examined aliskiren 300mg daily versus placebo in 8,606 high risk patients with type 2 diabetes already taking baseline ACE or ARB therapy. The trial was terminated in December 2011 due to increased adverse events in the group taking aliskiren. A higher incidence of certain adverse events was found in the aliskiren group versus the placebo group. Individuals in the aliskiren group were also at a slightly higher risk for death or stroke. However, at this time, the FDA has not reached a final conclusion regarding whether a link exists between aliskiren-containing drugs and death or stroke.

Adverse events in the ALTITUDE clinical trial		
	Aliskiren group	Placebo group
Decline in renal function	12.4%	10.4%
Hypotension	18.6%	14.8%
Hyperkalemia	36.9%	27.1%
Non-fatal stroke	2.7%	2.0%

Currently marketed medications containing aliskiren include Tekturna (aliskiren), Tekturna HCT (aliskiren/hctz), Amturnide (aliskiren/amlodipine/hctz), Tekamlo (aliskiren/amlodipine), and Valturna (aliskiren/valsartan). At this time, Novartis has planned to voluntarily withdraw Valturna from the market in July 2012. The labeling of other aliskiren-containing medications has been changed to reflect a contraindication for combination use of aliskiren with ARB or ACE inhibitors in patients with diabetes, and this combination should be avoided in patients with renal impairment (GFR<60mL/min).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ALISKIREN AND ALISKIREN COMBINATION AGENTS****REFERENCES**

-) Novartis. Amturnide prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: <http://www.pharma.us.novartis.com/product/pi/pdf/amturnide.pdf>
-) Novartis. Tekamlo prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: <http://www.pharma.us.novartis.com/product/pi/pdf/tekamlo.pdf>
-) Novartis. Tekturna prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: <http://www.pharma.us.novartis.com/product/pi/pdf/tekturna.pdf>
-) Novartis. Tekturna HCT prescribing information. East Hanover, NJ. March 2012. Accessed online May 2012: http://www.pharma.us.novartis.com/product/pi/pdf/tekturna_hct.pdf
-) U.S. Food and Drug Administration (FDA) Safety Warning. Accessed online April 2012: <http://www.fda.gov/Drugs/DrugSafety/ucm300889.htm>

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/12/15

Created: 05/12

Client Approval: 08/15

P&T Approval: 05/12

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-HOUSE DUST MITE

Generic	Brand	HICL	GCN	Exception/Other
HOUSE DUST MITE	ODACTRA		42527	ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis and meet **ALL** of the following criteria?
 -) Diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
 -) Patient is between 18 and 65 years old
 -) The medication is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
 -) The patient has persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
 -) The patient has moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
 -) The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet (12 SQ-HDM) per day.**

APPROVAL TEXT: Renewal requires an improvement in signs and symptoms of allergic rhinitis from baseline.

If no, do not approve.

DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires a diagnosis of house dust mite (HDM)-induced allergic rhinitis with or without conjunctivitis. The following criteria must also be met:

-) Diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
-) Patient is between 18 and 65 years old
-) The medication is prescribed by or in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
-) The patient has persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)

(Initial denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-HOUSE DUST MITE

INITIAL CRITERIA (CONTINUED)

-)] The patient has moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
-)] The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet (12 SQ-HDM) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline for renewal.

RATIONALE

Promote clinically appropriate utilization of Odactra based on its FDA approved indications.

FDA APPROVED INDICATION

Odactra is an allergen extract indicated as immunotherapy for house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in adults 18 through 65 years of age.

DOSAGE AND ADMINISTRATION

One tablet (12 SQ-HDM) daily. For sublingual use only.

Administer the first dose of Odactra in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. After receiving the first dose of Odactra, observe the patient for at least 30 minutes to monitor for signs or symptoms of a severe systemic or a severe local allergic reaction. If the patient tolerates the first dose, the patient may take subsequent doses at home.

REFERENCES

-)] Odactra [Prescribing Information]. Merck, Sharp & Dohme Corp. Whitehouse Station, NJ. March 2017.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-HOUSE DUST MITE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18

Created: 02/18
Client Approval: 02/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-MIXED GRASS POLLEN

Generic	Brand	HICL	GCN	Exception/Other
GR POL-ORC/SW VER/RYE/KENT/TIM	ORALAIR	39918		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of grass pollen-induced allergic rhinitis that is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for any of the five grass (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens) species included in Oralair?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Was Oralair prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-MIXED GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

5. Is the patient at least 10 years of age?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Is the patient at least 18 years of age?

If yes, **approve for 12 months by GPID for a quantity limit of #1 tablet (300 IR) per day.**

If no, **approve for 12 months by GPID for a quantity limit of #3 tablets of 100 IR for the first 2 days of therapy initiation and #1 tablet of 300 IR per day thereafter.**

INITIAL DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires a diagnosis of grass pollen-induced allergic rhinitis and a positive skin prick test and/or a positive titre to specific IgE antibodies for any of the five grass species (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens) included in Oralair; product must be prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases; presentation of persistent and moderate-to-severe symptoms of allergic rhinitis; age of at least 10 years old; and a current claim or prescription for auto-injectable epinephrine.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by GPID for a quantity limit of #1 tablet (300IR or 100 IR) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ALLERGEN EXTRACT-MIXED GRASS POLLEN**

RATIONALE

Promote appropriate utilization of Oralair based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma).

Oralair is the first allergen-specific immunotherapy agent with FDA approval for sublingual use in the United States. The approval of oral allergen immunotherapy for allergic rhinitis provides a convenient and safe alternative to customary allergy shots. Oralair improves symptoms of allergic rhinoconjunctivitis and reduces use of rescue medication in adults and children. Allergen immunotherapy should be considered in patients who have persistent and moderate to severe symptoms despite pharmacotherapy, patients who experience intolerable side effects to medications, and those desiring to limit cost burden associated with chronic medication use. According to ARIA guidelines, persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate to severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work.

Side effects of Oralair are considered mild, with the majority of adverse events involving oral pruritus (25.1%) and throat irritation (22.0%) in adults. There were no reports of death or anaphylaxis during clinical trials.

Oralair has a black box warning that cites the following: Oralair can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema; Do not administer Oralair to patients with severe, unstable or uncontrolled asthma; Observe patients in the office for at least 30 minutes following the initial dose; Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use; Oralair may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction; Oralair may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

DOSAGE

For adults 18 through 65 years of age, the dose is 300 IR daily.

For children and adolescents 10 through 17 years of age, the dose is increased over the first three days (day 1 = 1 x 100 IR, day 2 = 2 x 100 IR, day 3 = 1 x 300 IR).

FDA APPROVED INDICATIONS

Oralair (5-Grass Pollen Allergy Extract Sublingual tablet containing Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass) is indicated for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in Oralair, in people ages 10 through 65 years.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-MIXED GRASS POLLEN

REFERENCES

-) Brozek JL, Bousquet J, Baena-Cagnani CE, Bonini S, Canonica GW, Casale TB, et al. Allergic Rhinitis and Its Impact on Asthma (ARIA) guidelines: 2010 revision. J Allergy Clin Immunol. 2010;126:466–476
-) GREER Laboratories, Inc. Oralair Package Insert. Lenoir, NC. October 2014

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 05/14

Client Approval: 02/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

Generic	Brand	HICL	GCN	Exception/Other
WEED POLLEN-SHORT RAGWEED	RAGWITEK	41079		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of ragweed pollen-induced allergic rhinitis that is confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Was Ragwitek prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does patient have a current claim or prescription for auto-injectable epinephrine?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

INITIAL CRITERIA (CONTINUED)

5. Is the patient at least 18 years of age?

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet (12 Amb a 1-U) per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

INITIAL DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires a diagnosis of short ragweed pollen-induced allergic rhinitis and a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen; product must be prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases; presentation of persistent and moderate-to-severe symptoms of allergic rhinitis; age of at least 18 years old; and a current claim or prescription for auto-injectable epinephrine.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet (12 Amb a 1-U) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ALLERGEN EXTRACT-SHORT RAGWEED POLLEN**

RATIONALE

Promote appropriate utilization of Ragwitek based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma).

Ragwitek is a ragweed allergen-specific immunotherapy agent with FDA approval for sublingual use. The approval of oral allergen immunotherapy for allergic rhinitis provides a convenient and safe alternative to customary allergy shots. Ragwitek improves symptoms of allergic rhinoconjunctivitis and reduces use of rescue medication in adults. Allergen immunotherapy should be considered in patients who have persistent and moderate to severe symptoms despite pharmacotherapy, patients who experience intolerable side effects to medications, and those desiring to limit cost burden associated with chronic medication use. According to ARIA guidelines, persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate to severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work.

Side effects are considered mild, with the majority of adverse events involving throat irritation (16.6% Ragwitek, 3.3% placebo), oral pruritus (10.9% Ragwitek, 2.0% placebo), ear pruritus (10.4% Ragwitek, 1.1% placebo), and oral paresthesia (10.1% Ragwitek, 4.0% placebo). One subject (1/1057, 0.1%) who received Ragwitek experienced anaphylaxis which led to discontinuation from the trial. The subject fully recovered after treatment with epinephrine, antihistamines, and oral corticosteroids. There were no reports of death during clinical trials.

Ragwitek has a black box warning that cites the following: Ragwitek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction; Do not administer Ragwitek to patients with severe, unstable or uncontrolled asthma; Observe patients in the office for at least 30 minutes following the initial dose; Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use; Ragwitek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction; Ragwitek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

DOSAGE

For adults 18 through 65 years of age, the dose is 1 tablet (12 Amb a 1-U) daily.

FDA APPROVED INDICATIONS

Ragwitek (short ragweed pollen extract) approved and indicated for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by a positive skin prick test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen in adults 18 years through 65 years of age.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

REFERENCES

-) Brozek JL, Bousquet J, Baena-Cagnani CE, Bonini S, Canonica GW, Casale TB, et al. Allergic Rhinitis and Its Impact on Asthma (ARIA) guidelines: 2010 revision. J Allergy Clin Immunol. 2010;126:466–476.
-) Merck, Sharp & Dohme Corp. Ragwitek Package Insert. Whitehouse Station, NJ. April 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 05/14

Client Approval: 02/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

Generic	Brand	HICL	GCN	Exception/Other
GRASS POLLEN-TIMOTHY, STD	GRASTEK	22138		ROUTE = SUBLINGUAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of grass pollen-induced allergic rhinitis that is confirmed by a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens?

 If yes, continue to #2.
 If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.
- Was Grastek prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases?

 If yes, continue to #3.
 If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.
- Does the patient have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include one or more of the following: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)?

 If yes, continue to #4.
 If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.
- Does patient have a current claim or prescription for auto-injectable epinephrine within the past 365 days?

 If yes, continue to #5.
 If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

INITIAL CRITERIA (CONTINUED)

5. Is the patient at least 5 years of age?

If yes, **approve for 12 months by HICL for a quantity limit of #1 tablet (2800 BAU) per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires a diagnosis of grass pollen-induced allergic rhinitis and a positive skin prick test and/or a positive titre to specific IgE antibodies for Timothy grass or cross-reactive grass pollens; product must be prescribed or recommended by an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases; presentation of persistent and moderate-to-severe symptoms of allergic rhinitis; age of at least 5 years old; and a current claim or prescription for auto-injectable epinephrine.

RENEWAL CRITERIA

1. Has the patient experienced an improvement in signs and symptoms of allergic rhinitis from baseline?

If yes, **approve for 12 months by HICL for a quantity limit of #1 tablet (2800 BAU) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires that the patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline.

RATIONALE

Promote appropriate utilization of Grastek based on FDA approved indication, dosage, and guidelines adopted from ARIA (Allergic Rhinitis and its Impact on Asthma).

Grastek is a grass allergen-specific immunotherapy agent with FDA approval for sublingual use. The approval of oral allergen immunotherapy for allergic rhinitis provides a convenient and safe alternative to customary allergy shots. Grastek improves symptoms of allergic rhino conjunctivitis and reduces use of rescue medication in adults and children. Allergen immunotherapy should be considered in patients who have persistent and moderate to severe symptoms despite pharmacotherapy, patients who experience intolerable side effects to medications, and those desiring to limit cost burden associated with chronic medication use. According to ARIA guidelines, persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate to severe symptoms include one or more of the following items: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN****RATIONALE (CONTINUED)**

Side effects are considered mild, with the majority of adverse events involving oral pruritus (26.7% Grastek, 3.5% placebo), throat irritation (22.6% Grastek, 2.8% placebo), ear pruritus (12.5% Grastek, 1.1% placebo), and mouth edema (11.1% Grastek, 0.8% placebo). There were no reports of death or anaphylaxis during clinical trials.

Grastek has a black box warning that cites the following: Grastek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal edema; Do not administer Grastek to patients with severe, unstable or uncontrolled asthma; Observe patients in the office for at least 30 minutes following the initial dose; Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use; Grastek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction; Grastek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

DOSAGE

For children and adults 5 to 65 years of age, the dose is 1 tablet (2800 BAU) daily.

FDA APPROVED INDICATION

Grastek (Timothy grass pollen extract) approved and indicated for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens, in people ages 5 through 65 years.

REFERENCES

-) Brozek JL, Bousquet J, Baena-Cagnani CE, Bonini S, Canonica GW, Casale TB, et al. Allergic Rhinitis and Its Impact on Asthma (ARIA) guidelines: 2010 revision. J Allergy Clin Immunol. 2010;126:466–476.
-) Merck Sharp & Dohme Corp. Grastek Package Insert. Whitehouse Station, NJ. April 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 05/14

Client Approval: 02/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AMIKACIN LIPOSOMAL INHALATION

Generic	Brand	HICL	GCN	Exception/Other
AMIKACIN LIPOSOMAL/NEB. ACCESSR	ARIKAYCE	45298		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

- Does the patient have a diagnosis of *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) The patient has **NOT** achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
 -) Arikayce will be used as part of a combination antibacterial drug regimen
 -) Arikayce is being prescribed by or in consultation with a pulmonologist or infectious disease specialist physician

If yes, **approve for 6 months by HICL with a quantity limit of #1 vial (590mg/8.4mL) per day.**

APPROVAL TEXT: Renewal requires the patient has not had a positive MAC sputum culture after consecutive negative cultures and physician attestation of improvement in symptoms. Additionally, for first renewal requests, approval requires documentation of at least one negative sputum culture for MAC by six months of Arikayce treatment. For second and subsequent renewal requests, approval requires documentation of at least three negative sputum cultures for MAC by 12 months of Arikayce treatment.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires a diagnosis of *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options. In addition, the following criteria must also be met:

-) The patient is 18 years of age or older
-) The patient has NOT achieved negative sputum cultures after a minimum of 6 consecutive months of multidrug background regimen therapy
-) Arikayce will be used as part of a combination antibacterial drug regimen
-) Arikayce is being prescribed by or in consultation with a pulmonologist or infectious disease specialist physician

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AMIKACIN LIPOSOMAL INHALATION

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the first renewal of Arikayce for the treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?
 -) There is documentation of at least **ONE** negative sputum culture for MAC by 6 months of Arikayce treatment
 -) The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
 -) Physician attestation of improvement in symptoms

If yes, **approve for 6 months by HICL with a quantity limit of #1 vial (590mg/8.4mL) per day.**

If no, continue to #2.

2. Is the request for the second or subsequent renewal of Arikayce for treatment of patients with a diagnosis of *Mycobacterium avium complex* (MAC) lung disease and the patient meets **ALL** of the following criteria?
 -) There is documentation of at least **THREE** negative sputum cultures for MAC by 12 months of Arikayce treatment
 -) The patient has **NOT** had a positive MAC sputum culture after consecutive negative cultures
 -) Physician attestation of improvement in symptoms

If yes, **approve for 6 months by HICL with a quantity limit of #1 vial (590mg/8.4mL) per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the diagnosis of *Mycobacterium avium complex* (MAC) lung disease for renewal. In addition, the following criteria must be met:

-) The patient has not had a positive MAC sputum culture after consecutive negative cultures
-) Physician attestation of improvement in symptoms
-) The patient meets ONE of the following:
 - o For first requests for renewal, approval requires:
 - There is documentation of at least ONE negative sputum culture for MAC by 6 months of Arikayce treatment
 - o For second or subsequent requests for renewal, approval requires:
 - There is documentation of at least THREE negative sputum cultures for MAC by 12 months of Arikayce treatment

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AMIKACIN LIPOSOMAL INHALATION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arikayce.

REFERENCES

) Arikayce [Prescribing information]. Bridgewater, NJ: Insmmed Incorporated; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ANABOLIC STEROIDS

Generic	Brand	HICL	GCN	Exception/Other
OXYMETHOLONE	ANADROL-50	01409		ROUTE MISCELL.
OXANDROLONE	OXANDRIN	01412		ROUTE MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL

1. Does the patient have a diagnosis of anemia and meets the following criteria?
 -) Anemia caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's anemia
 -) Patient does **not** have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
 -) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 6 months.**

If no, continue to #2.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL (CONTINUED)

2. Does the patient have a diagnosis of cachexia associated with AIDS and meets the following criteria?

-) Patient on anti-retroviral therapy
-) Documented viral load (with date) of less than 200 copies per mL within the past 3 months
-) Prescribed by or in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist (SBS) or Infectious Disease Specialist
-) One of the following criteria must be met:
 - o 10% unintentional weight loss over 12 months, **or**
 - o 7.5% unintentional weight loss over 6 months, **or**
 - o 5% body cell mass (BCM) loss within 6 months, **or**
 - o BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared, **or**
 - o BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared, **or**
 - o BMI less than 18.5 kg per meter squared
-) Patient does **not** have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 12 weeks.**

If no, do not approve.

INITIAL DENIAL TEXT: Our guideline for **ANABOLIC STEROIDS-ANADROL** requires one of the following diagnoses: anemia or cachexia associated with AIDS. Additional guideline requirements apply.

For the diagnosis of anemia, approval requires:

-) Anemia caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's anemia
 -) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
 -) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes
- (Anadrol denial text continued on next page)**

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ANABOLIC STEROIDS

INITIAL CRITERIA - ANADROL (CONTINUED)

For the diagnosis of cachexia associated with AIDS, approval requires:

-) Patient on anti-retroviral therapy
-) Documented viral load (with date) of less than 200 copies per mL within the past 3 months
-) Prescribed by or in consultation with one of the following specialist: gastroenterologist, nutritional support specialist (SBS) or infectious disease specialist
-) One of the following criteria must be met:
 - o 10% unintentional weight loss over 12 months, **or**
 - o 7.5% unintentional weight loss over 6 months, **or**
 - o 5% body cell mass (BCM) loss within 6 months, **or**
 - o BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared, **or**
 - o BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared, **or**
 - o BMI less than 18.5 kg per meter squared
-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

OXANDRIN

1. Is the request for adjunctive therapy to promote weight gain and the patient meets the following criteria?
 -) Weight loss due to one of the following conditions: extensive surgery, chronic infections, or severe trauma
 -) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
 -) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 12 weeks.**

If no, continue to #2.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

2. Is the request for adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids and the patient meets the following criteria?

-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 6 months.**

If no, continue to #3.

3. Is the request for the relief of the bone pain accompanying osteoporosis and the patient meets the following criteria?

-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 6 months.**

If no, continue to #4.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

4. Does the patient have a diagnosis of cachexia associated with AIDS and meets the following criteria?
-) Patient on anti-retroviral therapy
 -) Documented viral load (with date) of less than 200 copies per mL within the past 3 months
 -) Prescribed by or in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist (SBS) or Infectious Disease Specialist
 -) One of the following criteria must be met:
 - o 10% unintentional weight loss over 12 months, **or**
 - o 7.5% unintentional weight loss over 6 months, **or**
 - o 5% body cell mass (BCM) loss within 6 months, **or**
 - o BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared, **or**
 - o BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared, **or**
 - o BMI less than 18.5 kg per meter squared
 -) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
 -) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 12 weeks.**

If no, continue to #4.

5. Does the patient have a diagnosis of Turner's Syndrome and meets all the following criteria?
-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
 -) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

If yes, **approve for 6 months.**

If no, do not approve.

DENIAL TEXT: (Oxandrin denial text continued on next page)

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

DENIAL TEXT: Our guideline for **ANABOLIC STEROIDS-OXANDRIN** requires one of the following diagnoses: weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, cachexia associated with AIDS, or Turner's Syndrome. Additional guideline requirements apply.

For the diagnosis of weight loss, approval requires:

-) Weight loss due to one of the following conditions: extensive surgery, chronic infections, or severe trauma
-) Use as adjunctive therapy to promote weight gain
-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

For the diagnosis of protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's Syndrome, approval requires:

-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

For the diagnosis of cachexia associated with AIDS, approval requires:

-) Patient on anti-retroviral therapy
-) Documented viral load (with date) of less than 200 copies per mL within the past 3 months
-) Prescribed by or in consultation with one of the following specialist: gastroenterologist, nutritional support specialist (SBS) or infectious disease specialist
-) One of the following criteria must be met:
 - o 10% unintentional weight loss over 12 months, **or**
 - o 7.5% unintentional weight loss over 6 months, **or**
 - o 5% body cell mass (BCM) loss within 6 months, **or**
 - o In men: BCM < 35% of total body weight and body mass index (BMI) < 27kg/m(2), **or**
 - o In women: BCM < 23% of total body weight and BMI < 27kg/m(2), **or**
 - o BMI < 18.5 kg/m(2)

(Oxandrin denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ANABOLIC STEROIDS

INITIAL CRITERIA - OXANDRIN (CONTINUED)

-) Patient does not have any of the following contraindications to anabolic steroid therapy:
 - o Known or suspected carcinoma of the prostate or breast in male patients
 - o Known or suspected carcinoma of the breast in females with hypercalcemia
 - o Known or suspected nephrosis (the nephrotic phase of nephritis)
 - o Known or suspected hypercalcemia
 - o Severe hepatic dysfunction
-) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes

RENEWAL CRITERIA

OXANDRIN and ANADROL

1. Is the request for cachexia associated with AIDS and the patient meets all the following criteria?
 -) Patient is on anti-retroviral therapy
 -) Patient's viral load is less than 200 copies per mL within the past 3 months
 -) Patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
 -) Patient has not received more than 24 weeks of therapy in calendar year

If yes, **approve for 12 weeks.** (Note: therapy is limited to 24 weeks per calendar year.)

If no, do not approve.

DENIAL TEXT: Our guideline for **ANABOLIC STEROIDS** renewal requires the diagnoses of cachexia associated with AIDS. The following criteria must also be met:

-) Patient is on anti-retroviral therapy
-) Patient's viral load is less than 200 copies per mL within the past 3 months
-) Patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
-) Patient has not received more than 24 weeks of therapy in calendar year

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ANABOLIC STEROIDS****RATIONALE**

To cover oxandrolone or oxymetholone for FDA approved indications and the following compendia indication: HIV wasting syndrome or HIV related cachexia.

FDA APPROVED INDICATIONS

Anadrol®-50 Tablets is indicated in the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond. Anadrol®-50 Tablets should not replace other supportive measures such as transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy and the appropriate use of corticosteroids.

Oxandrin is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis

Compendia uses include (but not limited):

-) Anadrol-50 (oxymetholone): Cachexia associated with AIDS & Fanconi's Anemia
-) Oxandrin (oxandrolone): Cachexia associated with AIDS & Turner's Syndrome

DOSAGE**Anadrol-50**

The recommended daily dose in children and adults is 1-5 mg/kg of body weight per day. The usual effective dose is 1-2 mg/kg/day but higher doses may be required, and the dose should be individualized. Response is not often immediate, and a minimum trial of three to six months should be given. Following remission, some patients may be maintained without the drug; others may be maintained on an established lower daily dosage. A continued maintenance dose is usually necessary in patients with congenital aplastic anemia.

Oxandrin: Therapy with anabolic steroids is adjunctive to and not a replacement for conventional therapy. The duration of therapy with Oxandrin (oxandrolone) will depend on the response of the patient and the possible appearance of adverse reactions. Therapy should be intermittent.

Adults: The response of individuals to anabolic steroids varies. The daily adult dosage is 2.5 mg to 20 mg given in 2 to 4 divided doses. The desired response may be achieved with as little as 2.5 mg or as much as 20 mg daily. A course of therapy of 2 to 4 weeks is usually adequate. This may be repeated intermittently as indicated.

Children: For children the total daily dosage of Oxandrin is 0.1 mg per kilogram body weight or 0.045 mg per pound of body weight. This may be repeated intermittently as indicated.

Geriatric Use: Recommended dose for geriatric patients is 5 mg bid.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ANABOLIC STEROIDS

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Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/15

Created: 05/15

Client Approval: 05/15

P&T Approval: 05/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASFOTASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ASFOTASE ALFA	STRENSIQ	42649		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is this a request for treatment of perinatal/infantile-onset hypophosphatasia (HPP)?

If yes, continue to #2.

If no, continue to #3.

2. Does the patient have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) and have **ALL** of the following criteria been met?

-) Prescribed by or in consultation with an endocrinologist
-) Patient was 6 months of age or younger at hypophosphatasia (HPP) onset
-) Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria:
 - o Serum alkaline phosphatase (ALP) level below that of normal range for patient age
 - o Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B₆ supplementation in the previous week
 - o Urine phosphoethanolamine (PEA) level above that of normal range for patient age
 - o Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
 - o Presence of **two or more** of the following:
 - Rachitic chest deformity
 - Craniosynostosis (premature closure of skull bones)
 - Delay in skeletal growth resulting in delay of motor development
 - History of vitamin B₆ dependent seizures
 - Nephrocalcinosis or history of elevated serum calcium
 - History or presence of non-traumatic postnatal fracture and delayed fracture healing

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is this a request for treatment of juvenile-onset hypophosphatasia (HPP)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a documented diagnosis of juvenile-onset hypophosphatasia (HPP) and have **ALL** of the following criteria been met?
-) Prescribed by or in consultation with an endocrinologist
 -) Patient was 18 years of age or younger at hypophosphatasia (HPP) onset
 -) Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria:
 - o Serum alkaline phosphatase (ALP) level below that of normal range for patient age
 - o Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B₆ supplementation in the previous week
 - o Urine phosphoethanolamine (PEA) level above that of normal range for patient age
 - o Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)
 - o Presence of **two or more** of the following:
 - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
 - Premature loss of primary teeth prior to 5 years of age
 - Delay in skeletal growth resulting in delay of motor development
 - History or presence of non-traumatic fractures or delayed fracture healing

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ALL** of the following criteria?
-) Patient is not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)].
 -) Patient does not have serum calcium or phosphate levels below the normal range.
 -) Patient does not have a treatable form of rickets.

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires that, while on therapy with Strensiq, the patient experiences a documented improvement in skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT: Our guideline for **ASFOTASE ALFA (Strensiq)** requires a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) or juvenile-onset hypophosphatasia (HPP). Additional guideline requirements apply.

For patients with perinatal/infantile-onset hypophosphatasia (HPP), all of the following criteria must be met:

-) Prescribed by or in consultation with an endocrinologist
-) Patient was 6 months of age or younger at hypophosphatasia (HPP) onset
-) Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria:
 - o Serum alkaline phosphatase (ALP) level below that of normal range for patient age
 - o Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B₆ supplementation in the previous week
 - o Urine phosphoethanolamine (PEA) level above that of normal range for patient age
 - o Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, widened growth plates, areas of radiolucency or sclerosis)
 - o Presence of **two or more** of the following:
 - Rachitic chest deformity
 - Craniosynostosis (premature closure of skull bones)
 - Delay in skeletal growth resulting in delay of motor development
 - History of vitamin B₆ dependent seizures
 - Nephrocalcinosis or history of elevated serum calcium
 - History or presence of non-traumatic postnatal fracture and delayed fracture healing

For patients with juvenile-onset hypophosphatasia (HPP), all of the following criteria must be met:

-) Prescribed by or in consultation with an endocrinologist
-) Patient was 18 years of age or younger at hypophosphatasia (HPP) onset
-) Positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meets at least **TWO** of the following criteria:
 - o Serum alkaline phosphatase (ALP) level below that of normal range for patient age
 - o Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** patient has not received vitamin B₆ supplementation in the previous week
 - o Urine phosphoethanolamine (PEA) level above that of normal range for patient age
 - o Radiographic evidence of hypophosphatasia (HPP) (e.g., flared and frayed metaphyses, osteopenia, osteomalacia, widened growth plates, areas of radiolucency or sclerosis)

(Initial denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASFOTASE ALFA

INITIAL CRITERIA (CONTINUED)

- Presence of **two or more** of the following:
 - Rachitic deformities (rachitic chest, bowed legs, knock-knees)
 - Premature loss of primary teeth prior to 5 years of age
 - Delay in skeletal growth resulting in delay of motor development
 - History or presence of non-traumatic fractures or delayed fracture healing

Strensiq will not be approved for the following patients:

-) Patients currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
-) Patients with serum calcium or phosphate levels below the normal range
-) Patients with a treatable form of rickets

RENEWAL CRITERIA

1. During the last 6 months of treatment, has the patient experienced improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ASFOTASE ALFA (Strensiq)** renewal requires that the patient has experienced an improvement in the skeletal characteristics of hypophosphatasia (HPP) (e.g., improvement of the irregularity of the provisional zone of calcification, physeal widening, metaphyseal flaring, radiolucencies, patchy osteosclerosis, ratio of mid-diaphyseal cortex to bone thickness, gracile bones, bone formation and fractures).

RATIONALE

To ensure appropriate use of Strensiq consistent with FDA approved indication.

Strensiq (asfotase alfa) is the first therapy approved for the treatment of hypophosphatasia (HPP), a genetic, ultra-rare metabolic disorder. HPP is caused by a mutation in the tissue non-specific alkaline phosphatase (TNSALP) gene, which results in defective bone mineralization. Its prevalence is estimated to be less than 20 patients per one million in the general population and it is estimated to affect approximately one in 100,000 live births. HPP can affect people of all ages and the forms of HPP are classified primarily by the age of onset of symptoms and diagnosis. The clinical manifestations vary widely, ranging from stillbirth without mineralized bone to skeletal abnormalities due to softened bones. In perinatal HPP (onset *in-utero*), signs of HPP manifest *in utero* and may cause stillbirth or neonatal death shortly after birth.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASFOTASE ALFA

RATIONALE (CONTINUED)

Patients with infantile HPP (onset prior to 6 months of age) often appear normal at birth but typically present with skeletal abnormalities and failure to thrive within the first 6 months of life. Mortality, usually due to pulmonary complications, has been reported to be as high as 50% within the first year of life. Juvenile or childhood HPP (onset 6 months to <18 years), is often first recognized when there is premature loss of the deciduous teeth, and radiographs reveal skeletal defects. First signs of HPP may also present later in life (onset 18 years of age); however, some adult patients report a history of early tooth loss or rickets during childhood. In adult HPP, hypomineralization manifests as osteomalacia. Manifestations of the disease can be severe and debilitating, often requiring multiple surgeries, multiple pain medications, and the use of supportive devices to perform activities of daily living.

Current treatment of HPP has been directed toward the management of specific symptoms and complications. The approval of Strensiq is the turning point for patients with HPP for which there is no cure. This biological agent targets the bone and replaces the deficient TNSALP enzyme, thereby preventing or reversing the complications of a defective mineralization process.

FDA APPROVED INDICATION

Strensiq is approved for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

DOSAGE

Perinatal/Infantile-Onset hypophosphatasia (HPP)

Recommended dosage regimen is 2mg/kg administered subcutaneously three times per week, or 1mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen. The dosage may be increased to 3mg/kg three times per week for insufficient efficacy.

Juvenile-Onset hypophosphatasia (HPP)

Recommended dosage regimen is 2mg/kg administered subcutaneously three times per week, or 1mg/kg six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

Please refer to prescribing information for tables of weight-based dosing by treatment regimen.

Strensiq is available as single-use vials in the following strengths: 18mg/0.45ml, 28mg/0.7ml, 40mg/ml, 80mg/0.8ml. The vials must be stored in the original carton until time of use under refrigerated conditions and protected from light. Once removed from refrigeration, Strensiq should be administered within 1 hour.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASFOTASE ALFA

AVAILABLE STRENGTHS:

-) 18mg/0.45ml single-use vial
-) 28mg/0.7ml single-use vial
-) 40mg/ml single-use vial
-) 80mg/0.8ml single-use vial

REFERENCES

-) Strensiq [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc. October 2015.
-) FDA [Online Press Release]. FDA approves new treatment for rare metabolic disorder. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm468836.htm> [Accessed November 2, 2015]
-) National Organization for Rare Disorders. Hypophosphatasia. Available at: <https://rarediseases.org/rare-diseases/hypophosphatasia/> [Accessed November 2, 2015]
-) Beck C., Morbach H., Stenzel M., Colmann H., Schneider P., and Girschick HJ. Hypophosphatasia- Recent Advances in Diagnosis and Treatment. The Open bone Journal, 2009; 1:8-15. Available at: <http://benthamopen.com/contents/pdf/TOBONEJ/TOBONEJ-1-8.pdf> [Accessed November 2, 2015]

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 11/15

Client Approval: 02/16

P&T Approval: 02/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASPIRIN ER

Generic	Brand	HICL	GCN	Exception/Other
ASPIRIN ER	DURLAZA		17988	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic coronary artery disease, (e.g., a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet the following criteria?

-) Patient has previously tried aspirin over-the-counter (OTC)
-) Durlaza is NOT being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

If yes, **approve for 12 months by GPID for a quantity limit of #30 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of guideline.

DENIAL TEXT: Our guideline for **ASPIRIN ER** requires a diagnosis of chronic coronary artery disease, (e.g., a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA). Additional guideline requirements apply.

-) Patient has previously tried aspirin over-the-counter (OTC)
-) Durlaza is not being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

RATIONALE

Promote appropriate utilization of Durlaza based on FDA approved indication and cost-effectiveness.

DURLAZA is a nonsteroidal anti-inflammatory drug indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

Limitation of Use: Use immediate-release aspirin, not DURLAZA in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ASPIRIN ER

RATIONALE (CONTINUED)

Durlaza is a 162.5mg extended release formulation of aspirin. Aspirin is available in multiple strengths as an over the counter (OTC) product. There were no new studies on the safety and efficacy of Durlaza performed. The platelet inhibitory effects of aspirin last for the life of the circulating platelets, which is ~10 days, thus an extended release formulation of aspirin has not been demonstrated to be superior to previously available OTC aspirin.

DOSAGE

The recommended dose is 162.5 mg per day with a full glass of water at the same time each day.

FDA APPROVED INDICATION

DURLAZA is a nonsteroidal anti-inflammatory drug indicated to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

Limitation of Use: Use immediate-release aspirin, not DURLAZA in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).

REFERENCES

-) New haven Pharmaceuticals, Inc. Durlaza Package Insert. North Haven, CT. September 2015.
-) Awtry, Eric H., Loscalzo, Joseph. Cardiology Drugs: Aspirin. Journal Circulation: 2000; 101: 1206-1218. Accessed online October 12, 2015 at: <http://circ.ahajournals.org/content/101/10/1206.full>

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/16

Created: 11/15

Client Approval: 11/15

P&T Approval: 11/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AZTREONAM INHALED

Generic	Brand	HICL	GCN	Exception/Other
AZTREONAM LYSINE	CAYSTON		28039	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient at least 7 years old?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a lung infection with a Gram negative species (such as *Pseudomonas aeruginosa*; not *Staphylococcus aureus* because it is not a Gram negative species)?

If yes, **approve for 12 months for 6 fills of #84 vials per 56 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of cystic fibrosis, patient age of at least 7 years, and lung infection with a Gram negative species.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AZTREONAM INHALED

RATIONALE

Promote appropriate utilization of Cayston based on FDA approved indication.

Dosage: One ampule three times daily in repeated cycles of 28 days on drug followed by 28 days off drug.

FDA APPROVED INDICATION

Cayston is indicated to improve respiratory symptoms in cystic fibrosis patients with *Pseudomonas aeruginosa*. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV₁ <25% or >75% predicted, or patients colonized with *Burkholderia cepacia*.

REFERENCES

) Gilead Sciences, Inc. Cayston package insert. Foster City, CA. February 2010.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/12

Created: 05/12

Client Approval: 05/12

P&T Approval: 05/12



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELIMUMAB

Generic	Brand	HICL	GCN	Exception/Other
BELIMUMAB	BENLYSTA		29633 29634	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of severe active lupus nephritis or severe active central nervous system lupus?

If yes, do not approve.

DENIAL TEXT: Benlysta is not covered for the treatment of severe active lupus nephritis or severe active central nervous system lupus. Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

If no, continue to #2.

2. Is the patient currently taking corticosteroids, antimalarials, NSAIDs or immunosuppressives?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and SELENA-SLEDAI score of at least 6; patient is currently taking standard of care lupus treatment such as corticosteroids, antimalarials, NSAIDs or immunosuppressives and not taking biologics or intravenous cyclophosphamide. Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

3. Is the patient currently taking biologics or intravenous cyclophosphamide?

If yes, do not approve.

DENIAL TEXT: Approval requires a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and SELENA-SLEDAI score of at least 6; patient is currently taking standard of care lupus treatment such as corticosteroids, antimalarials, NSAIDs or immunosuppressives and not taking biologics or intravenous cyclophosphamide. Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

If no, continue to #4.

4. Is the patient currently taking Benlysta?

If yes, continue to #7.

If no, continue to #5.

CONTINUED ON NEXT PAGE



BELIMUMAB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of lupus?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and SELENA-SLEDAI score of at least 6; patient is currently taking standard of care lupus treatment such as corticosteroids, antimalarials, NSAIDs or immunosuppressives and not taking biologics or intravenous cyclophosphamide. Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

6. Does the patient have a positive autoantibody test and a SELENA-SLEDAI score of at least 6?

If yes, **approve and enter two authorizations as follows:**

) **Approve for 1 month by GPID for #6 vials, AND**

) **Approve for 5 fills by GPID for #2 vials per month with a start date 1 week prior to the end date of the 1 month authorization.**

APPROVAL TEXT: Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and SELENA-SLEDAI score of at least 6; patient is currently taking standard of care lupus treatment such as corticosteroids, antimalarials, NSAIDs or immunosuppressives and not taking biologics or intravenous cyclophosphamide. Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

7. Has the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline?

If yes, **approve for 12 months by GPID with a quantity of #2 vials per month.**

If no, do not approve.

DENIAL TEXT: Renewal requires that the patient achieved or maintained at least a 4 point reduction in their SELENA-SLEDAI score from baseline.

RATIONALE

Ensure appropriate utilization of Benlysta consistent with its FDA approved indication.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELIMUMAB

FDA APPROVED INDICATIONS

Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Limitations of Use: Not recommended for patient with severe active lupus nephritis or severe active central nervous system lupus or in combination with other biologics or intravenous cyclophosphamide.

REFERENCES

-) Bertsias G, Ioannidis JPA, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics. *Ann Rheum Dis* 2008; 67:195-205.
-) Human Genome Sciences, Inc. Benlysta package insert. Rockville, MD. March 2011.
-) Mosca M, Bombardieri S. Assessing remission in systemic lupus erythematosus. *Clin Exp Rheumatol* 2006; 24 (Suppl. 43): S100-S104.

Library	Commercial	NSA
No	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 03/11

Client Approval: 02/16

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELIMUMAB - SQ

Generic	Brand	HICL	GCN	Exception/Other
BELIMUMAB	BENLYSTA		43658 43661	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and meet **ALL** of the following criteria?

-) The patient does **NOT** have severe active lupus nephritis or severe active central nervous system lupus
-) The medication will **NOT** be used in combination with biologics (e.g., Rituxan) or intravenous cyclophosphamide
-) The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives

If yes, **approve for 6 months by GPID for all formulations as follows:**

-) **200mg/mL autoinjector (GPID 43658): #4mL (#4 200 mg/mL autoinjectors) per 28 days**
-) **200mg/mL syringe (GPID 43661): #4mL (#4 200 mg/mL syringes) per 28 days**

APPROVAL TEXT: Renewal requires that the patient has achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline.

If no, do not approve.

DENIAL TEXT: The guideline named **BELIMUMAB (Benlysta SQ)** requires that the patient has a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and meets **ALL** of the following criteria:

-) The patient does **NOT** have severe active lupus nephritis or severe active central nervous system lupus
-) The medication will **NOT** be used in combination with biologics (e.g., Rituxan) or intravenous cyclophosphamide
-) The patient is currently using corticosteroids, antimalarials, NSAIDs, or immunosuppressives

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELIMUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) **AND** meet the following criterion?
 -) The patient has achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline

If yes, **approve for 12 months by GPID for all formulations as follows:**

 -) **200mg/mL autoinjector (GPID 43658): #4mL (#4 200 mg/mL autoinjectors) per 28 days**
 -) **200mg/mL syringe (GPID 43661): #4mL (#4 200 mg/mL syringes) per 28 days**

If no, do not approve.

DENIAL TEXT: The guidelines named **BELIMUMAB (Benlysta SQ)** requires that the patient have a diagnosis of autoantibody positive systemic lupus erythematosus (SLE) and has achieved or maintained at least a 4 point reduction in their Safety of Estrogens in Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score from baseline for renewal.

RATIONALE

Ensure appropriate utilization of Benlysta consistent with its FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Benlysta is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Limitations of Use: Not recommended for patient with severe active lupus nephritis or severe active central nervous system lupus or in combination with other biologics or intravenous cyclophosphamide.

DOSAGE AND ADMINISTRATION

The subcutaneous formulation of Benlysta is supplied as 200mg/mL syringes and auto-injectors. The recommended dose of Benlysta is 200mg SQ once weekly.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELIMUMAB - SQ

REFERENCES

-) Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc. July 2017.
-) Bertsias G, Ioannidis JPA, Boletis J et al. EULAR recommendations for the management of systemic lupus erythematosus. Report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics. *Ann Rheum Dis* 2008; 67:195-205.
-) Mosca M, Bombardieri S. Assessing remission in systemic lupus erythematosus. *Clin Exp Rheumatol* 2006; 24 (Suppl. 43): S100-S104.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/01/17

Created: 08/17

Client Approval: 08/17

P&T Approval: 02/11



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BINIMETINIB

Generic	Brand	HICL	GCN	Exception/Other
BINIMETINIB	MEKTOVI	45040		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
- ☐ The medication will be used in combination with Braftovi (encorafenib)

If yes, **approve for 12 months by HICL with a quantity limit of #6 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **BINIMETINIB (Mektovi)** requires a diagnosis of unresectable or metastatic melanoma. In addition, the following criteria must be met:

- ☐ The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
- ☐ The medication will be used in combination with Braftovi (encorafenib)

RATIONALE

To promote appropriate utilization of MEKTOVI based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Mektovi is a kinase inhibitor indicated, in combination with Braftovi (encorafenib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

DOSAGE & ADMINISTRATION

The recommended dosage of Mektovi is 45 mg (three 15 mg tablets) orally taken twice daily, approximately 12 hours apart, in combination with Braftovi (encorafenib) until disease progression or unacceptable toxicity. Refer to the Braftovi (encorafenib) prescribing information for recommended Braftovi (encorafenib) dosing information.

Mektovi may be taken with or without food. Do not take a missed dose of Mektovi within 6 hours of the next dose of Mektovi. Do not take an additional dose if vomiting occurs after Mektovi administration but continue with the next scheduled dose.

REFERENCES

- ☐ Mektovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BOSUTINIB

Generic	Brand	HICL	GCN	Exception/Other
BOSUTINIB	BOSULIF	39590		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient at least 18 years old?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)?

If yes, continue to #4.

If no, continue to #3.

3. Does the patient have a diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND** meet the following criterion?

) The patient previously tried or has a contraindication to Gleevec, Sprycel, or Tasigna

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that both the T315I and V299L mutations are not present?

If yes, **approve for 12 months by GPID with the following quantity limits:**

) **Bosulif 500mg (GPID 33202): #1 tablet per day.**

) **Bosulif 400mg (GPID 44162): #1 tablet per day.**

) **Bosulif 100mg (GPID 33199): #3 tablets per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BOSUTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **BOSUTINIB (Bosulif)** requires that the requested medication is used for newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) OR chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML). In addition, the patient must be at least 18 years old AND has had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that both the T315I and V299L mutations are not present. The following criteria must also be met:

For the diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), approval requires:

-) Previous trial of or contraindication to Gleevec, Sprycel, or Tasigna

RATIONALE

Ensure appropriate utilization of bosutinib based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Bosulif is a kinase inhibitor indicated for the treatment of adult patients with:

-) Newly diagnosed chronic phase Ph+ chronic myelogenous leukemia (CML). This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial.
-) Chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.

DOSAGE AND ADMINISTRATION

Newly Diagnosed chronic phase Ph+ CML: The recommended dose of Bosulif is 400 mg orally once daily with food and continues until disease progression or patient intolerance.

Chronic Phase, Accelerated Phase, or Blast Phase Ph+ CML with resistance or intolerance to prior therapy: The recommended dose of Bosulif is 500mg once daily with food and continues until disease progression or patient intolerance.

The tablet is to be swallowed whole and should not be broken or cut. Dose escalation to 600mg once daily, by increments of 100 mg once daily, can be considered for patients who do not reach complete hematological response (CHR) by week 8 or have a complete cytogenetic response by week 12, and do not have grade 3 or higher adverse reactions while taking the recommended starting dosage.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BOSUTINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

If liver transaminases exceed 5x the institutional upper limit of normal (ULN), withhold treatment until recovery of liver transaminases reach a level of no more than 2.5x ULN, and resume at 400mg once daily. If recovery takes longer than 4 weeks or transaminase elevations of at least 3x ULN occur with bilirubin elevations of least 2x ULN, or alkaline phosphates less than 3x ULN, discontinue treatment.

In the presence of grade 3 - 4 diarrhea, withhold Bosulif until recovery to Grade less than or equal to 1, and may resume Bosulif at 400 mg once daily.

For other clinically significant, moderate, or severe non-hematological toxicity, withhold treatment until the toxicity has resolved, then may resume at a dose reduced by 100 mg once daily. If clinically appropriate, consider re-escalating the dose to the starting dose taken once daily. Doses less than 300 mg/day have been used in patients; however, efficacy has not been established. Consider dose reduction by 100mg in the presence of neutropenia or thrombocytopenia.

For creatinine clearance 30 to 50 ml/min, consider dose reduction to 300mg daily for newly diagnosed Ph+ CML and 400mg daily for chronic, accelerated, or blast phase Ph+ CML. For creatinine clearance less than 30 ml/min, consider dose reduction to 200mg daily for 300mg daily for newly diagnosed Ph+ CML and 300mg daily for chronic, accelerated, or blast phase Ph+ CML. For mild, moderate, or severe hepatic impairment, consider dose reduction to 200mg daily.

DOSAGE STRENGTHS

-) 100 mg tablets
-) 400 mg tablets
-) 500 mg tablets

REFERENCES

-) Bosulif [Prescribing Information]. New York, NY: Pfizer; December 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18

Created: 09/12
Client Approval: 02/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

C1 ESTERASE INHIBITOR

Generic	Brand	HICL	GCN	Exception/Other
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE HAEGARDA	18568		
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST	37766		

This drug requires a written request for prior authorization.

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

BERINERT

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?

-) Diagnosis is confirmed via complement testing
-) The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
-) The medication is being used for acute attacks of hereditary angioedema

If yes, **approve Berinert for 12 months (up to 12 fills) by NDC 63833-0825-02.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **C1 ESTERASE INHIBITOR (Berinert)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

-) Diagnosis is confirmed via complement testing
-) The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
-) The medication is being used for acute attacks of hereditary angioedema

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

C1 ESTERASE INHIBITOR

INITIAL CRITERIA (CONTINUED)

CINRYZE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?

- ☐ Diagnosis is confirmed via complement testing
- ☐ The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
- ☐ The medication is being used for routine prophylaxis against angioedema attacks
- ☐ The patient is 6 years of age or older

If yes, **approve Cinryze for 12 months (up to 12 fills) by NDC 42227-0081-05 with a quantity limit of #40 vials per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

- ☐ Diagnosis is confirmed via complement testing
- ☐ The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
- ☐ The medication is being used for routine prophylaxis against angioedema attacks
- ☐ The patient is 6 years of age or older

HAEGARDA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?

- ☐ Diagnosis is confirmed via complement testing
- ☐ The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
- ☐ The medication is being used for routine prophylaxis against angioedema attacks

If yes, **approve Haegarda for 12 months (up to 12 fills) by GPID for all strengths as follows:**

- ☐ **Haegarda 2000 Units (GPID 39478)**
- ☐ **Haegarda 3000 Units (GPID 43356)**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

- ☐ Diagnosis is confirmed via complement testing
- ☐ The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
- ☐ The medication is being used for routine prophylaxis against angioedema attacks

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

C1 ESTERASE INHIBITOR

INITIAL CRITERIA (CONTINUED)

RUCONEST

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
 -) Diagnosis is confirmed via complement testing
 -) The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
 -) The medication is being used for acute attacks of hereditary angioedema

If yes, **approve Ruconest for 12 months (up to 12 fills) by GPID (30182) with a quantity limit of #8 vials per fill.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **C1 ESTERASE INHIBITOR (Ruconest)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

-) Diagnosis is confirmed via complement testing
-) The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
-) The medication is being used for acute attacks of hereditary angioedema

RENEWAL CRITERIA

CINRYZE

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet the following criterion?
 -) Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

If yes, **approve Cinryze for 12 months by NDC 42227-0081-05 with a quantity limit of #40 vials per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires a diagnosis of hereditary angioedema (HAE) for renewal. The following criterion must also be met:

-) Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

C1 ESTERASE INHIBITOR

RENEWAL CRITERIA (CONTINUED)

HAEGARDA

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet the following criterion?
 -) Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

If yes, **approve Haegarda for 12 months by GPID for all strengths as follows:**

-) **Haegarda 2000 Units (GPID 39478)**
-) **Haegarda 3000 Units (GPID 43356)**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires a diagnosis of hereditary angioedema (HAE) for renewal. The following criterion must also be met:

-) Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

RATIONALE

To ensure the appropriate use of Berinert, Cinryze, Haegarda and Ruconest in patients with hereditary angioedema (HAE).

FDA APPROVED INDICATIONS

Berinert:

-) Is a plasma-derived C1 esterase inhibitor (human) indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema in adult and pediatric patients.
-) The safety and efficacy of Berinert for prophylactic therapy have not been established.

Cinryze:

-) Is a C1 esterase inhibitor indicated for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years of age and older) with hereditary angioedema (HAE).

Haegarda:

-) Is a plasma-derived concentrate of C1 Esterase Inhibitor (Human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema (HAE) attacks in adolescent and adult patients.

Ruconest:

-) Is a C1 esterase inhibitor (recombinant) indicated for the treatment of acute attacks in adult and adolescent patients with hereditary angioedema (HAE).
-) Limitation of use: Effectiveness was not established in HAE patients with laryngeal attacks.

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C1 ESTERASE INHIBITOR

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Berinert

Berinert is for intravenous use after reconstitution only. The dose is 20 International Units (IU) per kg body weight by intravenous injection given at a rate of approximately 4mL/min. Doses lower than 20 IU/kg body weight should not be administered. Each Berinert vial contains 500 IU of C1 esterase inhibitor as a lyophilized concentrate for reconstitution with 10 mL of Sterile Water for Injection. Use a silicone-free syringe for reconstitution and administration. Administer at room temperature within 8 hours after reconstitution. Appropriately trained patients may self-administer Berinert upon recognition of an HAE attack.

Cinryze

Cinryze is for intravenous use after reconstitution only.

Adults and adolescents (12 years old and above): A dose of 1,000 Units with an infusion rate of 1mL/min for 10 minutes can be administered as an intravenous infusion every 3 or 4 days. For patients who have not responded adequately to 1,000 units of Cinryze every 3 or 4 days, doses up to 2,500 units (not to exceed 100 units/kg) every 3 or 4 days may be considered based on individual patient response.

Children (6 to 11 years old): A dose of 500 Units with an infusion rate of 1mL/min for 5 minutes can be administered as an intravenous infusion every 3 or 4 days. The dose may be adjusted according to individual response, up to 1,000 U every 3 to 4 days.

Reconstitute each Cinryze vial with one vial of Sterile Water for Injection, USP (5 mL each) using aseptic sterile technique. Reconstitute as many vials as needed to obtain the required dose. Administer at room temperature within 3 hours of reconstitution. Appropriately trained patients may self-administer Cinryze.

Haegarda

Haegarda is for subcutaneous use after reconstitution only. Haegarda is intended for self-administration after reconstitution at a dose of 60 International Units (IU) per kg body weight by subcutaneous (S.C.) injection twice weekly (every 3 or 4 days). The patient or caregiver should be trained on how to administer Haegarda. Reconstitute Haegarda prior to use using Sterile Water for Injection, USP. Use a silicone-free syringe for reconstitution and administration. Administer at room temperature within 8 hours after reconstitution.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

C1 ESTERASE INHIBITOR

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Ruconest

Ruconest is for intravenous use after reconstitution only. The dose is 50 U/kg administered as an intravenous injection for patients less than 84 kg, or 4200 U for patients who weigh 84 kg or more. Each vial (2100 U) should be reconstituted by adding 14mL of Sterile Water for injection to obtain a solution of 150 U/mL. The reconstituted product should be used immediately, or within 8 hours stored at 36°F to 46°F. After reconstitution the dose can be administered as a slow intravenous injection over approximately 5 minutes. If appropriately trained, patients may self-administer the dose as needed upon recognition of an HAE attack. No more than two doses should be administered within a 24- hour period, and no more than 4200 U per dose should be administered.

REFERENCES

-) Cinryze [Prescribing Information]. Lexington, MA: Shire Viropharma Inc. June 2018.
-) Berinert [Prescribing Information]. Kankakee, IL: CSL Behring LLC. September 2017.
-) Haegarda [Prescribing Information]. Marburg, German: CSL Behring LLC. October 2017.
-) Ruconest [Prescribing Information]. Raleigh, NC: Salix Pharmaceuticals; March 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 04/09

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARBIDOPA-LEVODOPA

Generic	Brand	HICL	GCN	Exception/Other
CARBIDOPA/LEVODOPA	DUOPA		37829	ROUTE = Percutaneous endoscopic gastrostomy with jejunal tube (PEG-J)

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease?

If yes, **approve for 12 months by GPID for 100mL per day.**

If no, do not approve.

DENIAL TEXT: Our guideline for **CARBIDOPA-LEVODOPA** requires a diagnosis of advanced Parkinson's disease.

RATIONALE

Promote appropriate utilization of Duopa based on FDA approved indication.

Duopa is the first agent to provide continuous treatment via the enteral route for motor fluctuations in patients with Parkinson's disease. It provides patients with the same active ingredients as orally-administered carbidopa and levodopa immediate release, but is delivered in a suspension that bypasses the stomach and goes directly into the small intestine via a tube placed by a percutaneous endoscopic gastrostomy with jejunal extension (PEG-J).

FDA APPROVED INDICATION

Duopa is indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.

DOSAGE

Duopa is administered over a 16-hour infusion period. The daily dose is determined by individualized patient titration and composed of a morning dose, a continuous dose, and extra doses. The maximum recommended daily dose of Duopa is 2000mg of the levodopa component. At the end of the daily 16-hour infusion, patients will disconnect with pump from the PEG-J and take their nighttime dose of oral immediate release carbidopa/levodopa tablets.

Duopa is administered into the jejunum through a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) with the CADD®-Legacy 1400 portable infusion pump. A Duopa cassette should be taken out of the refrigerator and out of the carton 20 minutes prior to use so that it can be administered at room temperature. The cassettes are for single-use only.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARBIDOPA-LEVODOPA

REFERENCES

) Duopa [Prescribing Information]. North Chicago, IL: Abbvie, Inc. January 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/15

Created: 05/15

Client Approval: 05/15

P&T Approval: 05/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CHENODIOL

Generic	Brand	HICL	GCN	Exception/Other
CHENODIOL	CHENODAL	01364		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being prescribed for the treatment of cerebrotendinous xanthomatosis (CTX)?

If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets daily.**
If no, continue to #2.

2. Is the requested medication being prescribed for the treatment of radiolucent gallstones?

If yes, continue to #3.
If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received previous chenodiol therapy with a total duration exceeding 24 months?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

4. Has the patient had a previous trial of or contraindication to ursodiol?

If yes, **approve for 12 months by HICL with a quantity limit of #7 tablets daily.**
If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **CHENODIOL (Chenodal)** requires a diagnosis of radiolucent gallstones or cerebrotendinous xanthomatosis. The following criteria must also be met:

For the diagnosis of radiolucent gallstones:

-) The patient has had a previous trial of or contraindication to ursodiol
-) The patient has not received previous chenodiol therapy with a total duration exceeding 24 months

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CHENODIOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the requested medication being used for radiolucent gallstones?

If yes, continue to #2.

If no, continue to #5.

2. Has the patient previously received a total duration of chenodiol therapy exceeding 24 months?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #3.

3. Does the patient have complete or no gallstone dissolution seen on imaging after 12 months of therapy?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #4.

4. Does the patient have partial gallstone dissolution seen on imaging after 12 months of therapy?

If yes, **approve for 12 months by HICL with a quantity limit of #7 tablets daily.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) **AND** meet the following criterion?

) Physician attestation of improvement in **ONE** of the following:

- Normalization of elevated serum or urine bile alcohols
- Normalization of elevated serum cholestanol levels
- Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets daily.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHENODIOL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline for **CHENODIOL (Chenodal)** requires a diagnosis of radiolucent gallstones or cerebrotendinous xanthomatosis. The following criteria must also be met:

For the diagnosis of radiolucent gallstones:

-) The patient has **NOT** exceeded a total of 24 months of previous chenodiol therapy
-) The patient does **NOT** have complete or no gallstone dissolution seen on imaging (e.g., oral cholecystograms or ultrasonograms) after 12 months of therapy
-) The patient has partial gallstone dissolution seen on imaging (e.g., oral cholecystograms or ultrasonograms) after 12 months of therapy

For the diagnosis of cerebrotendinous xanthomatosis:

-) Physician attestation of improvement in **ONE** of the following:
 - o Normalization of elevated serum or urine bile alcohols
 - o Normalization of elevated serum cholestanol levels
 - o Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

RATIONALE

Ensure appropriate utilization for chenodiol.

FDA APPROVED INDICATIONS

Chenodiol is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment. Safety of use beyond 24 months is not established. Chenodiol will not dissolve calcified (radiopaque) or radiolucent bile pigment stones.

Because of the potential hepatotoxicity of chenodiol, poor response rate in some subgroups of chenodiol-treated patients, and an increased rate of a need for cholecystectomy in other chenodiol-treated subgroups, chenodiol is not an appropriate treatment for many patients with gallstones. Chenodiol should be reserved for carefully selected patients and treatment must be accompanied by systematic monitoring for liver function alterations. Aspects of patient selection, response rates and risks versus benefits are given in the package insert.

Chenodiol is used off-label for the treatment of cerebrotendinous xanthomatosis.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CHENODIOL

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Radiolucent gallstones:

The recommended dose range for chenodiol is 13 to 16mg/kg/day in two divided doses, morning and night. Starting with 250 mg two times a day for the first two weeks and increasing by 250 mg/day each week thereafter until the recommended or maximum tolerated dose is reached. If diarrhea occurs during dosage buildup or later in treatment, it usually can be controlled by temporary dosage adjustment until symptoms abate, after which the previous dosage usually is tolerated. Dosage less than 10 mg/kg usually is ineffective and may be associated with increased risk of cholecystectomy, so is not recommended.

Cerebrotendinous xanthomatosis:

The recommended dose for chenodiol for adults is 250 mg three times a day and 15 mg/kg per day in three divided doses for children.

REFERENCES

-) Chenodal [Prescribing Information]. Manchester Pharmaceuticals, Inc. Fort Collins, CO. Sept 2009.
-) Ransohoff DF, Gracie WA. Guidelines for the Treatment of Gallstones. *Ann Intern Med.* 1993; 119:620-622.
-) UpToDate, Inc. Cerebrotendinous xanthomatosis. UpToDate [database online]. Last updated Dec 20, 2016.
-) UpToDate, Inc. Nonsurgical treatment of gallstones. UpToDate [database online]. Last updated Mar 6, 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 11/09

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CHOLIC ACID

Generic	Brand	HICL	GCN	Exception/Other
CHOLIC ACID	CHOLBAM	39124		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to one of the following conditions:
 -) Bile acid synthesis disorders **or**
 -) Peroxisomal disorders (i.e., Zellweger spectrum disorders)?

If yes, **approve for 3 months by HICL.**

If no, do not approve.

INITIAL DENIAL TEXT: Our guideline for **CHOLIC ACID** requires that the patient exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption secondary to one of the following conditions:

-) Bile acid synthesis disorders **or**
-) Peroxisomal disorders (i.e., Zellweger spectrum disorders).

RENEWAL CRITERIA

1. Did the patient experience improvement in liver function (as defined by at least one of the following criteria):
 -) ALT or AST values reduced to <50 U/L or baseline levels reduced by 80% **or**
 -) Total bilirubin values reduced to <1 mg/dl **or**
 -) No evidence of cholestasis on liver biopsy?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: Our guideline for **CHOLIC ACID** renewal requires improvement in liver function (as defined by at least one of the following criteria):

-) ALT or AST values reduced to <50 U/L or baseline levels reduced by 80% **or**
-) Total bilirubin values reduced to <1 mg/dL **or**
-) No evidence of cholestasis on liver biopsy.

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CHOLIC ACID

RATIONALE

Promote appropriate utilization of Cholbam (cholic acid) based on FDA approved indication.

Cholbam (cholic acid) is the first FDA approved treatment for pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects (SEDs), and for patients with peroxisomal disorders (PDs), including Zellweger spectrum disorders. Ursodeoxycholic acid treatment has been found to have limited benefits for the treatment of bile acid defects, however, oral primary bile acid replacement by chenodeoxycholic acid or cholic acid is required for these defects to down-regulate endogenous bile acid synthesis. Cholic acid is now recognized as the bile acid of choice because it is not hepatotoxic, and it is effective therapy for errors in bile acid synthesis due to SEDs. Cholic acid has previously been available as an Investigation New Drug (IND), and study trials for cholic acid have exceeded eighteen years in duration.

The combined incidence of peroxisomal disorders is in excess of 1 in 20,000 individuals. Zellweger syndrome (ZWS) is the most common peroxisomal disorder to manifest itself in early infancy. Its incidence has been estimated to be 1 in 50,000-100,000. Patients with these rare disorders lack the enzymes needed to synthesize cholic acid, a primary bile acid normally produced in the liver from cholesterol. The absence of cholic acid in these patients leads to reduced bile flow, and malabsorption of fats and fat-soluble vitamins in the diet. If untreated, patients fail to grow and can develop life-threatening liver injury.

FDA APPROVED INDICATION

-) Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs).
-) Adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.

Limitations of use: The effectiveness of Cholbam for the management of extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs has not been established.

DOSAGE

The dosage regimen for bile acid synthesis disorders due to SEDs and for PDs, including Zellweger Spectrum Disorders, is 10 to 15mg/kg given orally once daily or in two divided doses. Patients with newly diagnosed or a family history of familial hypertriglyceridemia may have poor absorption of Cholbam and require a 10% increase in the recommended dosage (11 to 17mg/kg orally once or twice daily).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CHOLIC ACID

DOSAGE (CONTINUED)

Cholbam is available in 50mg and 250mg capsules and should be given in the lowest dose that effectively maintains liver function. Cholbam should be taken with food, and at least one hour before or 4-6 hours after a bile acid binding resin or an aluminum-based antacid. For patients unable to swallow the capsules, the capsules can be opened and the contents mixed with either infant formula or expressed breast milk (for younger children), or soft food such as mashed potatoes or apple puree (for older children and adults) in order to mask any unpleasant taste.

REFERENCES

) Cholbam [Prescribing Information]. Baltimore, MD: Asklepiion Pharmaceuticals, LLC; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/15

Created: 04/15

Client Approval: 05/15

P&T Approval: 05/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

COBIMETINIB

Generic	Brand	HICL	GCN	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and have **ALL** of the following criteria been met?

- ☐ Positive for BRAF V600E **OR** V600K mutation
- ☐ Cobimetinib will be used in combination with vemurafenib (Zelboraf)

If yes, **approve for 12 months by HICL with a quantity limit of #63 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **COBIMETINIB (Cotellic)** requires a diagnosis of unresectable or metastatic melanoma. In addition, all of the following criteria must be met:

- ☐ Positive for BRAF V600E **OR** V600K mutation, and
- ☐ Cobimetinib will be used in combination with vemurafenib (Zelboraf).

RATIONALE

To ensure appropriate use of Cotellic consistent with FDA approved indication.

FDA APPROVED INDICATION

Cotellic (cobimetinib) is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma.

DOSAGE

The recommended dose is 60 mg orally once daily for the first 21 days of each 28-day cycle until disease progression or unacceptable toxicity.

AVAILABLE STRENGTHS:

- ☐ 20 mg tablet

REFERENCES

- ☐ Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; November 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 11/15

Client Approval: 02/16

P&T Approval: 02/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CRIZOTINIB

Generic	Brand	HICL	GCN	Exception/Other
CRIZOTINIB	XALKORI	37916		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meets **ONE** of the following criteria?

-) Presence of anaplastic lymphoma kinase (ALK-) positive tumors
-) Presence of ROS1-positive tumors

If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day.**

If no, do not approve.

DENIAL TEXT: Our guideline for **CRIZOTINIB (Xalkori)** requires a diagnosis metastatic non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK-) positive OR ROS1-positive tumors.

RATIONALE

Based on FDA approved indications and dosing.

Lung cancer is the leading cause of cancer death worldwide. About 85% of lung cancers are NSCLC, making it the most common type of lung cancer. However, only 2-7% of patients with NSCLC are ALK-positive. ROS1-positive NSCLC represents another particular molecular subgroup of NSCLC occurring in approximately 1% of NSCLC cases.

NSCLC remains difficult to treat, particularly in the metastatic setting. Approximately 75% of NSCLC patients are diagnosed late with metastatic, or advanced, disease where the five-year survival rate is only 5%.

Information on FDA-approved tests for the detection of ALK rearrangements in NSCLC is available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm>

An FDA-approved test for the detection of ROS1 rearrangements in NSCLC is not currently available.

FDA APPROVED INDICATIONS

Xalkori is a kinase inhibitor indicated for the treatment of patients with:

-) Metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.
-) Metastatic NSCLC whose tumors are ROS1-positive.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CRIZOTINIB

DOSING

The recommended dose of Xalkori is 250 mg orally, twice daily until disease progression or no longer tolerated by the patient.

If vomiting occurs after taking a dose of Xalkori, take the next dose at the regular time. Dose reduction to 200mg twice daily, 250mg daily, or discontinuation is recommended in the presence of certain toxicities.

REFERENCE

-) Xalkori [Prescribing Information]. Pfizer; New York, New York. March 2016.
-) Pfizer [online press release]. Available at: http://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_u_s_fda_breakthrough_therapy_designation_for_xalkori_crizotinib_for_the_treatment_of_patients_with_ros1_positive_non_small_cell_lung_cancer [epub April 21, 2015]. [Accessed March 14, 2016].
-) Food and Drug Administration. (2014). FDA approves Zykadia for late-stage lung cancer. <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm395299.htm> (Accessed on May 5, 2014)
-) Kim DW, Ahn MJ, De Pas TM, et al. Results of a Global Phase II Study with Crizotinib in Advanced ALK-Positive Non-Small-Cell Lung Cancer (NSCLC). *Ann Oncol*. [Online] October 2012. [Cited: October 4, 2013.] http://annonc.oxfordjournals.org/content/23/suppl_11/xi29.full.pdf+html?sid=881f3ade-513c-44ba-bb50-8cf2b098b4ce
-) Shaw AT, Kim DW, Nakagawa K, et al. Crizotinib versus Chemotherapy in Advanced ALK-Positive Lung Cancer. *The New England Journal of Medicine* 368:2385-94. [Online] June 20, 2013. [Cited: October 4, 2013.] <http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214886>
-) U.S. National Institutes of Health. A Clinical Trial Testing The Efficacy Of Crizotinib Versus Standard Chemotherapy Pemetrexed Plus Cisplatin Or Carboplatin In Patients With ALK Positive Non Squamous Cancer Of The Lung (PROFILE 1014). *ClinicalTrials.gov*. [Online] September 23, 2013. [Cited: October 7, 2013.] <http://clinicaltrials.gov/ct2/show/NCT01154140?term=crizotinib&rank=34>
-) Phase II Safety and Efficacy Study of Crizotinib in East Asian Patients with ROS1 Positive, ALK Negative Advanced NSCLC. *ClinicalTrials.gov*. [Online] September 13, 2013. [Cited: October 7, 2013.] <http://clinicaltrials.gov/ct2/show/NCT01945021?term=crizotinib+ros1&rank=1>
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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CRIZOTINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 05/01/16

Created: 09/11
Client Approval: 03/16

P&T Approval: 05/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DABRAFENIB

Generic	Brand	HICL	GCN	Exception/Other
DABRAFENIB MESYLATE	TAFINLAR	40360		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E mutation as detected by an FDA-approved test
- ☐ The medication will be used as a single agent

If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
- ☐ The medication will be used in combination with Mekinist (trametinib)

If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
- ☐ The medication has not previously been used for more than one year
- ☐ The medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
- ☐ There is involvement of lymph node(s) following complete resection

If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
If no, continue to #4.

4. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E mutation as detected by an FDA-approved test
- ☐ The medication will be used in combination with Mekinist (trametinib)

If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**
If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DABRAFENIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E mutation
- ☐ The medication will be used in combination with Mekinist (trametinib)
- ☐ The patient has no satisfactory locoregional treatment options available

If yes, **approve for 12 months by HICL with a quantity limit of #120 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **DABRAFENIB (Tafinlar)** requires a diagnosis of unresectable or metastatic melanoma, metastatic non-small cell lung cancer (NSCLC), melanoma, or locally advanced or metastatic anaplastic thyroid cancer (ATC). In addition, the following criteria must be met:

For diagnosis of unresectable or metastatic melanoma, approval requires:

- ☐ The patient has BRAF V600E mutation as detected by an FDA-approved test
- ☐ The medication will be used as a single agent

For diagnosis of unresectable or metastatic melanoma, approval requires:

- ☐ The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
- ☐ The medication will be used in combination with Mekinist (trametinib)

For diagnosis of melanoma, approval requires:

- ☐ The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
- ☐ The medication has not previously been used for more than one year
- ☐ The medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
- ☐ There is involvement of lymph node(s) following complete resection

For diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

- ☐ The patient has BRAF V600E mutation as detected by an FDA-approved test
- ☐ The medication will be used in combination with Mekinist (trametinib)

For diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC), approval requires:

- ☐ The patient has BRAF V600E mutation
- ☐ The medication will be used in combination with Mekinist (trametinib)
- ☐ The patient has no satisfactory locoregional treatment options available

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DABRAFENIB

RATIONALE

Ensure appropriate use of Tafinlar (dabrafenib) based on FDA approved indications and dosing.

FDA APPROVED INDICATIONS

Tafinlar is a kinase inhibitor indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.

Tafinlar is indicated, in combination with Mekinist (trametinib) for:

-) The treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.
-) The adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection.
-) The treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test.
-) The treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

Limitation of Use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma, wild-type BRAF NSCLC, or wild-type BRAF ATC.

DOSAGE AND ADMINISTRATION

Melanoma: Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with Tafinlar as a single agent.

Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to initiation of treatment with Tafinlar in combination with trametinib.

The recommended dose is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity for up to 1 year.

Unresectable or Metastatic Melanoma: The recommended dose is 150 mg orally taken twice daily, as a single agent or in combination with trametinib, until disease progression or unacceptable toxicity.

NSCLC and ATC: Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with Tafinlar in combination with trametinib.

The recommended dose is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DABRAFENIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Take Tafinlar at doses approximately 12 hours apart. Take at least 1 hour before or 2 hours after a meal. Do not take a missed dose within 6 hours of the next dose of Tafinlar. Do not open, crush, or break Tafinlar capsules.

Recommended Dose Reductions for Tafinlar for Adverse Reactions:

Dose Reductions	Dose and Schedule
First dose reduction	100 mg orally twice daily
Second dose reduction	75 mg orally twice daily
Third dose reduction	50 mg orally twice daily
Subsequent modification	Permanently discontinue Tafinlar if unable to tolerate 50 mg twice daily

REFERENCES

) Tafinlar [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/15/18

Created: 06/13

Client Approval: 05/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACLATASVIR

Generic	Brand	HICL	GCN	Exception/Other
DACLATASVIR DIHYDROCHLORIDE	DAKLINZA	41377		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hepatitis C, genotype 1 or genotype 3 infection and meet **ALL** of the following criteria?

-) Patient at least 18 years of age
-) Patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Evidence of current HCV infection and chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the past 6 months
-) Patient is 1) without cirrhosis or 2) has decompensated cirrhosis or 3) post-liver transplant patient (with or without cirrhosis)
-) The request is for Daklinza is in combination with Sovaldi

CLINICAL PHARMACIST: Patient must also meet all criteria in Sovaldi guideline to be approvable for both agents. Review hepatitis C MRF and Sovaldi request to ensure patient meets criteria for both agents.

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?

-) Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
-) Patient is concurrently taking the following medications:
 - o For Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin **OR**
 - o For Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ONE** of the following diagnoses?

-) Decompensated cirrhosis (moderate or severe hepatitis impairment (Child-Pugh B or C))
-) Status post-liver transplant (with or without cirrhosis)

If yes, continue to #4.

If no, continue to #6.

4. Is the request for triple therapy using Daklinza/Sovaldi and ribavirin?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria for the patient type? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]

-) Genotype 1, decompensated cirrhosis: short trial of Harvoni or Epclusa OR contraindication to Harvoni and Epclusa
-) Genotype 1, post-liver transplant: short trial of Harvoni or Mavyret OR contraindication to Harvoni and Mavyret
-) Genotype 3, decompensated cirrhosis short trial of or contraindication to Epclusa
-) Genotype 3, post-liver transplant WITHOUT cirrhosis: short trial of or contraindication to Mavyret
-) Genotype 3, post-liver transplant with compensated cirrhosis: short trial of Epclusa or Mavyret OR contraindication to Epclusa and Mavyret

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following criteria? [**NOTE:** An individual who has completed a full course of therapy with Mavyret, Harvoni or Epclusa that did not achieve SVR will not be approved]

-) Genotype 1, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa, Harvoni or Mavyret OR a contraindication Epclusa, Harvoni and Mavyret
-) Genotype 3, without cirrhosis: treatment naïve or treatment experienced with a peginterferon and ribavirin regimen AND a short trial of Epclusa or Mavyret OR a contraindication to Epclusa and Mavyret

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the patient using any of the following moderate CYP3A inducers while taking Daklinza in combination with Sovaldi: rifapentine, bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, or nevirapine?

CLINICAL PHARMACIST: Patient is on combination therapy with Sovaldi; please also review Sovaldi prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Sovaldi.

If yes, **approve Daklinza 90mg strength for 12 weeks by GPID with a quantity limit of #1 tablet per day. (NOTE: 90mg tablet used for drug interactions listed above)**

APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi.

If no, continue to #8.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

8. Is the patient concurrently using any of the following with Daklinza?

-) HIV protease inhibitors (atazanavir with ritonavir, indinavir, nelfinavir, saquinavir)
-) A cobicistat-containing regimen (exception: darunavir/cobicistat does not require Daklinza 30mg dose), such as atazanavir/cobicistat, elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate, or other cobicistat-containing regimen
-) Strong CYP3A inhibitors, such as clarithromycin, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, or voriconazole

If yes, **approve Daklinza 30mg strength for 12 weeks by GPID with a quantity limit of #1 tablet per day. (NOTE: 30mg tablet used for drug interactions listed above)**

APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi.

If no, **approve Daklinza 60mg strength for 12 weeks by GPID with a quantity limit of #1 tablet per day.**

APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi.

DENIAL TEXT: The guideline named **DACLATASVIR (Daklinza)** requires a diagnosis of hepatitis C genotype 1 or genotype 3 infection. **ALL** the following criteria must be met:

-) Age at least 18 years old
-) Currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Evidence of current HCV infection and chronic HCV infection as documented by at least ONE detectable HCV RNA level within past 6 months
-) Must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi

The medication will not be approved for ANY of the following:

-) Patient is concurrently using any of the following with Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
-) Patient is concurrently using any of the following medications with Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
-) Patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
-) *Patients with compensated cirrhosis (Child-Pugh A) that are not status post liver transplant*

(Denial text continued on next page)

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DACLATASVIR

GUIDELINES FOR USE (CONTINUED)

In addition, the following criteria must also be met:

For genotype 1 infection:

-) Patients without cirrhosis:
 - Patients must be treatment naïve or treatment experienced with previous trial of peginterferon and ribavirin **AND**
 - Previous trial of Epclusa, Harvoni or Mavyret required (e.g., adverse effect, intolerance early in therapy) or contraindication to Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
-) Patients with decompensated cirrhosis:
 - Previous trial of Epclusa or Harvoni required (e.g., adverse effect, intolerance early in therapy), or contraindication to Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
 - Concurrent ribavirin use required
-) Patients post-liver transplant:
 - Previous trial of Harvoni or Mavyret required (e.g., adverse effect, intolerance early in therapy, or contraindication to Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
 - Concurrent ribavirin use required

For genotype 3 infection:

-) Patients without cirrhosis:
 - Patients must be treatment naïve or treatment experienced with previous trial of peginterferon and ribavirin **AND**
 - Previous trial of Epclusa or Mavyret required (e.g., adverse effect, intolerance early in therapy), or contraindication to Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
-) Patients with decompensated cirrhosis:
 - Previous trial of Epclusa required (e.g., adverse effect, intolerance early in therapy, or contraindication to therapy; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
 - Concurrent ribavirin use required
-) Post-liver transplant, without cirrhosis:
 - Previous trial of Mavyret required (e.g., adverse effect, intolerance early in therapy), or contraindication to therapy; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
 - Concurrent ribavirin use required
-) Post-liver transplant, with compensated cirrhosis:
 - Previous trial of Epclusa or Mavyret required (e.g., adverse effect, intolerance early in therapy) or contraindication to Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR will not be approved]
 - Concurrent ribavirin use required

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACLATASVIR

RATIONALE

Ensure appropriate utilization of Daklinza (daclatasvir).

FDA APPROVED INDICATIONS

For use with Sovaldi (sofosbuvir), with or without ribavirin, for the treatment of chronic hepatitis C genotype 1 and 3 infections in adults.

Limitations of Use:

-) Sustained virologic response (SVR) rates are reduced in genotype 3 patients with cirrhosis receiving Daklinza in combination with Sovaldi for 12 weeks.

FDA APPROVED DOSAGE

One 60mg tablet taken once daily in combination with Sovaldi (sofosbuvir). Reduce Daklinza dosage to 30mg once daily with strong CYP3A inhibitors and increase dosage to 90mg once daily with moderate CYP3A inducers.

FDA APPROVED DOSAGE

Recommended treatment regimen and duration for Daklinza in patients with genotype 1 or 3 HCV:

Genotype 1	Patients without cirrhosis	Daklinza + Sovaldi for 12 weeks
	Compensated (Child-Pugh A) cirrhosis	
	Decompensated cirrhosis (Child-Pugh B or C)	Daklinza + Sovaldi + ribavirin for 12 weeks
	Post-transplant	
Genotype 3	Without cirrhosis	Daklinza + Sovaldi for 12 weeks
	Compensated (Child-Pugh A) or decompensated (Child Pugh B or C) cirrhosis; or post liver transplant	Daklinza + Sovaldi + ribavirin for 12 weeks

OTHER INFORMATION

EFFICACY

The efficacy of Daklinza for treatment of hepatitis C genotype 3 was studied in the phase 3 ALLY-3 trial, an open-label trial with 152 participants with chronic hepatitis C genotype 3 infection and compensated liver disease. Participants received Daklinza 60mg plus sofosbuvir for 12 weeks. The primary efficacy endpoint was SVR; SVR was defined as HCV RNA levels below the lower limit of quantification at post-treatment week 12 (SVR12). Of the participants, 66% (n=101) were treatment naïve and 34% (n=51) were treatment experienced. The majority of treatment-experienced patients had failed a prior regimen of peginterferon plus ribavirin, but 14% (7 subjects) had previously received a sofosbuvir regimen. Other patient characteristics in the ALLY-3 trial included the following: mean age 55 years (range 24-73 years), 21% with compensated cirrhosis, 59% male, 90% white, 5% Asian, and 4% of African descent. The majority of patients (76%) had baseline HCV RNA levels greater than or equal to 800,000 IU/mL.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACLATASVIR

FDA APPROVED INDICATIONS (CONTINUED)

OTHER INFORMATION

EFFICACY

Table 1- Treatment results of the ALLY-3 trial: Daklinza in combination with Sovaldi for treatment of hepatitis C genotype 3 (From Daklinza prescribing information)

Treatment Outcomes	Treatment-Naive n=101	Treatment-Experienced n=51	Total n=152
SVR			
All	90% (91/101)	86% (44/51)	89% (135/152)
No cirrhosis ^a	98% (80/82)	92% (35/38)	96% (115/120)
With cirrhosis	58% (11/19)	69% (9/13)	63% (20/32)
Outcomes for subjects without SVR			
On-treatment virologic failure ^b	1% (1/101)	0	0.7% (1/152)
Relapse ^c	9% (9/100)	14% (7/51)	11% (16/151)

^a Includes 11 subjects with missing or inconclusive cirrhosis status.

^b One subject had quantifiable HCV RNA at end of treatment.

^c Relapse rates are calculated with a denominator of subjects with HCV RNA not detected at the end of treatment.

Additional ALLY clinical trials are underway to study the Daklinza/Sovaldi combination for hepatitis C genotypes 1-6, in patients with cirrhotic and post-liver transplant patients, as well as those with HIV coinfection. However, the current prescribing information states that SVR rates are reduced in patients with cirrhosis, and the optimal duration of Daklinza and Sovaldi for patients with cirrhosis has not been established.

SAFETY

Common adverse effects of Daklinza (reported in 10% or more of participants in clinical trials) include headache and fatigue.

Daklinza is contraindicated for patients concurrently using medications that are strong inducers of CYP3A4, including phenytoin, carbamazepine, rifampin and St. John's Wort. Using Daklinza in combination with strong CYP3A4 inducers may lead to loss of virologic response with Daklinza.

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DACLATASVIR

FDA APPROVED INDICATIONS (CONTINUED)

SAFETY

Caution should be used with concurrent use of CYP3A inhibitors or CYP3A inducers. Patients using strong CYP3A inhibitors (e.g., atazanavir/ritonavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, saquinavir, telithromycin, or voriconazole) will require a dosage decrease to Daklinza 30mg daily. Patients using concurrent moderate CYP3A inducers (e.g., bosentan, dexamethasone, efavirenz, etravirine, modafinil, nafcillin, or rifapentine) will require a dosage increase to Daklinza 90mg daily.

Daklinza should not be administered concurrently with amiodarone for patients using the Daklinza/Sovaldi regimen. Serious and symptomatic bradycardia may result for individuals on amiodarone using Sovaldi with any other direct acting HCV antiviral, including Daklinza. The risk of bradycardia due to this drug interaction increases for patients using beta blockers, those with underlying cardiac comorbidities, or those with advanced liver disease. Cardiac monitoring can be considered for patients with no alternative treatment options that require this combination plus amiodarone.

Use of Daklinza in patients on digoxin will require digoxin dosage reduction (usually 30-50%) during Daklinza. Monitor serum digoxin concentrations before starting Daklinza.

Daklinza increases dabigatran serum concentrations, and could lead to increased risk of bleeding in certain populations. Patients with reduced renal function using dabigatran should use caution and avoid concurrent use of Daklinza when possible.

No dosage adjustment of Daklinza is required for patients with any degree of renal impairment. No dosage adjustment of Daklinza is required for patients with mild, moderate, or severe hepatic impairment. The safety and efficacy of Daklinza in patients with decompensated cirrhosis has not been established.

Daklinza has not been studied in human pregnancy and lactation studies. Animal studies show no evidence of fetal harm at exposures of 6-22 times the recommended human dose of Daklinza 60mg, but embryofetal toxicity occurred at doses of 33-98 times the recommended human dose. Animal studies showed daclatasvir is present in the milk of lactating rats.

Cross-resistance is expected for Daklinza and other NS5A inhibitors. Cross-resistance for other classes of direct-acting antivirals is not expected. The efficacy of Daklinza/Sovaldi has not been studied in patients who have previously failed treatment with regimens that include an NS5A inhibitor.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACLATASVIR

REFERENCES

-) Daklinza [Prescribing Information]. Princeton, NJ: Bristol Myers Squibb; February 2017.
-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed July 26, 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/15

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DACOMITINIB

Generic	Brand	HICL	GCN	Exception/Other
DACOMITINIB	VIZIMPRO	45283		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet **ALL** of the following criteria?
 -) The patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
 -) The requested medication will be used as first-line treatment

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **DACOMITINIB (Vizimpro)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC). In addition, the following criteria must be met:

-) The patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
-) The requested medication will be used as first-line treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vizimpro.

REFERENCES

-) Vizimpro [Prescribing Information]. New York, NY: Pfizer Labs; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DALFAMPRIDINE

Generic	Brand	HICL	GCN	Exception/Other
DALFAMPRIDINE	AMPYRA	13907		EXCLUDE MISCELL.; POWDER NON-DRUGS

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is this an initial request for Ampyra (dalfampridine)?

If yes, continue to #2.

If no, continue to #5.

2. Is the patient overseen by a neurologist?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: Approval requires that the patient is overseen by a neurologist, has a diagnosis of multiple sclerosis, and has symptoms of walking disability.

3. Does the patient have multiple sclerosis?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: Approval requires that the patient is overseen by a neurologist, has a diagnosis of multiple sclerosis, and has symptoms of walking disability.

4. Does the patient have symptoms of walking disability such as mild to moderate bilateral lower extremity weakness or unilateral weakness plus lower extremity or truncal ataxia?

If yes, **approve for 3 months for #2 tablets per day per month.**

APPROVAL TEXT: Renewal requires documentation of at least a 15% improvement in walking ability.

If no, do not approve.

DENIAL TEXT: Approval requires that the patient is overseen by a neurologist, has a diagnosis of multiple sclerosis, and has symptoms of walking disability.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DALFAMPRIDINE

GUIDELINES FOR USE (CONTINUED)

5. Has the patient experienced or maintained at least a 15% improvement in walking ability?

If yes, **approve for 12 months for #2 tablets per day per month.**

If no, do not approve.

DENIAL TEXT: Approval requires that the patient has experienced an improvement in walking ability.

RATIONALE

Ensure appropriate utilization for dalfampridine.

FDA APPROVED INDICATION

Dalfampridine is approved in patients with multiple sclerosis to improve walking.

REFERENCES

-) Acorda Therapeutics. Ampyra package insert. Hawthorne, NY. January 2010.
-) Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomized, double-blind, controlled trial. Lancet. 2009; 373:732-738.
-) Kachuck NJ. Sustained release oral fampridine in the treatment of multiple sclerosis. Expert Opin Pharmacother. 2009; 10:2025-2035.
-) Bever CT, Judge S. Sustained-release fampridine for multiple sclerosis. Expert Opin Investig Drugs. 2009; 18:1013-1024.
-) Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: July 6, 2011].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/10

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DASATINIB

Generic	Brand	HICL	GCN	Exception/Other
DASATINIB	SPRYCEL	33855		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase and meet **ONE** of the following criteria?
 -) The patient weighs at least 45kg and has a newly diagnosed chronic myeloid leukemia (CML)
 -) The patient weighs between 10kg and 44kg

If yes, approve Sprycel 100mg for 12 months by GPID with a quantity limit of #1 per day. (Approve additional strengths as requested by GPID with a quantity limit of #1 per day for all strengths with the exception of Sprycel 20mg that can be approved by GPID for up to #2 per day.)

If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, accelerated phase, or blast phase and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
 -) The patient has had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the patient is negative for the following mutations: T315I, V299L, T315A, or F317L/V/I/C

If yes, approve Sprycel 140mg for 12 months by GPID with a quantity limit of #1 per day. (Approve additional strengths as requested by GPID with a quantity limit of #1 per day for all strengths with the exception of Sprycel 20mg that can be approved by GPID for up to #2 per day.)

If no, continue to #3.

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?

-) The patient is 18 years of age or older
-) The patient has a resistance or intolerance to prior therapy (e.g., imatinib (Gleevec), or nilotinib (Tasigna))

If yes, **approve Sprycel 140mg for 12 months by GPID with a quantity limit of #1 per day. (Approve additional strengths as requested by GPID with a quantity limit of #1 per day for all strengths with the exception of Sprycel 20mg that can be approved by GPID for up to #2 per day.)**

If no, do not approve.

DENIAL TEXT: The guideline named **DASATINIB (Sprycel)** requires a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic, accelerated, or blast phase, or Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL). In addition, the following criteria must also be met:

For the diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, approval requires ONE of the following:

-) The patient weighs at least 45kg and has a newly diagnosed chronic myeloid leukemia (CML)
-) The patient weighs between 10kg and 44kg

For the diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, accelerated phase, or blast phase, approval requires:

-) The patient is 18 years of age or older
-) The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
-) The patient has had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the patient is negative for the following mutations: T315I, V299L, T315A, or F317L/V/I/C.

For the diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), approval requires:

-) The patient is 18 years of age or older
-) The patient has a resistance or intolerance to prior therapy (e.g., imatinib (Gleevec), or nilotinib (Tasigna))

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DASATINIB

RATIONALE

Ensure appropriate utilization of dasatinib based on FDA approved indication and NCCN guidelines. The recommended dose is 100mg daily for chronic phase chronic myeloid leukemia (CML) and 140mg daily for CML in accelerated phase or blast crisis. Dose escalation to 140mg in chronic phase CML and 180mg in advanced phase CML. Dosing for acute lymphoblastic leukemia is the same as for CML in blast crisis. Dose reduction to as low as 20mg daily can be considered for patients taking a strong CYP3A4 inhibitor.

FDA APPROVED INDICATIONS

Sprycel is FDA approved for the following:

-) Newly diagnosed adults with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase.
-) Adults with chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome-positive chronic myeloid leukemia with resistance or intolerance to prior therapy including imatinib.
-) Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy.
-) Pediatric patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase.

DOSAGE AND ADMINISTRATION

Tablets should not be crushed, cut, or chewed; they should be swallowed whole. Sprycel can be taken with or without a meal, either in the morning or in the evening.

The recommended dose is 100mg daily for chronic phase (CML) and 140mg daily for CML in accelerated phase or blast crisis. Dose escalation to 140mg in chronic phase CML and 180mg in advanced phase CML. Dosing for acute lymphoblastic leukemia is the same as for CML in blast crisis. Dose reduction to as low as 20mg daily can be considered for patients taking a strong CYP3A4 inhibitor.

Dosage of Sprycel (dasatinib) in Adult Patients

The recommended starting dosage of Sprycel for chronic phase chronic myeloid leukemia (CML) in adults is 100 mg administered orally once daily. The recommended starting dosage of Sprycel for accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL in adults is 140 mg administered orally once daily.

In clinical studies of adult CML and Ph+ ALL patients, dose escalation to 140 mg once daily (chronic phase CML) or 180 mg once daily (advanced phase CML and Ph+ ALL) was allowed in patients who did not achieve a hematologic or cytogenetic response at the recommended starting dosage.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DASATINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Dosage of Sprycel (dasatinib) in Pediatric Patients

The recommended starting dosage for pediatrics is based on body weight as shown in the table below. The recommended dose should be administered orally once daily with or without food. Recalculate the dose every 3 months based on changes in body weight, or more often if necessary.

Body Weight (kg)	Daily dose (mg)
10 to <20 kg	40 mg
20 to <30kg	60 mg
30 to <45kg	70 mg
45kg	100 mg

Please refer to the full prescribing information for dose modification recommendations for patients taking a strong CYP3A4 inducer or inhibitor, and for patients who experience toxicity.

REFERENCES

-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia. (Version 2.2012).
-) Sprycel [Prescribing information]. Bristol-Myers Squibb. Princeton, NJ. November 2017.

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 05/12

Client Approval: 03/18

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEFERIPRONE

Generic	Brand	HICL	GCN	Exception/Other
DEFERIPRONE	FERRIPROX	18544		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the medication prescribed by or given in consultation with a hematologist or hematologist-oncologist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of transfusional iron overload due to a thalassemia syndrome?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the request due to intolerable toxicities, clinically significant adverse effects, or contraindication to current chelation therapy with Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)?

If yes, **approve for 6 months by HICL.**

If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEFERIPRONE

INITIAL CRITERIA (CONTINUED)

5. Is the current chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferrioxamine]) inadequate as defined by one of the following criteria?
-) Serum ferritin levels consistently above 2500mcg/L (at least 2 lab values in the previous 3 months)
 -) The patient has evidence of cardiac iron accumulation (i.e., cardiac T2* MRI <10 milliseconds, iron induced cardiomyopathy, fall in left ventricular ejection fraction [LVEF], arrhythmia indicating inadequate chelation)

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DEFERIPRONE (Ferriprox)** requires a diagnosis of transfusional iron overload due to a thalassemia syndrome. Treatment must be prescribed by or given in consultation with a hematologist or hematologist-oncologist. The following criteria must be also be met:

-) Trial of Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferrioxamine) and the patient is experiencing one of the following:
 -) Intolerable toxicities, clinically significant adverse effects, or contraindication to current chelation therapy with Exjade, Jadenu, or Desferal
 -) Chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferrioxamine]) is inadequate defined by one of the following:
 - o Serum ferritin levels consistently above 2500mcg/L (at least 2 lab values in the previous 3 months)
 - o The patient has evidence of cardiac iron accumulation (i.e., cardiac T2* MRI <10 milliseconds, iron induced cardiomyopathy, fall in left ventricular ejection fraction [LVEF], arrhythmia indicating inadequate chelation)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of transfusional iron overload due to a thalassemia syndrome and meet the following criteria?
-) Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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DEFERIPRONE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **DEFERIPRONE (Ferriprox)** requires a diagnosis of transfusional iron overload due to thalassemia syndromes for renewal. The following criteria must be met:

-) Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

RATIONALE

Promote appropriate utilization of **DEFERIPRONE** based on FDA approved indication and treatment guidelines.

FDA APPROVED INDICATIONS

Ferriprox (deferiprone) is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

DOSAGE AND ADMINISTRATION

Ferriprox (deferiprone): 25mg/kg to 33mg/kg orally three times per day for a total daily dose of 75mg/kg to 99mg/kg per day. Consider interrupting therapy if serum ferritin level consistently falls below 500mcg/L.

AVAILABLE STRENGTHS

Ferriprox (deferiprone) is available in 500mg film coated tablets and 100mg/mL oral solution.

REFERENCES

-) Ferriprox [Package Insert]. ApoPharma, Inc. Rockville, MD. February 2015.
-) Standards of Care Guidelines for Thalassemia. 2012. Children's Hospital & Research Center, Oakland CA. Available from: <http://thalassemia.com/documents/SOCGuidelines2012.pdf>
-) Cappellini MD, et al. Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT): Iron Overload and Chelation. 3rd edition. Nicosia (CY):Thalassaemia International Federation;2014. Accessed 4/10/2017. Access here: <http://www.resonancehealth.com/images/files/clinician-information/patient-management-guidelines/TIF%20Guidelines%20for%20the%20Management%20of%20Transfusion%20Dependent%20Thalassaemia.pdf>
-) Taher A, et al. Guidelines for the Management of Non Transfusion Dependent Thalassaemia (NTDT): Iron Overload and Chelation. Nicosia (CY):Thalassaemia International Federation;2013. Accessed 4/10/2017. Access here: <http://thalassemia.com/documents/NTDT-TIF-guidelines.pdf>

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEFERIPRONE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/17

Created: 08/17
Client Approval: 08/17

P&T Approval: 07/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEFEROXAMINE

Generic	Brand	HICL	GCN	Exception/Other
DEFEROXAMINE	DESFERAL	01104		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet ALL of the following criteria?
 -) The medication is being prescribed by or given in consultation with a hematologist or hematologist-oncologist
 -) The patient is 3 years of age or older
 -) Serum ferritin levels consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DEFEROXAMINE (Desferal)** requires a diagnosis of chronic iron overload due to transfusion-dependent anemias. Treatment must be prescribed by or given in consultation with a hematologist or hematologist-oncologist. The following criteria must also be met:

-) The patient is 3 years of age or older
-) Serum ferritin levels consistently greater than 1000mcg/L (at least 2 lab values in the previous 3 months)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic iron overload due to transfusion-dependent anemias and meet the following criteria?
 -) Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DEFEROXAMINE (Desferal)** requires a diagnosis of chronic iron overload due to transfusion-dependent anemias for renewal. The following criteria must also be met:

-) Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEFEROXAMINE

RATIONALE

Promote appropriate utilization of **DEFEROXAMINE** based on FDA approved indication and treatment guidelines.

FDA APPROVED INDICATIONS

Desferal (deferoxamine) is indicated for the treatment of acute iron intoxication and chronic iron overload due to transfusion-dependent anemias.

DOSAGE AND ADMINISTRATION

-) Acute iron intoxication:
 - o IM (this route for patient not in shock): 1000mg following by 500mg every 4 hours for two doses. Depending on the clinical response, subsequent 500mg may be administered every 4 to 12 hours. Total amount should not exceed 6000mg in 24 hours.
 - o IV (this route for patients in shock): 1000mg at a rate of 15mg/kg/hr. This may be followed by 500mg over 4 hours for a two doses. Depending on the clinical response, subsequent 500mg may be administered every 4 to 12 hours. Total amount should not exceed 6000mg in 24 hours.
-) Chronic iron overload due to transfusion-dependent anemias
 - o SQ: 1000 to 2000mg per day (20-40mg/kg/day) should be administered over 8 to 24 hours via a continuous infusion pump.
 - o IV: in patients with intravenous access, the daily dose is 20-40mg/kg/day for children and 50-40mg/kg/day over 8 to 12 hours in adults for 5-7 days per week. Max dose in children is 40mg/kg/day and adults is 60mg/kg/day. In patients who are poorly compliant, Desferal may be administered prior to or following same day blood transfusion; however, the contribution of this mode of administration to iron balance is limited.
 - o IM: 500 to 1000mg daily.

REFERENCES

-) Desferal [Prescribing Information]. Novartis Pharmaceuticals Corporation: East Hanover, NJ. December 2011.
-) Standards of Care Guidelines for Thalassemia. 2012. Children's Hospital & Research Center, Oakland CA. Available from: <http://thalassemia.com/documents/SOCGuidelines2012.pdf>
-) Cappellini MD, et al. Guidelines for the Management of Transfusion Dependent Thalassemia (TDT): Iron Overload and Chelation. 3rd edition. Nicosia (CY):Thalassaemia International Federation;2014. Accessed 4/10/2017. Access here: <http://www.resonancehealth.com/images/files/clinician-information/patient-management-guidelines/TIF%20Guidelines%20for%20the%20Management%20of%20Transfusion%20Dependent%20Thalassaemia.pdf>
-) Taher A, et al. Guidelines for the Management of Non Transfusion Dependent Thalassemia (NTDT): Iron Overload and Chelation. Nicosia (CY):Thalassaemia International Federation;2013. Accessed 4/10/2017. Access here: <http://thalassemia.com/documents/NTDT-TIF-guidelines.pdf>

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEFEROXAMINE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/17

Created: 08/17
Client Approval: 08/17

P&T Approval: 07/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DESIRUDIN

Generic	Brand	HICL	GCN	Exception/Other
DESIRUDIN	IPRIVASK	19072		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the request for Iprivask for the prevention (prophylaxis) of deep vein thrombosis (DVT) for a patient undergoing elective hip replacement surgery?

If yes, **approve for a total of 35 days of treatment. Enter two authorizations as follows:**

) **Approve for 12 days for #24 vials.**

) **Also enter one fill for 23 days for #46 vials with a start date of 7 days following the initial approval.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: Approval requires that the patient is receiving Iprivask for the prevention of deep vein thrombosis (DVT) undergoing elective hip replacement surgery.

RATIONALE

To ensure appropriate use of desirudin for the prevention of deep vein thrombosis (DVT) in patients undergoing hip replacement surgery. The desirudin prescribing information states that the average duration of treatment is 9 to 12 days. The 2008 ACCP guidelines recommend venous thromboembolism treatment of up to 35 days.

FDA APPROVED INDICATIONS

Prophylaxis of deep vein thrombosis (DVT) in elective hip replacement surgery.

REFERENCES

-) Canyon Pharmaceuticals, Inc. Iprivask package insert. Hunt Valley, MD. January 2010.
-) MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: August 19, 2010].
-) Geerts W, Bergquist D, and Pineo G et al. Prevention of Venous Thromboembolism supplement; The eighth ACCP conference on antithrombotic and thrombolytic therapy. *Chest* 2008; 133 (6 Suppl): 381S-453S.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DESIRUDIN

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/14

Created: 08/10
Client Approval: 11/13

P&T Approval: 11/1



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEUTETRABENAZINE

Generic	Brand	HICL	GCN	Exception/Other
DEUTETRABENAZINE	AUSTEDO	44192		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meet the following criterion?

☐ Therapy is prescribed by or given in consultation with a neurologist or movement disorder specialist

If yes, **approve for 12 months by GPID for all the dosage strengths with the following quantity limits:**

- ☐ **6mg tablet (GPID 43228): #2 tablets per day**
☐ **9mg tablet (GPID 43236): #4 tablets per day**
☐ **12mg tablet (GPID 43237): #4 tablets per day**

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe tardive dyskinesia and meet ALL of the following criteria?

- ☐ Moderate to severe tardive dyskinesia has been present for at least 3 months
☐ The patient is at least 18 years of age
☐ Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
☐ Patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

If yes, **approve for 12 months by GPID for all the dosage strengths with the following quantity limits:**

- ☐ **6mg tablet (GPID 43228): #2 tablets per day**
☐ **9mg tablet (GPID 43236): #4 tablets per day**
☐ **12mg tablet (GPID 43237): #4 tablets per day**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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DEUTETRABENAZINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **DEUTETRABENAZINE (Austedo)** requires a diagnosis of chorea (involuntary movements) associated with Huntington's disease or moderate to severe tardive dyskinesia. In addition, the following criteria must be met:

For diagnosis of chorea (involuntary movements) associated with Huntington's disease, approval requires:

-) Therapy is prescribed by or given in consultation with a neurologist or movement disorder specialist

For diagnosis of moderate to Severe Tardive Dyskinesia, approval requires:

-) Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
-) The patient is at least 18 years of age
-) Moderate to severe tardive dyskinesia has been present for at least 3 months
-) Patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

RATIONALE

Promote appropriate utilization of **DEUTETRABENAZINE (Austedo)** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Austedo is indicated for the treatment of chorea associated with Huntington's disease and for the treatment of adults with tardive dyskinesia.

DOSAGE AND ADMINISTRATION

The dose of Austedo is determined individually for each patient based on reduction of chorea or tardive dyskinesia and tolerability.

Dosing Recommendations to Initiate DEUTETRABENAZINE (Austedo) treatment

When first prescribed to patients who are not being switched from tetrabenazine, the dosing recommendations are as follows:

-) The recommended starting dose of Austedo is 6 mg administered orally once daily for patients with chorea associated with Huntington's Disease and 12 mg orally once daily for patients with tardive dyskinesia
-) The dose may be increased at weekly intervals in increments of 6 mg per day to a maximum recommended daily dosage of 48 mg
-) Administer total daily dosages of 12 mg or above in two divided doses
-) Administer Austedo with food. Swallow Austedo whole. Do not chew, crush, or break tablets

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEUTETRABENAZINE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE

Initial Dosing Recommendations for Patients Switching from Tetrabenazine to Austedo

Discontinue tetrabenazine and initiate Austedo the following day. The recommended initial dosing regimen of Austedo in patients switching from tetrabenazine to Austedo is as follows:

Current tetrabenazine daily dosage	Initial regimen of Austedo
12.5 mg	6 mg once daily
25 mg	6 mg twice daily
37.5 mg	9 mg twice daily
50 mg	12 mg twice daily
62.5 mg	15 mg twice daily
75 mg	18 mg twice daily
87.5 mg	21 mg twice daily
100 mg	24 mg twice daily

Dosage Adjustment with Strong CYP2D6 Inhibitors

In patients receiving strong CYP2D6 inhibitors (e.g., quinidine, antidepressants such as paroxetine, fluoxetine, and bupropion), the total daily dosage of Austedo should not exceed 36 mg (maximum single dose of 18 mg).

Dosage Adjustment in Poor CYP2D6 Metabolizers

In patients who are poor CYP2D6 metabolizers, the total daily dosage of Austedo should not exceed 36 mg (maximum single dose of 18 mg).

REFERENCES

) Austedo [Prescribing Information]. North Wales, PA. Teva Pharmaceuticals, Inc. August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 04/17

Client Approval: 02/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DEXTROMETHORPHAN with QUINIDINE

Generic	Brand	HICL	GCN	Exception/Other
DEXTROMETHORPHAN/ QUINIDINE	NUEDEXTA	37278		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pseudobulbar affect (PBA)?

If yes, **approve for 12 months by HICL for #2 per day per month.**

If no, do not approve.

DENIAL TEXT: Our guideline for **DEXTROMETHORPHAN with QUINIDINE** requires a diagnosis of pseudobulbar affect (PBA).

RATIONALE

Ensure that Nuedexta is used solely for its FDA approved indication and in patients for whom it has been determined to be safe and efficacious.

FDA APPROVED INDICATION

Nuedexta is indicated for treatment of pseudobulbar affect (PSA).

REFERENCES

-) Avanir Pharmaceuticals, Inc. Nuedexta package insert. Aliso Viejo, CA. January 2015.
-) Miller A, Pratt H, and Schiffer R. Pseudobulbar affect: the spectrum of clinical presentations, etiologies and treatments. Expert Rev Neurother. 2011; 11(7) 1077-1088:
-) National Stroke Association. Pseudobulbar affect and stroke. Stroke Clinical Updates. Volume XV, Issue 1: January/February 2005.
-) Pioro E. Current concepts in pharmacotherapy of pseudobulbar affect. Drugs 2004; 71 (9): 1192-1207.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/01/15

Created: 02/11

Client Approval: 03/15

P&T Approval: 01/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DICHLORPHENAMIDE

Generic	Brand	HICL	GCN	Exception/Other
DICHLORPHENAMIDE	KEVEYIS	03642		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary hypokalemic periodic paralysis and have all of the following criteria been met?
 -) The patient has tried acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene)
 -) The patient is at least 18 years old
 -) The prescription is written by or currently supervised by a neurologist
 -) The patient does not have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use of high-dose aspirin

If yes, **approve for two months by HICL with a quantity limit of #4 tablets per day.**

If no, continue to #2.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DICHLORPHENAMIDE

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of primary hyperkalemic periodic paralysis or Paramyotonia Congenita and have all of the following criteria been met?
-) The patient has tried acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide)
 -) The patient is at least 18 years old
 -) The prescription is written by or currently supervised by a neurologist
 -) The patient does not have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use of high-dose aspirin

If yes, **approve for two months by HICL with a quantity limit of #4 tablets per day.**

If no, do not approve.

DENIAL TEXT: Our guideline for **DICHLORPHENAMIDE** requires that the patient has a diagnosis of primary hypokalemic periodic paralysis, primary hyperkalemic periodic paralysis, or Paramyotonia Congenita and meets all of the following criteria:

-) patient age of at least 18 years
-) prescription written by or currently supervised by a neurologist
-) patient does not have hepatic insufficiency, pulmonary obstruction, or a health condition that warrants concurrent use of high-dose aspirin.

Additional guideline requirements apply.

-) **For patient with primary hypokalemic periodic paralysis**, a trial of acetazolamide AND a potassium-sparing diuretic (i.e., spironolactone, triamterene) is required.
-) **For patient with primary hyperkalemic periodic paralysis or Paramyotonia Congenita**, a trial of acetazolamide AND a thiazide diuretic (i.e., hydrochlorothiazide) is required.

RENEWAL CRITERIA

1. Has the patient experienced at least two fewer attacks per week from their baseline?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**

If no, do not approve.

DENIAL TEXT: Our guideline for **DICHLORPHENAMIDE** renewal requires that the patient experiences at least two fewer attacks per week from their baseline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DICHLORPHENAMIDE

RATIONALE

Promote appropriate utilization of dichlorphenamide based on FDA approved indication, dosing, and contraindications. A step therapy has been implemented to promote cost-effective therapies based on previously available agents. A specialist edit has also been implemented to promote appropriate diagnosis and on-label use due to rare neuromuscular condition.

Keveyis is the first FDA approved treatment for primary hyperkalemic and primary hypokalemic periodic paralysis. The only clinical trials demonstrating a benefit for treatment in periodic paralysis involve the carbonic anhydrase inhibitor, dichlorphenamide. Dichlorphenamide was initially approved in 1958 as the branded drug Daranide for the treatment of elevated intraocular pressure but was discontinued in May 2003. In 2015, it was reintroduced as Keveyis as an orphan drug.

Affecting almost 5,000 people in the United States, periodic paralysis is a rare neuromuscular disorder related to a defect in muscle ion channels, characterized by episodes of painless but debilitating muscle weakness or paralysis (lasting minutes to an hour or two), which may be precipitated by heavy exercise, fasting, or high-carbohydrate meals. Periodic paralysis (PP) is classified as hypokalemic when episodes occur in association with low potassium blood levels or as hyperkalemic when episodes can be induced by elevated potassium. Most cases of periodic paralysis are hereditary, usually with an autosomal dominant inheritance pattern. Acquired cases of hypokalemic PP have been described in association with hyperthyroidism. When there is an established family history, episodes of periodic paralysis often require no further diagnostic evaluation. Otherwise, the diagnosis of PP is suggested by documentation of hypo/hyperkalemia during a typical attack of weakness. Even when this is demonstrated, diagnosis is not as easily accomplished as other testing is required to rule out alternative diagnoses. Genetic testing is available for most, but not all of the mutations underlying hypokalemic PP. Evidence of myotonia (seen in up to 80% with this subtype) during electromyographic (EMG) examination can help support the diagnosis of hyperkalemic PP.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DICHLORPHENAMIDE

RATIONALE (CONTINUED)

Nonpharmacologic interventions that may be effective for preventing attacks include a low-carbohydrate diet and refraining from vigorous exercise. When attacks continue to be disabling, prophylactic treatment is indicated to avoid morbidity, even mortality, which can be associated with hospitalization and acute treatment. When lifestyle changes are not sufficiently effective, symptomatic potassium supplementation, diuretics, and medications such as carbonic anhydrase inhibitors are used. The mechanism whereby carbonic anhydrase inhibitors are effective in PP is not clear, but appears to be independent of carbonic anhydrase inhibition. Studies in animal models suggest that these agents trigger calcium-activated potassium channels on skeletal muscle. Acetazolamide, another carbonic anhydrase inhibitor, is also commonly reported to be effective in reducing attacks when dosed at 250mg twice daily. However, one retrospective study found that only half of patients respond to acetazolamide therapy. The subset of patients who might find acetazolamide treatment helpful are those who experience mild, fluctuating weakness between attacks. For hypokalemic PP, potassium-sparing diuretics such as spironolactone (100mg daily) or triamterene (150mg daily) can be used as a supplement or as an alternative to a carbonic anhydrase inhibitor in patients who experience worsening or intolerance. For hyperkalemic PP, thiazide diuretics (i.e. hydrochlorothiazide 25-50mg daily) have been reported as helpful in controlling attacks in some patients.

DOSAGE

Initiate dosing at 50 mg twice daily. The initial dose may be increased or decreased based on individual response, at weekly intervals (or sooner in case of adverse reaction). The maximum total daily dose is 200 mg.

Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants are a heterogeneous group of conditions, for which the response to Keveyis may vary. Therefore, prescribers should evaluate the patient's response after 2 months of treatment to decide whether Keveyis should be continued.

FDA APPROVED INDICATION

Keveyis is an oral carbonic anhydrase inhibitor indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

AVAILABLE STRENGTHS

) 50 mg tablet

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DICHLORPHENAMIDE

REFERENCES

-) Keveyis [Prescribing Information]. Hawthorne, NY: Taro Pharmaceuticals; August 2015.
-) UpToDate, Inc. Hypokalemic periodic paralysis. UpToDate [database online]. Waltham, MA. Available at: <http://www.uptodate.com/home/index.html>. Updated July 23, 2014.
-) UpToDate, Inc. Hyperkalemic periodic paralysis. UpToDate [database online]. Waltham, MA. Available at: <http://www.uptodate.com/home/index.html>. Updated June 13, 2014.
-) Jeffrey S. FDA Nod for Keveyis in Primary Periodic Paralysis. Available at: <http://www.medscape.com/viewarticle/850050> Updated August 25, 2015.
-) Periodic paralysis international. Available at: <http://hkpp.org/patients/hyperkpp-FAQ> Updated June 25, 2011.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/16

Created: 09/15

Client Approval: 11/15

P&T Approval: 11/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DICLOFENAC TOPICAL

Generic	Brand	HICL	GCN	Exception/Other
DICLOFENAC SODIUM 3%	SOLARAZE		86831	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Actinic Keratosis and meets **ALL** of the following criteria?

-) The patient had a previous trial of or contraindication to topical fluorouracil (e.g., Efudex, Fluoroplex, Carac)
-) The medication is prescribed by a dermatologist or oncologist

If yes, **approve for 3 months by GPID with a quantity limit up to #100 grams per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **DICLOFENAC SODIUM (Solaraze)** requires a diagnosis of Actinic Keratosis. In addition, the following criteria must also be met:

-) The patient had a previous trial of or contraindication to topical fluorouracil (e.g., Efudex, Fluoroplex, Carac)
-) The medication is prescribed by a dermatologist or oncologist

RATIONALE

To promote clinically appropriate utilization of Solaraze for Actinic Keratosis.

FDA APPROVED INDICATIONS

Solaraze (diclofenac sodium) gel is indicated for the topical treatment of actinic keratoses (AK). Sun avoidance is indicated during therapy.

REFERENCES

-) Solaraze [Prescribing Information]. PharmaDerm: Melville, NY. April 2016.
-) De Berker D., et al. Guidelines for the Management of Actinic Keratosis. Br J Dermatol. 2007; 156:222-230.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/01/16

Created: 02/03

Client Approval: 09/16

P&T Approval: 11/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DORNASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
DORNASE ALFA	PULMOZYME	08832		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of cystic fibrosis and requests for twice daily dosing require a trial of once daily dosing.

2. Is the request for once daily dosing (30 ampules per month)?

If yes, **approve for 12 months with a quantity limit of #30 ampules per month.**

If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?

If yes, **approve for 12 months with a quantity limit of #60 ampules per month.**

If no, do not approve. **Enter a proactive authorization for 12 months with a quantity limit of #30 ampules per month.**

DENIAL TEXT: Approval requires a diagnosis of cystic fibrosis and requests for twice daily dosing require a trial of once daily dosing.

RATIONALE

Promote appropriate utilization of Pulmozyme based on FDA approved indication.

Dosage: The recommended dose for use in most cystic fibrosis patients is one 2.5mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.

FDA APPROVED INDICATION

Pulmozyme is indicated in conjunction with standard therapies in the management of cystic fibrosis patients to improve pulmonary function.

REFERENCE

) Genentech, Inc. Pulmozyme package insert. South San Francisco, CA. October 2010.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DORNASE ALFA

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/07/13

Created: 05/12
Client Approval: 01/13

P&T Approval: 05/12



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DROXIDOPA

Generic	Brand	HICL	GCN	Exception/Other
DROXIDOPA	NORTHERA	40936		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of Neurogenic Orthostatic Hypotension (NOH) caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy and meets the following criteria?

-) Patient is 18 years or older
-) Prescription was initiated by or given in consultation with a neurologist or cardiologist
-) Previous trial of or contraindication to midodrine **OR** fludrocortisone

If yes, continue to #2.

If no, do not approve

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the prescriber performed baseline blood pressure readings while the patient is sitting and also within minutes of standing from a supine (lying face up) position?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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DROXIDOPA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have persistent symptoms of neurogenic orthostatic hypotension, which include dizziness, lightheadedness, and the feeling of 'blacking out'?

If yes, **approve for 1 month by HICL for #180 capsules per 30 days.**

APPROVAL TEXT: Renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:

-) Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
-) Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

If no, do not approve.

DENIAL TEXT: The guideline for **DROXIDOPA (Northera)** requires a diagnosis of Neurogenic Orthostatic Hypotension and is at least 18 years of age or older. The following criteria must also be met.

-) Patient has a documented diagnosis of Neurogenic Orthostatic Hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
-) Previous trial of or contraindication to midodrine **OR** fludrocortisone
-) Prescription was initiated by or given in consultation with a neurologist or cardiologist
-) Patient has persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'
-) Prescriber performed baseline blood pressure reading while the patient is sitting and also within 3 minutes of standing from a supine (lying face up) position
-) Patient has a documented decrease of at least 20 mmHg in systolic blood pressure or 10 mmHg diastolic blood pressure within 3 minutes after standing from a sitting position

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DROXIDOPA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and meets **ALL** of the following criteria?

-) Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
-) Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

If yes, **approve for 3 months by HICL for #180 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline for **DROXIDOPA (NORTHERA)** renewal requires a diagnosis of Neurogenic Orthostatic Hypotension (NOH) and that the patient meets **ALL** of the following criteria while on therapy with Northera:

-) Patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like the patient may black out
-) Patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (laying face up) position

RATIONALE

Promote clinically appropriate utilization of Northera (droxidopa) based on its FDA approved indication and dosing.

Northera is indicated for the treatment neurogenic orthostatic hypotension (NOH) that is associated with Parkinson's disease (PD), multiple system atrophy, and pure autonomic failure. People with NOH are severely limited in their ability to perform routine daily activities that require walking or standing. Northera is a synthetic amino acid precursor of norepinephrine, which increases blood pressure by inducing peripheral arterial and venous vasoconstriction.

Orthostatic hypotension is diagnosed when within two to five minutes of quiet standing (after a five-minute period of supine rest), one or both of the following is present:

-) At least a 20 mmHg fall in systolic pressure
-) At least a 10 mmHg fall in diastolic pressure

Northera has a boxed warning regarding the risk of increased blood pressure while lying down (supine hypertension). The most common adverse events seen in clinical trials were headache, dizziness, nausea, hypertension, and fatigue.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DROXIDOPA

RATIONALE (CONTINUED)

In the clinical trials referenced in the Northera prescribing information, a 'responder' to treatment had to demonstrate improvement on the OHSA item #1 score by at least 1 point, as well as an increase in systolic blood pressure of at least 10 mmHg post-standing, during the open-label dose titration period.

Effectiveness of Northera beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically.

DOSE

The recommended starting dose of Northera is 100mg orally three times a day, upon arising in the morning, at midday, and in the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep). Northera may be administered with or without food.

Titrate to symptomatic response, in increments of 100mg three times daily every 24-48 hours up to a maximum dose of 600mg three times daily (maximum total daily dose of 1800mg).

FDA APPROVED INDICATIONS

Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure [Parkinson's disease (PD), multiple system atrophy and pure autonomic failure], dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

Northera received orphan-product designation from the FDA.

REFERENCES

-] Northera [Prescribing Information]. Charlotte, NC, Chelsea Therapeutics, Aug 2014.
-] Low PA, Singer W. Update on Management of Neurogenic Orthostatic Hypotension. Lancet Neurol. May 2008; 7(5):451-458.
-] Hauser, Robert, Cameron Szakacs, and Horacio Kaufmann. "Integrated Efficacy and Safety Analyses of Droxidopa for Symptomatic Neurogenic Orthostatic Hypotension (P1. 284)." Neurology 84.14 Supplement (2015): P1-284.
-] Kaufmann, Horacio, et al. "Droxidopa for neurogenic orthostatic hypotension A randomized, placebo-controlled, phase 3 trial." Neurology 83.4 (2014): 328-335.
-] Kaufmann, Horacio, et al. "Treatment of Neurogenic Orthostatic Hypotension with Droxidopa: Results from a Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Induction Design Study (PL02. 001)." Neurology 78.Meeting Abstracts 1 (2012): PL02-001.
-] Freeman, Roy et al. "Consensus statement on the definition of orthostatic hypotension, neurally mediated syncope and the postural tachycardia syndrome." Clin Auton Res Clinical autonomic research , 2011, Vol.21(2), p.69-72

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DROXIDOPA

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/16

Created: 9/14
Client Approval: 06/16

P&T Approval: 11/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DUVELISIB

Generic	Brand	HICL	GCN	Exception/Other
DUVELISIB	COPIKTRA	45269		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) **AND** meet the following criterion?

) The patient has received at least two prior therapies for CLL or SLL

If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day.**

If no, continue to #3.

3. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND** meet the following criterion?

) The patient has received at least two prior systemic therapies for FL

If yes, **approve for 12 months by HICL with a quantity limit of #2 capsules per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **DUVELISIB (Copiktra)** requires a diagnosis of relapsed or refractory chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or follicular lymphoma (FL). In addition, the following criteria must be met:

) The patient is 18 years of age or older

For patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval requires:

) The patient has received at least two prior therapies for CLL or SLL

For patients with relapsed or refractory follicular lymphoma (FL), approval requires:

) The patient has received at least two prior systemic therapies for FL

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DUVELISIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Copiktra (duvelisib).

REFERENCES

) Copiktra [Prescribing Information]. Needham, MA: Verastem, Inc.; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELBASVIR/GRAZOPREVIR

Generic	Brand	HICL	GCN	Exception/Other
ELBASVIR/GRAZOPREVIR	ZEPATIER	43030		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, with genotype 1 or genotype 4 and meet **ALL** the following criteria?
 -) The patient have a recent HCV infection documented by one detectable HCV RNA level within the last 6 months
 -) The patient at least 18 years old
 -) The patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet at least **ONE** of the following criteria?
 -) The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (via physician attestation)
 -) Zepatier will be taken concurrently with Sovaldi (sofosbuvir)
 -) The patient has moderate or severe hepatitis impairment (Child-Pugh B or C)
 -) Patient is currently taking any of the following medications: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., Prezcoibix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have **ONE** of the following?

-) The patient has a contraindication to Epclusa, Harvoni **AND** Mavyret
-) The patient has previously failed a short trial with Epclusa, Harvoni, or Mavyret (e.g., inability to tolerate, adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Harvoni, Mavyret or Epclusa that did not achieve SVR will not be approved.]
-) Patient has stage 4 or 5 chronic kidney disease (CKD) **AND** has previously failed a short trial of or has contraindication to Mavyret

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient **ONE** of the following?

-) Genotype 1a infection, treatment naïve, and **NO** baseline NS5A polymorphisms
-) Genotype 1a infection, previously treated with peginterferon/ribavirin, and **NO** baseline NS5A polymorphisms
-) Genotype 1b infection, treatment naïve
-) Genotype 1b infection, previously treated with peginterferon/ribavirin
-) Genotype 4 infection, treatment naïve

If yes, **approve for 12 weeks by HICL for #1 tablet per day.**

If no, continue to #5.

5. Is the requested medication being used with ribavirin and the patient meets **ONE** of the following criteria?

-) Genotype 1a infection, previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (e.g., Victrelis, Incivek, Olysio) plus peginterferon/ribavirin)
-) Genotype 1b infection, previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (e.g., Victrelis, Incivek, Olysio) plus peginterferon/ribavirin)

If yes, **approve for 12 weeks by HICL for #1 tablet per day.**

If no, continue to #6.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

6. Is the requested medication being used with ribavirin and the patient meets **ONE** of the following criteria?

-) Genotype 1a infection, treatment naïve, and has baseline NS5A polymorphisms
-) Genotype 1a infection, previously treated with peginterferon/ribavirin, and has baseline NS5A polymorphisms
-) Genotype 4 infection, previously treated with peginterferon/ribavirin

If yes, **approve for 16 weeks by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires a diagnosis of hepatitis C. The following criteria must also be met:

-) Patient has genotype 1 or genotype 4 hepatitis C
-) Patient is at least 18 years old
-) Patient must have a trial of Epclusa, Harvoni or Mavyret OR contraindication to Epclusa, Harvoni AND Mavyret prior to approval (patient with previous failure of a full treatment of Epclusa, Harvoni or Mavyret will not be approved)
-) Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Documentation of HCV infection (e.g., at least one detectable HCV RNA level within the last 6 months)
-) Testing for baseline NS5A polymorphisms is required for patients with genotype 1a infection
-) Ribavirin use is required for certain treatment-experienced patients or for treatment naïve patients with genotype 1a infection and baseline NS5A polymorphisms (per product labeling)
-) Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4; previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELBASVIR/GRAZOPREVIR

GUIDELINES FOR USE (CONTINUED)

Zepatier will not be approved for the following patients:

-) Patients using any of the following interacting medications concurrently while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (e.g., Atripla, Sustiva), atazanavir (e.g., Evotaz, Reyataz), darunavir (e.g., PrezcoBix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (e.g., Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
-) Patients taking Sovaldi (sofosbuvir) with Zepatier
-) Patients with moderate or severe hepatic impairment (Child-Pugh B or C)
-) Patients with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

RATIONALE

Ensure appropriate utilization of Zepatier.

FDA APPROVED INDICATIONS

Indicated with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 and 4 infection in adults.

FDA APPROVED DOSAGE

-) One tablet taken once daily with or without food.

Duration of therapy is as follows:

Patient type and infection type	Regimen	Duration
Genotype 1a: Treatment naïve or previous treatment with peginterferon/ribavirin without baseline NS5A polymorphisms	Zepatier	12 weeks
Genotype 1a: Treatment naïve or previous treatment with peginterferon/ribavirin with baseline NS5A polymorphisms	Zepatier plus ribavirin	16 weeks
Genotype 1b: Treatment naïve or previous treatment with peginterferon/ribavirin	Zepatier	12 weeks
Genotype 1a or 1b: Treatment experienced, HCV protease inhibitor triple therapy	Zepatier plus ribavirin	12 weeks
Genotype 4: Treatment naïve	Zepatier	12 weeks
Genotype 4: Treatment experienced, previous failure of peginterferon/ribavirin	Zepatier plus ribavirin	16 weeks

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OTHER INFORMATION

All patients should receive hepatic laboratory testing prior to starting Zepatier. Patients with genotype 1a should receive testing for NS5A resistance-associated polymorphisms.

AASLD/IDSA Guidance for treatment of HCV infection (adapted from AASLD/IDSA HCV Guidance from July 2016, see hcvguidelines.org for most recent recommendations):

AASLD/IDSA Guidance - Initial Treatment of Patients Initiating Therapy for HCV infection (Treatment naïve or previous relapsers)	
Genotype	Recommended Regimen
1a	<ol style="list-style-type: none"> 1. Zepatier daily for 12 weeks (no baseline high fold NS5A resistance associated variants (RAVs) for elbasvir detected) - Rating 1A; <i>Alternative regimen</i>: Zepatier with ribavirin for 16 weeks if genotype 1a AND baseline high fold NS5A RAVs) - Rating IIa-B 2. Harvoni daily for 12 wk, for treatment naïve patients with genotype 1a (with or without cirrhosis) Rating 1A; [Harvoni for 8 weeks is an option if pretreatment HCV RNA level < 6million, but should be done with caution and at the discretion of the prescriber] 3. Epclusa for 12 weeks (for patients with or without cirrhosis) - Rating 1A 4. Viekira with ribavirin for 12 wk (no cirrhosis) or <i>Alternative regimen</i>: Viekira Pak for 24 wk with ribavirin(with cirrhosis), for treatment naïve patients with genotype 1a - Rating 1A 5. Sovaldi + Olysio daily for 12 wk (no cirrhosis) - Rating 1A or <i>Alternative regimen</i>: Sovaldi + Olysio for 24 wk (cirrhosis) without the Q80K polymorphism), for treatment naïve patients with genotype 1a - Rating II-B Daklinza + Sovaldi for 12 weeks (no cirrhosis) - Rating 1B or <i>Alternative regimen</i> if cirrhosis: Daklinza + Sovaldi for **24 weeks with or without weight based ribavirin if cirrhosis present (Adjust Daklinza dose for drug interactions if needed), for treatment naïve patients with genotype 1a.** - Rating IIa-B
1b	<ol style="list-style-type: none"> 1. Zepatier daily for 12 weeks (with or without cirrhosis) (no baseline high fold NS5A resistance associated variants (RAVs) for elbasvir detected) - Rating 1A 2. Harvoni daily for 12 weeks, for treatment naïve patients with genotype 1b (with or without cirrhosis) - Rating 1A 3. Epclusa for 12 weeks (for patients with or without cirrhosis) - Rating 1A 4. Viekira for 12 weeks for treatment naïve patients with genotype 1b (with or without cirrhosis) - Rating 1A 5. Sovaldi + Olysio daily for 12 weeks (no cirrhosis) - Rating 1A, <i>Alternative regimen</i>, if cirrhosis: Sovaldi plus Olysio for 24 weeks, with or without weight based ribavirin, for treatment naïve patients with genotype 1b - Rating IIa-B 6. Daklinza + Sovaldi for 12 weeks (no cirrhosis) - Rating 1B or <i>Alternative regimen</i>, if cirrhosis: Daklinza + Sovaldi for **24 weeks with or without weight based ribavirin (Adjust Daklinza dose for drug interactions if needed), for treatment naïve patients with genotype 1b. - Rating IIa-B
4	<ol style="list-style-type: none"> 1. Epclusa for 12 weeks for treatment naïve patients with genotype 4 (for patients with or without cirrhosis) - Rating 1A 2. Technivie and ribavirin for 12 weeks, for treatment naïve patients (for patients with or without cirrhosis) - Rating 1A



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	3. Zepatier daily for 12 weeks (for patients with or without cirrhosis) - Rating IIa-B Harvoni daily for 12 weeks, for treatment naïve patients with genotype 4 (for patients with or without cirrhosis) - Rating IIa-B
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AASLD/IDSA Guidance - Retreatment of HCV infection (recommendations for patients in whom previous treatment has failed)		
GT	Previous agent/regimen failed	Recommended Regimen
1	Peginterferon/ribavirin regimen	<ol style="list-style-type: none"> 1. Zepatier daily for 12 weeks (if genotype 1a, use 12-week regimen only if no baseline high fold-change NS5A resistance-associated variants (RAVs) for elbasvir), for patients with or without cirrhosis - Rating 1A Alternative regimen is Zepatier for 16 weeks with RBV for those with genotype 1a AND NS5A RAVs - Rating IB/ IIa-B 2. Epclusa for 12 weeks - Rating 1A 3. Harvoni daily for 12 weeks (no cirrhosis) – Rating 1A If cirrhosis: Harvoni and ribavirin for 12 weeks OR Alternative regimen is Harvoni for 24 weeks (cirrhosis) - Rating 1A 4. Viekira for 12 weeks with ribavirin (genotype 1a, no cirrhosis) Viekira for 12 weeks for genotype 1b [no ribavirin if genotype 1b] - Rating 1A Alternative regimen, if genotype 1a with cirrhosis: Viekira and ribavirin for 24 weeks, for those who have failed peginterferon/ribavirin - Rating 1A 5. Olysio + Sovaldi daily for 12 weeks if no cirrhosis - Rating 1A <i>Alternative regimen</i> for cirrhosis: Olysio plus Sovaldi with or without ribavirin, daily for 24 weeks - Rating IIa-B 6. Daklinza + Sovaldi for 12 weeks (if no cirrhosis), for treatment experienced, genotype 1 patients in whom peginterferon/ribavirin has failed (Adjust Daklinza dose for drug interactions if needed) - Rating 1B Alternative regimen, if cirrhosis: **Daklinza + Sovaldi for **24 weeks with or without ribavirin - Rating IIa-B
1	Sovaldi regimen (with ribavirin, and with or without peginterferon)	<ol style="list-style-type: none"> 1. Harvoni with ribavirin for 12 weeks (no cirrhosis) - Rating IIa-B, or Harvoni with ribavirin for 24 weeks (cirrhosis) - Rating IIa-B
1	HCV protease inhibitor/peginterferon/ribavirin	<ol style="list-style-type: none"> 1. Harvoni daily for 12 weeks for patients without cirrhosis. If cirrhosis: Harvoni plus ribavirin for 12 weeks OR Harvoni for 24 weeks - Rating 1A 2. Epclusa for 12 weeks - Rating 1A 3. Daklinza + Sovaldi daily for 12 weeks (no cirrhosis); or ** Daklinza and Sovaldi for 24 weeks (cirrhosis),



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AASLD/IDSA Guidance - Retreatment of HCV infection (recommendations for patients in whom previous treatment has failed)		
		with or without weight based ribavirin for those with cirrhosis - Rating IIa-B 4. Zepatier daily with ribavirin for 12 weeks (16 weeks if baseline NS5A RAVs for elbasvir) Rating IIa-B
1	Olysio + Sovaldi	If no cirrhosis, defer treatment if possible, if there are no reasons for urgent retreatment -Testing for RAVs that lead to decreased susceptibility for NS3 protease inhibitors and to NS5A inhibitors is recommended for patients with compensated cirrhosis or have reasons for retreatment. -If retreating with sofosbuvir-based therapy with 2 drugs, a treatment of 24 weeks is recommended, and ribavirin should be added when possible, unless contraindicated. Consider triple or quadruple nucleotide-based (e.g., sofosbuvir) therapies if available, with treatment duration from 12 to 24 weeks and weight-based ribavirin, unless contraindicated.
1	NS5A inhibitors	If no cirrhosis, defer treatment if possible, if there are no reasons for urgent retreatment. Test for resistance associated variants for NS3 protease inhibitors or NS5A inhibitors. -If retreating with sofosbuvir-based therapy, use 24 week duration regimens when possible, and add ribavirin if tolerated. Consider triple or quadruple nucleotide-based (e.g., sofosbuvir) therapies if available, with treatment duration from 12 to 24 weeks and weight-based ribavirin, unless contraindicated.
4	Peginterferon/ribavirin regimen	1. Epclusa for 12 weeks - Rating 1A 2. Technivie with ribavirin for 12 weeks - Rating 1A 3. Zepatier daily for 12 weeks (use 16 weeks if previous on-treatment virologic failure after peg/RBV, add ribavirin for if previous failure to suppress or patient had breakthrough) - Rating IIa-B 4. Harvoni daily for 12 weeks (add ribavirin if cirrhosis and patient is eligible for ribavirin), <i>Alternative</i> , if cirrhosis, is Harvoni for 24 weeks - Rating IIa-B

ELBASVIR/GRAZOPREVR

FDA APPROVED INDICATIONS (CONTINUED)

EFFICACY

The efficacy of Zepatier was studied in two placebo-controlled trials and four uncontrolled phase 2 and phase 3 clinical trials in 1401 study participants with genotype 1, 4, or 6 HCV infection with compensated liver disease (with or without cirrhosis). Table 2 below describes a total of six trials used for the assessment of efficacy for treatment of genotype 1 or 4 infection (Zepatier was not approved by

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the FDA for treatment of genotype 6 infection). All patients in the active treatment groups received Zepatier (grazoprevir 100mg/elbasvir 50mg) once daily. Those receiving ribavirin received weight-based dosing (800-1400mg per day), divided twice daily. The primary endpoint in all trials was sustained virologic response (SVR), defined as HCV RNA less than the lower limit of quantification at 12 weeks after ending treatment (SVR12).

Clinical trials for Zepatier (elbasvir/grazoprevir) [From Zepatier prescribing information]

Trial	Population	Study Groups and Duration (Number of Subjects Treated)
C-EDGE TN (double-blind)	GT 1, 4 TN with or without cirrhosis	<ul style="list-style-type: none"> • ZEPATIER for 12 weeks (N=306) • Placebo for 12 weeks (N=102)
C-EDGE COINFECTION (open-label)	GT 1, 4 TN with or without cirrhosis HCV/HIV-1 co-infection	<ul style="list-style-type: none"> • ZEPATIER for 12 weeks (N=217)
C-SURFER (double-blind)	GT 1 TN or TE with or without cirrhosis Severe Renal Impairment including Hemodialysis	<ul style="list-style-type: none"> • EBR* + GZR* for 12 weeks (N=122) • Placebo for 12 weeks (N=113)
C-SCAPE (open-label)	GT 4 TN without cirrhosis	<ul style="list-style-type: none"> • EBR* + GZR* for 12 weeks (N=10) • EBR* + GZR* + RBV for 12 weeks (N=10)
C-EDGE TE (open-label)	GT 1, 4 TE with or without cirrhosis HCV/HIV-1 co-infection	<ul style="list-style-type: none"> • ZEPATIER for 12 or 16 weeks (N=105, and 101, respectively) • ZEPATIER + RBV for 12 or 16 weeks (N=104 and 104, respectively)
C-SALVAGE (open-label)	GT 1 TE with HCV protease inhibitor regimen [†] with or without cirrhosis	<ul style="list-style-type: none"> • EBR* + GZR* + RBV for 12 weeks (N=79)

GT = Genotype

TN = Treatment-Naïve

TE = Treatment-Experienced (failed prior treatment with interferon [IFN] or peginterferon alfa [PegIFN] with or without ribavirin [RBV] or were intolerant to prior therapy).

*EBR = elbasvir 50 mg; GZR = grazoprevir 100 mg; EBR + GZR = co-administered as single agents.

[†] Failed prior treatment with boceprevir, telaprevir, or simeprevir in combination with PegIFN + RBV.

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ELBASVIR/GRAZOPREVIR

FDA APPROVED INDICATIONS (CONTINUED)

Efficacy - Treatment naïve patients with genotype 1 infection

C-EDGE TREATMENT NAÏVE (TN) study was a phase 3, multi-center, international, randomized, blinded, placebo-controlled, parallel group trial of treatment naïve cirrhotic and non-cirrhotic patients with chronic HCV genotype 1, genotype 4, or genotype 6 infection. In the initial treatment period, 316 patients received Zepatier and 105 patients received placebo once daily. The median age was 54 years (range: 20-78 years); other patient characteristics included: 46% female, 37% non-white, 91% with genotype 1 infections (50% of those with genotype 1 had genotype 1a), 22% with cirrhosis (28% of patients with cirrhosis had biopsy as evidence of cirrhosis), and 68% of patients had HCV RNA levels above 800,000 IU/mL.

C-EDGE COINFECTION was an uncontrolled, non-randomized, open-label, single arm study that enrolled 218 treatment naïve, HCV/HIV co-infected patients with genotype 1, 4, or 6 HCV infection. Patient characteristics included the following: mean age 50 years (age range 21-71 years); 85% male; 75% Caucasian, 19% of African descent, 6% Hispanic or Latino; mean body mass index (BMI) 25kg/m²; 16% had cirrhosis; 76% had genotype 1a, 23% had genotype 1b, and 1% had genotype 1-other infection; and patients were either naïve to HIV antiretroviral therapy (ART) or stable on ART for at least 8 weeks.

C-EDGE TN and C-EDGE COINFECTION: SVR12 in treatment naïve subjects with or without cirrhosis with genotype 1 HCV treated with Zepatier for 12 weeks [From Zepatier prescribing information]

	C-EDGE TN [Immediate treatment group] (n = 288)	C-EDGE CO-INFECTION [HCV/HIV co-infection] (n = 189)
Regimen	Zepatier for 12 weeks	Zepatier for 12 weeks
Overall SVR in genotype 1	95% (273/288)	95% (179/189)
SVR – genotype 1a	92% (144/157)	94% (136/144)
SVR – genotype 1b	98% (129/131)	96% (43/45)
SVR – no cirrhosis	94% (207/220)	94% (148/158)
SVR – cirrhosis	97% (66/68)	100% (31/31)
Relapse	3% (10/288)	3% (6/189)

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ELBASVIR/GRAZOPREVIR

FDA APPROVED INDICATIONS (CONTINUED)

Efficacy - Treatment experienced patients with genotype 1 infection

C-EDGE TE was a randomized, open-label study that enrolled patients with genotype 1 or 4 HCV infection, with or without cirrhosis, with or without HIV-1 co-infection, who had failed previous treatment with peginterferon/ribavirin. Participants were randomized to one of four treatment arms: 1) Zepatier for 12 weeks, 2) Zepatier and ribavirin for 12 weeks, 3) Zepatier for 16 weeks, or 4) Zepatier plus ribavirin for 16 weeks. Patient characteristics included the following: median age 57 years (range: 19-77 years); 64% male; 67% Caucasian, 18% of African descent, 9% Hispanic or Latino; mean BMI 28kg/m²; 78% with baseline HCV RNA levels above 800,000 IU/mL; 34% had cirrhosis; 60% had genotype 1a, 39% had genotype 1b, and 1% had genotype 1-other.

C-EDGE TE: SVR12 in treatment experienced subjects (previous trial of peginterferon/ribavirin) with or without cirrhosis with genotype 1 HCV treated with Zepatier *[From Zepatier prescribing information]*

	Zepatier for 12 weeks (n = 96)	Zepatier and ribavirin for 16 weeks (n = 96)
Overall SVR in genotype 1	94% (90/96)	97% (93/96)
SVR – genotype 1a	90% (55/61)	95% (55/58)
SVR – genotype 1b	100% (35/35)	100% (38/38)
SVR – no cirrhosis	94% (61/65)	95% (61/64)
SVR – cirrhosis	94% (29/31)	100% (32/32)
Relapse	100% (33/33)	100% (35/35)

C-SALVAGE was an open-label, single arm trial that enrolled participants with genotype 1 infection, with or without cirrhosis, who failed previous treatment with HCV protease inhibitor/peginterferon/ribavirin triple therapy. Protease inhibitors were one of the following: Victrelis (boceprevir), Incivek (telaprevir), or Olysio (simeprevir). Participants received Zepatier and ribavirin for 12 weeks. Patient characteristics included the following: median age 55 years (range 23 to 75); 58% male; 97% Caucasian, 3% of African descent, 15% Hispanic or Latino; mean BMI 28kg/m²; 63% had baseline HCV RNA levels greater than 800,000 IU/mL; 43% had cirrhosis; and 46% had baseline NS3 resistance-associated substitutions. The overall SVR was 96%, whereas 4% (3/79) were unable to attain SVR due to relapse.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ELBASVIR/GRAZOPREVR****FDA APPROVED INDICATIONS (CONTINUED)****Efficacy - Patients with severe renal impairment and genotype 1 infection**

C-SURFER was a randomized, double-blind, placebo-controlled study in patients with genotype 1 infection, with or without cirrhosis, with CKD stage 4 or 5 (eGFR <30 mL/min/1.73m²). Approximately 52% had genotype 1a infection, and 48% had genotype 1b infection. Patients were treatment naïve (80.4%) or treatment experienced (19.6%). Stage 4 CKD was seen in 18.7% and stage 5 in 81.3%, with 76.2% currently receiving hemodialysis. The majority (94%) had no cirrhosis. The distribution of fibrosis stage at the start of the study was as follows: F0-F2: 69.4%, F3: 11.9%, F4: 6%, and 12.8% as other. Enrolled patients had a mean age 56 of years (18-70 years of age). More than half (57.4%) had baseline HCV RNA levels above 800,000 IU/mL.

Results from C-SURFER clinical trials for treatment naïve patients with genotype 1 HCV infection

	Grazoprevir/elbasvir immediate treatment group and pharmacokinetic population
SVR	
All patients	99% (115/116)
Intent-to-treat population	94% (115/122)
Genotype 1a	97% (61/63)
Genotype 1b	92% (54/59)
No cirrhosis	95% (109/115)
Patients with cirrhosis	86% (6/7)
Treatment naïve	95% (96/101)
Treatment experienced	90% (19/21)
Hemodialysis	93% (86/92)
No hemodialysis	97% (29/30)
CKD stage 4	100% (22/22)
CKD stage 5	93% (93/100)
Relapse after treatment	
All patients	<1% (1/116)

Efficacy - Treatment naïve and treatment experienced patients with genotype 4 infection

Four trials (C-EDGE TN, C-EDGE COINFECTION, C-EDGE TE, and C-SCAPE) evaluated the efficacy of Zepatier for treatment of genotype 4 infection. C-SCAPE randomized treatment naïve participants to 12 weeks of Zepatier with or without ribavirin. Study details for the other three studies are listed above. The combined genotype 4 study population from the four trials was 64% treatment naïve, 66% male, 87% Caucasian, 10% of African descent, 22% with cirrhosis, and 30% with HCV/HIV-1 co-infection. The overall SVR12 for the combined results of the four trials was 97% (64/66).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELBASVIR/GRAZOPREVR

FDA APPROVED INDICATIONS (CONTINUED)

SAFETY

Contraindications for Zepatier include moderate or severe hepatic impairment (Child-Pugh B or C). As OATP1B1/3 inhibitors and CYP3A inhibitors may increase serum concentrations of Zepatier, the concurrent use of the following OATP1B1/3 inhibitors and strong CYP3A4 inhibitors with Zepatier is contraindicated: anticonvulsants (e.g., phenytoin, carbamazepine), antimycobacterials (e.g., rifampin), St. John's Wort, HIV medications (e.g., efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir), and cyclosporine. When Zepatier is prescribed with ribavirin, prescribers must also consider contraindications, warnings, and precautions associated with ribavirin therapy.

For patients using a 12-week regimen of Zepatier, the most common adverse reactions reported in clinical trials include headache, nausea, and fatigue. Patients using Zepatier with ribavirin for 16 weeks most commonly experienced anemia (8%) and headache (6%). In clinical trials liver enzyme elevations occurred in approximately 1% of patients taking Zepatier, and were more common in female and Asian patients. Hepatic laboratory testing should be completed as clinically indicated, as well as prior to starting therapy, at treatment week 8, and at treatment week 12 for patients receiving 16 weeks of therapy.

No dose adjustments are necessary in patients with mild hepatic impairment (Child-Pugh A), but Zepatier is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C). No dose adjustment is required for patients with severe renal impairment or for those using hemodialysis.

The safety and efficacy of Zepatier have not been evaluated in the pediatric population. Clinical trials of Zepatier included 187 participants age of 65 and older; higher plasma concentrations of Zepatier and a higher rate of ALT elevations were noted in participants age 65 years and older than in those younger than age 65.

There are no human data on the safety of Zepatier use in pregnant humans; however, animal studies in rats and rabbits indicate that no adverse developmental effects were observed with Zepatier at 10-18 times the recommended human dose of elbasvir and 41-78 times the human dose of grazoprevir. While it is not known whether Zepatier is present in human breast milk, Zepatier was present in the milk of rats, but was not found to affect growth and development of nursing rat pups.

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ELBASVIR/GRAZOPRE VIR

REFERENCES

-) Zepatier [Prescribing Information]. Kenilworth, NJ: Merck; January 2016.
-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed July 2016.
-) Rochstroh J, Nelson M, Katlama C, Lalezari J, Mallolas J, et al. Efficacy and safety of grazoprevir (MK-5172) and elbasvir (MK-9742) in patients with hepatitis C virus and HIV co-infection (C-EDGE COINFECTION): a non-randomized, open-label trial. Lancet HIV 2015; 2 (8): e319-327.
-) Zeuzem S, Ghalib R, Reddy K, Pockros P, Ben Ari Z, et al. Grazoprevir/elbasvir combination therapy for treatment naïve, cirrhotic and non-cirrhotic patients with chronic hepatitis C virus genotype 1, 4 or 6 infection: a randomized trial. Annals of Internal Medicine 2015; 163 (1):1-13.
-) Roth D, Nelson D, Bruchfield A, Liapakis A, Silva M, et al. Grazoprevir plus elbasvir in treatment-naïve and treatment-experienced patients with hepatitis C virus genotype 1 infection and stage 4-5 chronic kidney disease (C-SURFER study): a combination phase 3 study.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 02/16

Client Approval: 12/17

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EFINACONAZOLE

Generic	Brand	HICL	GCN	Exception/Other
EFINACONAZOLE	JUBLIA	41184		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenail(s) and meets the following criteria?

-) The patient previously tried or has a contraindication to oral terbinafine **OR** oral itraconazole **AND** ciclopirox topical solution
-) The patient has at least **ONE** of the following conditions:
 - o The patient has diabetes, peripheral vascular disease (PVD), or immunosuppression
 - o The patient has pain surrounding the nail or soft tissue involvement

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Are five or less toenails affected?

If yes, **approve for 48 weeks by HICL with a quantity limit of #4mL (1 bottle) per 30 days.**

If no, **approve for 48 weeks by HICL with a quantity limit of #8mL (2 bottles) per 30 days.**

DENIAL TEXT: The guideline named **EFINACONAZOLE (Jublia)** requires a diagnosis of onychomycosis of the toenail(s) and that the patient meets the following criteria.

-) The patient previously tried or has a contraindication to oral terbinafine **OR** oral itraconazole **AND** ciclopirox topical solution
-) The patient has at least **ONE** of the following conditions:
 - o The patient has diabetes, peripheral vascular disease (PVD), or immunosuppression
 - o The patient has pain surrounding the nail or soft tissue involvement

RATIONALE

Promote cost-effective utilization of Jublia (efinaconazole) based on complicating factors of onychomycosis as well as FDA approved indication and dosing.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EFINACONAZOLE

RATIONALE (CONTINUED)

Jublia is an azole antifungal indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophyte*. Onychomycosis refers to nail infections caused by any fungus, including yeasts and non-dermatophyte molds. Although onychomycosis is usually a cosmetic concern to patients, it also causes physical discomfort for some, particularly with more severe or advanced disease. Patients may experience chronic pain or acute pain exacerbated by nail cutting, footwear, or pressure from bedclothes. Additionally, in patients with diabetes or other immunocompromised states, onychomycosis may increase the risk of bacterial infections such as cellulitis.

Jublia may not be as efficacious as oral antifungals (e.g. terbinafine and itraconazole) in the treatment of onychomycosis, but its safety profile is improved. The most common adverse reactions associated with Jublia are ingrown toenails, application site dermatitis, application site vesicles, and application site pain. Additionally, Jublia neither interacts with cytochrome P450 enzymes nor is associated with hepatotoxicity, as seen with oral antifungals.

DOSE

Apply one drop onto each affected toenail once daily (for the big toenail, also apply a second drop to the end of the toenail) for 48 weeks. Use the brush attached to the bottle to gently spread Jublia to the entire toenail including the cuticle, toenail folds, toenail bed, hyponychium, and the undersurface of the toenail plate.

For topical use only and not for oral, ophthalmic, or intravaginal use.

Note: One bottle of 4mL contains 200 applications.

FDA APPROVED INDICATIONS

Topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophyte*

REFERENCES

-] Jublia [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; September 2016.
-] UpToDate, Inc. Onychomycosis. UpToDate [database online]. Waltham, MA. Available at: <http://www.uptodate.com/home/index.html>. Updated April 1, 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 03/01/17

Created: 06/14

Client Approval: 02/17

P&T Approval: 01/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELAGOLIX

Generic	Brand	HICL	GCN	Exception/Other
ELAGOLIX	ORILISSA	45108		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) The requested medication is prescribed by or in consultation with an obstetrician/gynecologist
 -) The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have normal liver function or mild hepatic impairment (Child-Pugh Class A)?

If yes, **approve by GPID for the requested strength with the following quantity limits and approval durations:**

-) **Orilissa 150mg (GPID 45026): #1 tablet per day for 12 months.**
-) **Orilissa 200mg (GPID 45028): #2 tablets per day for 6 months.**

If no, continue to #3.

3. Does the patient have moderate hepatic impairment (Child-Pugh Class B)?

If yes, **approve for 6 months by GPID for the following strength and quantity limit:**

-) **Orilissa 150mg (GPID 45026): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELAGOLIX

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ELAGOLIX (Orilissa)** requires a diagnosis of moderate to severe pain associated with endometriosis. Additionally, the following criteria must be met:

- ☐ The patient is 18 years of age or older
- ☐ The requested medication is prescribed by or in consultation with an obstetrician/gynecologist
- ☐ The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

Requests for Orilissa 200mg twice daily will only be approved in patients with normal liver function or mild hepatic impairment (Child-Pugh Class A).

RENEWAL CRITERIA

1. Has the patient received **ONE** of the following regimens?

- ☐ A 6-month course of Orilissa 200mg twice daily
- ☐ A 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
- ☐ A 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

If yes, do not approve.

RENEWAL DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe pain associated with endometriosis and meet the following criteria?

- ☐ Physician attestation of improvement of pain related to endometriosis while on therapy
- ☐ The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

If yes, **approve for 12 months by GPID for the following strength and quantity limit:**

- ☐ **Orilissa 150mg (GPID 45026): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELAGOLIX

RENWEAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ELAGOLIX (Orilissa)** requires a diagnosis of moderate to severe pain associated with endometriosis for renewal. The following criteria must also be met:

-) Physician attestation of improvement of pain related to endometriosis while on therapy
-) The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

Requests will not be approved if the patient meets one of the following conditions:

-) The patient has received a 6-month course of Orilissa 200mg twice daily
-) The patient has received a 6-month course of Orilissa 150mg once daily and the patient has moderate hepatic impairment (Child-Pugh Class B)
-) The patient has received a 24-month course of Orilissa 150mg once daily and the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

RATIONALE

Ensure appropriate utilization and safety criteria are used for the management of requests for Orilissa (elagolix).

FDA-APPROVED INDICATION

Orilissa (elagolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

DOSING AND ADMINISTRATION

Pregnancy should be excluded before starting Orilissa (elagolix), or Orilissa (elagolix) can be initiated within 7 days from the onset of menses. The lowest effective dose should be used, taking into account the severity of symptoms and treatment objectives. Treatment duration should be limited due to the potential for decreases in bone mineral density that may not be completely reversible.

Orilissa (elagolix) is dosed according to the following table:

Hepatic Function	Dosing Regimen	Maximum Treatment Duration
Normal hepatic function or mild hepatic impairment (Child-Pugh Class A)	150 mg once daily	24 months
	200 mg twice daily*	6 months
Moderate hepatic impairment (Child-Pugh Class B)	150 mg once daily	6 months
Severe hepatic impairment (Child-Pugh Class C)	Contraindicated	
*Regimen to be considered for those with coexisting dyspareunia		

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELAGOLIX

REFERENCES

) Orilissa [Prescribing Information]. North Chicago, IL: AbbVie Inc.; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/24/18

Created: 08/18
Client Approval: 08/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELIGLUSTAT TARTRATE

Generic	Brand	HICL	GCN	Exception/Other
ELIGLUSTAT TARTRATE	CERDELGA		36988	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meets the following criteria?

- ☐ is a CYP2D6 extensive metabolizer (EMs)
- ☐ is not a CYP2D6 ultra-rapid metabolizer
- ☐ is not a CYP2D6 indeterminate metabolizer
- ☐ is age 18 years of age and older

If yes, **approve for 12 months by GPID with a quantity limit of #2 capsules per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meets the following criteria?

- ☐ is a CYP2D6 intermediate metabolizer (IMs)
- ☐ is not a CYP2D6 ultra-rapid metabolizer
- ☐ is not a CYP2D6 indeterminate metabolizer
- ☐ is age 18 years of age and older

If yes, **approve for 12 months by GPID with a quantity limit of #2 capsules per day.**

If no, continue to #3.

3. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meets the following criteria?

- ☐ is a CYP2D6 poor metabolizer (PMs)
- ☐ is not CYP2D6 ultra-rapid metabolizer
- ☐ is not CYP2D6 indeterminate metabolizer
- ☐ is age 18 years of age and older

If yes, **approve for 12 months by GPID with a quantity limit of #1 capsule per day.**

If no, do not approve.

DENIAL TEXT: See text at the end of the guideline.

CONTINUE ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELIGLUSTAT TARTRATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline for **ELIGLUSTAT TARTRATE** requires a diagnosis of type 1 (non-neuronopathic) Gaucher's disease in a patient at least 18 years of age. Twice daily dosing will be approved for patients who are extensive or immediate metabolizers of CYP2D6 inhibitors. Once daily dosing will be approved for patients who are poor metabolizers of CYP2D6. This medication is not approved for the following patients: CYP2D6 ultra-rapid metabolizers or CYP2D6 indeterminate metabolizers.

RATIONALE

Promote appropriate utilization and dosing of Cerdelga (eliglustate tartrate) based on the FDA approved indication. Eliglustat is a CYP2D6 and CYP3A substrate. Drugs that inhibit CYP2D6 and CYP3A metabolism pathways may significantly increase the exposure to eliglustat and result in prolongation of the PR, QTc, and/or QRS cardiac intervals that could result in cardiac arrhythmias.

The recommended dosage of CERDELGA is 84 mg twice daily in CYP2D6 extensive metabolizers (EMs), and intermediate metabolizers (IMs). The recommended dosage in CYP2D6 poor metabolizers (PMs) is 84 mg once daily.

Some inhibitors of CYP2D6 and CYP3A are contraindicated with CERDELGA depending on the patient's metabolizer status. Co-administration of CERDELGA with other CYP2D6 and CYP3A inhibitors may require dosage adjustment depending on the patient's CYP2D6 metabolizer status to reduce the risk of potentially significant adverse reactions.

Reduce the dosage of CERDELGA to 84 mg once daily for:

- CYP2D6 EMs and IMs taking strong or moderate CYP2D6 inhibitors
- CYP2D6 EMs taking strong or moderate CYP3A inhibitors

CONTINUE ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELIGLUSTAT TARTRATE

RATIONALE (CONTINUED)

Table 1. Established and other potentially significant drug interactions: Alteration in Cerdelga Dosage May be Recommended Based on Predicted Interaction in Extensive Metabolizers (EM) and Intermediate Metabolizers (IM)

	Recommended CERDELGA Dosage, by CYP2D6 Metabolizer Status	
CYP450 Inhibitors	EM	IM
Strong or Moderate CYP2D6 inhibitors concomitantly with Strong or Moderate CYP3A inhibitors	Contraindicated	Contraindicated
Strong CYP2D6 inhibitors e.g., paroxetine	84 mg once daily	84 mg once daily
Moderate CYP2D6 inhibitors e.g., terbinafine	84 mg once daily	84 mg once daily
Strong CYP3A inhibitors e.g., ketoconazole	84 mg once daily	Contraindicated
Moderate CYP3A inhibitors e.g., fluconazole	84 mg once daily	Not recommended

Table 2. Established and other potentially significant drug interactions: Alteration in Cerdelga Dosage May be Recommended Based on Predicted Interaction in Poor Metabolizers

CYP450 Inhibitors	Recommended CERDELGA Dosage for PMs
Strong CYP3A inhibitors e.g., ketoconazole	Contraindicated
Moderate CYP3A inhibitors e.g., fluconazole	Not recommended
Weak CYP3A inhibitors e.g., ranitidine	Not recommended

CONTINUE ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELIGLUSTAT TARTRATE

FDA APPROVED INDICATIONS

CERDELGA is a glucosylceramide synthase inhibitor indicated for the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

Limitations of Use:

-) CYP2D6 ultra-rapid metabolizers may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect
-) A specific dosage cannot be recommended for CYP2D6 indeterminate metabolizers

REFERENCES

-) Cerdelga [Prescribing Information]. Waterford, Ireland: Genzyme; August 2014

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 09/14

Client Approval: 11/14

P&T Approval: 11/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EMICIZUMAB-KXWH

Generic	Brand	HICL	GCN	Exception/Other
EMICIZUMAB-KXWH	HEMLIBRA	44640		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet **ALL** of the following criteria?
 - A The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
 - A The medication is prescribed by or given in consultation with a hematologist

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.
2. Is the request for a patient **WITH** factor VIII inhibitors and the patient meets the following criterion?
 - A The patient has a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter

If yes, **approve for 12 months by HICL.**
APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline.

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EMICIZUMAB-KXWH

INITIAL CRITERIA (CONTINUED)

3. Is the request for a patient **WITHOUT** factor VIII inhibitors and the patient meets **ONE** of the following criteria?
-) The patient has severe hemophilia A defined as less than 1% factor VIII activity compared to normal, **OR**
 -) The patient has *mild* or *moderate* hemophilia A **AND** a history of 2 or more bleeds per year

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires a diagnosis of hemophilia A (congenital factor VIII deficiency). In addition, the following criteria must also be met:

-) The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
-) The medication is prescribed by or given in consultation with a hematologist
-) Patients with Factor VIII inhibitors must have a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
-) Patients without Factor VIII inhibitors must meet one of the following criteria:
 - o The patient has severe hemophilia A defined as less than 1% factor VIII activity compared to normal
 - o The patient has *mild* or *moderate* hemophilia A and a history of 2 or more bleeds per year

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet the following criterion?
-) Physician attestation of clinical benefit compared to baseline

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires a diagnosis of hemophilia A (congenital factor VIII deficiency). In addition, the following criterion must also be met:

-) Physician attestation of clinical benefit compared to baseline

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EMICIZUMAB-KXWH

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hemlibra.

REFERENCES

) Hemlibra [Prescribing Information]. Genentech, Inc.: South San Francisco, CA; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 02/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ENASIDENIB

Generic	Brand	HICL	GCN	Exception/Other
ENASIDENIB	IDHIFA	44450		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?

-) The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test
-) The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENASIDENIB (Idhifa)** requires a diagnosis of relapsed or refractory acute myeloid leukemia (AML). In addition, the following criteria must be met:

-) The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test
-) The patient is 18 years of age or older

RATIONALE

Promote appropriate utilization of **ENASIDENIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Idhifa is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION

The recommended dose of Idhifa is 100mg taken orally once daily with or without food. Idhifa tablets should not be split or crushed.

REFERENCES

-) Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/17

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ENCORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
ENCORAFENIB	BRAFTOVI	45039		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?

- ✓ The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
- ✓ The medication will be used in combination with Mektovi (binimetinib)

If yes, **approve for 12 months by HICL with a quantity limit of #6 capsules per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENCORAFENIB (Braftovi)** requires a diagnosis of unresectable or metastatic melanoma. In addition, the following criteria must be met:

- ✓ The patient has BRAF V600E or V600K mutation as detected by an FDA-approved test
- ✓ The medication will be used in combination with Mektovi (binimetinib)

RATIONALE

To promote appropriate utilization of BRAFTOVI based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Braftovi is a kinase inhibitor indicated, in combination with Mektovi (binimetinib), for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma.

DOSAGE & ADMINISTRATION

The recommended dosage of Braftovi is 450 mg orally taken once daily in combination with Mektovi (binimetinib) until disease progression or unacceptable toxicity. Refer to the Mektovi (binimetinib) prescribing information for recommended Mektovi (binimetinib) dosing information.

Braftovi may be taken with or without food. Do not take a missed dose of Braftovi within 12 hours of the next dose of Braftovi. Do not take an additional dose if vomiting occurs after Braftovi administration but continue with the next scheduled dose.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ENCORAFENIB

REFERENCES

) Braftovi [Prescribing Information]. Boulder, CO: Array BioPharma Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/18

Created: 08/18
Client Approval: 07/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ERLOTINIB

Generic	Brand	HICL	GCN	Exception/Other
ERLOTINIB	TARCEVA	26745		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet the following criteria?
 -) The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

If yes, **approve for 12 months by GPID as requested with the following quantity limits:**

-) **25mg (GPID 23795): #60 tablets per 30 days.**
-) **100mg (GPID 23794): #60 tablets per 30 days.**
-) **150mg (GPID 23793): #90 tablets per 30 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer and meet the following criteria?
 -) The requested medication will be used in combination with gemcitabine
 -) The medication will be used as a first line treatment

If yes, **approve for 12 months by GPID as requested with the following quantity limits:**

-) **25mg (GPID 23795): #60 tablets per 30 days.**
-) **100mg (GPID 23794): #60 tablets per 30 days.**
-) **150mg (GPID 23793): #90 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ERLOTINIB (Tarceva)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) or locally advanced, unresectable, or metastatic pancreatic cancer. In addition, the following criteria must also be met.

For the diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

-) The patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

For the diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer, approval requires:

-) The requested medication will be used in combination with gemcitabine
-) The medication will be used as a first line treatment

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ERLOTINIB

RATIONALE

To promote appropriate utilization of erlotinib based on FDA approved indications.

FDA approved dosage of 100mg daily for pancreatic cancer and 150mg daily for NSCLC, available as 25mg, 100mg, and 150mg tablets. Dose reduction in 50mg increments for specific adverse effects and drug interactions. Dose increase in 50mg increments for drug interactions to a maximum of 450mg daily.

FDA APPROVED INDICATIONS

Tarceva is a kinase inhibitor indicated for:

-) Treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second-line or greater treatment.
-) First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Limitations of Use:

-) Tarceva is not recommended for use in combination with platinum-based chemotherapy.
-) Safety and efficacy of Tarceva have not been evaluated in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution.

DOSAGE & ADMINISTRATION

The recommended daily dose of Tarceva for NSCLC is 150 mg taken on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity.

The recommended daily dose of Tarceva for pancreatic cancer is 100 mg taken once daily in combination with gemcitabine. Take Tarceva on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity.

REFERENCES

-) Tarceva [Prescribing Information]. Northbrook, IL. Astellas Pharma US, Inc. October 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 03/12/18

Created: 11/10

Client Approval: 02/18

P&T Approval: 11/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EVEROLIMUS

Generic	Brand	HICL	GCN	Exception/Other
EVEROLIMUS	AFINITOR		20784 20844 28783 31396	
EVEROLIMUS	AFINITOR DISPERZ		34589 34590 34592	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

AFINITOR DISPERZ

1. Does the patient have **ONE** of the following diagnoses and associated criteria?
 -) Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) AND meet the following:
 - o The patient is 1 year of age or older
 - o The patient's diagnosis requires therapeutic intervention but cannot be curatively resected
 -) Tuberous sclerosis complex (TSC)-associated partial-onset seizures AND meet the following:
 - o The patient is 2 years of age or older
 - o The medication will be used as adjunctive treatment

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: The guideline named **EVEROLIMUS (Afinitor Disperz)** requires a diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) or tuberous sclerosis complex (TSC)-associated partial-onset seizures. In addition, the following criteria must be met:

For diagnosis of subependymal giant cell astrocytoma (SEGA) in tuberous sclerosis complex (TSC), approval requires:

-) The patient is 1 year of age or older
-) The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

For diagnosis of TSC-associated partial-onset seizures, approval requires:

-) The patient is 2 year of age or older
-) The medication will be used as adjunctive treatment

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EVEROLIMUS

GUIDELINES FOR USE (CONTINUED)

AFINITOR

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has failed or is contraindicated to treatment with Sutent (sunitinib) **OR** Nexavar (sorafenib)

If yes, **approve for 12 months by GPID with the following quantity limits:**

- ☐ **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**
- ☐ **Afinitor 5mg (GPID 20784): #1 tablet per day.**
- ☐ **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**
- ☐ **Afinitor 10mg (GPID 20844): #2 tablets per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) and meet **ALL** of the following criteria?

- ☐ The patient is 1 year of age or older
- ☐ The patient's diagnosis requires therapeutic intervention but cannot be curatively resected

If yes, **approve for 12 months by GPID.**

If no, continue to #3.

3. Is the patient 18 years of age or older and have a diagnosis of progressive neuroendocrine tumor (NET) with unresectable, locally advanced or metastatic disease and meet **ONE** of the following criteria?

- ☐ Neuroendocrine tumor (NET) of pancreatic origin (PNET)
- ☐ Well-differentiated, non-functional neuroendocrine tumor (NET) of gastrointestinal (GI) or lung origin

If yes, **approve for 12 months by GPID with the following quantity limits:**

- ☐ **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**
- ☐ **Afinitor 5mg (GPID 20784): #1 tablet per day.**
- ☐ **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**
- ☐ **Afinitor 10mg (GPID 20844): #2 tablets per day.**

If no, continue to #4.

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EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

4. Does the patient have a diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC) that does not require immediate surgery **AND** meet the following criterion?

) The patient is 18 years of age or older

If yes, **approve for 12 months by GPID with the following quantity limits:**

) **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**

) **Afinitor 5mg (GPID 20784): #1 tablet per day.**

) **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**

) **Afinitor 10mg (GPID 20844): #2 tablets per day.**

If no, continue to #5.

5. Is the patient a postmenopausal woman with a diagnosis of advanced hormone receptor (HR)-positive, HER2-negative breast cancer (defined as IHC less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0) and meet **ALL** of the following criteria?

) The patient has failed or is contraindicated to treatment with Femara (letrozole) or Arimidex (anastrozole)

) Afinitor will be used in combination with Aromasin (exemestane).

If yes, **approve for 12 months by GPID with the following quantity limits:**

) **Afinitor 2.5mg (GPID 28783): #1 tablet per day.**

) **Afinitor 5mg (GPID 20784): #1 tablet per day.**

) **Afinitor 7.5mg (GPID 31396): #2 tablets per day.**

) **Afinitor 10mg (GPID 20844): #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: See AFINITOR denial text on the next page.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EVEROLIMUS

GUIDELINES FOR USE - AFINITOR (CONTINUED)

AFINITOR DENIAL TEXT: The guideline named **EVEROLIMUS (Afinitor)** requires ONE of the following FDA approved indications:

-) Advanced renal cell carcinoma (RCC) after failure of or contraindication to treatment with sunitinib (Sutent) or sorafenib (Nexavar), which may also require prior authorization AND the patient is 18 years of age or older
-) Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC) that requires therapeutic intervention but cannot be curatively resected AND the patient is 1 year of age or older
-) Progressive neuroendocrine tumor (NET) with unresectable, locally advanced or metastatic disease, either neuroendocrine tumor (NET) of pancreatic origin (PNET) or well-differentiated, non-functional neuroendocrine tumor (NET) of gastrointestinal or lung origin AND the patient must also be 18 years of age or older
-) Renal angiomyolipoma, and tuberous sclerosis complex (TSC) that does not require immediate surgery AND the patient is 18 years of age or older
-) For postmenopausal women with a diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer (defined as IHC less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0) in combination with Aromasin (exemestane) after failure of or contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole).

RATIONALE

Ensure appropriate utilization of everolimus based on FDA approved indication and NCCN guidelines.

DOSAGE AND ADMINISTRATION

Afinitor and Afinitor Disperz are two different dosage forms. Select the recommended dosage form based on the indication. Do not combine Afinitor and Afinitor disperz to achieve the total dose. Modify the dosage for patients with hepatic impairment or for patients taking drugs that inhibit or induce pglycoprotein (P-gp) and CYP3A4.

Advanced HR+ BC, advanced NET, advanced RCC, or renal angiomyolipoma with TSC:

-) Afinitor 10 mg once daily orally until disease progression or unacceptable toxicity.

SEGA with TSC:

-) Afinitor/Afinitor Disperz 4.5 mg/m² once daily orally until disease progression or unacceptable toxicity.
-) Titrate the dose to attain trough concentrations of 5-15 ng/mL.

TSC-Associated Partial-Onset Seizures

-) Afinitor Disperz 5 mg/m² once daily orally until disease progression or unacceptable toxicity.
-) Titrate the dose to attain trough concentrations of 5-15 ng/mL.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EVEROLIMUS

FDA APPROVED INDICATIONS

AFINITOR is a kinase inhibitor indicated for the treatment of:

-) Postmenopausal women with advanced hormone receptor-positive, HER2negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole.
-) Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) or gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors.
-) Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib.
-) Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.

Afinitor and Afinitor Disperz are kinase inhibitors indicated for the treatment of:

-) Adult and pediatric patients aged 1 year and older with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.

Afinitor Disperz is a kinase inhibitor indicated for:

-) Adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC associated partial-onset seizures.

REFERENCES

-) Afinitor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/25/18

Created: 05/11

Client Approval: 05/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL NASAL SPRAY

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL NASAL SPRAY	LAZANDA		27648 29146	ROUTE = NASAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried, or does the patient have a contraindication to at least 1 immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

If yes, continue to #5.

If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient tried, or does the patient have a contraindication to generic fentanyl citrate lozenge?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL NASAL SPRAY

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried, or does the patient have a contraindication to Abstral, Fentora, or Onsolis?

If yes, **approve for 6 months with a quantity limit of #15 per month.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **FENTANYL NASAL SPRAY** requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge AND a trial of Abstral, Fentora, or Onsolis, which also requires a prior authorization.

RATIONALE

To ensure use of nasal fentanyl spray is consistent with indication.

FDA APPROVED INDICATIONS

LAZANDA is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

REFERENCES

) Archimedes Pharma US. Lazanda package insert. Bedminster, NJ. July 2011.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 08/11

Client Approval: 10/14

P&T Approval: 11/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL SUBLINGUAL SPRAY

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL SUBLINGUAL SPRAY	SUBSYS		31187 31188 31189 31192 31193 31596 31597	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

If yes, continue to #5.

If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL SUBLINGUAL SPRAY

GUIDELINES FOR USE (CONTINUED)

5. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient tried or does the patient have a contraindication to Abstral, Fentora, or Onsolis?

If yes, **approve for 6 months with a quantity limit of #120 per month.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **FENTANYL SUBLINGUAL SPRAY** requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge AND a trial of Abstral, Fentora, or Onsolis, all of which may also require a prior authorization.

RATIONALE

To ensure the use of fentanyl sublingual spray is consistent with the FDA approved indication.

FDA APPROVED INDICATIONS

SUBSYS is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

REFERENCES

) Insys Therapeutics, Subsys package insert. Phoenix, AZ. January 2012.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 04/12

Client Approval: 10/14

P&T Approval: 11/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL TRANSMUCOSAL AGENTS

Generic	Brand	HICL	GCN	Exception/Other
FENTANYL CITRATE	ACTIQ ABSTRAL FENTORA ONSOLIS	01747		ROUTE = BUCCAL, SUBLINGUAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cancer?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient on a maintenance dose of controlled release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to at least one immediate-release oral pain agent (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these)?

If yes, continue to #5.

If no, continue to #4.

4. Does the patient have difficulty swallowing tablets or capsules?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for generic fentanyl citrate lozenge?

If yes, **approve for 6 months with a quantity limit of #120 per month.**

APPROVAL TEXT: See the approval text at the end of the guideline.

If no, continue to #6.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL TRANSMUCOSAL AGENTS

GUIDELINES FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to generic fentanyl citrate lozenge?

If yes, **approve for 6 months with a quantity limit of #120 per month.**

APPROVAL TEXT: See the approval text at the end of the guideline.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

DENIAL TEXT: Our guideline for **FENTANYL TRANSMUCOSAL AGENTS** requires a diagnosis of cancer-related pain, and concurrent use with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs), a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), AND a trial of generic fentanyl citrate lozenge, which also requires a prior authorization.

RATIONALE

To ensure use of transmucosal fentanyl is consistent with indication.

FDA APPROVED INDICATIONS

ABSTRAL is an opioid analgesic indicated only for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

ACTIQ is indicated for breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to opioid therapy for persistent cancer pain. Patients must remain on around-the-clock opioids when taking Actiq.

FENTORA is indicated for breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FENTANYL TRANSMUCOSAL AGENTS

FDA APPROVED INDICATIONS (CONTINUED)

FENTORA is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

ONSOLIS is indicated for the management of breakthrough pain in patients with cancer, 18 years of age and older, who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

REFERENCES

-) Cephalon, Inc. Actiq package insert. Frazer, PA. September 2009.
-) Cephalon, Inc. Fentora package insert. Frazer, PA. January 2011.
-) Meda Pharmaceuticals, Inc. Onsolis package insert. Somerset, NJ July 2009.
-) ProStrakan Inc. Abstral package insert. Bedminster, NJ. January 2011.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 02/03

Client Approval: 10/14

P&T Approval: 11/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FLUOROURACIL 0.5% CREAM

Generic	Brand	HICL	GCN	Exception/Other
FLUOROURACIL 0.5%	CARAC		12514	

This drug requires a written request for prior authorization.

GUIDELINE FOR USE

1. Does the patient have a diagnosis of actinic or solar keratosis?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient had a previous trial of at least **ONE** of the following?

-) Generic topical agents (e.g., imiquimod 5%, diclofenac 3%, fluorouracil 5%)
-) Preferred topical agents (e.g., Picato)

If yes, **approve fluorouracil 0.5% for 1 month by GPID 12514 with no quantity limit.**

If no, do not approve.

DENIAL TEXT: The guideline named **FLUOROURACIL 0.5% CREAM (Carac)** requires a diagnosis of actinic or solar keratosis. In addition, the following criterion must be met:

-) The patient has received a trial of **ONE** of the following:
 - o Generic topical agents (e.g., imiquimod 5%, diclofenac 3%, fluorouracil 5%)
 - o Preferred topical agents (e.g., Picato)

RATIONALE

To ensure appropriate utilization of topical fluorouracil 0.5% cream based on approved FDA indications and dosing.

FDA APPROVED INDICATIONS

Fluorouracil is indicated for the topical treatment of multiple actinic or solar keratoses of the face and anterior scalp.

DOSAGE AND ADMINISTRATION

Fluorouracil cream should be applied once a day to the skin where actinic or solar keratosis lesions appear, using enough to cover the entire area with a thin film. Fluorouracil cream should not be applied near the eyes, nostrils, or mouth. It should be applied 10 minutes after thoroughly washing, rinsing, and drying the entire area. It may be applied using the fingertips. Immediately after application, the hands should be thoroughly washed. Fluorouracil cream should be applied up to 4 weeks as tolerated.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FLUOROURACIL 0.5% CREAM

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Continued treatment up to 4 weeks results in greater lesion reduction. Local irritation is not markedly increased by extending treatment from 2 to 4 weeks, and is generally resolved within 2 weeks of cessation of treatment.

REFERENCES

-) Carac [Prescribing Information]. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. May 2017.
-) Werner RN, Stockfleth E, Connolly SM, et al. Evidence-and consensus-based (S3) Guidelines for the Treatment of Actinic Keratosis – International League of Dermatological Societies in cooperation with the European Dermatology Forum – Short version. *JEADV*. 2015; 29:2069-2079.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FREMANEZUMAB-VFRM

Generic	Brand	HICL	GCN	Exception/Other
FREMANEZUMAB-VFRM	AJOVY	45236		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of episodic migraines and meet **ALL** the following criteria?
-) The patient is 18 years of age or older
 -) Ajoovy is prescribed for the preventive treatment of migraines
 -) The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

If yes, **approve for 6 months by HICL with a quantity limit of #1.5mL (1 syringe) per 30 days.**

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, **OR** that the patient has experienced a reduction in migraine severity **OR** migraine duration with Ajoovy therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** the following criteria?
-) The patient is 18 years of age or older
 -) Ajoovy is prescribed for the preventive treatment of migraines
 -) The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox **[Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]**

If yes, **approve for 6 months by HICL with a quantity limit of #1.5mL (1 syringe) per 30 days.**

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, **OR** that the patient has experienced a reduction in migraine severity **OR** migraine duration with Ajoovy therapy.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FREMANEZUMAB-VFRM

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires a diagnosis of migraines. The following criteria must also be met:

For episodic migraines, approval requires:

- ☐ The patient is 18 years of age or older
- ☐ Ajovy is prescribed for the preventive treatment of migraines
- ☐ The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

For chronic migraines, approval requires:

- ☐ The patient is 18 years of age or older
- ☐ Ajovy is prescribed for the preventive treatment of migraines
- ☐ The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox

RENEWAL CRITERIA

1. Is Ajovy being prescribed for the preventive treatment of migraines **AND** does the patient meet at least **ONE** of the following criteria?

- ☐ The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
- ☐ The patient has experienced a reduction in migraine severity with Ajovy therapy
- ☐ The patient has experienced a reduction in migraine duration with Ajovy therapy

If yes, **approve for 12 months by HICL with a quantity limit of #1.5mL (1 syringe) per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires that Ajovy is being prescribed for preventive treatment of migraines. At least **ONE** of the following criteria must also be met:

- ☐ The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
- ☐ The patient has experienced a reduction in migraine severity with Ajovy therapy
- ☐ The patient has experienced a reduction in migraine duration with Ajovy therapy

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FREMANEZUMAB-VFRM

RATIONALE

Ensure appropriate criteria are used for the management of requests for AJOVY according to approved indication, dosing, and national treatment guidelines.

FDA APPROVED INDICATIONS

AJOVY is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults.

HOW SUPPLIED

225 mg/1.5 mL solution in a single-dose prefilled syringe.

DOSING & ADMINISTRATION

AJOVY is for subcutaneous use only.

Two subcutaneous dosing options of AJOVY are available to administer the recommended dosage:

- ✓ 225 mg monthly
- ✓ 675 mg every 3 months (quarterly) - administered as 3 consecutive injections of 225 mg each.

REFERENCES

- ✓ Ajoy [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc. September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/08/18

Created: 09/18

Client Approval: 09/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GEFITINIB

Generic	Brand	HICL	GCN	Exception/Other
GEFITINIB	IRESSA	25178		ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and has the patient met all of the following criteria?

-) Has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test

If yes, **approve for 12 months by HICL for quantity of #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: Our guideline for **GEFITINIB** requires that the patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

RATIONALE

Promote appropriate utilization of gefitinib based on FDA approved indication and dosing.

About 85% to 90% of lung cancer is classified as NSCLC and of that population, an estimated 10% is due to an EGFR mutation. Iressa targets a specific subset of this EGFR mutation population. Although Iressa was withdrawn from the market in 2012 due to failure to demonstrate clinical benefit in NSCLC, it is now reapproved due to efficacy findings in a specific population whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

DOSAGE

The recommended dose of Iressa is 250 mg by mouth daily until disease progression or unacceptable toxicity.

Increase Iressa dose to 500 mg daily when taken concomitantly with a strong CYP3A4 inducer. Return to recommended dose of 250 mg daily 7 days after discontinuation of the strong inducer.

FDA APPROVED INDICATION

Iressa is a tyrosine kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

Limitation of Use: Safety and efficacy of Iressa have not been established in patients whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GEFITINIB

REFERENCES

) Iressa [Prescribing Information]. AstraZeneca Pharmaceuticals. Wilmington, DE. July 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/15

Created: 07/15

Client Approval: 08/15

P&T Approval: 08/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GLYCOPYRRONIUM TOPICAL

Generic	Brand	HICL	GCN	Exception/Other
GLYCOPYRRONIUM 2.4% CLOTH	QBREXZA	45086		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary axillary hyperhidrosis and meet **ALL** of the following criteria?
-) The patient is 9 years of age or older
 -) The patient has had a trial of prescription strength aluminum chloride product (e.g., Drysol)
 -) Physician attestation by primary care provider that the patient has primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least six months duration with all secondary causes ruled out
 -) Physician attestation that the patient has at least **TWO** of the following:
 - o Symptoms occur bilaterally
 - o Symptoms impair daily activities
 - o Patient has at least one episode per week
 - o Onset occurred prior to patient turning 25 years old
 - o Patient has a family history of primary axillary hyperhidrosis
 - o Symptoms do not occur during sleep

If yes, **approve for 12 months by HICL with a quantity limit of #1 packet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires that the patient must have a diagnosis of primary axillary hyperhidrosis. In addition, the following criteria must be met:

-) The patient is 9 years of age or older
-) The patient has had a trial of prescription strength aluminum chloride product (e.g., Drysol)
-) Physician attestation by primary care provider patient has primary axillary hyperhidrosis as evidenced by focal, visible, excessive sweating of at least six months duration with all secondary causes ruled out
-) Physician attestation that the patient has at least two of the following:
 - o Symptoms occur bilaterally
 - o Symptoms impair daily activities
 - o Patient has at least one episode per week
 - o Onset occurred prior to patient turning 25 years old
 - o Patient has a family history of primary axillary hyperhidrosis
 - o Symptoms do not occur during sleep

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GLYCOPYRRONIUM TOPICAL

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qbrexza.

REFERENCES

) Qbrexza [Prescribing Information]. Menlo Park, CA. Dermira, Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ICATIBANT

Generic	Brand	HICL	GCN	Exception/Other
ICATIBANT	FIRAZYR	35962		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary angioedema and meet ALL of the following criteria?
- ☐ Diagnosis is confirmed via complement testing
 - ☐ The medication is being used for treatment of acute attacks of hereditary angioedema
 - ☐ The patient is 18 years of age or older
 - ☐ The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist

If yes, **approve for a duration of 12 months, each fill of #6 syringes (total of 18mL), up to 12 fills per year.**

If no, do not approve.

DENIAL TEXT: The guideline named **ICATIBANT (Firazyr)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

- ☐ Diagnosis is confirmed via complement testing
- ☐ The medication is being used for treatment of acute attacks of hereditary angioedema
- ☐ The patient is 18 years of age or older
- ☐ The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist

RATIONALE

Ensure appropriate use of Firazyr (icatibant) based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Firazyr (icatibant) is indicated for the treatment of acute attacks of hereditary angioedema in adults 18 years of age and older.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ICATIBANT

FDA APPROVED INDICATION (CONTINUED)

DOSING AND ADMINISTRATION

The recommended dose of Firazyr (icatibant) is 30 mg administered subcutaneously in the abdominal area. Additional doses may be administered at intervals of at least 6 hours if response is inadequate or if symptoms recur. No more than 3 doses may be administered in any 24-hour period (for a total of 90 mg). Patients may self-administer Firazyr (icatibant) upon recognition of symptoms of an HAE attack after training under the guidance of a healthcare professional.

REFERENCE

) Firazyr [Prescribing Information]. Lexington, MA: Shire Orphan Therapies; December 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 09/11

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IDELALISIB

Generic	Brand	HICL	GCN	Exception/Other
IDELALISIB	ZYDELIG	41297		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed chronic lymphocytic leukemia (CLL)?

If yes, continue to #2.

If no, continue to #3.

2. Is the patient on chemotherapy in combination with rituximab?

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of relapsed follicular B-cell non-Hodgkin lymphoma (FL) and has received two prior systemic therapies?

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, continue to #4.

4. Does the patient have a diagnosis of relapsed small lymphocytic lymphoma (SLL) and has received at least two prior systemic therapies?

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **IDELALISIB** requires a diagnosis of relapsed chronic lymphocytic leukemia (CLL) with concomitant treatment with rituximab, relapsed follicular B-cell non-Hodgkin lymphoma (FL) or relapsed small lymphocytic lymphoma (SLL) and having received two prior systemic therapies.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IDELALISIB

GUIDELINES FOR USE (CONTINUED)

Table 1. Chronic Lymphocytic Leukemia (CLL) Treatment Options (please refer to NCCN for most current guideline)

<u>chlorambucil</u>
<u>ibrutinib</u>
<u>Obinutuzumab+chlorambucil</u>
<u>Idelalisib+rituximab</u>
<u>Bendamustine+/-rituximab</u>
<u>ofatumumab</u>
<u>fludarabine</u>
<u>cladribine</u>
<u>rituximab</u>
<u>alemtuzumab IV</u>
<u>alemtuzumab (Campath) SC+/-rituximab</u>
<u>chlorambucil + prednisone</u>
<u>fludarabine+prednisone</u>
<u>fludarabine+cyclophosphamide (FC)</u>
<u>Fludarabine+alemtuzumab</u>
<u>Rituximab+chlorambucil</u>
<u>fludarabine+rituximab</u>
<u>fludarabine+cyclophosphamide rituximab (FCR)</u>
<u>cladribine+mitoxantrone+cyclophosphamide (CMC)</u>
<u>cyclophosphamide+vincristine+prednisone (CVP)</u>
<u>lenalidomide+/-rituximab</u>
<u>pentostatin+cyclophosphamide+rituximab (PCR)</u>
<u>cyclophosphamide+fludarabine+alemtuzumab+rituximab (CFAR)</u>
<u>rituximab+cyclophosphamide+doxorubicin+vincristine+prednisone (RCHOP)</u>
<u>Oxaliplatin+fludarabine+cytarabine+rituximab (OFAR)</u>

RATIONALE

Promote appropriate utilization and dosing of idelalisib based on their FDA approved indication.

DOSAGE

The recommended maximum starting dose of Zydelig is 150 mg administered orally twice daily.

Dose modification may be required for specific toxicities related to Zydelig. If resuming Zydelig after interruption for other severe or life-threatening toxicities, reduce the dose to 100 mg twice daily.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IDELALISIB

FDA APPROVED INDICATIONS

Zydelig is a kinase inhibitor indicated for the treatment of patients with:

-) Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
-) Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
-) Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

Accelerated approval was granted for FL and SLL based on overall response rate. Improvement in patient survival or disease related symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.

REFERENCES

-) Gilead Sciences, Inc. Zydelig package insert. Foster City, CA. July 2014
-) NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 4.2014. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf [Accessed October 15, 2014]

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 08/14

Client Approval: 11/14

P&T Approval: 11/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ILOPROST

Generic	Brand	HICL	GCN	Exception/Other
ILOPROST	VENTAVIS	26287		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meets **ALL** of the following criteria?
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory hypertension pulmonary arterial (PAH) diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
 -) The patient has NYHA/WHO Functional Class III-IV symptoms

If yes, **approve up to 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **ILOPROST (Ventavis)** requires a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). The following criteria must also be met.

-) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-) Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
-) The patient has NYHA/WHO Functional Class III-IV symptoms.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ILOPROST

RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: The guideline for **ILOPROST (Ventavis)** renewal requires a diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1 with WHO Class III-IV symptoms. The following criteria must also be met:

-) The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
-) The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

RATIONALE

Ensure appropriate use of Ventavis.

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (e.g., diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ILOPROST

FDA APPROVED INDICATION

VENTAVIS is indicated for treatment of pulmonary artery hypertension (WHO group 1) in patients with NYHA/WHO class III or IV symptoms to improve exercise capacity.

World Health Organization Classification of Pulmonary Hypertension Group 1:

- Idiopathic (familial)
- Congenital systemic-to-pulmonary shunts
- HIV infection
- Collagen vascular disease
- Portal Hypertension
- Drugs and toxins

REFERENCES

) Actelion. Ventavis® (iloprost) prescribing information. South San Francisco, CA. April 2013.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 01/08

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IMATINIB

Generic	Brand	HICL	GCN	Exception/Other
IMATINIB MESYLATE	GLEEVEC	22096		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, accelerated phase, or blast crisis?

If yes, continue to #2.

If no, continue to #4.

2. Has the patient been previously treated with Tassigna, Sprycel, Bosulif, or Iclusig?

If yes, continue to #3.

If no, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #2 tablets per day for Gleevec 100mg (enter two authorizations).**

3. Has the patient had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are not present: T315I, V299L, F317L/V/I/C, Y253H, E255K/V, or F359V/C/I?

If yes, **approve for 12 months by GPID with a quantity limit of #2 tablets per day for both Gleevec 100mg and 400mg (enter two authorizations).**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, accelerated phase, or blast crisis. Patients previously treated with therapy such as Tassigna, Sprycel, Bosulif, or Iclusig require a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are not present: T315I, V299L, F317L/V/I/C, Y253H, E255K/V, or F359V/C/I.

4. Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)?

If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #2 tablets per day for Gleevec 100mg (enter two authorizations).**

If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IMATINIB

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of a myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements?

If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg.**

If no, continue to #6.

6. Does the patient have a diagnosis of aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown?

If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #3 tablets per day for Gleevec 100mg (enter two authorizations).**

If no, continue to #7.

7. Does the patient have a diagnosis of hypereosinophilic syndrome and/or chronic eosinophilic leukemia?

If yes, **approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg and #3 tablets per day for Gleevec 100mg (enter two authorizations).**

If no, continue to #8.

8. Does the patient have a diagnosis of unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans?

If yes, **approve for 12 months by GPID with a quantity limit of #2 tablets per day for both Gleevec 100mg and 400mg (enter two authorizations).**

If no, continue to #9.

9. Does the patient have a diagnosis of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive or platelet derived growth factor-alpha (PDGFRA) mutation?

If yes, continue to #11.

If no, continue to #10.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IMATINIB

GUIDELINES FOR USE (CONTINUED)

10. Is the request for adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST)?

If yes, continue to #11.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML), Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), myelodysplastic/myeloproliferative diseases associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, hypereosinophilic syndrome and/or chronic eosinophilic leukemia, unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) with a Kit (CD117) positive or PDGFRA (platelet-derived growth factor receptor-alpha) mutation, or adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST.

11. Is the request for Gleevec 400mg twice daily?

If yes, continue to #12.

If no, **approve as follows:**

-) **For adjuvant GIST treatment: approve for 36 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg.**
-) **For unresectable and/or metastatic malignant GIST: approve for 12 months by GPID with a quantity limit of #1 tablet per day for Gleevec 400mg.**

12. Has patient tried Gleevec 400mg once daily or does the patient have GIST tumor expressing a KIT exon 9 mutation?

If yes, **approve as follows:**

-) **For adjuvant GIST treatment: approve for 36 months by GPID with a quantity limit of #2 tablets per day for Gleevec 400mg.**
-) **For unresectable and/or metastatic malignant GIST: approve for 12 months by GPID with a quantity limit of #2 tablets per day for Gleevec 400mg.**

If no, do not approve.

DENIAL TEXT: Approval of Gleevec 400mg twice daily for the treatment gastrointestinal stromal tumor (GIST) requires a trial of Gleevec 400mg once daily or a GIST tumor expressing a KIT exon 9 mutation.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IMATINIB

RATIONALE

Ensure appropriate utilization of imatinib based on FDA approved indication and NCCN guidelines. Doses of 400mg or 600mg should be administered once daily, while a dose of 800mg should be given as 400mg twice daily.

FDA APPROVED INDICATIONS

Gleevec is FDA approved for the following:

-) Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase.
-) Patients with Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.
-) Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia.
-) Adult patient with myelodysplastic/myeloproliferative diseases associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements.
-) Adult patient with aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown.
-) Adult patients with hypereosinophilic syndrome and/or chronic eosinophilic leukemia who have the FIP1L1-PDGFR fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFR fusion kinase negative or unknown.
-) Adult patients with unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans.
-) Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors.
-) Adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST.

REFERENCES

-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma. (Version 1.2011).
-) Novartis Pharmaceuticals Corporation. Gleevec package insert. East Hanover, NJ. January 2012.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 11/11

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INDOMETHACIN RECTAL

Generic	Brand	HICL	GCN	Exception/Other
INDOMETHACIN	INDOCIN		20240	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?

-) The patient has dysphagia, difficulty swallowing capsules, or has a feeding tube placed (e.g., G-tube, J-tube)
-) The patient had a previous trial of at least **TWO** prescription strength oral NSAIDs (e.g., ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

If yes, **approve for 12 months by GPID with a quantity limit of 30 rectal suppositories per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **INDOMETHACIN RECTAL (Indocin)** requires that the patient meets one of the following criteria:

-) The patient has dysphagia, difficulty swallowing capsules, or has a feeding tube placed (e.g., G-tube, J-tube)
-) The patient had a previous trial of at least two prescription strength oral NSAIDs (e.g., ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

RATIONALE

To promote appropriate utilization of Indocin (indomethacin rectal suppositories).

FDA APPROVED INDICATIONS

Indocin is a nonsteroidal anti-inflammatory drug indicated for:

-) Moderate to severe rheumatoid arthritis including acute flares of chronic disease
-) Moderate to severe ankylosing spondylitis
-) Moderate to severe osteoarthritis
-) Acute painful shoulder (bursitis and/or tendinitis)
-) Acute gouty arthritis

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INDOMETHACIN RECTAL

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

-) Use lowest effective dosage for shortest duration consistent with individual patient treatment goals.
-) Indocin suppositories are not for oral or intravaginal use.
-) Indocin suppositories 50 mg can be substituted for indomethacin capsules; however, there will be significant differences between the two dosage regimens in indomethacin blood levels.
-) The recommended dosage is as follows:
 - o For moderate to severe rheumatoid arthritis including acute flares of chronic disease, moderate to severe ankylosing spondylitis, and moderate to severe osteoarthritis: Indomethacin capsules 25 mg two or three times a day.
 - o Acute painful shoulder (bursitis and/or tendinitis): Indomethacin capsules 75-150 mg daily in 3 or 4 divided doses.
 - o Acute gouty arthritis: Indomethacin capsules 50 mg three times a day.

REFERENCES

-) Incodin [Prescribing Information]. Iroko Pharmaceuticals, LLC: Philadelphia, PA; May 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INOTERSEN

Generic	Brand	HICL	GCN	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) and meet **ALL** the following criteria?
 -) The patient is 18 years of age or older
 -) The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
 -) Physician attestation that the patient has Stage 1 or 2 polyneuropathy
 -) The patient has documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
 -) Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR protein **OR**
 -) DNA genetic sequencing to confirm hATTR mutation

If yes, **approve for 6 months by HICL with a quantity limit of #6mL per 28 days (each prefilled syringe is 284mg/1.5mL).**

APPROVAL TEXT: Renewal requires physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **INOTERSEN (Tegsedi)** requires a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR). In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
-) Physician attestation that the patient has Stage 1 or 2 polyneuropathy
-) The patient has documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
 -) Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR protein **OR**
 -) DNA genetic sequencing to confirm hATTR mutation

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INOTERSEN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary TTR amyloidosis (hATTR) **AND** meet the following criterion?

-) Physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

If yes, **approve for 12 months by HICL with a quantity limit of #6mL per 28 days (each prefilled syringe is 284mg/1.5mL).**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **INOTERSEN (Tegsedi)** requires a diagnosis of hereditary TTR amyloidosis (hATTR) and physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

RATIONALE

Promote appropriate utilization of INOTERSEN based on clinical trial patient inclusion and FDA approved indication and dosing.

FDA APPROVED INDICATIONS

TEGSEDI is a transthyretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

NOTE: Tegsedi is available only through a restricted distribution program called the TEGSEDI REMS Program. Prescribers must be certified within the program by enrolling and completing training. Patients must enroll in the program and comply with ongoing monitoring requirements (platelet count and kidney function every 1 to 2 weeks or more frequently). Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive Tegsedi.

DOSING AND ADMINISTRATION

The recommended dosage is 284 mg administered by subcutaneous injection once weekly. Laboratory tests must be measured prior to treatment, continue to be monitored after treatment initiation, and for 8 weeks following discontinuation of treatment, as directed.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INOTERSEN

REFERENCES

- J Inotersen [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; October 2018.
- J Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. NEJM. 2018;379(1):22-31. doi:10.1056/NEJMoa1716793.
- J Holmes R. Amyloidosis: Definition of Amyloid and Amyloidosis, Classification Systems, Systemic Amyloidosis. Available at: <https://emedicine.medscape.com/article/335414-overview>. Accessed May 10, 2018.
- J Coelho T, Ericzon B, Falk R, et al. A Guide to Transthyretin Amyloidosis. Available at: <http://www.amyloidosis.org/wp-content/uploads/2017/05/2017-ATTR-guide.pdf>. Accessed May 18, 2018.
- J Rambaran R, Serpell LC. Amyloid Fibrils. Prion. 2008;2(3):112-117.
- J A is for. Amyloidosis: Facts. Available at: <http://amyloidosis.org/facts/>. Accessed May 18, 2018.
- J Gertz, M. Hereditary ATTR Amyloidosis: Burden of Illness and Diagnostic Challenges. Am J Manag Care. 2017;23:S107-S112.
- J Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8(1):1-18. doi:10.1186/1750-1172-8-31.
- J Buxbaum J. Oligonucleotide Drugs for Transthyretin Amyloidosis. NEJM. 2018;379(1):82-85. doi:10.1056/NEJMe1805499.
- J What causes hereditary ATTR (hATTR) amyloidosis? Available at: <https://hattribridge.com/about-hattr-amyloidosis/cause-and-symptoms>. Accessed May 18, 2018.
- J Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements, Appendix C- Summary of Coverage Policy Medicare Part B Versus Part D Coverage Issues. Rev 10, 02-19-10. Available at: http://www.cms.gov/prescriptiondrugcovcontra/12_partdmanuals.asp. [Accessed July 20, 2011].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/12/18

Created: 10/18

Client Approval: 10/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON ALFA-2B	INTRON A	04528		

This drug requires a written request for prior authorization. All requests for medications used to treat hepatitis C require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

1. Is the request for continuation of current therapy (also consider continuation if member has a claim for the currently requested interferon in past 120 days) or a renewal?

If yes, continue to #8.

If no, continue to #2.

2. Is the patient being treated for one of the following?

- ☐ hairy cell leukemia, or
- ☐ condylomata acuminata, or
- ☐ AIDS-related Kaposi's sarcoma, or
- ☐ Chronic hepatitis B, or
- ☐ Non-Hodgkin's lymphoma, or
- ☐ Malignant melanoma, or
- ☐ Chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis), or
- ☐ Follicular lymphoma, or
- ☐ Angioblastoma, or
- ☐ Carcinoid tumor, or
- ☐ Chronic myeloid leukemia, or
- ☐ Laryngeal papillomatosis, or
- ☐ Multiple myeloma, or
- ☐ Neoplasm of conjunctiva-neoplasm of cornea, or
- ☐ Ovarian cancer, or
- ☐ Polycythemia vera, or
- ☐ Renal cell carcinoma, or
- ☐ Skin cancer, or
- ☐ Thrombocytosis, or
- ☐ Vulvar vestibulitis

If yes, **approve by HICL for 24 weeks (6 months).**

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON ALFA-2B

GUIDELINES FOR USE (CONTINUED)

3. Is the patient being treated for chronic hepatitis C and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) OR interferon use is treatment of one of the following: hairy cell leukemia, condylomata acuminata, AIDS-related Kaposi's sarcoma, chronic hepatitis B, non-Hodgkin's lymphoma, malignant melanoma, chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis), follicular lymphoma, angioblastoma, carcinoid tumor, chronic myeloid leukemia, laryngeal papillomatosis, multiple myeloma, neoplasm of conjunctiva-neoplasm of cornea, ovarian cancer, polycythemia vera, renal cell carcinoma, skin cancer, Thrombocytosis, or vulvar vestibulitis.

4. Is the request for interferon being used with ribavirin or does the patient have a contraindication to ribavirin?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) ,requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

5. Does the patient have a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) ,requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON ALFA-2B

GUIDELINES FOR USE (CONTINUED)

6. Has the patient had a trial of peginterferon alfa-2a or peginterferon alfa-2b, or contraindication to pegylated interferon?

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist), requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

7. Is the patient infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C?

If yes, **approve by HICL for 24 weeks (6 months).**

APPROVAL TEXT: Recommend obtaining HCV RNA level at 12 weeks of treatment to determine if the patient has achieved at least a 2 log reduction (100 fold decrease) in HCV RNA. Renewal requires HCV RNA undetectable (less than 50 IU/mL) at 24 weeks.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist), requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

8. Is the patient being treated for chronic hepatitis C and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist)?

If yes, continue to #9.

If no, **approve by HICL for 24 weeks (6 months).**

9. Has the patient already received 24 weeks or more of interferon during this treatment?

If yes, continue to #10.

If no, **approve by HICL for 24 weeks (6 months).**

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INTERFERON ALFA-2B

GUIDELINES FOR USE (CONTINUED)

10. Is the patient HCV RNA undetectable (less than 50 IU/mL) at 24 weeks?

If yes, **approve by HICL for 24 weeks (6 months).**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) and HCV RNA undetectable (less than 50 IU/mL) at 24 weeks.

RATIONALE

Ensure that ribavirin and interferon are used for combination treatment of chronic hepatitis C. The 16 week initial approval for hepatitis C allow a sufficient length of time for the 12-week HCV RNA result (EVR) to be reported and evaluated by the physician. If the patient did not achieve undetectable viral load at 12 weeks then a total of 72 weeks may be considered if the 24-week HCV RNA is undetectable. Total therapy time for HCV genotypes 1, 4, 5 and 6 is 48 weeks, and for HCV genotypes 2 and 3 is 16 to 24 weeks.

Note on HCV RNA levels defined by lab as undetectable versus detectable but not quantifiable:

Commercially available quantitative HCV RNA assays may have differing limits for quantification and detection. The lower limit of detection is 10 or 50 IU/mL HCV RNA (depends on assay used by lab). The FDA suggests that labs testing HCV RNA levels for patients taking protease inhibitors must use an assay with a lower limit of quantification of 25 IU/mL or less, and a lower limit of detection of 10-15 IU/mL. Generally, patients with detectable but not quantifiable levels of HCV RNA will have lower SVR rates with triple therapy; a detectable but not quantifiable HCV RNA level should not be considered equivalent to an undetectable level. When the product package insert (or MedImpact PA guideline) specifies "undetectable HCV RNA level", generally an undetectable HCV RNA result is required.

FDA APPROVED INDICATIONS

INTRON A (Interferon alfa-2b) is indicated for treatment of hairy cell leukemia, condylomata acuminata, AIDS-related Kaposi's sarcoma, hepatitis C (in combination), malignant melanoma, follicular lymphoma and chronic hepatitis B.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INTERFERON ALFA-2B

REFERENCES

-) Ghany et al. AASLD Practice Guidelines. Diagnosis, Management, and Treatment of Hepatitis C. Hepatology 2009, 49(4) 1335-74.
-) Merck/Schering Corporation. Intron A Product Information. Whitehouse Station, NJ. January 2014.
-) Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: January 12, 2013].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/14

Created: 02/14

Client Approval: 03/14

P&T Approval: 02/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IVABRADINE

Generic	Brand	HICL	GCN	Exception/Other
IVABRADINE HCL	CORLANOR	33396		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of heart failure and meets the following criteria?

- ☐ Prescribed by or in consultation with a cardiologist
- ☐ Age 18 years or older
- ☐ NYHA Class II – IV Heart failure
- ☐ Left ventricular ejection fraction of 35% or less
- ☐ Patient is in sinus rhythm (for example, patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block, or 2nd or 3rd degree AV block unless a functioning demand pacemaker is present)
- ☐ Resting heart rate 70 beats per minute

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a demand pacemaker that is set to a rate of 60 beats per minute or greater?

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #3.

3. Is the patient currently being treated with or have intolerance to one of the following: beta-blockers: metoprolol succinate, bisoprolol, or carvedilol?

If yes, **approve for 12 months by HICL with a quantity limit of #60 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IVABRADINE

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT: Our guideline for **IVABRADINE** requires a diagnosis of heart failure. In addition, following criteria must also be met:

-) Prescribed by or in consultation with a cardiologist
-) Age 18 years old
-) NYHA Class II – IV Heart failure
-) Left ventricular ejection fraction of 35% or less
-) Patient is in sinus rhythm (for example, patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block, or 2nd or 3rd degree AV block unless a functioning demand pacemaker is present)
-) Resting heart rate 70 beats per minute
-) Patient does not have a demand pacemaker that is set to a rate of 60 beats per minute or greater
-) Patient is currently being treated with or has an intolerance to one of the following: beta-blockers: metoprolol succinate, bisoprolol, or carvedilol

RENEWAL CRITERIA

1. Does the patient have a diagnosis of heart failure and meets the following criteria?
 -) Patient is in sinus rhythm (for example, patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block, or 2nd or 3rd degree AV block unless a functioning demand pacemaker is present)

If yes, **approve for 12 months by HICL with a quantity limit of #60 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **IVABRADINE** renewal requires a diagnosis of heart failure. In addition, the following criteria must also be met:

-) Patient is in sinus rhythm (for example, patient does not have atrial fibrillation, sick sinus syndrome, sinoatrial block, or 2nd or 3rd degree AV block unless a functioning demand pacemaker is present)

RATIONALE

Promote appropriate utilization of ivabradine based on FDA approved indication.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IVABRADINE

RATIONALE (CONTINUED)

Corlanor is approved for use in patients with systolic heart failure to reduce heart rate with the goal of reducing hospitalizations for worsening heart failure. It is not indicated for the treatment of angina. Beta blockers should be used first-line unless contraindicated. The most recent ACCF/AHA guidelines for the management of heart failure recommend use of 1 of the 3 beta-blockers proven to reduce mortality (eg. bisoprolol, carvedilol, and sustained-release metoprolol succinate) for all patients with current or prior symptoms of reduced ejection fraction heart failure, unless contraindicated, to reduce morbidity and mortality. The guidelines recommend beta-blocker therapy should be initiated as soon as HFrEF is diagnosed due to the favorable effect on survival and disease progression.

Patients who have a demand pacemaker set to a rate of 60 beats per minute or greater cannot achieve the ivabradine therapy target heart rate of 50- 60 beats per minute. Corlanor increases the risk of atrial fibrillation. In the SHIFT trial, the rate of atrial fibrillation was 5.0% per patient-year in patients treated with Corlanor and 3.9% per patient-year in patients treated with placebo. Patients should be in sinus rhythm when taking Corlanor, and Corlanor should be discontinued if atrial fibrillation develops. Bradycardia, sinus arrest, and heart block have occurred with Corlanor. Corlanor should be avoided in patients with 2nd degree atrioventricular block, and is contraindicated with 3rd degree atrioventricular block unless a functioning demand pacemaker is present. Safety and effectiveness in pediatric patients have not been established.

FDA APPROVED INDICATIONS & DOSING

Corlanor is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction \geq 35%, who are in sinus rhythm with resting heart rate \geq 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.

The recommended starting dose of Corlanor is 5 mg twice daily with meals. Assess patient after two weeks and adjust dose to achieve a resting heart rate between 50 and 60 beats per minute (bpm). Thereafter, adjust dose as needed based on resting heart rate and tolerability. The maximum dose is 7.5 mg twice daily.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IVABRADINE

FDA APPROVED INDICATIONS & DOSING (CONTINUED)

Dose Adjustments for Ivabradine	
Heart Rate	Dose Adjustment
> 60 bpm	Increase dose by 2.5 mg (given twice daily), up to a maximum dose of 7.5mg twice daily
50 – 60 bpm	Maintain dose
< 50 bpm or signs and symptoms of bradycardia	Decrease dose by 2.5mg (given twice daily) If current dose is 2.5mg twice daily, discontinue therapy
BPM = beats per minute	

In patients with a history of conduction defects, or other patients in whom bradycardia could lead to hemodynamic compromise, initiate therapy at 2.5 mg twice daily before increasing the dose based on heart rate.

REFERENCES

-) Corlanor [Prescribing Information]. Thousand Oaks, California. Amgen, Inc. April 2015.
-) Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines. Circulation. 2013;128:e240-e327.
-) Swedberg K, Komajada M, Bohm M, et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. Lancet. 2010 Sep 11;376(9744):875-85.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/15

Created: 08/15

Client Approval: 08/15

P&T Approval: 08/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXAZOMIB

Generic	Brand	HICL	GCN	Exception/Other
IXAZOMIB CITRATE	NINLARO	42826		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma and have **ALL** of the following criteria been met?

-) Ninlaro (ixazomib) will be used in combination with lenalidomide and dexamethasone
-) Patient has received at least one prior therapy for the treatment of multiple myeloma such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

If yes, **approve for 12 months by HICL with a quantity limit of #3 capsules per 28 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **IXAZOMIB (Ninlaro)** requires a diagnosis of multiple myeloma and that it will be used in combination with lenalidomide and dexamethasone in patients who have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation.

RATIONALE

Promote appropriate utilization of IXAZOMIB (Ninlaro) based on FDA approved indication.

Ninlaro, in combination with lenalidomide and dexamethasone offers the first all-oral treatment option for patients with relapsed and/or refractory multiple myeloma (RRMM). According to the National Cancer Institute (NCI), MM is the third most common blood cancer (after lymphoma and leukemia) in the United States. NCI estimates there will be 26,850 new cases of multiple myeloma and 11,240 related deaths in the US this year.

Standard treatment options for MM include proteasome inhibitors (Velcade [bortezomib], Kyprolis [carfilzomib]), immunomodulators (IMiDs) (Revlimid [lenalidomide], Thalomid [thalidomide], Pomalyst [pomalidomide]), alkylating agents (Alkeran [melphalan], Cytoxan [cyclophosphamide]), anthracyclines (Doxil [liposomal doxorubicin]), and corticosteroids (dexamethasone). Regimens may contain two or three drug combinations, with selected patients undergoing hematopoietic cell transplantation (HCT).

NCCN guidelines added a category 1 recommendation for Ninlaro in combination with lenalidomide and dexamethasone for previously untreated MM. While ongoing studies are evaluating Ninlaro for newly diagnosed MM, current labeling for Ninlaro requires at least one prior line of therapy, as the FDA approval was based only on patients with RRMM. Although Ninlaro has the convenience of an all-oral regimen, it should be reserved for patients who have progressed on currently recommended regimens.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXAZOMIB

RATIONALE (CONTINUED)

The efficacy of Ninlaro was evaluated in a phase 3, randomized, double-blind, placebo-controlled, multicenter trial (Tourmaline-MM1) in 722 patients with RRMM. Patients had to receive at least one prior line of therapy (60-62% received one, 38-40% received two or three), but patients who were refractory to lenalidomide or PIs (e.g., Velcade) were excluded from the study. The most common types of prior therapy included melphalan-containing (80-81%), bortezomib-containing (69%), thalidomide-containing (44-47%), and stem cell transplantation (55-59%). Other prior therapies included lenalidomide-containing and carfilzomib containing regimens.

FDA APPROVED INDICATION

Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

DOSAGE

The recommended starting dose of Ninlaro (ixazomib) is 4mg taken orally on Days 1, 8, and 15 of a 28-day cycle. Treatment should be continued until disease progression or unacceptable toxicity.

The dose may be reduced due to adverse reactions as shown in the table below.

Recommended starting dose	First reduction to	Second reduction to	Discontinue
4mg	3mg	2.3mg	

REFERENCES

) Ninlaro [Prescribing Information]. Cambridge, MA: Takeda Pharmaceutical Company Limited; 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 12/15

Client Approval: 02/16

P&T Approval: 02/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LANADELUMAB

Generic	Brand	HICL	GCN	Exception/Other
LANADELUMAB-FLYO	TAKHZYRO	45177		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet **ALL** of the following criteria?
 -) Diagnosis of HAE is confirmed via complement testing
 -) The medication is being used for prophylaxis to prevent HAE attacks
 -) The patient is 12 years of age or older
 -) The medication is prescribed by or in consultation with an allergist/immunologist or hematologist

If yes, **approve for 12 months by HICL with a quantity limit of #4mL per 28 days.**

APPROVAL TEXT: Renewal requires physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **LANADELUMAB (Takhzyro)** requires a diagnosis of hereditary angioedema (HAE). Additionally, the following criteria must be met:

-) Diagnosis of HAE is confirmed via complement testing
-) The medication is being used for prophylaxis to prevent HAE attacks
-) The patient is 12 years of age or older
-) The medication is prescribed by or in consultation with an allergist/immunologist or hematologist

RENEWAL CRITERIA

2. Does the patient have a diagnosis of hereditary angioedema (HAE) and meet the following criteria?
 -) Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

If yes, **approve for 12 months by HICL with a quantity limit of #4mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **LANADELUMAB (Takhzyro)** requires a diagnosis of hereditary angioedema (HAE) for renewal. The following criteria must also be met:

-) Physician attestation of improvement (i.e., reductions in attack frequency or attack severity) compared to baseline in HAE attacks with routine prophylaxis

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LANADELUMAB

RATIONALE

Ensure appropriate utilization of LANADELUMAB (Takhzyro) based on FDA-approved indication and clinical trial design.

FDA APPROVED INDICATIONS

Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.

DOSING AND ADMINISTRATION

The recommended starting dosage of Takhzyro is 300 mg given subcutaneously every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack-free) for more than 6 months.

Takhzyro should be administered subcutaneously into the abdomen, thigh, or upper arm and is provided as a ready-to-use solution in a single-dose vial that does not require additional reconstitution or dilution for administration. Takhzyro is intended for self-administration or administration by a caregiver, following training by a healthcare professional. In clinical studies, the majority of patients self-administered Takhzyro over 10 to 60 seconds.

REFERENCES

) Takhzyro [Prescribing Information]. Lexington, MA: Dyax Corp.; August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/24/18

Created: 09/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LAPATINIB

Generic	Brand	HICL	GCN	Exception/Other
LAPATINIB DITOSYLATE	TYKERB	34541		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have breast cancer?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient's breast cancer HER2 positive (defined as IHC 3+ or FISH amplification ratio greater than 2.0)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the requested medication being used in combination with Xeloda (capecitabine), Herceptin (trastuzumab), or Femara (letrozole)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have estrogen or progesterone receptor-positive breast cancer?

If yes, **approve for 12 months with a quantity limit of up to #6 per day per month.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LAPATINIB

GUIDELINES FOR USE (CONTINUED)

5. Has the patient's prior therapy included Herceptin (trastuzumab)?

If yes, **approve for 12 months with a quantity limit of up to #6 per day per month.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval criteria require concurrent treatment with Xeloda (capecitabine), Herceptin (trastuzumab), or Femara (letrozole) for patients with a diagnosis of HER2-positive breast cancer with estrogen/progesterone receptor-positive breast cancer; or a diagnosis of HER2-positive breast cancer in a patient with a previous trial of Herceptin (trastuzumab).

RATIONALE

To ensure that lapatinib is used in the appropriate patient population with HER2 positive breast cancer. Lapatinib in combination with capecitabine or trastuzumab is recommended for trastuzumab-exposed HER2 positive breast cancer. Lapatinib is recommended in combination with other chemotherapy for HER2 positive breast cancer that is either estrogen or progesterone receptor-positive or negative.

FDA APPROVED INDICATIONS

Tykerb is indicated in combination with:

Capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors over express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.

Letrozole, for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that over expresses the HER2 receptor for whom hormonal therapy is indicated.

REFERENCES

-) GlaxoSmithKline. Tykerb package insert. Research Triangle Park, NC. April, 2010.
-) National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v.2.2011
-) Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at:
<https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: June 27, 2011].

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LAPATINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/13

Created: 04/10
Client Approval: 08/13

P&T Approval: 08/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LETERMOVIR PO

Generic	Brand	HICL	GCN	Exception/Other
LETERMOVIR	PREVYMIS		44049 44061	

GUIDELINES FOR USE

1. Is the patient undergoing an allogeneic hematopoietic stem cell transplant (HSCT) and meet **ALL** of the following criteria?

- ☐ The patient is at least 18 years of age or older
- ☐ The patient is CMV-seropositive [R+]
- ☐ Prevyms will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
- ☐ Prevyms will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
- ☐ Patient is not receiving the medication beyond 100 days post-transplantation

If yes, **approve for 98 days (14 weeks) by GPID for all daily dosage strengths with the following quantity limits:**

- ☐ **240mg tablets (GPID 44049): #1 tablet per day. AND**
- ☐ **480mg tablets (GPID 44061): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **LETERMOVIR PO (Prevymis)** requires the patient to be undergoing an allogeneic hematopoietic stem cell transplant (HSCT). In addition, the following criteria must also be met:

- ☐ The patient is at least 18 years of age or older
- ☐ The patient is CMV-seropositive [R+]
- ☐ Prevyms will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
- ☐ Prevyms will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
- ☐ Patient is not receiving the medication beyond 100 days post-transplantation

RATIONALE

Promote appropriate utilization of **LETERMOVIR** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Prevymis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LETERMOVIR PO

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. Prevymis is recommended to be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment), and continue through Day 100 post-transplantation. Dosage of Prevymis should be decreased to 240mg once daily when co-administered with cyclosporine.

-) If cyclosporine is initiated after starting Prevymis, the next dose of Prevymis should be decreased to 240mg once daily.
-) If cyclosporine is discontinued after starting Prevymis, the next dose of Prevymis should be increased to 480mg once daily.
-) If cyclosporine dosing is interrupted due to high cyclosporine levels, no dose adjustment of Prevymis is needed.

Prevymis injection, which contains hydroxypropyl betadex, should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis as soon as they are able to take oral medications. Prevymis tablet and injection may be used interchangeably at the discretion of the physician, and no dosage adjustment is necessary when switching formulations.

AVAILABLE STRENGTHS

Tablet: 240mg, 480mg tablets; Injection: 240mg/12 mL (20mg/mL), 480mg/24mL (20mg/mL) single dose vials

REFERENCES

-) Prevymis [Prescribing Information]. Merck & Co, Inc.; Whitehouse Station, NJ. November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOFEXIDINE

Generic	Brand	HICL	GCN	Exception/Other
LOFEXIDINE	LUCEMYRA	07803		

GUIDELINES FOR USE

1. Is the requested medication being used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation and the patient meets **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) The patient is in a setting with close patient monitoring for a duration of Lucemyra (lofexidine) treatment not to exceed 18 days
 -) Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

If yes, **approve for 1 fill with a quantity limit of #264 tablets per 18 days.**

If no, do not approve.

DENIAL TEXT: The guideline name **LOFEXIDINE (Lucemyra)** requires that the requested medication is used to mitigate opioid withdrawal symptoms to facilitate abrupt opioid discontinuation. In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) The patient is in a setting with close patient monitoring for a duration of Lucemyra (lofexidine) treatment not to exceed 18 days
-) Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (e.g., stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

RATIONALE

To ensure appropriate use of Lucemyra (lofexidine) consistent with FDA approved indications.

FDA APPROVED INDICATION

Lucemyra is indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

DOSAGE AND ADMINISTRATION

The usual Lucemyra starting dosage is three 0.18 mg tablets taken orally 4 times daily during the period of peak withdrawal symptoms (generally the first 5 to 7 days following last use of opioid) with dosing guided by symptoms and side effects. There should be 5 to 6 hours between each dose. The total daily dosage of Lucemyra should not exceed 2.88 mg (16 tablets) and no single dose should exceed 0.72 mg (4 tablets).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOFEXIDINE

FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION

Lucemyra treatment may be continued for up to 14 days with dosing guided by symptoms. Discontinue Lucemyra with a gradual dose reduction over a 2- to 4-day period to mitigate Lucemyra withdrawal symptoms (e.g., reducing by 1 tablet per dose every 1 to 2 days). The Lucemyra dose should be reduced, held, or discontinued for individuals who demonstrate a greater sensitivity to Lucemyra side effects. Lower doses may be appropriate as opioid withdrawal symptoms wane.

REFERENCES

) Lucemyra [Prescribing Information]. Louisville, KY. US Worldmeds, LLC. May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOMITAPIDE

Generic	Brand	HICL	GCN	Exception/Other
LOMITAPIDE	JUXTAPID	39883		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Does the patient meet **ONE** of the following criteria?
 -) The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
 -) The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
If yes, continue to #3.
If no, continue to #4.
3. Will the patient continue statin treatment as described above in combination with Juxtapid?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?

-) The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
-) The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?

-) The patient has had a previous trial of Repatha (evolocumab)
-) The patient lacks functioning LDL receptors

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?

-) Simon Broome diagnostic criteria (definite)
-) Dutch Lipid Network criteria with a score of at least 8
-) A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

-) **Juxtapid 5mg (GPID 33909): #45 per 30 days.**
-) **Juxtapid 10mg (GPID 33912): #30 per 30 days.**
-) **Juxtapid 20mg (GPID 33913): #90 per 30 days.**
-) **Juxtapid 30mg (GPID 38574): #30 per 30 days.**
-) **Juxtapid 40mg (GPID 38571): #30 per 30 days.**
-) **Juxtapid 60mg (GPID 38573): #30 per 30 days.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

DENIAL TEXT: The guideline named **LOMITAPIDE (Juxtapid)** requires a diagnosis of homozygous familial hypercholesterolemia (HoFH). The following criteria must also be met:

-) The diagnosis of homozygous familial hypercholesterolemia (HoFH) is determined by meeting **ONE** of the following criteria:
 - o Simon Broome diagnostic criteria (definite)
 - o Dutch Lipid Network criteria with a score of at least 8
 - o A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents
-) The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
-) The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment
-) The patient has had a previous trial of Repatha (evolocumab) unless the patient lacks functional LDL receptors

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOMITAPIDE

GUIDELINES FOR USE (CONTINUED)

For statin tolerant patients, approval also requires the following:

-) The patient meets **ONE** of the following criteria:
 - o The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
 - o The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
-) The patient will continue statin treatment in combination with Juxtapid

For statin intolerant patients, approval also requires ONE of the following:

-) The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
-) The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

RATIONALE

Ensure appropriate utilization of Juxtapid according to approved indications, dosing, clinical trial data, and national treatment guidelines.

FDA APPROVED INDICATIONS

Juxtapid is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of use:

-) The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH)
-) The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOMITAPIDE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Initiate treatment at 5 mg once daily. Titrate dose based on acceptable safety/tolerability: increase to 10 mg daily after at least 2 weeks; and then, at a minimum of 4-week intervals, to 20 mg, 40 mg, and up to the maximum recommended dose of 60 mg daily.

Take once daily, whole, with water and without food, at least 2 hours after evening meal.

REFERENCES

) Juxtapid [Prescribing Information]. Cambridge, MA: Aegerion Pharmaceuticals, Inc.; August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 01/13

Client Approval: 05/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LOMUSTINE

Generic	Brand	HICL	GCN	Exception/Other
LOMUSTINE	GLEOSTINE	03900		

GUIDELINES FOR USE

1. Is the request for treatment of Hodgkin's Lymphoma?

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Is the request for treatment of primary and metastatic brain tumors and the patient has previously received appropriate surgical and/or radiotherapeutic procedures?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Will the patient be using this medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine) **OR** has the patient had a previous trial of IV carmustine?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **LOMUSTINE (Gleostine)** requires a diagnosis of Hodgkin's Lymphoma or that the request is being used for the treatment of primary and metastatic brain tumors in patients who previously received appropriate surgical and/or radiotherapeutic procedures. Patients with primary and metastatic brain tumors must be using the medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine) or had a previous trial of IV carmustine.

RATIONALE

To promote appropriate utilization of Gleostine based on its FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATIONS

Gleostine is an alkylating drug indicated for the treatment of patients with:

-) Brain tumors, primary and metastatic, following appropriate surgical and/or radiotherapeutic procedures
-) Hodgkin's lymphoma in combination with other chemotherapies, following disease progression with initial chemotherapy.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****LOMUSTINE****FDA APPROVED INDICATIONS (CONTINUED)****DOSING**

The recommended dose of Gleostine in adult and pediatric patients is 130 mg/m² taken as a single oral dose every 6 weeks.

-) Round doses to the nearest 5 mg.
-) Give as a single oral dose and do not repeat for at least 6 weeks.
-) Reduce dose to 100 mg/m² every 6 weeks in patients with compromised bone marrow function. Also reduce dose accordingly when using with other myelosuppressive drugs.

Perform weekly complete blood counts and withhold each subsequent dose for more than 6 weeks if needed until platelet counts recover to 100,000/mm³ or greater and leukocytes recover to 4000/mm³ or greater. Modify each dose of Gleostine according to the hematologic response of the preceding dose as described in the table below.

Nadir After Prior Dose		Dose Adjustment
Leukocytes (/mm ³)	Platelets	
4,000	100,000	None
3,000-3,999	75,000-99,999	None
2,000-2,999	25,000-74,999	Reduce dose by 30%
<2,000	< 25,000	Reduce dose by 50%

REFERENCES

-) Gleostine [Prescribing Information]. NextSource Biotechnology, LLC: Miami, FL; January 2016.
-) National Comprehensive Cancer Network. NCCN Guidelines: Central Nervous System Cancers Version 1. 2017. Updated September 25, 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 16, 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 03/18

P&T Approval: 01/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****LUSUTROMBOPAG**

Generic	Brand	HICL	GCN	Exception/Other
LUSUTROMBOPAG	MULPLETA	45127		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
- ☐ The patient is 18 years of age or older
 - ☐ The patient has chronic liver disease
 - ☐ The patient is scheduled to undergo a procedure 8 to 14 days following initiation of Mulpleta (lusutrombopag) therapy
 - ☐ The patient has a platelet count of less than 50×10^9 cells/L measured within the last 30 days
 - ☐ The medication is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
 - ☐ The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., avatrombopag, romiplostim, eltrombopag)

If yes, **approve for 1 fill by HICL with a quantity limit of #7 tablets.**

If no, do not approve.

DENIAL TEXT: The guideline named **LUSUTROMBOPAG (Mulpleta)** requires a diagnosis of thrombocytopenia. In addition, the following criteria must be met:

- ☐ The patient is 18 years of age or older
- ☐ The patient has chronic liver disease
- ☐ The patient is scheduled to undergo a procedure 8 to 14 days following initiation of Mulpleta (lusutrombopag) therapy
- ☐ The patient has a platelet count of less than 50×10^9 cells/L measured within the last 30 days
- ☐ The medication is prescribed by or in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
- ☐ The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., avatrombopag, romiplostim, eltrombopag)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mulpleta.

REFERENCES

- ☐ Mulpleta [Prescribing Information]. Florham Park, NJ: Shionogi & Co, Ltd. July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MEBENDAZOLE

Generic	Brand	HICL	GCN	Exception/Other
MEBENDAZOLE	EMVERM		43181	

GUIDELINES FOR USE

1. Is the patient being treated for *enterobius vermicularis* (pinworm) **AND** meet the following criterion?
J The patient has had a trial of or has a contraindication to pyrantel pamoate (OTC)

If yes, **approve for 1 month by GPID with a quantity limit of #2 tablets per 30 days.**

If no, continue to #2.

2. Is the patient being treated for *trichuris trichiura* (whipworm) **OR** *ascaris lumbricoides* (common roundworm) and meet ALL of the following criteria?
J Documentation confirming a diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
J The patient has had a trial of or has a contraindication to albendazole (Albenza)

If yes, **approve for 1 month by GPID with a quantity limit of #6 tablets per 30 days.**

If no, continue to #3.

3. Is the patient being treated for *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm) and meet **ALL** of the following criteria?
J Documentation confirming a diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
J The patient has had a trial of or has a contraindication to albendazole (Albenza) **OR** pyrantel pamoate (OTC)

If yes, **approve for 1 month by GPID with a quantity limit of #6 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **MEBENDAZOLE (Emverm)** requires that the medication is used for the treatment of *Enterobius vermicularis* (pinworm), *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm). The following criteria must also be met:

For treatment of *enterobius vermicularis* (pinworm), approval requires:

- J The patient has had a trial of or has a contraindication to pyrantel pamoate (OTC)

For treatment of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm), approval requires:

- J Documentation confirming a diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)

- J The patient has had a trial of or has a contraindication to albendazole (Albenza)

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MEBENDAZOLE

GUIDELINES FOR USE (CONTINUED)

For treatment of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm), approval requires:

-) Documentation confirming a diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
-) The patient has had a trial of or has a contraindication to albendazole (Albenza) **OR** pyrantel pamoate (OTC)

RATIONALE

To ensure appropriate use of mebendazole consistent with FDA approved use and CDC treatment guidelines.

FDA APPROVED INDICATION

Emverm (mebendazole) is indicated for the treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections.

DOSAGE AND ADMINISTRATION

-) Treatment of *Enterobius vermicularis* (pinworm)
 - o 1 tablet (100mg), once.
 - o If the patient is not cured three weeks after treatment, a second course of treatment is advised.
-) Treatment of *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm)
 - o 1 tablet (100mg) twice daily for three consecutive days.
 - o If the patient is not cured three weeks after treatment, a second course of treatment is advised.

AVAILABLE STRENGTHS:

-) Mebendazole 100mg chewable tablet

REFERENCES

-) Emverm [Prescribing Information]. Horsham, PA: Amedra Pharmaceuticals LLC; September 2017. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=13631e94-269d-45db-a433-2aa4f8d465c6>. Accessed November 14, 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 03/16

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECAMYLAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Exception/Other
MECAMYLAMINE HCL	VECAMYL		1471	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of moderately severe to severe essential (or primary) hypertension or uncomplicated malignant hypertension?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried or does the patient have a contraindication to three of the following: angiotensin converting enzyme (ACE) inhibitor or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker?

PAC NOTE: These drugs include: benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECAMYLAMINE HYDROCHLORIDE

GUIDELINES FOR USE

DENIAL TEXT: Approval requires that Vecamyl be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension; and a trial or a contraindication to at least three of the following: angiotensin converting enzyme (ACE) inhibitor or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

Therapy is usually started with one 2.5 mg tablet of Vecamyl twice a day. This initial dosage should be modified by increments of one 2.5 mg tablet at intervals of not less than 2 days until the desired blood pressure response occurs (the criterion being a dosage just under that which causes signs of mild postural hypotension).

The average total daily dosage of Vecamyl is 25 mg, usually in three divided doses. However, as little as 2.5 mg daily may be sufficient to control hypertension in some patients. Since the blood pressure response to antihypertensive drugs is increased in the early morning, the larger dose should be given at noontime and perhaps in the evening.

Vecamyl joins several different agents used in the treatment of hypertension. The most commonly prescribed drug classes for primary hypertension include thiazide-type diuretics, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), calcium channel blockers, and beta blockers; all of which have generic formulations available. Each category of antihypertensive agent has similar levels of efficacy in lowering the blood pressure, producing a good antihypertensive response in 30 to 50 percent of patients. Malignant hypertension most often occurs in patients with long-standing uncontrolled hypertension, many of whom have discontinued antihypertensive therapy. The oral drug of choice in uncomplicated malignant hypertension is the ACE inhibitor, captopril, since it can substantially lower the BP within 10 to 30 minutes for most patients and has a relatively short duration that facilitates dose titration.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECAMYLAMINE HYDROCHLORIDE

RATIONALE (CONTINUED)

In more recent years, there has been considerable interest in evaluating Vecamyl for the treatment of other clinical indications, including smoking cessation and depression. The principal focus of research on other clinical indications largely involves Vecamyl's potent blockade of brain nicotinic receptors at doses that do not have a significant effect on parasympathetic function (2.5-10 mg/day). Recently Vecamyl was studied as an add-on treatment to existing anti-depressants. However, it failed two short-term Phase 3 clinical trials in 2011, showing no significant difference in patients when compared to a placebo.

The package insert for Vecamyl does not include any clinical trials as it was approved using an abbreviated new drug application (ANDA) of the innovator product, Inversine (mecamylamine). The distribution of Inversine was discontinued in 2009. Approved on March 1, 1956, Inversine was available prior to the 1962 amendments to the Federal Food, Drug, and Cosmetic Act (commonly referred to as the Kefauver-Harris Amendments) which established a framework requiring drug manufacturers to prove scientifically that a medication was not only safe, but effective. Since drugs approved between 1938 and 1962 were approved only on the grounds of safety, the FDA's Drug Efficacy Study Implementation (DESI) program has been retrospectively evaluating the effectiveness of these medications.

The Journal of the American Medical Association published a study in 1957 examining the effects of mecamylamine alone on 17 patients with sustained blood pressure above 150/100 mm Hg. Each patient was initiated on mecamylamine 2.5mg twice daily before undergoing a set dose titration. Treatment response was defined as a decrease in mean blood pressure by at least 20 mm Hg or a reduction of blood pressure to the normotensive level (defined by the investigators as less than 150/100 mm Hg). A little more than half of this small group responded to mecamylamine alone. Among the responders, the average dose was 34mg daily. However, there were some patients, who despite doubling this average dose, did not respond satisfactorily to mecamylamine.

Vecamyl is contraindicated in those with coronary insufficiency or recent myocardial infarction, uremia, glaucoma, organic pyloric stenosis as well as patients with hypersensitivity to the product.

Vecamyl should be given with great discretion, if at all, in patients with renal insufficiency. Patients receiving antibiotics and sulfonamides should generally not be treated with ganglion blockers such as Vecamyl.

Vecamyl should not be used in mild, moderate, labile hypertension and may prove unsuitable in uncooperative patients. When ganglion blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. For some patients, particularly those with malignant hypertension, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure. Vecamyl should be gradually discontinued and substituted with other antihypertensive therapy.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECAMYLAMINE HYDROCHLORIDE

RATIONALE (CONTINUED)

At therapeutic antihypertensive doses (30 to 90 mg per day), Vecamyl has parasympathetic-blocking activity which results in side effects such as constipation, urinary retention, dryness of the mouth and skin, dilation of the pupils, and loss of visual accommodation in some patients. Since urinary retention may occur, caution is required in patients with prostatic hypertrophy, bladder neck obstruction, and urethral stricture. Vecamyl should be discontinued immediately if a patient is showing signs of paralytic ileus (for example frequent loose bowel movements with abdominal distention and decreased bowel sounds).

Since Vecamyl readily penetrates into the brain, it can cause central nervous system effects such as tremor, choreiform movements, mental aberrations, and convulsions. Although rare in nature, these effects have occurred most often when large doses of Vecamyl were used, especially in patients with cerebral or renal insufficiency.

Vecamyl is pregnancy category C. Because of the potential for serious adverse reactions in nursing infants from Vecamyl, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

FDA APPROVED INDICATIONS

For the management of moderately severe to severe essential (or primary) hypertension and in uncomplicated cases of malignant hypertension.

REFERENCES

-] Vecamyl [Prescribing Information]. Fort Collins, CO: Manchester Pharmaceuticals; February 2012.
-] UpToDate, Inc. Choice of therapy in primary (essential) hypertension: Recommendations. UpToDate [database online]. Waltham, MA. Available at <http://www.uptodate.com/home/index.html>. Updated March 25, 2013.
-] UpToDate, Inc. Malignant hypertension and hypertensive encephalopathy in adults. UpToDate [database online]. Waltham, MA. Available at <http://www.uptodate.com/home/index.html>. Updated July 17, 2012.
-] Shytle RD, Penny, E, et. al. Mecamylamine (Inversine): an old antihypertensive with new research directions. Journal of Human Hypertension. 2002; (16): 453-457.
-] The Death of TC-5214. Available at <http://scienceleftuntitled.wordpress.com/2012/05/11/the-death-of-tc-5214/> Accessed on May 9, 2013.
-] Kefauver-Harris Amendments Revolutionized Drug Development. Updated on October 10, 2012. Available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm322856.htm#> Accessed on May 9, 2013.
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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECAMYLAMINE HYDROCHLORIDE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/13

Created: 05/13
Client Approval: 08/13

P&T Approval: 08/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECHLORETHAMINE GEL

Generic	Brand	HICL	GCN	Exception/Other
MECHLORETHAMINE HCL	VALCHLOR		35387	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy)?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs) and prior skin-directed therapy (such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy).

RATIONALE

To promote appropriate utilization of Valchlor based on FDA approved indication and NCCN guidelines.

Valchlor is for topical dermatological use only. Apply a thin film of Valchlor gel once daily to affected areas of the skin. Stop treatment with Valchlor for any grade of skin ulceration, blistering, or moderately-severe or severe dermatitis (i.e., marked skin redness with edema). Upon improvement, treatment with Valchlor can be restarted at a reduced frequency of once every 3 days. If reintroduction of treatment is tolerated for at least one week, the frequency of application can be increased to every other day for at least one week and then to once daily application if tolerated.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECHLORETHAMINE GEL

RATIONALE (CONTINUED)

Warnings and precautions include: mucosal or eye injury; secondary exposure to Valchlor; dermatitis; non-melanoma skin cancer; embryo-fetal toxicity; and flammable gel. The most common adverse reactions (5%) are dermatitis, pruritus, bacterial skin infection, skin ulceration or blistering, and hyperpigmentation. Valchlor is contraindicated in patients with severe hypersensitivity to mechlorethamine.

Valchlor is pregnancy category D. No drug interaction studies have been performed with Valchlor. Systemic exposure has not been observed with topical administration of Valchlor; therefore, systemic drug interactions are not likely.

Valchlor is a gel formulation of mechlorethamine (nitrogen mustard), an alkylating agent which inhibits rapidly proliferating cells. Mechlorethamine was previously approved as an intravenous formulation for the treatment of mycosis fungoides. Prior to the approval of Valchlor, there were no FDA-approved topical mechlorethamine products; only pharmacy-compounded petroleum ointment or aqueous-based topical preparations were available.

Developed primarily in the skin, CTCLs may progress to involve lymph nodes, blood and visceral organs. They account for about 5 percent of all non-Hodgkin lymphomas (NHL). There will be an estimated 69,740 new cases of NHL and 19,020 deaths from NHL in 2013. The overall 5-year relative survival rate for patients with NHL is 68 percent.

The National Comprehensive Cancer Network (NCCN) recommends skin-directed therapies for the initial treatment of patients with patch/plaque mycosis fungoides-type CTCL with the addition of milder systemic therapy. Localized skin-directed therapies include topical therapy with corticosteroids, mechlorethamine (previously compounded formulations and now Valchlor), carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy. Generalized skin directed therapies such as phototherapy (UVB or PUVA) and total skin electronic beam therapy are indicated for patients with widespread skin involvement. Systemic therapies with extracorporeal photopheresis, interferons, systemic retinoids, or histone deacetylase inhibitors are preferred over traditional chemotherapy for patients who do not respond to initial skin-directed therapies. They include oral Targretin and intravenous formulations Istodax and Ontak.

The efficacy of Valchlor was assessed in a randomized, active-controlled, non-inferiority clinical trial of 260 patients with Stage IA, IB, and IIA mycosis fungoides-type cutaneous T-cell lymphoma (CTCL) who had received at least one prior skin-directed therapy. Qualifying prior therapies included topical corticosteroids, phototherapy, Targretin gel, and topical nitrogen mustard. Patients were not required to be refractory to or intolerant of prior therapies.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MECHLORETHAMINE GEL

RATIONALE (CONTINUED)

Patients were stratified based on Stage (IA vs. IB and IIA) and then randomized to receive Valchlor 0.016% (equivalent to 0.02% mechlorethamine HCL) or Aquaphor-based Mechlorethamine HCL 0.02% ointment (comparator). Eighteen patients were excluded from the efficacy analysis due to protocol violations involving randomization at a single site. Study drug was to be applied topically on a daily basis for 12 months. Concomitant use of topical corticosteroids was not permitted during the study. Dosing could be suspended or continued with reduced frequency for dermatitis. The mean daily usage of Valchlor gel was 2.8 g (1 to 2 tubes per month). The maximum daily usage was 10.5 g (5 to 6 tubes per month). Patients were evaluated for a response on a monthly basis for the first 6 months and then every 2 months for the last 6 months using the Composite Assessment of Index Lesion Severity (CAILS) score. The CAILS score is obtained by adding the severity score of each of the following categories for up to 5 index lesions: erythema, scaling, plaque elevation, and surface area. Severity was graded from 0 (none) to 8 (severe) for erythema and scaling; 0 to 3 for plaque elevation; and 0 to 9 for surface area. A response was defined as greater than or equal to 50% reduction in baseline CAILS score which was confirmed at the next visit at least 4 weeks later. A complete response was defined as a confirmed CAILS score of 0. Non-inferiority was considered to have been demonstrated if the lower bound of the 95% confidence interval (CI) around the ratio of response rates (Valchlor/Comparator) was greater than or equal to 0.75. Patients were also evaluated using the Severity Weighted Assessment Tool (SWAT). The SWAT score is derived by measuring each involved area as a percentage of total body surface area (%BSA) and multiplying it by a severity weighting factor (1=patch, 2=plaque, 3=tumor or ulcer). A response was defined as greater than or equal to 50% reduction in baseline SWAT score which was confirmed at the next visit at least 4 weeks later. The baseline demographics and disease characteristics were balanced between treatment arms. The median age was 57 years in the Valchlor arm and 58 years in the comparator arm. The majority of the patients were male (60% in Valchlor arm, 59% in Comparator arm) and white (75% in both treatment arms). The median number of prior therapies was 2 in both treatment arms. The most common prior therapy was topical corticosteroids (used in 86% of patients in both treatment arms). The median body surface area (BSA) involvement at baseline was 8.5% (range 1%, 61%) in the Valchlor arm and 9% (range 1%, 76%) in the comparator arm.

Sixty percent (60%) of the patients on the Valchlor arm and 48% of patients on the comparator arm achieved a response based on the CAILS score. Valchlor was non-inferior to the comparator based on a CAILS overall response rate ratio of 1.24 (95% CI 0.98, 1.58). Complete responses constituted a minority of the CAILS or SWAT overall responses. The onset of CAILS overall response for both treatment arms showed a wide range from 1 to 11 months.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****MECHLORETHAMINE GEL****RATIONALE (CONTINUED)**

Efficacy in Patients with Mycosis Fungoides-Type CTCL (From Valchlor Prescribing Information)

Response Rates	VALCHLOR N=119	Comparator N=123
CAILS Overall Response (CR+PR), %(N)	60%	48%
Complete Response (CR)	14%	11%
Partial Response (PR)	45%	37%
SWAT Overall Response (CR+PR), %(N)	50%	46%
Complete Response (CR)	7%	3%
Partial Response (PR)	43%	43%

FDA APPROVED INDICATIONS

Valchlor (mechlorethamine) is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (CTCLs) in patients who have received prior skin-directed therapy.

REFERENCES

-) Ceptaris Therapeutics, Inc. Valchlor [Prescribing Information]. August 2013. Available at: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo [Accessed October 21, 2013]
-) NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 2.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nhl.pdf [Accessed October 21, 2013]
-) American Cancer Society. Lymphoma of the Skin Detail Guide. Available at: <http://www.cancer.org/cancer/lymphomaoftheskin/detailedguide/lymphoma-of-the-skin-detailed-guide-toc> [Accessed October 21, 2013]

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 11/13

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

METHYLNALTREXONE

Generic	Brand	HICL	GCN	Exception/Other
METHYLNALTREXONE BROMIDE	RELISTOR	35611		

GUIDELINES FOR USE

1. Is the request for methylnaltrexone (Relistor) tablets or injection for a patient with constipation due to an opioid (such as morphine or methadone) and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has chronic non-cancer pain (including chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation)
- ☐ The patient has been taking opioids for at least four weeks
- ☐ The patient has a previous trial of or contraindication to naloxegol (Movantik)

If yes, **approve for 12 months by GPID for all of the following listed agents and quantity limits:**

- ☐ Relistor 12mg vial: #1 vial per day.
- ☐ Relistor 12mg syringe: #1 syringe per day.
- ☐ Relistor 150mg tablets: #3 tablets per day.

If no, continue to #2.

2. Is the request for methylnaltrexone (Relistor) injection for a patient with constipation due to an opioid (such as morphine or methadone) and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has advanced (terminal) illness or pain caused by active cancer who require opioid dosage escalation for palliative care

If yes, **approve Relistor injection for 6 months by GPID with the following quantity limits:**

- ☐ Relistor 12 mg vial: #1 vial per day.
- ☐ Relistor 12 mg syringe: #1 syringe per day.
- ☐ Relistor 8 mg syringe: #1 syringe per day.

If no, do not approve.

DENIAL TEXT: The guideline for **METHYLNALTREXONE (Relistor)** requires that the patient have a diagnosis of opioid-induced constipation with chronic non-cancer pain, OR with advanced (terminal) illness or pain caused by active cancer who require opioid dosage escalation for palliative care. The patient must also be 18 years of age or older. For patients with advanced (terminal) illness, or pain caused by active cancer who require opioid dosage escalation for palliative care, only Relistor injection may be approved. The following criteria must also be met:

For patients with chronic non-cancer pain, approval requires all of the following:

- ☐ The patient has been taking opioids for at least four weeks
- ☐ The patient had a previous trial of or contraindication to naloxegol (Movantik)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

METHYLNALTREXONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Relistor.

REFERENCES

) Relistor [Prescribing Information]. Bridgewater, NJ: Salix Pharmaceuticals. March 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/19/18

Created: 11/08

Client Approval: 11/18

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIDOSTAURIN

Generic	Brand	HICL	GCN	Exception/Other
MIDOSTAURIN	RYDAPT	44227		

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
 -) The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
 -) The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
 -) The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML
 -) The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #56 capsules per 28 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)?

If yes, **approve for 12 months by HICL with a quantity limit of #224 capsules per 28 days.**
If no, do not approve.

DENIAL TEXT: The guideline named **MIDOSTAURIN (Rydapt)** requires a diagnosis of newly diagnosed acute myeloid leukemia (AML), aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). The following criteria must also be met:

For newly diagnosed acute myeloid leukemia (AML), approval requires all of the following:

-) The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
-) The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
-) The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML
-) The patient is 18 years of age or older

RATIONALE

Promote appropriate utilization of **MIDOSTAURIN** based on FDA approved indication and dosage.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIDOSTAURIN

FDA APPROVED INDICATIONS

Rydapt is a kinase inhibitor indicated for the treatment of adults with:

-) Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
-) Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

Limitations of Use:

Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

DOSAGE AND ADMINISTRATION

Rydapt is available as 25 mg capsules. Rydapt should be taken twice daily with food. Rydapt capsules should not be opened or crushed.

Recommended Dosage in Acute Myeloid Leukemia

The recommended dose of Rydapt for patients with acute myeloid leukemia is 50 mg orally twice daily with food on Days 8 to 21 of each cycle of induction with cytarabine and daunorubicin and on Days 8 to 21 of each cycle of consolidation with high-dose cytarabine.

FLT3 mutation status must be reported using the FDA-approved, in-vitro companion diagnostic LeukoStrat® CDx FLT3 Mutation Assay to ensure correct selection of patients eligible to be treated with Rydapt.

Recommended Dosage in ASM, SM-AHN, and MCL

The recommended dose of Rydapt for patients with ASM, SM-AHN, and MCL is 100 mg orally twice daily with food. Continue treatment until disease progression or unacceptable toxicity occurs. Dose modifications for therapy-related toxicities can be found in the prescribing information.

REFERENCES

-) Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; April 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/17

Client Approval: 12/17

P&T Approval: 07/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIFEPRISTONE

Generic	Brand	HICL	GCN	Exception/Other
MIFEPRISTONE	KORLYM		31485	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of endogenous Cushing's syndrome and meet **ALL** of the following criteria?
 -) The patient also has a diagnosis of type 2 diabetes mellitus **OR** glucose intolerance
 -) Patient has failed surgical treatment for Cushing's syndrome **OR** is not a candidate for surgery

If yes, **approve for 1 year by GPID up to #4 tablets per day.**

APPROVAL TEXT: Please note this medication has an important FDA Safety Warning; pregnancy must be excluded before the initiation of treatment with Korlym or when therapy is interrupted for more than 14 days. For more information, discuss with your physician or pharmacist.

If no, do not approve.

DENIAL TEXT: The guideline named **MIFEPRISTONE (Korlym)** requires a diagnosis of endogenous Cushing's syndrome. In addition, the following criteria must be met:

-) The patient also has a diagnosis of type 2 diabetes mellitus OR glucose intolerance
-) Patient has failed surgical treatment for Cushing's syndrome OR is not a candidate for surgery

RATIONALE

To ensure appropriate use of Korlym.

FDA APPROVED INDICATIONS

-) Korlym is a cortisol receptor antagonist indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.
-) Korlym should not be used for the treatment of diabetes type 2 unrelated to endogenous Cushing's syndrome.

REFERENCE

-) Korlym [Prescribing Information]. Menlo Park, CA: Corcept Therapeutics; December 2017.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIFEPRISTONE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 03/01/18

Created: 04/12
Client Approval: 02/18

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIGALASTAT

Generic	Brand	HICL	GCN	Exception/Other
MIGALASTAT	GALAFOLD	44433		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Fabry disease and meet **ALL** of the following criteria?
 -) The patient is 18 years or older
 -) The patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data as interpreted by clinical genetics professional as pathogenic/likely pathogenic (i.e., patient does not have a benign amenable GLA variant)
 -) The requested medication is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
 -) The patient is NOT concurrently using enzyme replacement therapy (i.e., Fabrazyme)
 -) The patient is symptomatic **OR** has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a female patient who meets the following criteria?
 -) Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

If yes, **approve for 6 months by HICL with a quantity limit of #14 capsules per 28 days.**

If no, continue to #3.

3. Is the request for a male patient who meets **ONE** of the following criteria?
 -) Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal -A)
 -) Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

If yes, **approve for 6 months by HICL with a quantity limit of #14 capsules per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIGALASTAT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **MIGALASTAT (Galafold)** requires a diagnosis of Fabry disease. In addition, the following criteria must be met:

-) The patient is 18 years or older
-) The patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data as interpreted by clinical genetics professional as pathogenic/likely pathogenic (i.e., patient does not have a benign amenable GLA variant)
-) The requested medication is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
-) The patient is NOT concurrently using enzyme replacement therapy (i.e., Fabrazyme)
-) The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)
-) The patient meets one of the following:
 - o Female patients: Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation
 - o Male patients: Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal -A) or genetic test documenting galactosidase alpha gene (GLA) mutation

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease and meet the following criteria?

-) The prescribing provider attests that the patient **has demonstrated improvement or maintenance/stabilization** while on therapy in regards to at least **ONE** of the following:
 - o Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
 - o Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
 - o Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

If yes, **approve for 12 months by HICL with a quantity limit of #14 capsules per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **MIGALASTAT (Galafold)** requires a diagnosis of Fabry disease for renewal. In addition, the following criteria must be met:

-) The prescribing provider attests that the patient has demonstrated improvement or maintenance/stabilization while on therapy in regards to at least one of the following:
 - o Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
 - o Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
 - o Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIGALASTAT

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Galafold.

REFERENCES

) Galafold [Prescribing Information]. Cranbury, NJ: Amicus Therapeutics; August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIGLUSTAT

Generic	Brand	HICL	GCN	Exception/Other
MIGLUSTAT	ZAVESCA	25098		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient 18 years of age or older?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is enzyme replacement therapy not a therapeutic option for this patient due to constraints such as allergy, hypersensitivity, or poor venous access?

If yes, **approve for up to 12 months with a quantity limit of #90 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of type 1 Gaucher disease in patients 18 years of age or older for whom enzyme replacement therapy is not an option.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIGLUSTAT

RATIONALE

Ensure that Zavesca is being used to treat patients with type 1 Gaucher disease.

FDA APPROVED INDICATION

ZAVESCA® is indicated for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).

REFERENCES

-) Actelion Pharmaceuticals. Zavesca package insert. South San Francisco. November 2010.
-) Elstein D, Dweck A, Attias D et al. Oral maintenance clinical trial with miglustat for type I Gaucher disease: switch from or combination with intravenous enzyme replacement. Blood. 2007;110:2296-2301.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/12

Created: 05/05

Client Approval: 08/12

P&T Approval: 08/12



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MILTEFOSINE

Generic	Brand	HICL	GCN	Exception/Other
MILTEFOSINE	IMPAVIDO	16200		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Leishmaniasis and meets **ALL** of the following criteria?

- ☐ Patient is 12 years of age or older
- ☐ Infection type is **ONE** of the following:
 - ☐ Visceral leishmaniasis caused by *Leishmania donovani*
 - ☐ Cutaneous leishmaniasis caused by **ALL** of the following: *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*
 - ☐ Mucosal leishmaniasis caused by *Leishmania braziliensis*
- ☐ Leishmaniasis species is identified via **ONE** of the following CDC recommended tests:
 - ☐ Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings)
 - ☐ Culture medium
 - ☐ Polymerase chain reaction (PCR)
 - ☐ Serologic testing (e.g. rK39 Rapid Test)

If yes, **approve for 12 months by HICL with a quantity limit of #84 capsules per 28 days.**

If no, do not approve

DENIAL TEXT: The guideline for **MILTEFOSINE (Impavido)** requires that the patient is 12 years of age or older and has a diagnosis of Leishmaniasis with one of the following types of infection:

- ☐ Visceral leishmaniasis due to *Leishmania donovani*
- ☐ Cutaneous leishmaniasis due to **ALL** of the following: *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*
- ☐ Mucosal leishmaniasis due to *Leishmania braziliensis*

In addition, species identification must be confirmed via one of the following CDC recommended tests:

- ☐ Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings)
- ☐ Culture medium
- ☐ Polymerase chain reaction (PCR)
- ☐ Serologic testing (e.g. rK39 Rapid Test)

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MILTEFOSINE

RATIONALE

Promote appropriate utilization of **MILTEFOSINE** based on FDA approved indication

Impavido (miltefosine) is the first FDA-approved drug to treat cutaneous and mucosal leishmaniasis, and the first oral treatment approved for visceral leishmaniasis. Pentostam (sodium stibogluconate) has been the standard of care for treating leishmaniasis since the 1940s; however, it is not commercially available in the US, but in some cases, may be obtained via an investigational new drug (IND) protocol through the CDC and FDA. Amphotericin B (liposome and conventional) is the only FDA-approved treatment for visceral leishmaniasis and has been used off label as rescue therapy for cutaneous and mucosal leishmaniasis. Ambisome (amphotericin B liposomal) is preferred due to a better safety profile and shorter treatment duration. Topical paromomycin, is not available commercially in the US, but may be obtained via an IND protocol. Prior to Impavido's approval, off label use of oral azoles have been used in specific circumstances, although efficacy is limited and treatment failure is common.

Leishmaniasis is a disease caused by *Leishmania*, a parasite which is transmitted to humans through sand fly bites and occurs primarily in the tropic, subtropics and southern Europe. Overall, infection in humans is caused by more than 20 species of *Leishmania* parasites, which are spread by about 30 species of sand fly vectors. New cases diagnosed in the US are most often as a result of acquired disease during overseas travel. According to the Centers for Disease Control (CDC), the estimated number of new cases of cutaneous leishmaniasis ranges approximately from 700,000 to 1.2 million and for visceral leishmaniasis, estimates range from approximately 200,000 to 400,000.

Leishmaniasis encompasses multiple clinical syndromes including cutaneous, mucosal, and visceral forms, which result from infection of macrophages in the dermis, in the naso-opharyngeal mucosa, and throughout multiple organ systems, respectively. For all three forms, the infection can range from asymptomatic to severe. Cutaneous and mucosal leishmaniasis can cause lesions associated with substantial morbidity, whereas visceral leishmaniasis can be life threatening. Clinical manifestation of disease after initial exposure is typically delayed in all forms of leishmaniasis. In general, skin lesions caused from cutaneous leishmaniasis develop within several weeks or months after exposure and can persist for months or years. Mucosal leishmaniasis develops as a result of untreated or suboptimal treatment of cutaneous leishmaniasis. Thus, mucosal lesions may not appear for several years after the original cutaneous lesions. If left untreated, cutaneous leishmaniasis and mucosal leishmaniasis can progress to ulcerative destruction, disfigurement, and/or secondary bacterial infections. Visceral leishmaniasis is characterized by irregular bouts of fever, weight loss, enlargement of the spleen and liver, and anemia. The onset of visceral leishmaniasis can present as chronic, subacute or acute and may not be clinically evident for years to decades after exposure. In the absence of treatment, the case fatality rate of visceral leishmaniasis is more than 90 percent.

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MILTEFOSINE

RATIONALE (CONTINUED)

Diagnosis of leishmaniasis is made by combining clinical signs with parasitological or serological tests. Detection of parasites can be made from tissue specimens, such as from skin lesions for cutaneous and mucosal leishmaniasis, or from bone marrow, for visceral leishmaniasis. Blood tests that detect antibodies to the parasite may assist diagnosis of visceral leishmaniasis. Due to limited availability of laboratory methods used for diagnosis, the CDC can assist with testing. The CDC provides the following diagnostic services as gratis: examination of slides (e.g., of biopsy specimens, impression smears, and dermal scrapings), provision of leishmanial culture medium, *In vitro* culture and PCR for diagnosis of leishmaniasis and species identification, serologic testing using the rK39 Rapid Test, for detection of antibodies against organisms in the *Leishmania donovani* species complex (useful primarily for visceral leishmaniasis).

Treatment decisions should be individualized, taking into account the form of leishmaniasis, species, geographic region of acquired infection, and the patient's underlying health. Expert consultation is highly recommended, preferably with guidance from the CDC staff to determine the appropriate course. In general, all clinically manifest cases of visceral leishmaniasis and mucosal leishmaniasis should be treated, whereas not all cases of cutaneous leishmaniasis require treatment.

DOSAGE

The treatment duration is 28 consecutive days. Administration with food is recommended to ameliorate gastrointestinal adverse reactions. Dosage is based on weight:

-) 30kg to 40kg – administer one 50mg capsule twice daily with food (breakfast and dinner)
-) ≥45kg – administer one 50mg capsule three times daily with food (breakfast, lunch, and dinner)

FDA APPROVED INDICATION

Impavido (miltefosine) is an antileishmanial drug indicated in adults and adolescents ≥12 years of age weight ≥30kg (66lbs) for the treatment of:

-) Visceral leishmaniasis due to *Leishmania donovani*
-) Cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*
-) Mucosal leishmaniasis due to *Leishmania braziliensis*
-) Limitations of use: *Leishmania* species evaluated in clinical trials were based on epidemiologic data. There may be geographic variation in the response of the same *Leishmania* species to Impavido. The efficacy of Impavido in the treatment of other *Leishmania* species has not been evaluated.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MILTEFOSINE

REFERENCES

-) Impavido [Prescribing Information]. Profounda, Inc. Orlando, FL. October 2015.
-) FDA Press Release [Online Press Release]. FDA approves Impavido to treat tropical disease leishmaniasis. March 19, 2014. Accessed April 19, 2016. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm389671.htm>
-) Centers for Disease Control and Prevention. Parasites – Leishmaniasis. Accessed on April 19, 2016. Available at: <http://www.cdc.gov/parasites/leishmaniasis/epi.html>
-) UpToDate, Inc [database online]. Treatment of visceral leishmaniasis. Last updated March 2016. Accessed on April 19, 2016. Available at: <http://www.uptodate.com/contents/treatment-of-visceral-leishmaniasis?source=machineLearning&search=impavido&selectedTitle=4%7E7§ionRank=1&anchor=H17#H17>
-) UpToDate, Inc [database online]. Treatment of cutaneous leishmaniasis. Last updated Feb 3 2016. Accessed on April 19, 2016. Available at : http://www.uptodate.com/contents/treatment-of-cutaneous-leishmaniasis?source=search_result&search=impavido&selectedTitle=5%7E7

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/16

Created: 04/16

Client Approval: 06/16

P&T Approval: 05/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

1. Is this medication excluded from coverage?

If yes, guideline does not apply.
If no, continue to #2.

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets **ALL** of the following criteria?
-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
 -) No history of minocycline or tetracycline sensitivity or allergy
 -) No history of candidiasis or active oral candidiasis
 -) Not being used for acutely abscessed periodontal pocket
 -) Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
 - o Uncontrolled diabetes mellitus
 - o Chemotherapy
 - o Radiation therapy
 - o HIV infection
 -) Not being used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants
 -) Age 18 years or older
 -) Prescribed and administered by an oral health care professional

If yes, **approve for 3 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
-) No history of minocycline or tetracycline sensitivity or allergy
-) No history of candidiasis or active oral candidiasis
-) Not being used for acutely abscessed periodontal pocket
-) Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
 - o Uncontrolled diabetes mellitus
 - o Chemotherapy
 - o Radiation therapy
 - o HIV infection
-) Not being used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants
-) Age 18 years or older
-) Prescribed and administered by an oral health care professional

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

If yes, guideline does not apply.

If no, continue to #2.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets the following criteria?

-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

If yes, **approve for 6 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**

If no, do not approve.

DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** renewal requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

RATIONALE

Ensure appropriate use of ARESTIN consistent with its FDA approved indication, dosing, contraindications, and precautions. In clinical trials, an average of 29.5 (5-114), 31.7 (4-137), and 31 (5-108) sites were treated at baseline in the scaling and root planning (SRP) alone, SRP + vehicle, and SRP + ARESTIN groups, respectively.

FDA APPROVED INDICATIONS

ARESTIN is indicated as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis. ARESTIN may be used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing.

DOSAGE

ARESTIN is provided as a dry powder, packaged in a unit dose cartridge with a deformable tip, which is inserted into a spring-loaded cartridge handle mechanism to administer the product.

The oral health care professional removes the disposable cartridge from its pouch and connects the cartridge to the handle mechanism. ARESTIN is a variable dose product, dependent on the size, shape, and number of pockets being treated. In US clinical trials, up to 122 unit dose cartridges were used in a single visit and up to 3 treatments, at 3-month intervals, were administered in pockets with pocket depth of 5 mm or greater.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

REFERENCES

) Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma. August 2015.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 08/01/18

Created: 08/16
Client Approval: 07/18

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIPOMERSEN SODIUM

Generic	Brand	HICL	GCN	Exception/Other
MIPOMERSEN SODIUM	KYNAMRO	40041		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Does the patient meet **ONE** of the following criteria?
 -) The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
 -) The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
If yes, continue to #3.
If no, continue to #4.
3. Will the patient continue statin treatment as described above in combination with Kynamro?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?

-) The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
-) The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ONE** of the following criteria?

-) The patient has had a previous trial of Repatha (evolocumab)
-) The patient lacks functioning LDL receptors

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?

-)] Simon Broome diagnostic criteria (definite)
-)] Dutch Lipid Network criteria with a score of at least 8
-)] A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

If yes, **approve for 12 months by HICL with a quantity limit of #4mL (4 syringes) per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **MIPOMERSEN SODIUM (Kynamro)** requires a diagnosis of homozygous familial hypercholesterolemia (HoFH). The following criteria must also be met:

-)] The diagnosis of homozygous familial hypercholesterolemia (HoFH) is determined by meeting **ONE** of the following criteria:
 - o Simon Broome diagnostic criteria (definite)
 - o Dutch Lipid Network criteria with a score of at least 8
 - o A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents
-)] The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
-)] The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment
-)] The patient has had a previous trial of Repatha (evolocumab) unless the patient lacks functional LDL receptors

For statin tolerant patients, approval also requires the following:

-)] The patient meets **ONE** of the following criteria:
 - o The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks, **OR**
 - o The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
-)] The patient will continue statin treatment in combination with Kynamro

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIPOMERSEN SODIUM

GUIDELINES FOR USE (CONTINUED)

For statin intolerant patients, approval also requires ONE of the following:

-) The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
-) The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

RATIONALE

Ensure appropriate utilization of Kynamro according to approved indications, dosing, clinical trial data, and national treatment guidelines.

FDA APPROVED INDICATIONS

Kynamro is indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Limitations of use:

-) The safety and effectiveness of Kynamro have not been established in patients with hypercholesterolemia who do not have HoFH.
-) The effect of Kynamro on cardiovascular morbidity and mortality has not been determined.
-) The safety and effectiveness of KYNAMRO as an adjunct to LDL apheresis have not been established; therefore, the use of KYNAMRO as an adjunct to LDL apheresis is not recommended

DOSAGE AND ADMINISTRATION

The recommended dose of Kynamro is 200 mg once weekly as a subcutaneous injection.

Kynamro is intended for subcutaneous use only. Do not administer intramuscularly or intravenously. The injection should be given on the same day every week, but if a dose is missed, the injection should be given at least 3 days from the next weekly dose.

REFERENCES

-) Kynamro [Prescribing Information]. Chicago, IL: Kastle Therapeutics; May 2016.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MIPOMERSEN SODIUM

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/18

Created: 03/13
Client Approval: 05/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOMETASONE FUROATE	SINUVA		44214	

GUIDELINES FOR USE

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has had previous ethmoid sinus surgery (ESS)
- ☐ The medication is prescribed by or given in consultation with an otolaryngologist
- ☐ The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
- ☐ The patient had a previous trial of at least **TWO** intranasal corticosteroids (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

If yes, **approve #2 implants (1 per sinus) by GPID per lifetime.**

If no, do not approve.

DENIAL TEXT: The guideline named **MOMETASONE IMPLANT (Sinuva)** requires a diagnosis of nasal polyps. In addition, the following criteria must also be met:

- ☐ The patient is 18 years of age or older
- ☐ The patient has had previous ethmoid sinus surgery (ESS)
- ☐ The medication is prescribed by or given in consultation with an otolaryngologist
- ☐ The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
- ☐ The patient had a previous trial of at least **TWO** intranasal corticosteroids (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOMETASONE SINUS IMPLANT (NSA)

RATIONALE

To promote appropriate utilization of SINUVA based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Sinuva Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients 18 years of age who have had ethmoid sinus surgery

DOSAGE & ADMINISTRATION

One Sinuva Sinus Implant containing 1350 mcg of mometasone furoate. There are no studies evaluating repeat implantation of the Sinuva Sinus Implant.

The Sinuva Sinus Implant is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. The Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The Implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. Sinuva must be inserted by physicians trained in otolaryngology.

REFERENCES

) Sinuva [Prescribing Information]. Menlo Park, CA: Intersect ENT. December 2017.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 08/01/18

Created: 05/18

Client Approval: 07/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NILOTINIB

Generic	Brand	HICL	GCN	Exception/Other
NILOTINIB HCL	TASIGNA	35149		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase **AND** meet the following criterion?
J The patient is 1 year of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in accelerated phase and meet **ALL** of the following criteria?
J The patient is 18 years of age or older
J The patient is resistant or intolerant to prior therapy including imatinib (Gleevec)
J The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, or F359V/C/I

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, continue to #3.

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase **AND** meet the following criterion?
J The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, or F359V/C/I

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient between 1 and 17 years of age **AND** meet the following criterion?
J The patient is resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib)

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NILOTINIB

GUIDELINES FOR USE (CONTINUED)

5. Is the patient 18 years of age or older **AND** meet the following criterion?
-) The patient is resistant or intolerant to prior therapy including imatinib (Gleevec)

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **NILOTINIB (Tasigna)** requires a diagnosis of newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, OR Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic or accelerated phase. In addition, the following criteria must be met:

For patients with newly diagnosed Ph+ CML in chronic phase, approval requires:

-) The patient is 1 year of age or older

For patients with Ph+ CML in accelerated phase, approval requires:

-) The patient is 18 years of age or older
-) The patient is resistant or intolerant to prior therapy including imatinib (Gleevec)
-) The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, or F359V/C/I

For patients with Ph+ CML in chronic phase, approval requires:

-) The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, or F359V/C/I
-) The patient must also meet **ONE** of the following criteria:
 - o The patient is between 1 and 17 years of age AND has resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy (e.g., imatinib, dasatinib)
 - o The patient is 18 years of age or older AND has resistance or intolerance to prior therapy including imatinib (Gleevec)

RATIONALE

Ensure appropriate utilization of nilotinib based on its FDA approved indications.

FDA APPROVED INDICATIONS

Tasigna is a kinase inhibitor indicated for the following:

-) Newly diagnosed adults and pediatric patients greater than or equal to 1 year of age with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase.
-) Adult patients with chronic phase (CP) or accelerated phase (AP) Philadelphia chromosome-positive chronic myeloid leukemia with resistance or intolerance to prior therapy that included imatinib.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NILOTINIB

FDA APPROVED INDICATIONS (CONTINUED)

-) Pediatric patients greater than or equal to 1 year of age with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

DOSAGE AND ADMINISTRATION

Tasigna should be taken twice daily at approximately 12-hour intervals and must be taken on an empty stomach. No food should be consumed for at least 2 hours before the dose is taken and for at least 1 hour after the dose is taken. Advise patients to swallow the capsules whole with water.

For patients who are unable to swallow capsules, the contents of each capsule may be dispersed in 1 teaspoon of applesauce (puréed apple). The mixture should be taken immediately (within 15 minutes) and should not be stored for future use.

Adult patients with Newly diagnosed Ph+ CML in chronic phase

-) The recommended dose of Tasigna is 300 mg orally twice daily.

Adult Patients with Resistant or Intolerant Ph+ CML-CP and CML-AP

-) The recommended dose of Tasigna is 400 mg orally twice daily.

Pediatric Patients with Newly Diagnosed Ph+ CML-CP or Resistant or Intolerant Ph+ CML-CP

-) The recommended dose of Tasigna for pediatric patients is 230 mg/m^2 orally twice daily, rounded to the nearest 50 mg dose (to a maximum single dose of 400 mg)
-) If needed, attain the desired dose by combining different strengths of Tasigna capsules. Continue treatment as long as clinical benefit is observed or until unacceptable toxicity occurs.

REFERENCES

-) Novartis Pharmaceuticals Corporation. Tasigna package insert. East Hanover, NJ. March 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/16/18

Created: 05/12

Client Approval: 04/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NIRAPARIB

Generic	Brand	HICL	GCN	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
 -) The requested medication will be used as monotherapy
 -) The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
 -) The patient is in complete or partial response to their most recent platinum based-chemotherapy
 -) Patient has completed at least 2 or more lines of platinum-based chemotherapy
 -) The requested medication will be used for maintenance treatment
 -) The patient is greater than 18 years of age

If yes, **approve for 12 months by HICL with a quantity limit of #90 capsules per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **NIRAPARIB (Zejula)** requires a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. In addition, the following criteria must be met:

-) The requested medication will be used as monotherapy
-) The requested medication is started no later than 8 weeks after the patient's most recent platinum-containing regimen
-) The patient is in complete or partial response to their most recent platinum based-chemotherapy
-) Patient has completed at least 2 or more lines of platinum-based chemotherapy
-) The requested medication will be used for maintenance treatment
-) The patient is greater than 18 years of age

RATIONALE

Promote appropriate utilization of **NIRAPARIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Zejula is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NIRAPARIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dose of Zejula as monotherapy is 300 mg (three 100 mg capsules) taken orally once daily with or without food. Bedtime administration may be a potential method for managing nausea. Patients should start treatment with Zejula no later than 8 weeks after their most recent platinum-containing regimen.

Instruct patients to take their dose of Zejula at approximately the same time each day. Each capsule should be swallowed whole.

Zejula treatment should be continued until disease progression or unacceptable toxicity. In the case of a missed dose of Zejula, instruct patients to take their next dose at its regularly scheduled time. If a patient vomits or misses a dose of Zejula, an additional dose should not be taken.

To manage adverse reactions, consider interruption of treatment or dose reduction. Recommended dose reductions are indicated in Table 1.

Table 1. Recommended Dose Adjustments

Dose Level	Dose
Starting dose	300 mg/day (three 100 mg capsules)
First dose reduction	200 mg/day (two 100 mg capsules)
Second dose reduction	100/day* (one 100 mg capsule)

REFERENCES

) Zejula [Prescribing Information]. Waltham, MA: Tesaro; 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 08/17

Client Approval: 08/17

P&T Approval: 07/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NITISINONE

Generic	Brand	HICL	GCN	Exception/Other
NITISINONE	ORFADIN, NITYR	23253		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary tyrosinemia type 1 (HT-1) **AND** meet **ALL** of the following criteria?
 -) The patient has elevated urinary or plasma succinylacetone (SA) levels **OR** a mutation in the fumarylacetoacetate hydrolase (FAH) gene
 -) The medication is being prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
 -) The patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for Nityr (nitisinone) tablets?

If yes, **approve for 6 months by GPID for all strengths with no quantity limit.**

APPROVAL TEXT: Renewal requires that the patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

If no, continue to #3.

3. Is the request for Orfadin capsules and has the patient had a trial of or contraindication to Nityr tablets?

If yes, **approve for 6 months by GPID for all strengths with no quantity limit.**

APPROVAL TEXT: Renewal requires that the patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

If no, continue to #4.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NITISINONE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Orfadin suspension and has the patient had a trial of or contraindication to Orfadin (nitisinone) capsules or Nityr tablets?

If yes, **approve for 6 months by GPID with no quantity limit.**

APPROVAL TEXT: Renewal requires that the patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **NITISINONE (Orfadin, Nityr)** requires a documented diagnosis of hereditary tyrosinemia type 1 (HT-1) as confirmed by elevated urinary or plasma succinylacetone (SA) levels or a mutation in the fumarylacetoacetate hydrolase (FAH) gene. In addition, the following criteria must also be met:

-) The medication must be prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
-) The patient must be counseled on maintaining dietary restriction of tyrosine and phenylalanine
-) For requests of Orfadin capsules, the patient must have tried Nityr tablets
-) For requests of Orfadin oral suspension, the patient must have tried or have a contraindication to Orfadin capsules or Nityr tablets. For patients who have difficulties swallowing capsules, Orfadin capsules may be opened and the contents suspended in a small amount of water, formula, or applesauce immediately before use.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary tyrosinemia type 1 **AND** meet the following criterion?

-) The patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

If yes, **approve for 12 months by GPID for all strengths of the requested formulation with no quantity limit.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **NITISINONE (Orfadin, Nityr)** requires a diagnosis of hereditary tyrosinemia type 1 (HT-1). In addition, the following renewal criterion must be met:

-) The patients urinary or plasma succinylacetone (SA) levels have decreased from baseline while on treatment with nitisinone.

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NITISINONE

RATIONALE

Promote appropriate utilization of **NITISINONE** based on FDA approved indication.

FDA APPROVED INDICATION

Orfadin (nitisinone) is a 4-hydroxyphenylpyruvate dioxygenase inhibitor indicated for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Nityr is a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

DOSAGE

Recommended Dosage:

-) The recommended initial dosage is 0.5 mg/kg orally twice daily.
-) Titrate the dose based on biochemical and/or chemical response, as described in the full prescribing information.
-) The maximum dosage is 1 mg/kg orally twice daily.

Preparation and Administration Instructions for Orfadin:

-) For instructions on preparing, measuring and administering the oral suspension, see the full prescribing information.
-) Maintain dietary restriction of tyrosine and phenylalanine.
-) Take Orfadin capsules at least one hour before, or two hours after a meal.
-) For patients who have difficulties swallowing capsules and who are intolerant to the oral suspension, the capsules may be opened and the contents suspended in a small amount of water, formula or applesauce immediately before use.
-) Take Orfadin oral suspension without regard to meals.

Preparation and Administration Instructions for Nityr:

-) Take with or without food.
- For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information.

DOSAGE FORMS AND STRENGTHS

Orfadin:

-) Capsules: 2 mg, 5 mg, 10 mg, 20 mg
-) Oral suspension: 4 mg/mL

Nityr:

-) Tablets: 2 mg, 5 mg, 10 mg

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NITISINONE

REFERENCES

-) Orfadin [Prescribing Information]. Waltham, MA: Sobi, Inc. June 2016.
-) Nityr [Prescribing Information]. Cambridge, UK: Cycle Pharmaceuticals Ltd. July 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/16

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBETICHOLIC ACID

Generic	Brand	HICL	GCN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis as confirmed by at least **TWO** of the following criteria?

-) An alkaline phosphatase level of at least 1.5 times the upper limit of normal
-) The presence of antimitochondrial antibodies at a titer of 1:40 or higher
-) Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet **ALL** of the following criteria?

-) The patient is at least 18 years of age and older
-) The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15mg/kg/day for at least 1 year, **OR** as monotherapy in adults unable to tolerate ursodeoxycholic acid
-) The patient does not have complete biliary obstruction
-) The medication is prescribed by or given in consultation with a gastroenterologist or hepatologist

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**

APPROVAL TEXT: Renewal requires that the patient's alkaline phosphatase levels have decreased by at least 15% from baseline while on treatment with obeticholic acid. The following criteria must also be met:

-) The patient has not developed complete biliary obstruction

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT: The guideline named **OBETICHOLIC ACID (Ocaliva)** requires a diagnosis of primary biliary cholangitis, as confirmed by two of the following criteria:

-) An alkaline phosphatase level of at least 1.5 times the upper limit of normal
-) The presence of antimitochondrial antibodies at a titer of 1:40 or higher
-) Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

In addition, the following criteria must also be met.

-) The patient is at least 18 years of age and older
-) The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15 mg/kg/day for at least 1 year, OR as monotherapy in adults unable to tolerate ursodeoxycholic acid
-) The patient does not have complete biliary obstruction
-) The medication is prescribed by or given in consultation with a gastroenterologist or hepatologist

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis and meets **ALL** of the following criteria?

-) The patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal **OR** have decreased by at least 15% from baseline while on treatment with obeticholic acid
-) The patient has not developed complete biliary obstruction

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **OBETICHOLIC ACID (Ocaliva)** renewal requires that the patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal **OR** have decreased by at least 15% from baseline while on treatment with obeticholic acid. In addition, the following criteria must also be met.

-) The patient has not developed complete biliary obstruction

RATIONALE

Promote appropriate utilization of **OBETICHOLIC ACID** based on FDA approved indication.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBETICHOLIC ACID

RATIONALE (CONTINUED)

DOSAGE

-) Starting Dosage: The recommended starting dosage of Ocaliva is 5 mg orally once daily in adults who have not achieved an adequate response to an appropriate dosage of UDCA for at least 1 year or are intolerant to UDCA.
-) Dosage Titration: If adequate reduction in ALP and/or total bilirubin has not been achieved after 3 months of Ocaliva 5 mg once daily and the patient is tolerating Ocaliva, increase dosage to 10 mg once daily.
-) Maximum Dosage: 10 mg once daily
-) Administration Instructions: Take with or without food. For patients taking bile acid binding resins (e.g., cholestyramine, colestipol, colesevelam), take Ocaliva at least 4 hours before or 4 hours after taking a bile acid binding resin, or at as great an interval as possible.

FDA APPROVED INDICATION

Ocaliva (obeticholic acid), a farnesoid X receptor (FXR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

REFERENCES

-) Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2016.
-) Lindor KD, Gershwin ME, Poupon R, et al. Primary biliary cirrhosis. Hepatology. 2009;50:291-308.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/16

Created: 08/16
Client Approval: 09/16

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMACETAXINE MEPESUCCINATE

Generic	Brand	HICL	GCN	Exception/Other
OMACETAXINE MEPESUCCINATE	SYNRIBO	24243		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic myeloid leukemia (CML)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is this for induction therapy?

If yes, continue to #3.

If no, continue to #5.

3. Has the patient previously tried at least two of the following or does the patient have a contraindication to Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient received less than 6 fills for Synribo?

If yes, **approve for 3 fills by HICL with a quantity limit of #28 vials per 28 days supply.**

PAC Note: Patient should receive a maximum of 6 fills of Synribo when used as induction therapy.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient achieved a hematologic response (defined as an absolute neutrophil count (ANC) greater than or equal to $1.5 \times 10^9/L$, AND platelets greater than or equal to $100 \times 10^9/L$, AND no blood blasts; OR bone marrow blasts less than 5 percent)?

If yes, **approve for 12 fills by HICL with a quantity limit of #14 vials per 28 days supply.**

If no, **approve for 3 fills by HICL with a quantity limit of #28 vials per 28 days supply.**

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMACETAXINE MEPESUCCINATE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline for **OMACETAXINE** requires a diagnosis of chronic myeloid leukemia (CML) and a trial of at least two of the following therapies: Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig. Approval of Synribo beyond 6 treatment cycles requires evidence of a hematologic response.

RATIONALE

Ensure appropriate utilization of Synribo based on FDA approved indication and dosage.

Synribo should be prepared in a healthcare facility and must be reconstituted by a healthcare professional. Before a decision is made to allow Synribo to be administered by someone other than a healthcare professional, ensure that the patient is an appropriate candidate for self-administration or for administration by a caregiver. Provide training on proper handling, storage conditions, administration, disposal, and clean-up of accidental spillage of the product. Ensure that patients receive the necessary supplies for home administration. At minimum these should include:

-] Reconstituted Synribo in syringe with a capped needle for subcutaneous injection. Syringe(s) should be filled to the patient-specific dose.
-] Protective eyewear.
-] Gloves.
-] An appropriate biohazard container.
-] Absorbent pad(s) for placement of administration materials and for accidental spillage.
-] Alcohol swabs.
-] Gauze pads.
-] Ice packs or cooler for transportation of reconstituted Synribo syringes

If a patient or caregiver cannot be trained for any reason, then in such patients, Synribo should be administered by a healthcare professional.

DOSAGE

The recommended induction dosing schedule is 1.25 mg/m² administered subcutaneously twice daily for 14 consecutive days every 28 days, over a 28-day cycle, and should be repeated every 28 days until patients achieve a hematologic response.

The recommended maintenance schedule is 1.25 mg/m² administered subcutaneously twice daily for 7 consecutive days every 28 days, over a 28-day cycle, and should continue as long as patients are clinically benefiting from therapy.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMACETAXINE MEPESUCCINATE

RATIONALE (CONTINUED)

Complete blood counts (CBCs) should be performed weekly during induction and initial maintenance cycles followed by every two weeks thereafter, or as clinically indicated. If a patient experiences Grade 4 neutropenia (absolute neutrophil count (ANC) $<0.5 \times 10^9/L$) or Grade 3 thrombocytopenia (platelet counts $<50 \times 10^9/L$) during a cycle, the next cycle should be delayed until the ANC is $>1.0 \times 10^9/L$ and platelet count is $>50 \times 10^9/L$, and the number of dosing days should be reduced by two days (for example to 12 or 5 days).

Synribo is a first-in-class cephalotaxine that functions as a protein synthesis inhibitor in CML. CML is a malignant clonal disorder that results in rapid growth of myeloid stem cells in the bone marrow. It is usually associated with a chromosomal abnormality that results from the fusion of the BCR and ABL1 genes, called the Philadelphia (Ph) chromosome. Normally, the ABL1 gene produces a protein with tyrosine kinase catalytic activity that is tightly regulated. The fused BCR-ABL1 gene in the Ph chromosome however, produces a protein with deregulated and constitutively active kinase activity that is fundamental to the pathogenesis of CML. The mainstay of treatment in CML over the last decade has been inhibition of the enzymatic activity of those proteins, and thus the TKIs Gleevec, Sprycel, and Tasigna are designated as first line treatment of CML in the National Comprehensive Cancer Network clinical practice guidelines. Another TKI, Bosulif, was approved earlier this year for treatment-resistant patients. It is currently being studied in a phase III open-label trial versus Gleevec for patients with newly diagnosed CML. However, because there are patients that fail, cannot tolerate, or are resistant to TKI therapy, new therapies, such as Synribo, are being explored. Synribo is unique in that it inhibits protein synthesis independently of direct BCR-ABL1 binding, and therefore, provides a different mechanism to help control the cancer and delay its progression to an acute leukemia for those who have already tried TKI based therapy.

Synribo was approved under the FDA's accelerated approval program. The accelerated approval allows the FDA to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. All accelerated approvals come with the caveat that the manufacturer must conduct additional clinical studies to confirm the drug's clinical benefit and safe use.

Effectiveness was based on data from two Phase II, open-label, multicenter, single-arm trials enrolling a combined cohort of 111 patients with chronic phase CML or accelerated phase CML who had received 2 or more approved TKIs and had, at a minimum, documented evidence of resistance or intolerance to dasatinib and/or nilotinib.

The efficacy endpoint for the 76 patients in chronic phase CML was major cytogenetic response (MCyR) as demonstrated by a reduction in the percentage of cells expressing the Philadelphia chromosome genetic mutation. MCyR was achieved in 14 out of 76 patients (18.4 percent) with a mean onset time of 3.5 months and Kaplan-Meier estimated median reduction duration of 12.5 months.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMACETAXINE MEPESUCCINATE

RATIONALE (CONTINUED)

For the 35 patients in accelerated phase CML, the efficacy endpoints of MCyR or major hematologic response (MaHR) as demonstrated by either normalization of white blood cell counts (complete hematologic response [CHR]) or no evidence of leukemia (NEL) were evaluated. Five out of the 35 patients (14.3 percent) achieved MaHR with a mean response onset time of 2.3 months and Kaplan-Meier estimated median duration of 4.7 months. MCyR was not achieved in any of the 35 patients.

Warnings and precautions for Synribo include: myelosuppression, including severe and fatal thrombocytopenia, neutropenia and anemia; bleeding, including fatal cerebral hemorrhage and severe, non-fatal gastrointestinal hemorrhage; hyperglycemia, including glucose intolerance and hyperosmolar non-ketotic hyperglycemia; and embryo-fetal toxicity.

The most common adverse reactions observed in clinical trials include thrombocytopenia, anemia, neutropenia, including febrile neutropenia, diarrhea, nausea, weakness and fatigue, injection site reaction, and lymphopenia. Synribo is pregnancy category D and may cause fetal harm. Females of reproductive potential should avoid pregnancy while undergoing Synribo treatment. Clinical drug interaction trials were not performed on Synribo based on the lack of interactions seen during in vitro studies.

FDA APPROVED INDICATIONS

Treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI) based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival with Synribo.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****OMACETAXINE MEPESUCCINATE****REFERENCES**

- J Synribo [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2014.
- J FDA News Release. FDA approves Synribo for chronic myelogenous leukemia. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm325895.htm> [Accessed November 19, 2012].
- J National Comprehensive Cancer Network. Chronic Myelogenous Leukemia 4.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cml.pdf [Accessed April 23, 2013]
- J Teva News Release. Teva Receives Approval For SYNRIBO™ (Omacetaxine Mepesuccinate) for Injection. Available at <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-newsArticle&ID=1750668&highlight> [Accessed November 20, 2012].
- J Omacetaxine: issues you may want to know. Available at: <http://www.omacetaxine.info/> [Accessed November 20, 2012].
- J Van Etten, RA. Clinical manifestations and diagnosis of chronic myeloid leukemia. In: UpToDate, Larson, RA (Ed), UpToDate, Waltham, MA, 2012.
- J Tefferi, A. Overview of the myeloproliferative neoplasms. In: UpToDate, Schrier, SL (Ed), UpToDate, Waltham, MA, 2012.
- J Negrin, RS., Schiffer, CA. Overview of the treatment of chronic myeloid leukemia. In: UpToDate, Larson, RA (Ed), UpToDate, Waltham, MA, 2012.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/14

Created: 12/12

Client Approval: 05/14

P&T Approval: 05/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVIR/RITONAVIR

Generic	Brand	HICL	GCN	Exception/Other
OMBITASVIR/PARITAPREVIR/ RITONAVIR	TECHNIVIE	41734		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
 -) Age at least 18 years old
 -) Diagnosis of hepatitis C, genotype 4
 -) Patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)
 -) Currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

2. Does the patient have one or more of the following conditions?

- ☐ Patient is on hemodialysis
- ☐ Moderate or severe liver impairment (Child-Pugh B or Child-Pugh C), or decompensated liver disease
- ☐ A limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
- ☐ Concurrent use with any of these medications (contraindicated or not recommended by the manufacturer): alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylegonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz (Atripla, Sustiva), Revatio (sildenafil dose of 20mg and/or dosed TID for PAH), triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, salmeterol
- ☐ Prior use (failure of a full course of therapy) or concurrent use of any HCV protease inhibitors including Olysio (simeprevir), Victrelis (boceprevir), or Incivek (telaprevir)
- ☐ Prior use (failure of a full course of therapy) or concurrent use of any NS5B polymerase inhibitor including Sovaldi (sofosbuvir)
- ☐ Prior use (failure of a full course of therapy) of concurrent use of any NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
- ☐ Prior use (short trial or failure of a full course of therapy) of Viekira Pak or Viekira XR

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

3. Does the patient have evidence of current HCV infection and chronic HCV infection as documented by one detectable HCV RNA level within the past 6 months?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?

-) Patient has a contraindication to therapy with Epclusa, Harvoni, **AND** Mavyret
-) Patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved.]

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the requested medication being used with ribavirin?

If yes, **approve for 12 weeks by HICL for #56 tablets (1 monthly carton) per 28 days.**

(**NOTE:** Approval allows patients to complete a total maximum of 12 weeks of therapy.)

If no, continue to #6.

6. Is the patient treatment naïve and without cirrhosis?

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have an intolerance or contraindication to ribavirin?

If yes, **approve for 12 weeks by HICL for #56 tablets (1 monthly carton) per 28 days.**

(**NOTE:** Approval allows patients to complete a total maximum of 12 weeks of therapy.)

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVIR/RITONAVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR (Technivie)** requires a diagnosis of chronic hepatitis C, genotype 4 without cirrhosis or with compensated cirrhosis (Child-Pugh A). The following criteria must also be met:

-) Patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)
-) Concurrent use with ribavirin unless patient is treatment naïve without cirrhosis and has an intolerance or contraindication to ribavirin
-) Patient is at least 18 years old
-) Patient has failed a previous trial of Harvoni or Epclusa or Mavyret (intolerance, adverse effect or contraindication to all three therapies) (**NOTE:** An individual who has completed a full course of therapy with Harvoni, Epclusa or Mavyret that did not achieve SVR will not be approved)
-) Currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Evidence of current HCV infection and chronic HCV infection as documented by at least one detectable HCV RNA levels within past 6 months

A total of 12 weeks of therapy will be approved.

Technivie will not be approved for the following patients:

-) Patient using any of the following medications concurrently while on Technivie: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine, dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, or salmeterol
-) Patients with moderate or severe liver impairment (Child Pugh B or Child Pugh C)
-) Patient is on hemodialysis
-) Individual with a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
-) Any patient with prior use of or concurrent use of Viekira Pak or Viekira XR, or a previous failure of any of the following regimens: a nucleotide NS5B polymerase inhibitor including Sovaldi (sofosbuvir), a combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir), and/or a HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVIR/RITONAVIR

RATIONALE

Ensure appropriate utilization of Technivie (ombitasvir/paritaprevir/ritonavir) based on FDA approved indication, current treatment guideline recommendations and other P&T approved criteria to promote cost-effective use.

FDA APPROVED INDICATIONS

For the treatment of chronic hepatitis C genotype 4 infection in adults without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin.

TECHNIVIE administered without ribavirin for 12 weeks may be considered for treatment-naïve patients without cirrhosis who cannot take or tolerate ribavirin.

TECHNIVIE includes ombitasvir, a hepatitis C virus NS5A inhibitor, and paritaprevir, a hepatitis C virus NS3/4A protease inhibitor with ritonavir, a CYP3A inhibitor.

The efficacy of TECHNIVIE has not been studied in subjects who have failed prior treatment with another NS5A inhibitor, NS3/4A protease inhibitor, or NS5B inhibitor.

FDA APPROVED DOSAGE

Recommended dosage: Two ombitasvir, paritaprevir, ritonavir 12.5/75/50 mg tablets once daily (in the morning) with a meal without regard to fat or calorie content. Take with ribavirin.

OTHER INFORMATION

AASLD/IDSA Guidance - Initial Treatment of Patients Initiating Therapy for HCV infection – For Genotype 4 Infection [From July 2016 Guideline update; see hcvguidelines.org for most recent recommendations]

Genotype	Recommended Regimen
4	4. Epclusa for 12 weeks for treatment naïve patients with genotype 4 (for patients with or without cirrhosis) - Rating 1A 5. Technivie and ribavirin for 12 weeks, for treatment naïve patients (for patients with or without cirrhosis) - Rating 1A 6. Zepatier daily for 12 weeks (for patients with or without cirrhosis) - - Rating IIa-B 7. Harvoni daily for 12 weeks, for treatment naïve patients with genotype 4 (for patients with or without cirrhosis) - Rating IIa-B

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVR/RITONAVIR

FDA APPROVED INDICATIONS (CONTINUED)

OTHER INFORMATION

AASLD/IDSA Guidance - Retreatment of HCV infection (recommendations for patients in whom previous treatment has failed) [From July 2016 Guideline update; see hcvguidelines.org for most recent recommendations]		
GT	Previous agent/regimen failed	Recommended Regimen
4	Peginterferon/ribavirin regimen	5. Epclusa for 12 weeks - Rating 1A 6. Technivie with ribavirin for 12 weeks - Rating 1A 7. Zepatier daily for 12 weeks (use 16 weeks if previous on-treatment virologic failure after peg/RBV, add ribavirin for if previous failure to suppress or patient had breakthrough) - Rating IIa-B 8. Harvoni daily for 12 weeks (add ribavirin if cirrhosis and patient is eligible for ribavirin), <i>Alternative</i> , if cirrhosis, is Harvoni for 24 weeks - Rating IIa-B

EFFICACY

The approval of Technivie is based on data from the PEARL-I study, which was a randomized, global, multicenter, open-label trial that consisted of 135 adults with HCV genotype 4 infection without cirrhosis. The participants were either treatment-naïve (64%) or did not achieve a virologic response with prior treatment with pegylated interferon/ribavirin (pegIFN/RBV) (36%). Those with previous exposure to HCV direct-acting antivirals were excluded. Participants were randomized (1:1 ratio) to receive ombitasvir 25mg, paritaprevir 150mg, and ritonavir 100mg once daily with or without ribavirin for 12 weeks. The ribavirin dosage was 1000mg per day for subjects weighing less than 75kg or 1200mg per day for subjects weighing greater than or equal to 75kg. The primary endpoint was sustained virologic response defined as HCV RNA below the lower limit of quantification (<LLOQ) 12 weeks after the end of treatment (SVR12) using the COBAS TaqMan HCV test (version 2.0), for use with the High Pure System, which has an LLOQ of 25 IU per mL.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPRE VIR/RITONAVIR

FDA APPROVED INDICATIONS (CONTINUED)

EFFICACY

Table 1. SVR12 for HCV Genotype 4-infected Subjects without Cirrhosis (from *Technivie Prescribing Information*)

Treatment outcome	Ombitasvir + Paritaprevir + Ritonavir with RBV for 12 weeks		Ombitasvir + Paritaprevir + Ritonavir for 12 weeks
	Treatment-naïve	Treatment- experienced	Treatment-naïve
	% (n/N)	% (n/N)	% (n/N)
Overall SVR12	100 % (42/42)	100% (49/49)	91% (40/44)
Outcome for subjects without SVR12			
On-treatment VF ^a	0% (0/42)	0% (0/49)	2% (1/44)
Relapse ^b	0% (0/42)	0% (0/49)	5% (2/42)
Other ^c	0% (0/42)	0% (0/49)	2% (1/44)

VF = virologic failure

a. On-treatment VF was defined as confirmed HCV ≥ 25 IU/mL after HCV RNA < 25 IU/mL during treatment, confirmed increase from nadir in HCV RNA $> 1 \log_{10}$ IU/mL during treatment, or HCV RNA ≥ 25 IU/mL persistently during treatment with at least 6 weeks of treatment.

b. Relapse was defined as confirmed HCV RNA ≥ 25 IU/mL post-treatment before or during SVR12 window among subjects with HCV RNA less than 25 IU/mL at last observation during at least 11 weeks of treatment.

c. Other includes subjects not achieving SVR12 but not experiencing on-treatment VF or relapse (e.g. lost to follow-up).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPRE VIR/RITONAVIR

FDA APPROVED INDICATIONS (CONTINUED)

SAFETY

Technivie is contraindicated in patients with severe hepatic impairment and those with known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis, Stevens-Johnson syndrome). Co-administration of Technivie is also contraindicated with drugs that are highly dependent on CYP3A for clearance as well as moderate and strong inducers of CYP3A. Since Technivie is to be used in combination with ribavirin, the contraindications to ribavirin also apply e.g., pregnancy, autoimmune hepatitis, hemoglobinopathies, creatinine clearance less than 50 mL/min, coadministration with didanosine, known hypersensitivity reactions such as Stevens-Johnson syndrome, toxic, epidermal necrolysis, and erythema multiforme to ribavirin).

Technivie has warnings and precautions in place regarding ALT elevations, drug interactions, and the risks associated with ribavirin combination treatment.

Technivie may affect the plasma concentrations of other drugs since paritaprevir is an inhibitor of OATP1B1 and OATP1B3, paritaprevir and ritonavir are inhibitors of BCRP and P-glycoprotein (P-gp), and ritonavir is an inhibitor of CYP3A4. Co-administration of Technivie with drugs that are substrates of CYP3A, P-gp, BCRP, OATP1B1 or OATP1B3 may result in increased plasma concentrations of such drugs.

Other drugs may also affect the plasma concentrations of Technivie. Since paritaprevir and ritonavir are primarily metabolized by CYP3A enzymes, co-administration of Technivie with strong inhibitors of CYP3A may increase paritaprevir and ritonavir concentrations. Ombitasvir, paritaprevir and ritonavir are substrates of P-gp whereas paritaprevir is a substrate of BCRP, OATP1B1 and OATP1B3. Drugs which inhibit P-gp, BCRP, OATP1B1 or OATP1B3 may increase the plasma concentrations of the various components of Technivie.

Established drug interactions include certain antiarrhythmics, anti-fungals, antipsychotics, calcium channel blockers, corticosteroids, diuretics, HIV anti-viral agents, statins, immunosuppressants, long-acting beta-adrenoceptor agonist, narcotic analgesics, proton pump inhibitors, sedatives/hypnotics.

The most common adverse drug reactions (ADRs) were asthenia, fatigue, nausea and insomnia. The incidence of these ADRs is shown in Table 2.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVR/RITONAVIR

FDA APPROVED INDICATIONS (CONTINUED)

SAFETY

Table 2. Selected Adverse Reactions (all Grades) with 5% Frequency Reported in PEARL-I Subjects Treated with Ombitasvir, Paritaprevir and Ritonavir with or without Ribavirin for 12 weeks (from Technivie Prescribing Information)

Adverse Reaction	PEARL-I	
	Ombitasvir, paritaprevir, ritonavir + RBV 12 Weeks N = 91 %	Ombitasvir, paritaprevir, ritonavir 12 Weeks N = 44 %
Asthenia	29	25
Fatigue	15	7
Nausea	14	9
Insomnia	13	5
Pruritus*	7	5
Skin reactions ^{§,¶}	7	5

*Grouped term 'pruritus' includes the preferred terms pruritus and pruritus generalized.
§Grouped term 'skin reactions' includes the preferred terms rash, erythema, eczema, rash maculo-papular, rash macular, dermatitis, rash papular, skin exfoliation, rash pruritic, rash erythematous, rash generalized, dermatitis allergic, dermatitis contact, exfoliative rash, photosensitivity reaction, psoriasis, skin reaction, ulcer and urticaria.
¶The majority of events were graded as mild in severity. There were no serious events or severe cutaneous reactions, such as Stevens Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), erythema multiforme (EM) or drug rash with eosinophilia and systemic symptoms (DRESS).

Technivie is Pregnancy Category B when administered without ribavirin. Although Technivie has not been studied in pregnant women, animal studies show no evidence of teratogenicity with the administration of ombitasvir (mice and rabbits), paritaprevir or ritonavir (mice and rats) at exposures higher than the recommended clinical dose. When Technivie is administered with ribavirin, the combination regimen is contraindicated in pregnant women and in men whose female partners are pregnant. Unchanged ombitasvir, paritaprevir and its hydrolysis product M13 were the predominant components observed in the milk of lactating rats, without effect on nursing pups. It is not known whether any of the components of Technivie or their metabolites are present in human milk.

Safety and effectiveness of Technivie in pediatric patients less than 18 years of age have not been established. In geriatric patients, no dosage adjustment of Technivie is warranted. No dosage adjustment of Technivie is required in patients with mild, moderate or severe renal impairment; however, Technivie has not been studied in patients on dialysis. No dosage adjustment of Technivie is required in patients with mild hepatic impairment (Child-Pugh A). Technivie is contraindicated in patients with moderate or severe (Child-Pugh B or C) hepatic impairment.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMBITASVIR/PARITAPREVIR/RITONAVIR

REFERENCES

-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed July 28, 2016.
-) Technivie [Prescribing Information]. North Chicago, IL: Abbvie Inc.; February 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/15

Client Approval: 12/17

P&T Approval: 04/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?
) **REJ- 433-1201: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY
 (H:DUR_CONCURRENT_USE)**

If yes, continue to #2.
If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?
) Patient has a diagnosis of active cancer
) Patient is in hospice care
) Patient is receiving palliative care or end-of-life care
) Patient is a resident of a long-term care facility

If yes, **approve for 12 months by HICL and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
Please include the quantity limit based on any applicable restriction.
If no, continue to #3.

3. Is the prescriber aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and has provided attestation to proceed with an opioid and benzodiazepine treatment for a clinically appropriate indication?

If yes, **approve for 12 months by HICL and set DUR_CONCURRENT_OVR to 'OP_BZD'.**
Please include the quantity limit based on any applicable restriction.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID-BENZODIAZEPINE CONCURRENT USE

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:

While your request for [enter requested drug] has been granted, the drug cannot be covered by your plan due to the use of an opioid drug and a benzodiazepine drug together.

[Proceed to enter Denial Text Below]

DENIAL TEXT: The guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval for patients who are receiving an opioid with a benzodiazepine. An approval for concurrent use will be provided when one of the following criteria is met:

- / Diagnosis of active cancer
- / Receiving palliative care or end-of-life care
- / Enrolled in hospice
- / Resident of a long-term care facility
- / Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine treatment for a clinically appropriate indication.

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:

"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019." *CMS 2019 Call Letter, page 251*

The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.

This guideline allows an approval for patients with one of the following conditions:

- / Diagnosis of active cancer
- / Receiving palliative care or end-of-life care
- / Enrolled in hospice
- / Resident of a long-term care facility
- / Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID-BENZODIAZEPINE CONCURRENT USE

REFERENCES

-) Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at:
<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf> [Accessed 4/2/18].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 10/17

Client Approval: 12/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID DEPENDENCY AGENTS

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE	SUBUTEX	01762		ROUTE = SUBLINGUAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of opioid addiction/dependence and meet the following criteria?
 -) Therapy is prescribed by a physician certified to prescribe buprenorphine for opioid addiction/dependence as confirmed by checking the SAMHSA buprenorphine physician locator website or by phone at 1-866-BUP-CSAT
 -) Not currently dependent on/abusing alcohol
 -) Not currently dependent on/abusing CNS depressants (i.e., benzodiazepines, barbiturates, sedative hypnotics) **OR** is being rapidly tapered off these medications

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for buprenorphine HCL (generic for Subutex) monotherapy in a patient who is pregnant?

If yes, continue to #3.

If no, continue to #4.

3. Is the request for a new start of buprenorphine HCL (generic for Subutex) and induction dosing is needed?

If yes, **approve and enter authorizations as follows:**

-) **1ST AUTHORIZATION:** Approve buprenorphine HCL 2mg SL tablet for 2 days by GPID (GPID 64672): #12 SL tablets per 2 days (override quantity limits for induction dosing).
-) **2ND AUTHORIZATION:** Approve buprenorphine HCL SL tablet for 12 months by GPID with no fill count (starting after initial 2 day authorization) for all the following strengths with the following quantity limits:
 - o 2mg (GPID 64672): #3 SL tablets per day
 - o 8mg (GPID 64673): #3 SL tablets per day

If no, **approve buprenorphine HCL SL tablet for 12 months by GPID with no fill count for all the following strengths with the following quantity limits:**

-) 2mg (GPID 64672): #3 SL tablets per day
-) 8mg (GPID 64673): #3 SL tablets per day

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID DEPENDENCY AGENTS

GUIDELINES FOR USE (CONTINUED)

4. Is the request for buprenorphine HCL (generic for Subutex) monotherapy in a patient who has documentation of naloxone-induced anaphylaxis, bronchospasm, or angioneurotic edema?

If yes, continue to #5.

If no, continue to #6.

5. Is the request for a new start of buprenorphine HCL (generic for Subutex) and induction dosing is needed?

If yes, **approve and enter authorizations as follows:**

-) **1ST AUTHORIZATION: Approve buprenorphine HCL 2mg SL tablet for 2 days by GPID (GPID 64672): #12 SL tablets per 2 days (override quantity limits for induction dosing).**
-) **2ND AUTHORIZATION: Approve buprenorphine HCL SL tablet for 12 months by GPID with no fill count (starting after initial 2 day authorization) for all the following strengths with the following quantity limits:**
 - o **2mg (GPID 64672): #3 SL tablets per day**
 - o **8mg (GPID 64673): #3 SL tablets per day**

If no, **approve buprenorphine HCL SL tablet for 12 months by GPID with no fill count for all the following strengths with the following quantity limits:**

-) **2mg (GPID 64672): #3 SL tablets per day**
-) **8mg (GPID 64673): #3 SL tablets per day**

6. Is the request for buprenorphine HCL (generic for Subutex) monotherapy and is the patient being transitioned **directly** from a long-acting opioid (i.e., methadone, fentanyl patch, or other ER opioids)?

If yes, **approve buprenorphine HCL 2mg SL tablet for 2 days by GPID (GPID 64672): #12 SL tablets per 2 days (override quantity limits for induction dosing).**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID DEPENDENCY AGENTS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **OPIOID DEPENDENCY AGENTS** requires that all of the following criteria are met:

-) A diagnosis of opioid addiction/dependence
-) The prescriber is a buprenorphine-certified prescriber in accordance with the Drug Addiction Treatment Act
-) The patient is not currently dependent on/abusing CNS depressants (i.e., benzodiazepines, barbiturates, sedative hypnotics) **OR** is being rapidly tapered off these medications
-) The patient is not currently dependent on/abusing alcohol

In addition, requests for buprenorphine monotherapy (generic for Subutex) may be approved if one of the following conditions is met:

-) Patient is pregnant
-) Patient has documentation of naloxone-induced anaphylaxis, bronchospasm, or angioneurotic edema
-) Patient is being transitioned directly from a long-acting opioid (i.e., methadone) during induction only

RATIONALE

Avoid use for unapproved indications (i.e. acute or chronic pain). Ensure that therapy is prescribed by a physician certified to prescribe buprenorphine for opioid dependency as confirmed by checking the SAMHSA buprenorphine physician locator website or by phone at 1-866-BUP-CSAT. Provide appropriate quantity limits for induction and maintenance therapy. Encourage dose consolidation since buprenorphine has a high-risk potential for abuse. Due to the risk for fatal respiratory depression, ensure that the patient is not currently dependent on/abusing alcohol or CNS depressants (i.e. benzodiazepines, barbiturates, sedative hypnotics) or is being rapidly tapered of CNS depressants. Comorbid dependence on benzodiazepines or other central nervous system depressants (including alcohol) may preclude a patient as a candidate for office-based buprenorphine treatment. Examples of benzodiazepines include estazolam, flurazepam, quazepam, temazepam, triazolam. Examples of barbiturates include phenobarbital and secobarbital. Examples of sedative hypnotics include eszopiclone, ramelteon, suvorexant, zaleplon, zolpidem.

Ensure that buprenorphine monotherapy is limited to certain qualifying patient populations. Treatment guidelines recommend that the buprenorphine/naloxone combination be used for induction treatment (and for stabilization and maintenance) for most patients. Besides a history of hypersensitivity (i.e. bronchospasm, angioneurotic edema, anaphylactic shock), the only two patient populations named as exceptions to the combination product are pregnant patients and patients who are converting directly from long-acting opioids (i.e. methadone). Although pregnant patients can be induced and maintained on buprenorphine monotherapy, those converting from long-acting opioids should be switched the buprenorphine/naloxone combination as early in treatment as possible.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID DEPENDENCY AGENTS

FDA APPROVED INDICATIONS

Buprenorphine SL tablets (generic for Subutex) are indicated for the treatment of opioid dependence and are preferred for induction. Subutex sublingual tablet should be used as part of a complete treatment plan to include counseling and psychosocial support.

PLEASE NOTE:

-) Some products are only approved for use during the *maintenance* phase of treatment (i.e. Bunavail, generic Suboxone SL tablets), whereas other products are approved for the *treatment* of opioid dependence (use during both induction and maintenance phases) such as Suboxone SL films, Zubsolv, generic Subutex SL tablets.
-) Branded Subutex and Suboxone SL tablets were discontinued in January 2012 and March 2013, respectively.
-) The physician must obtain a unique ID# from the DEA prior to prescribing Suboxone, Subutex, Zubsolv, Bunavail and the generics for Suboxone and Subutex.
-) Each of the branded products (Bunavail, Suboxone, and Zubsolv) as well as the Suboxone and Subutex generics have a warning in the package insert that these products are NOT appropriate as an analgesic.

HOW SUPPLIED

Buprenorphine (buprenorphine) SL tablets (generic for Subutex)

-) 2mg
-) 8mg

FDA APPROVED DOSING

Buprenorphine SL tablets (generic for Subutex)

Induction

It is recommended that an adequate treatment dose, titrated to clinical effectiveness, should be achieved as rapidly as possible. In some studies, gradual induction over several days led to a high rate of dropout of buprenorphine patients during the induction period.

Day 1: 8mg

Day 2: 16mg

From Day 3 onward, patients received either buprenorphine and naloxone sublingual tablets or buprenorphine sublingual tablets at the same buprenorphine dose as Day 2 based on their assigned treatment. Induction in the studies of buprenorphine solution was accomplished over 3-4 days, depending on the target dose.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID DEPENDENCY AGENTS

FDA APPROVED INDICATIONS (CONTINUED)

FDA APPROVED DOSING

Maintenance

Buprenorphine and naloxone is preferred for maintenance treatment. Where buprenorphine sublingual tablets are used in maintenance in patients who cannot tolerate the presence of naloxone, the dosage of buprenorphine sublingual tablets should be progressively adjusted in increments/decrements of 2 mg or 4 mg buprenorphine to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms. The maintenance dose is generally in the range of 4 mg to 24 mg buprenorphine per day depending on the individual patient. Doses higher than this have not been demonstrated to provide any clinical advantage.

REFERENCES

-) Buprenorphine [Prescribing Information]. Actavis Pharma, Inc.: Parsippany, NJ. January 2015.
-) Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 08/03

Client Approval: 08/17

P&T Approval: 07/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID LONG-ACTING DUPLICATIVE THERAPY

Generic	Brand	HICL	GCN	Exception/other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim is rejecting with the following error code?

) **REJ-1045: THERAPEUTIC DUPLICATION DENIAL (DRUG_TD)**

(The incoming claim for a long-acting (LA) opioid will reject when the patient is concurrently taking a different long-acting opioid [different HICL] from a different prescriber.)

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?

-) Patient has a diagnosis of active cancer
-) Patient is in hospice care
-) Patient is receiving palliative care or end-of-life care
-) Patient is a resident of a long-term care facility

If yes, **approve for 12 months by HICL and set DRUG_TD_OVR to 'Y' for Yes. Please include the quantity limit based on any applicable restriction(s).**

If no, continue to #3.

3. Has the prescriber provided attestation that they are aware the patient is concurrently receiving more than one long-acting opioid therapy?

If yes, **approve for 12 months by HICL and set DRUG_TD_OVR to 'Y' for Yes. Please include the quantity limit based on any applicable restriction(s).**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUE ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID LONG-ACTING DUPLICATIVE THERAPY

GUIDELINES FOR USE (CONTINUED)

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:

While your request for [enter requested drug] has been granted, the drug cannot be covered by your plan due to the use of two long-acting opioid drugs together that are from different prescribers. [Proceed to enter Denial Text Below]

DENIAL TEXT: The guideline named **OPIOID LONG ACTING DUPLICATIVE THERAPY** allows approval of the requested drug when taken together with other long-acting opioid drug(s) from different prescribers. An approval will be provided if you meet one of the following conditions:

- / Diagnosis of active cancer
- / Receiving palliative care or end-of-life care
- / Enrolled in hospice
- / Resident of a long-term care facility
- / Physician attestation that the prescriber is aware that the patient is concurrently receiving long-acting duplicative therapy and would like to proceed with treatment for a clinically appropriate indication

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:

“...we expect all Part D plan sponsors to implement a soft POS safety edit (which can be overridden by the pharmacist) for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion.” *CMS 2019 Call Letter, page 252*

Prior authorization will be required for Long Acting (LA) opioid prescriptions when an incoming claim for a long-acting opioid overlaps with another a long acting opioid (different HICL) claim(s) from a different prescriber(s). The edit can be overridden by professional pharmacy professional service (PPS) code at POS or by a PA. This requirement does not apply to patients with a diagnosis of active cancer, patients receiving palliative care or end-of-life care, those enrolled in hospice or resident of a long-term care facility. This guideline also allows an override when there is physician attestation that the prescriber is aware that the patient is concurrently receiving long acting duplicative therapy and would like to proceed with treatment for a clinically appropriate indication.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID LONG-ACTING DUPLICATIVE THERAPY

REFERENCES

-) Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at:
<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf> [Accessed 4/2/18].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 12/18

Client Approval: 12/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

Generic	Brand	HICL	GCN	Exception/other
OPIOIDS	OPIOIDS			

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold (50 morphine milligram equivalent [MME]) or hard-stop threshold (90 morphine milligram equivalent [MME])?

NOTE: Claims should stop for DUR_MAX_SINGLE_DOSE edit with Soft_DENY_LIMIT = 50 or HARD_DENY_LIMIT = 90 (i.e., morphine milligram equivalent of [patient's current MME] = / exceeds threshold of [50 MME or 90 MME per day]).

If yes, continue to #2.
If no, guideline does not apply.

2. Is the request for an opioid product less than or equal to 89 MME?

If yes, **approve 12 months by HICL up to 89 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
If no, continue to #3.

3. Does the patient meet **ANY** of the following criteria?

- ☐ Diagnosis of active cancer
- ☐ Diagnosis of palliative care
- ☐ Diagnosis of sickle cell disease
- ☐ Patient is enrolled in hospice
- ☐ Prescriber is a pain management specialist

If yes, **approve 12 months by HICL. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**
If no, continue to #4.

4. Has the physician provided attestation that the requested high dose is considered medically necessary?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

5. Is the request for an opioid with an MME equal to or exceeding the hard-stop threshold (90 MME) and the prescriber has not indicated an opioid MME threshold value?

If yes, **approve 12 months by HICL up to 112.5 MME OR up to 25% greater than the previously approved MME via the patient's claim profile or physician attestation, up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

If no, continue to #6.

6. Did the physician indicate a maximum opioid threshold for the requested drug that is less than 300 MME?

If yes, **approve 12 months by HICL as requested up to 300 MME. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

If no, continue to #7.

7. Is the request for an opioid with an MME equal to or exceeding the maximum threshold (300 MME) for a patient who is currently stable on this MME?

If yes, **approve for 3 months by HICL. (NOTE: If the claim rejects after analyzing, follow the clinical prior authorization process).**

APPROVAL TEXT: While your prior authorization for (enter requested drug) has been granted, your opiate amount is equal to or exceeds [300 morphine milligram equivalent (MME)] and is considered a high dose of opiate. Please consult with your pain management specialist regarding your treatment options.

If no, do not approve.

DENIAL TEXT: The guideline named **OPIOID SINGLE CLAIM DOSING AT POS** allows for an override of an opioid product equal to or exceeding the soft-stop threshold (50 morphine milligram equivalent [MME]) at the pharmacy or by a prior authorization. The hard-stop threshold (90 MME) is not overridable and requires a prior authorization.

An override will be provided for patients with any of the following conditions:

- ☐ Diagnosis of active cancer
- ☐ Diagnosis of palliative care
- ☐ Diagnosis of sickle cell disease
- ☐ Patient is enrolled in hospice
- ☐ Prescriber is a pain management specialist

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPIOID SINGLE CLAIM DOSING AT POS (OSCDP)

GUIDELINES FOR USE (CONTINUED)

For all other patients, the physician must provide attestation that the requested high dose is considered medically necessary. In addition, if the requested dose is lower than 300 MME, the prescriber must provide a maximum opioid threshold. If the prescriber does not provide a maximum threshold and the request is for an opioid with an MME equal to or exceeding 90 MME, the claim will be approved up to 25 percent greater than the previously approved MME or up to 112.5 MME. If the requested dose is equal to or greater than 300 MME, approval will be granted if the patient is stable on the dose. Please consult your pain management specialist regarding your treatment options.

RATIONALE

To align with opioid restrictions required by several states and to prevent overutilization of opioids and increase safety.

This advanced POS intervention blocks an incoming claim when a single claim's Morphine Milligram Equivalent (MME) is equal to or exceeds a specified hard-stop threshold (e.g. over 90 MME). The hard-stop is non-overridable except via prior authorization. The edit allows a soft stop on an incoming claim with an MME equal to or over a lower threshold (e.g. over 50 MME) that can be overridden by Pharmacy Professional Service (PPS) codes at the point-of-sale (POS) or by prior authorization. Overriding the hard threshold for OSCDP will also override the OSCDP soft threshold, but does not affect Opioid Cumulative Dosing Program (OCDP).

This requirement does not apply to patients with a diagnosis of active cancer, sickle cell disease, in palliative care, hospice patients, or patients with a prescription from a pain management specialist.

REFERENCES

- J Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1> [Accessed June 28, 2018].
- J Jones B, Cynthia. (2016). Implementation of CDC Guideline for Prescribing Opioids for Chronic Pain Coeverage of Non-Opioid Pain Relievers and Uniform, Streamlines Prior Authorization for New Opioid Prescription Effective December 1, 2016. Department of Medical Assistance Services. Available at https://www.msv.org/sites/default/files/PDFs/12.1.16_guideline_for_opioids_non_opioid_pain_reliefers_revised_final.pdf [Accessed June 28, 2018].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/19/18

Created: 06/18

Client Approval: 11/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OSIMERTINIB

Generic	Brand	HICL	GCN	Exception/Other
OSIMERTINIB MESYLATE	TAGRISSO	42803		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 -) The patient is positive for an epidermal growth factor receptor (EGFR) T790M mutation that has been confirmed by an FDA-approved test
 -) The patient has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])
 -) The patient is **NOT** receiving concurrent therapy with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])

If yes, **approve for 12 months by HICL with a quantity limit of #30 tablets per 30 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 -) The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations and is confirmed by an FDA-approved test
 -) The patient has **NOT** received prior systemic treatment for metastatic non-small cell lung cancer (NSCLC)

If yes, **approve for 12 months by HICL with a quantity limit of #30 tablets per 30 days.**
If no, do not approve.

DENIAL TEXT: The guideline named **OSIMERTINIB (Tagrisso)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC). In addition, **ONE** of the following criteria must be met:

-) The patient is positive for an epidermal growth factor receptor (EGFR) T790M mutation as confirmed by an FDA-approved test AND meets all of the following:
 - o The patient has progressed while on or after epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor therapy (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])
 - o The patient is **NOT** receiving concurrent therapy with an epidermal growth factor receptor (EGFR) tyrosine kinase-inhibitor (e.g., Tarceva [erlotinib], Iressa [gefitinib], or Gilotrif [afatinib dimaleate])

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OSIMERTINIB

GUIDELINES FOR USE (CONTINUED)

- ⌋ The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by an FDA-approved test **AND** meets the following:
 - The patient has not received prior systemic treatment for metastatic non-small cell lung cancer (NSCLC)

RATIONALE

To ensure appropriate use of osimertinib (Tagrisso) consistent with FDA-approved indications.

FDA-APPROVED INDICATIONS

Osimertinib (Tagrisso) is a kinase inhibitor indicated for:

- ⌋ For the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy.
- ⌋ First-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION

The recommended dose is 80 mg orally once daily, with or without food, until disease progression or unacceptable toxicity.

AVAILABLE STRENGTHS

- ⌋ 40 mg tablets
- ⌋ 80 mg tablets

REFERENCES

- ⌋ Tagrisso [Prescribing Information]; Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/25/18

Created: 11/15

Client Approval: 05/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PANOBINOSTAT

Generic	Brand	HICL	GCN	Exception/Other
PANOBINOSTAT	FARYDAK	41794		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of multiple myeloma and meets **ALL** of the following criteria?
 -) The patient has been treated with at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent, such as Thalomid, Revlimid, or Pomalyst
 -) The requested agent will concurrently be used with Velcade (bortezomib) and dexamethasone

If yes, **approve for 12 months by HICL for #6 capsules per 21 days with a fill count of 8 (8 cycles).**

If no, do not approve.

DENIAL TEXT: Our guideline for **PANOBINOSTAT (Farydak)** requires that the patient has a diagnosis of multiple myeloma. The following criteria must also be met.

-) The patient has been treated with at least 2 prior regimens, including Velcade (bortezomib) and an immunomodulatory agent, such as Thalomid, Revlimid, or Pomalyst
-) The requested agent will concurrently be used with Velcade (bortezomib) and dexamethasone

RENEWAL CRITERIA

1. Has the patient tolerated the first 8 cycles of therapy without any severe or medically significant toxicity?

If yes, **approve for 12 months by HICL for #6 capsules per 21 days with fill count of 8 (8 cycles).**

If no, do not approve.

DENIAL TEXT: Our guideline for **PANOBINOSTAT (Farydak)** renewal requires that the patient has tolerated therapy without experiencing any severe or medically significant toxicity.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PANOBINOSTAT

RATIONALE

Promote appropriate utilization of **Farydak (panobinostat)** based on FDA approved indication. Initial dosing for up to 8 cycles. Renewal provided for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity (maximum duration of therapy up to 16 cycles which allows up to 96 capsules in 48 weeks).

The most common prior antineoplastic therapies in the PANORAMA-1 (Panobinostat Oral in Multiple Myeloma) trial were corticosteroids (90%), melphalan (80%), thalidomide (53%), cyclophosphamide (47%), bortezomib (44%), and lenalidomide (19%).

Given the toxicity concerns, a regimen containing Farydak may be less preferred over other regimens for relapsed/refractory MM. As of March 2015, the NCCN lists the following as Category 1 recommendations (please check NCCN treatment guidelines for other possible regimens):

- ✓ Velcade
- ✓ Velcade with liposomal doxorubicin (i.e. Doxil, Lipodox)
- ✓ Revlimid/dexamethasone
- ✓ Kyprolis (carfilzomib)/Revlimid/dexamethasone

Farydak might also be reserved for patients less than 65 years of age with good performance status who either have not been exposed to or have been exposed to, but are not refractory to, proteasome inhibitors (i.e. Velcade and Kyprolis).

DOSAGE

The recommended starting dose of Farydak is 20 mg, taken orally once every other day for 3 doses per week in Weeks 1 and 2 of each 21-day cycle for up to 8 cycles. Consider continuing treatment for an additional 8 cycles for patients with clinical benefit who do not experience unresolved severe or medically significant toxicity. The total duration of treatment may be up to 16 cycles (48 weeks). Farydak is administered in combination with bortezomib and dexamethasone.

21-Day Cycle												
Cycles 1 to 8 (3-Week cycles)	Week 1						Week 2					
	Days						Days					
FARYDAK	1		3		5		8		10		12	
Bortezomib	1			4			8			11		
Dexamethasone	1	2		4	5		8	9		11	12	
												Rest period
												Rest period
												Rest period

FDA APPROVED INDICATION

Indicated in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PANOBINOSTAT

REFERENCES

-) Farydak [Prescribing Information]. East Hanover, NJ: Novartis; February 2015.
-) NCCN Clinical Practice Guideline in Oncology: Multiple Myeloma Version 3.2015. National Comprehensive Cancer Network. Available at:
http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf [Accessed February 23, 2015].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/01/16

Created: 03/15

Client Approval: 05/16

P&T Approval: 05/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PARATHYROID HORMONE

Generic	Brand	HICL	GCN	Exception/Other
PARATHYROID HORMONE	NATPARA	34000		ROUTE = SUBCUTANE.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hypocalcemia secondary to hypoparathyroidism and meets the following criteria?
 -) Previous trial of activated vitamin D (calcitriol) and calcium
 -) Patient's hypoparathyroidism is **not** due to a calcium sensing receptor (CSR) mutation
 -) Patient's hypoparathyroidism is **not** considered acute post-surgical hypoparathyroidism (surgery in past 30 days)
 -) Therapy initiated by or in consultation with an endocrinologist

If yes, **approve for 12 months by HICL for quantity of #2 cartridges per 28 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **PARATHYROID HORMONE** requires a diagnosis of hypocalcemia secondary to hypoparathyroidism. Additional guideline requirements apply.

-) Previous use of activated vitamin D (calcitriol) and calcium
-) Patient's hypoparathyroidism is not due to a calcium sensing receptor (CSR) mutation
-) Patient's hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (surgery in past 30 days)
-) Therapy initiated by or in consultation with an endocrinologist

RATIONALE

Promote appropriate utilization of parathyroid hormone based on FDA approved indication, dosing and best practices.

DOSAGE

The starting dose of Natpara is 50 mcg injected once daily in the thigh.

The dose of Natpara may be increased in increments of 25 mcg every four weeks up to a maximum daily dose of 100 mcg if serum calcium cannot be maintained above 8 mg/dL without an active form of vitamin D and/or oral calcium supplementation.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PARATHYROID HORMONE

FDA APPROVED INDICATION

Natpara is a parathyroid hormone indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism.

Limitations of Use

-) Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone.
-) Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations.
-) Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

REFERENCES

-) Natpara [Prescribing Information]. Bedminster, NJ: NPS Pharmaceuticals, Inc. January 22, 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/15

Created: 04/15

Client Approval: 05/15

P&T Approval: 05/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PASIREOTIDE

Generic	Brand	HICL	GCN	Exception/Other
PASIREOTIDE	SIGNIFOR	39866		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Cushing's disease?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient undergone pituitary surgery or is pituitary surgery not an option for this patient?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried ketoconazole, metyrapone, or cabergoline?

If yes, **approve for 12 months by HICL with a quantity limit of #2 ampules per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of Cushing's disease for which the patient has undergone pituitary surgery or pituitary surgery is not an option, and a trial of ketoconazole, metyrapone, or cabergoline.

RATIONALE

To ensure appropriate use of Signifor consistent with FDA approved indication and dose.

Signifor's recommended dosage range is 0.3 mg to 0.9 mg twice a day. The recommended initial dose is either 0.6 mg or 0.9 mg injected subcutaneously twice a day. For patients with moderate hepatic impairment (Child Pugh B), the recommended initial dosage is 0.3 mg twice a day and the maximum dosage is 0.6 mg twice a day. Avoid the use of SIGNIFOR in patients with severe hepatic impairment (Child Pugh C).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PASIREOTIDE

RATIONALE (CONTINUED)

Cushing's disease is caused by a pituitary gland tumor that produces adrenocorticotrophic hormone (ACTH). This additional ACTH acts as a signal to the adrenal glands to make excess cortisol. Signifor binds and activates the human somatostatin receptor subtype 5 resulting in inhibition of ACTH secretion by the pituitary tumor cells, which leads to decreased cortisol secretion. First line treatment for Cushing's disease is transsphenoidal surgery and resection of the pituitary tumor. If surgery is delayed, contraindicated, or unsuccessful, adjunct medical therapy is usually required. Adrenal enzyme inhibitors, ketoconazole, and metyrapone (not FDA approved for this indication) are most commonly prescribed, followed by cabergoline (also not FDA approved for this indication) which targets the corticotrophin tumor. Combination therapy, such as Signifor, cabergoline, and/or ketoconazole, may be necessary to achieve an acceptable response.

A total of 162 patients were enrolled in a Phase III, multicenter, randomized study over a 6-month treatment period to evaluate the safety and efficacy of Signifor in patients with Cushing's disease. The majority of clinical trial subjects (83%) had persistent or recurrent disease despite pituitary surgery whereas surgery was not indicated or surgery was refused in the remaining subjects. Patients with a baseline 24-hour urine free cortisol (UFC) $>1.5 \times$ upper limit of normal (ULN) were randomized to receive a twice-daily, subcutaneous injection of either Signifor 0.6 mg or 0.9 mg. The primary efficacy endpoint was the proportion of patients who achieved normalization of mean 24-hour UFC levels after six months of treatment and did not dose increase during this period. At Month 6, the percentages of responders for the primary endpoint were 15% and 26% in the 0.6 mg twice daily and 0.9 mg twice daily groups, respectively. Signifor resulted in a decrease in the mean 24-hour UFC after 1 month of treatment. For patients (n=78) who stayed in the trial, similar UFC lowering was observed at Month 12.

Most common adverse reactions occurring in 20% of patients are diarrhea, nausea, hyperglycemia, cholelithiasis, headache, abdominal pain, fatigue, and diabetes mellitus.

Other clinically significant adverse reactions include hypocortisolism, bradycardia and QT prolongation, liver test elevations, and pituitary hormone deficiency.

Treatment with Signifor leads to suppression of adrenocorticotrophic hormone (ACTH) secretion in Cushing's disease. Suppression of ACTH may lead to a decrease in circulating levels of cortisol and potentially hypocortisolism. Pituitary hormones other than ACTH may also be inhibited since Signifor mimics the acts of somatostatin. Monitoring of pituitary function (e.g., TSH/free T4, GH/IGF-1) should occur prior to initiation of therapy with Signifor and periodically during treatment. Patients who have undergone transsphenoidal surgery and pituitary irradiation are particularly at increased risk for deficiency of pituitary hormones.

Drug interactions include cyclosporine (decreased cyclosporine levels), bromocriptine (increased bromocriptine levels), and anti-arrhythmic drugs or other medications that prolong QT interval (additive effects on QT interval prolongation).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PASIREOTIDE

RATIONALE (CONTINUED)

Signifor is Pregnancy Category C.

FDA APPROVED INDICATIONS

Signifor is a somatostatin analog indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

REFERENCES

-) Signifor [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2012.
-) UpToDate, Inc. Overview of the treatment of Cushing's syndrome. UpToDate [database online]. Waltham, MA. Available at <http://www.uptodate.com/home/index.html>. Updated January 17, 2013.
-) UpToDate, Inc. Medical therapy of hypercortisolism (Cushing's syndrome). UpToDate [database online]. Waltham, MA. Available at <http://www.uptodate.com/home/index.html>. Updated January 18, 2013.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/13

Created: 05/13

Client Approval: 05/13

P&T Approval: 05/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PAZOPANIB

Generic	Brand	HICL	GCN	Exception/Other
PAZOPANIB	VOTRIENT	36709		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of advanced soft tissue sarcoma (STS) and meets the following criteria?

The patient had a trial of or contraindication to chemotherapy (e.g., anthracycline treatment),

The patient does not have a diagnosis of adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **PAZOPANIB (Votrient)** requires a diagnosis of advanced renal cell carcinoma (RCC) or advanced soft tissue sarcoma (STS). In addition, the following criteria must also be met.

For patients with a diagnosis of advanced soft tissue sarcoma (STS), approval requires all of the following:

The patient had a trial of or contraindication to chemotherapy (e.g., anthracycline treatment)

The patient does not have a diagnosis of adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)

RATIONALE

Ensure appropriate utilization of pazopanib based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Votrient is indicated for the treatment of patients with:

Advanced renal cell carcinoma (RCC)

Advanced soft tissue sarcoma (STS) who have received prior chemotherapy

Limitation of use: the efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors (GIST) has not been demonstrated.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PAZOPANIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended starting dose of Votrient is 800 mg orally once daily without food (at least 1 hour before or 2 hours after a meal). The dose of Votrient should not exceed 800 mg.

Do not crush tablets due to the potential for increased rate of absorption, which may affect systemic exposure. If a dose is missed, it should not be taken if it less than 12 hours until the next dose.

REFERENCES

Votrient [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 05/11

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

Generic	Brand	HICL	GCN	Exception/Other
SILDENAFIL	REVATIO		24758 28273 33186	
TADALAFIL	ADCIRCA		26587	

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ADCIRCA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meets **ALL** of the following criteria?
 -) The patient had a previous trial of or contraindication to sildenafil (Revatio)
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
 -) The patient has NYHA-WHO Functional Class II to IV symptoms
 -) The patient is not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
 -) The patient is not concurrently taking guanylate cyclase stimulators (e.g. Adempas)

If yes, **approve for 12 months by GPID with the quantity limit of up to #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Adcirca)** requires that the patient has a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

-) The patient had a previous trial of or contraindication to sildenafil (Revatio)
-) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

GUIDELINES FOR USE-ADCIRCA (CONTINUED)

-) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
-) The patient has NYHA-WHO Functional Class II to IV symptoms
-) The patient is not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
-) The patient is not concurrently taking guanylate cyclase stimulators (e.g. Adempas)

REVATIO TABLETS OR INJECTION

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meets **ALL** of the following criteria?
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
 -) The patient has NYHA-WHO Functional Class II to IV symptoms
 -) The patient is not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
 -) The patient is not concurrently taking guanylate cyclase stimulators (e.g. Adempas)

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

-) **sildenafil (Revatio, GPID 24758) 20mg tablets: #3 tablets per day**
-) **sildenafil (Revatio, GPID 28273) 10mg/12.5mL vial: 37.5mL (#3 vials) per day**

If no, do not approve.

DENIAL TEXT: See the denial text on the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

GUIDELINES FOR USE- REVATIO TABLETS OR INJECTION (CONTINUED)

DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio/Sildenafil tablets or injection)** requires that the patient has a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

-) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
-) The patient has NYHA-WHO Functional Class II to IV symptoms
-) The patient is not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
-) The patient is not concurrently taking guanylate cyclase stimulators (e.g. Adempas)

REVATIO ORAL SUSPENSION

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I) and meets **ALL** of the following criteria?
 -) The patient is unable to swallow pills and has tried crushed sildenafil tablets
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
 -) The patient has NYHA-WHO Functional Class II to IV symptoms
 -) The patient is not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
 -) The patient is not concurrently taking guanylate cyclase stimulators (e.g. Adempas)

If yes, **approve for 12 months by GPID with the quantity limit of up to #224mL (2 bottles) per 30 days.**

If no, do not approve.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

GUIDELINES FOR USE- REVATIO ORAL SUSPENSION (CONTINUED)

DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio Oral Suspension)** requires that the patient has a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I). The following criteria must also be met.

-)] The patient is unable to swallow pills and has tried crushed sildenafil tablets
-)] The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-)] Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
-)] The patient has NYHA-WHO Functional Class II to IV symptoms
-)] The patient is not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form
-)] The patient is not concurrently taking guanylate cyclase stimulators (e.g. Adempas)

RENEWAL CRITERIA

ADCIRCA-RENEWAL

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I)?

If yes, continue to #2

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve tadalafil (Adcirca, GPID 26587) by GPID for 12 months with a quantity limit of #2 tablets per day.**

If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RENEWAL CRITERIA-ADCIRCA (CONTINUED)

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve tadalafil (Adcirca, GPID 26587) by GPID for 12 months with a quantity limit of #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Adcirca)** renewal requires that the patient has a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

-) The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
-) The patient has a stable 6-minute walk distance test with a stable **OR** improved WHO functional class.

REVATIO TABLETS OR INJECTION-RENEWAL

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

-) **sildenafil (Revatio, GPID=24758) 20mg tablets: #3 tablets per day.**
-) **sildenafil (Revatio, GPID=28273) 10mg/12.5mL vial: #37.5mL (#3 vials) per day.**

If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RENEWAL CRITERIA-REVATIO TABLETS OR INJECTION (CONTINUED)

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

-) **sildenafil (Revatio, GPID 24758) 20mg tablets: #3 tablets per day.**
-) **sildenafil (Revatio, GPID 28273) 10mg/12.5mL vial: #37.5mL (#3 vials) per day.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio/sildenafil tablets or injection)** renewal requires that the patient has a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

-) The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
-) The patient has a stable 6-minute walk distance test with a stable **OR** improved WHO functional class.

REVATIO ORAL SUSPENSION-RENEWAL

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group I)?

If yes, continue to #2

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by GPID with the quantity limit of up to #224mL (2 bottles) per 30 days.**

If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

RENEWAL CRITERIA- REVATIO ORAL SUSPENSION (CONTINUED)

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve for 12 months by GPID with the quantity limit of up to #224mL (2 bottles) per 30 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: The guideline for **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio/sildenafil oral suspension)** renewal requires that the patient has a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

-) The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
-) The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

RATIONALE

Ensure appropriate utilization of PDE5 inhibitors, Revatio and Adcirca. FDA indicated dosage for Revatio tablets in the treatment of PAH is 20mg three times daily. For Revatio injection, the dosage is 10mg (12.5mL) three times daily administered as an IV bolus injection. The 10mg dose of Revatio injection is predicted to provide an equivalent pharmacological effect of 20mg Revatio tablet. For Adcirca, the dosage is 40mg once daily.

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing pulmonary hypertension due to other etiologies, for example PH due to left heart disease (e.g. diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

FDA APPROVED INDICATIONS

Revatio and Adcirca are indicated for treatment of pulmonary artery hypertension (WHO Group 1) to improve exercise capacity and delay clinical worsening.

World Health Organization Classification of Pulmonary Hypertension Group 1:

- Idiopathic (familial)
- Congenital systemic-to-pulmonary shunts
- HIV infection
- Collagen vascular disease
- Portal Hypertension
- Drugs and toxins

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

REFERENCES

-) Pfizer, Inc. Revatio® (Sildenafil) package insert. New York, NY. November 2009.
-) Eli Lilly and Company. Adcirca™ (Tadalafil) package insert. Indianapolis, IN. May 2009.
-) Taichman DB, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. CHEST 2014 Aug;146(2):449-75.
-) N Galiè et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS) endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). Eur Heart J 2015 Aug 29.
-) Hoeper MM, et al. Definitions and diagnosis of pulmonary hypertension. J Am Coll Cardiol 2013;62(Suppl):D42-D50.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 01/08

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEG-INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Exception/Other
PEG-INTERFERON ALFA-2B	SYLATRON, SYLATRON 4-PACK		29809, 29811, 29812	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient currently taking requested medication?

If yes, continue to #2.

If no, continue to #3.

2. Has the patient received 5 years of therapy with Sylatron?

If yes, do not approve.

DENIAL TEXT: Duration of therapy is limited to 5 years per FDA approved indication.

If no, **approve for 12 months with a quantity limit of one 296mcg 4-pack or four 296mcg single dose kits per month.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

3. Does the patient have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection?

If yes, **approve. Enter two authorizations as follows:**

-) **2 months with a quantity limit of one 4-pack or four single dose kits per month, AND**
) **10 months with a quantity limit of one 296mcg 4-pack or four 296mcg single dose kits per month with a start date 1 week prior to the end date of the authorization for 2 months.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEG-INTERFERON ALFA-2B

RATIONALE

Ensure appropriate utilization of Sylatron based on FDA approved indication and NCCN guidelines. Peg-interferon in combination with wide excision is recommended for the treatment of Melanoma. Sylatron's dosing is weight based as follows: 6mcg/kg/week for 8 doses followed by 3mcg/kg/week subcutaneously for up to 5 years. This guideline approves the appropriate quantities for a patient weighing up to 98kg. Patients weighing over 98kg should be reviewed by clinical to determine the appropriate dose.

FDA APPROVED INDICATION

Sylatron is indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

REFERENCES

-) Eggermont AMM, Sucio S, Santinami M et al. Adjuvant therapy with pegylated interferon alfa-2b versus observation alone in resected stage III melanoma: final results of EORTC 18991, a randomised phase III trial. Lancet 200; 372:117-126.
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Melanoma. (Version 4.2011).
-) Schering Corporation. Sylatron package insert. Kenilworth, NJ. March 2011.
-) Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: June 22, 2011].

Part D Effective: N/A
Commercial Effective: 01/01/14

Created: 05/11
Client Approval: 11/13

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

Generic	Brand	HICL	GCN	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	24035		
PEGINTERFERON ALFA-2B	PEGINTRON	21367		GCN 29809, 29811, 29812

This drug requires a written request for prior authorization. All requests for hepatitis C medications require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

1. Is the request for continuation of current therapy (also consider continuation if member has a claim for the currently requested interferon in the past 120 days) or a renewal?

If yes, continue to #9.
If no, continue to #2.

2. Is the request for Pegasys vial, kit, or syringes?

If yes, continue to #3.
If no, continue to #4.

3. Is the patient being treated for chronic hepatitis B and meet **ALL** of the following criteria?

-) Patient is 3 years of age or older
-) The medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist) or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Patient has no cirrhosis
-) Patient has serum HBeAg positive chronic hepatitis B
-) Patient has evidence of viral replication with elevated serum ALT

If yes, **approve for 24 weeks (6 months) by HICL with a quantity limit of #4 vials/syringes per 28 days.**
If no, continue to #5.

4. Is the request for PegIntron **AND** the patient is between 3 and 11 years old?

If yes, continue to #6.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

GUIDELINES FOR USE (CONTINUED)

5. Is the patient between 3 and 11 years old?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?

-) Patient is being treated for chronic hepatitis C and the medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
-) Patient has extrahepatic manifestations of hepatitis C such as cryoglobulinemia, rashes, and glomerulonephritis - as well as advanced fibrosis that requires urgent HCV treatment to minimize future morbidity and mortality
-) Peginterferon is being used with ribavirin or patient has a contraindication to ribavirin
-) Patient has a detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the patient infected with genotype 2 or genotype 3 hepatitis C?

If yes, **approve by HICL as follows:**

-) **For two-drug regimen with ribavirin (peginterferon plus ribavirin only): approve for up to 24 weeks.**

If no, continue to #8.

8. Is the patient infected with genotype 1, 4, 5 or 6 hepatitis C?

If yes, **approve by HICL as follows:**

-) **For two-drug regimen with ribavirin (peginterferon plus ribavirin only): approve for 48 weeks (12 months).**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

GUIDELINES FOR USE (CONTINUED)

9. Is the request for the treatment of hepatitis B?

If yes, continue to #10.

If no, continue to #11.

10. Is the request for Pegasys?

If yes, **approve for 24 weeks (6 months) by HICL with a quantity limit of #4 vials/syringes per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the request for the treatment of chronic hepatitis C and meet **ONE** of the following criteria?

-) Requested medication will be used in combination with ribavirin
-) Patient has a contraindication to combination therapy with ribavirin

If yes, continue to #12.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

12. Is the patient infected with genotype 1, 4, 5 or 6 hepatitis C?

If yes, **approve by HICL for up to 32 weeks for a total of 48 weeks of treatment.**

If no, continue to #13.

13. Does the patient have genotype 2 or 3 hepatitis C?

If yes, **approve by HICL for a maximum total of 24 weeks of treatment.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6. Requests for Pegasys will also be approved for a diagnosis of chronic hepatitis B. In addition, the following criteria must be met:

For diagnosis of chronic hepatitis B, approval requires:

-) Patient is 3 years of age or older
-) The medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist) or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Patient has no cirrhosis
-) Patient has serum HBeAg positive chronic hepatitis B
-) Patient has evidence of viral replication with elevated serum ALT

For diagnosis of chronic hepatitis C, approval requires:

-) Patient age is between 3 and 11 years old
-) The medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
-) Patient has extrahepatic manifestations of hepatitis C such as cryoglobulinemia, rashes, and glomerulonephritis - as well as advanced fibrosis that requires urgent HCV treatment to minimize future morbidity and mortality
-) Peginterferon is being used with ribavirin or patient has a contraindication to ribavirin
-) Patient has a detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)

Please discuss the requirements for approval: specific diagnosis, specific lab test (blood test), and the requirement of a physician specialist consult.

RATIONALE

Ensure that ribavirin and interferon are used in combination for treatment of chronic hepatitis C, when indicated. When peginterferon is used as dual therapy in combination with ribavirin, total therapy time for HCV genotypes 1, 4, 5 and 6 is 48 weeks, and for HCV genotypes 2 and 3 is 16 to 24 weeks.

Note on HCV RNA levels defined by lab as undetectable versus detectable but not quantifiable:

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

RATIONALE (CONTINUED)

Commercially available quantitative HCV RNA assays may have differing limits for quantification and detection. The lower limit of detection is 10 or 50 IU/mL HCV RNA (depends on assay used by lab). The FDA suggests that labs testing HCV RNA levels for patients taking protease inhibitors must use an assay with a lower limit of quantification of 25 IU/mL or less, and a lower limit of detection of 10-15 IU/mL. Generally, patients with detectable but not quantifiable levels of HCV RNA will have lower SVR rates with triple therapy; a detectable but not quantifiable HCV RNA level should not be considered equivalent to an undetectable level. When the product package insert (or MedImpact PA guideline) specifies "undetectable HCV RNA level", generally an undetectable HCV RNA result is required.

FDA APPROVED INDICATIONS

PEGASYS (peg-interferon alfa-2a) alone or in combination with COPEGUS (ribavirin) is indicated for the treatment of patient's age 5 years and older with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon or peginterferon alfa.

PEGASYS is also indicated for treatment of adults with chronic hepatitis C virus infection in patients with HIV/HCV co-infection.

PEGASYS is also indicated for treatment of adults with HBeAg positive and negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and inflammation.

PEGASYS is also indicated for treatment of chronic hepatitis B in children age 3 years and older without cirrhosis, with HBeAg positive chronic hepatitis B and evidence of viral replication with elevated serum ALT.

PEGINTRON (peg-interferon alfa-2B) is indicated for use alone for the treatment of chronic hepatitis C in adults at least 18 years of age with compensated liver disease who have and those who have not been previously treated with interferon alfa.

PEGINTRON (peg-interferon alfa-2B) in combination with REBETOL (ribavirin) is indicated for use in the treatment of chronic hepatitis C in adults and children at least 3 years of age with compensated liver disease.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

REFERENCES

-) Genentech. Pegasys Product Information. South San Francisco, CA. July 2013.
-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed September 2017.
-) Harrington P, Zeng W, and Naeger L. Clinical relevance of detectable but not quantifiable hepatitis C virus RNA during boceprevir or telaprevir treatment. *Hepatology* 2012; Apr 55 (4): 1048-1057.
-) Jacobson I. SVR results of a once-daily regimen of simeprevir (TMC-438) plus sofosbuvir (GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: the COSMOS study. Program and abstracts of American Association for the Study of Liver Diseases The *Liver Meeting® 2013; November 1-5, 2013. Abstract LB-3.*
-) Wantuck J, Ahmed A, and Nguyen M. The epidemiology and therapy of chronic hepatitis C genotypes 4, 5 and 6. *Aliment Pharmacol Ther* 2014; 39 (2): 137-147.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 02/14

Client Approval: 12/17

P&T Approval: 01/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGVALIASE

Generic	Brand	HICL	GCN	Exception/Other
PEGVALIASE-PQPZ	PALYNZIQ	44944		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of phenylketonuria and meet **ALL** of the following criteria?
-) The patient is 18 years of age or older
 -) The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
 -) The patient has had a previous trial of Kuvan (sapropterin)
 -) The patient is not concurrently receiving Kuvan (sapropterin)

If yes, **approve for 6 months by GPID for all strengths with the following quantity limits:**

) **Palynziq 2.5mg/0.5mL (GPID 44791): #1mL (2 syringes) per 7 days.**

) **Palynziq 10mg/0.5mL (GPID 44792): #0.5mL (1 syringe) per day.**

) **Palynziq 20mg/mL (GPID 44793): #2mL (2 syringes) per day.**

APPROVAL TEXT: Renewal requires that the patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PEGVALIASE (Palynziq)** requires a diagnosis of phenylketonuria. In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
-) The patient has had a previous trial of Kuvan (sapropterin)
-) The patient is not concurrently receiving Kuvan (sapropterin)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGVALIAS

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of phenylketonuria and meet the following criteria?
 -) The patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

-) **Palynziq 2.5mg/0.5mL (GPID 44791): #1mL (2 syringes) per 7 days.**
-) **Palynziq 10mg/0.5mL (GPID 44792): #0.5mL (1 syringe) per day.**
-) **Palynziq 20mg/mL (GPID 44793): #2mL (2 syringes) per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PEGVALIAS (Palynziq)** requires a diagnosis of phenylketonuria. In addition, the following criteria must be met:

-) The patient has demonstrated a reduction in phenylalanine levels, compared to baseline, by at least 20% or to a level below 600 micromol/L

RATIONALE

To ensure appropriate use of Palynziq (pegvalias) consistent with FDA-approved indication and dosing.

FDA APPROVED INDICATION

Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

DOSAGE AND ADMINISTRATION

Treatment with Palynziq should be managed by a healthcare provider experienced in the management of phenylketonuria. Before initiating treatment, baseline blood phenylalanine concentrations should be obtained. After initiating treatment with Palynziq, blood phenylalanine concentrations should be obtained every 4 weeks until a maintenance dosage is established. After a maintenance dosage is established, periodic blood phenylalanine monitoring is recommended to assess blood phenylalanine control.

For hypersensitivity reactions, premedication may be considered with an H₁-receptor antagonist, H₂-receptor antagonist, and/or antipyretic prior to Palynziq administration based upon individual patient tolerability.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGVALIASE

FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION

Induction:

The recommended initial induction dosage for Palynziq is 2.5 mg subcutaneously once weekly for 4 weeks. The initial dose should be administered under the supervision of a healthcare provider.

Titration:

Palynziq doses should be titrated in a stepwise manner based on tolerability, over at least 5 weeks, to achieve a dosage of 20 mg subcutaneously once daily.

Maintenance:

Therapeutic response may not be achieved until the patient is titrated to an effective maintenance dosage. The lowest effective and tolerated dosage of Palynziq should be used. Palynziq should be maintained at a dosage of 20 mg subcutaneously once daily for at least 24 weeks. Increasing the dosage to a maximum of 40 mg subcutaneously once daily may be considered in patients who have been maintained continuously on 20 mg once daily for at least 24 weeks and who have not achieved either a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline levels or blood phenylalanine concentrations ≤ 600 micromol/L. Patient tolerability, blood phenylalanine concentrations, and dietary protein and phenylalanine intake should be assessed throughout treatment.

Discontinuation:

Palynziq should be discontinued in patients who have not achieved a response (at least a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline levels or blood phenylalanine concentrations ≤ 600 micromol/L) after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily.

Phase of Treatment	Palynziq Dosing Regimen	Duration ^a
Induction	2.5 mg SC once weekly	4 weeks
Titration	2.5 mg SC twice weekly	1 week
	10 mg SC once weekly	1 week
	10 mg SC twice weekly	1 week
	10 mg SC four times per week	1 week
	10 mg SC once daily	1 week
Maintenance ^b	20 mg SC once daily	24 weeks

^aAdditional time may be required prior to each dosage escalation based on patient tolerability.
^bTreatment should be individualized to the lowest effective and tolerated dosage. Increasing Palynziq to a maximum dosage of 40 mg once daily may be considered in patients who have not achieved a therapeutic response with at least 24 weeks of 20 mg once daily.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGVALIASE

REFERENCES

) Palynziq [prescribing information]. Novato, CA. BioMarin Pharmaceutical, Inc. May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PHENOXYBENZAMINE

Generic	Brand	HICL	GCN	Exception/Other
PHENOXYBENZAMINE	DIBENZYLINE	02098		ROUTE = ORAL

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pheochromocytoma and meet **ALL** of the following criteria?

-) The requested medication is used for the treatment of pheochromocytoma prior to pheochromocytoma resection/removal
-) Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist - oncologist
-) The patient has had a previous trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, or prazosin)

If yes, **approve for one fill by HICL with a quantity limit of #10 capsules per day for 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline for **PHENOXYBENZAMINE (Dibenzyliline)** requires a diagnosis of pheochromocytoma. In addition, the following criteria must also be met:

-) The requested medication is used for the treatment of pheochromocytoma prior to pheochromocytoma resection/removal
-) Therapy is prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist - oncologist
-) The patient has had a previous trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (e.g., doxazosin, terazosin, or prazosin)

RATIONALE

Ensure appropriate utilization for phenoxybenzamine based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Phenoxybenzamine is indicated for the treatment of pheochromocytoma, to control episodes of hypertension and sweating. If tachycardia is excessive, it may be necessary to use a beta-blocking agent concomitantly.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PHENOXYBENZAMINE

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Initial dose for phenoxybenzamine is 10 mg orally twice a day. Dosage should be increased every other day, usually to 20 to 40 mg 2 or 3 times a day, until an optimal dosage is obtained, as judged by blood pressure control.

Dosage should be adjusted to fit the needs of each patient. Small initial doses should be slowly increased until the desired effect is obtained or the side effects from blockade become troublesome. After each increase, the patient should be observed on that level before instituting another increase. The dosage should be carried to a point where symptomatic relief and/or objective improvement are obtained, but not so high that the side effects from blockade become troublesome.

Long-term use of phenoxybenzamine is not recommended.

REFERENCES

-) Phenoxybenzamine [Prescribing Information]. West-Ward Pharmaceuticals Corp. Eatontown, NJ. May 2016.
-) Lenders JWM, Duh QY, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* June 2014; 99 (6):1915-1942.
-) UpToDate, Inc. Treatment of pheochromocytoma in adults. UpToDate [database online]. Last updated Oct 20, 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PIMAVANSERIN

Generic	Brand	HICL	GCN	Exception/Other
PIMAVANSERIN	NUPLAZID	43373		ROUTE = ORAL

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Parkinson's disease psychosis and meets **ALL** of the following criteria?

-) Patient is 18 years of age or older
-) Medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as psychiatrist)

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

-) **34mg capsules (GPID 44963): #30 capsules per 30 days.**
-) **17mg tablets (GPID 41264): #60 tablets per 30 days.**
-) **10mg tablets (GPID 44959): #30 tablets per 30 days.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline for **PIMAVANSERIN (Nuplazid)** requires a diagnosis of Parkinson's disease psychosis. The following criteria must also be met.

-) Patient is 18 years of age or older
-) The medication is prescribed by or given in consultation with a physician specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as a psychiatrist)

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PIMAVANSERIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. During the past 12 months of therapy, has the patient experienced an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment?

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

-) **34mg capsules (GPID 44963): #30 capsules per 30 days.**
-) **17mg tablets (GPID 41264): #60 tablets per 30 days.**
-) **10mg tablets (GPID 44959): #30 tablets per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline for **PIMAVANSERIN (Nuplazid)** renewal requires that the patient has experienced an improvement in psychosis symptoms from baseline during the past 12 months of therapy and demonstrates a continued need for treatment.

RATIONALE

Promote appropriate utilization of **pimavanserin** based on FDA approved indication.

Parkinson's disease (PD) has both motor and non-motor symptoms that can lead to disability, morbidity, and mortality. Parkinson's disease associated psychosis (PDP) is a non-motor symptom that develops at least a year after noticeable motor dysfunction. The psychotic symptoms of PDP are most commonly visual hallucinations, however patients may also experience sensory, somatic, or auditory hallucinations, as well delusions. Many times PDP develops as a result of medication(s) taken to aid with PD motor dysfunction. Current antipsychotic medications have been shown to worsen PD and motor dysfunction.

In clinical trials, pimavanserin was shown to significantly reduce The Scale for the Assessment of Positive Symptoms in Parkinson's Disease (SAPS-PD) scores leading to decreased caregiver burden, as well as improvement in sleep and daytime wakefulness. The SAPS-PD scale assesses the severity and frequency of hallucinations and delusions in PD patients; higher values indicate severer symptoms. A reduction in The Clinical Global Impression-Severity (CGI-S) and improvement scales (CGI-I) were also observed in patients both PDP treatment naïve, as well as those switched from currently available antipsychotics. Clinical trials were also able to show that pimavanserin is able to exhibit antipsychotic effects without negative impact on motor function as UPDRS parts II (activities of daily living) and III (motor function) scores demonstrated that pimavanserin was non-inferior to placebo. Extension studies demonstrated that treatment benefits are sustained over time. Clinical trials determined that an NNT of 11 was necessary to see a 50% reduction in psychotic symptoms.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PIMAVANSERIN

RATIONALE (CONTINUED)

In clinical trials, pimavanserin was shown to improve scores on The Scale for the Assessment of Positive Symptoms in Parkinson's Disease (SAPS-PD), The Clinical Global Impression-Severity (CGI-S) and improvement scales (CGI-I) scores, and caregiver burden scale.

DOSAGE

The recommended dosage of Nuplazid is 34mg orally once daily, without titration, taken with or without food. Reduce dose to 10mg once daily when administering with a strong CYP3A4 inhibitor.

FDA APPROVED INDICATION

Nuplazid (pimavanserin) is indicated as treatment of hallucinations and delusions associated Parkinson's disease psychosis.

Boxed warning:

-) Increased risk of death in dementia-related psychosis treated with antipsychotic drugs.
-) Nuplazid is not approved for the treatment of dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis.

REFERENCES

-) Nuplazid [Prescribing Information]. San Diego, CA. Arcadia Pharmaceuticals Inc. June 2018.
-) Cummings J, Isaacson S, Mills R, et al. Pimavanserin for patients with Parkinson's disease psychosis: a randomized, placebo-controlled phase 3 trial. *The Lancet*. 2014; 383 (9916): 533-540.
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-) Fernandez HH, Aarsland D, Fénelon G, et al. Scales to Assess Psychosis in Parkinson's Disease: Critique and Recommendations. *Mov Disord*. 2008; 23(4): 484-500. pdf

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/24/18

Created: 04/16

Client Approval: 08/18

P&T Approval: 05/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PIRFENIDONE

Generic	Brand	HICL	GCN	Exception/Other
PIRFENIDONE	ESBRIET	40237		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
 -) Patient does not have other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
 -) Treatment is prescribed by or given in consultation with a pulmonologist
 -) Patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
 -) Patient has a predicted forced vital capacity (FVC) of at least 50%
 -) Patient has obtained liver function tests prior to starting pirfenidone
 -) Patient does not currently smoke cigarettes

If yes, **approve for 12 months by GPID for all dosage strengths with the following quantity limits:**

-) **267mg capsule (GPID 34553): #9 capsules (2403mg) per day.**
-) **267mg tablet (GPID 42903): #9 tablets (2403mg) per day.**
-) **801mg tablet (GPID 42905): #3 tablets (2403mg) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **PIRFENIDONE (Esbriet)** requires a diagnosis of idiopathic pulmonary fibrosis (IPF). IPF is defined by the American Thoracic Society with the following criteria: a) Exclusion of other known causes of interstitial lung disease (ILD) (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer) **AND** b) The presence of usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT. In addition, the guideline requires:

-) Treatment is prescribed by or given in consultation with a pulmonologist
-) Patient must obtained liver function tests prior to starting pirfenidone
-) Patient has a predicted forced vital capacity (FVC) of at least 50%
-) Patient does not currently smoke cigarettes

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PIRFENIDONE

RATIONALE

Promote appropriate utilization of Esbriet based on FDA approved indication and dosage.

Esbriet (pirfenidone) is one of the first drugs to be approved by the FDA to treat idiopathic pulmonary fibrosis (IPF). Ofev (nintedanib), the other agent for the treatment of IPF, was also approved on the same day. These two drugs were granted Breakthrough Therapy Designation as well as Orphan Drug status since there are no other drugs to date for the treatment of IPF, a disease that affects an estimated 100,000 people (mostly adults over the age of 40) in the United States. IPF is a chronic, progressive disorder of the lower respiratory tract in which lung tissue becomes scarred or fibrotic over time. As a result, patients with IPF experience shortness of breath, cough, and difficulty participating in everyday physical activities.

The American Thoracic Society guidelines state the diagnosis of IPF requires:

- a) Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity)
- b) The presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) in patients not subjected to surgical lung biopsy
- c) Specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy.

There is no cure for IPF; many people live only about 3 to 5 years, with the most common cause of death related to IPF being respiratory failure. The exact cause of IPF is not known, but the associated risk factors include cigarette smoking, viral infection, environmental pollutants, chronic aspiration, genetic predisposition, and drugs.

Treatment options for IPF have been extremely limited, mainly consisting of supportive care (oxygen therapy, pulmonary rehabilitation) and lung transplantation. The approval of Esbriet provides a new treatment option that may slow disease progression for patients with IPF. It is an orally administered pyridine that exerts anti-inflammatory effects by interfering with the production of Transforming Growth Factor (TGF)-beta, a small protein in the body involved in how cells grow, and Tumor Necrosis Factor (TNF)-alpha, a small protein that is involved in inflammation. In addition, it behaves as an antifibrotic by directly altering the expression, synthesis, and possibly accumulation of collagen.

Esbriet is metabolized primarily (70 to 80%) via CYP1A2 with minor contributions from other CYP isoenzymes including CYP2C9, 2C19, 2D6 and 2E1. The concomitant administration of Esbriet and fluvoxamine or other strong CYP1A2 inhibitors is not recommended because it significantly increases exposure to Esbriet. Concomitant administration of Esbriet and ciprofloxacin moderately increases exposure to Esbriet. Conversely, concomitant use of Esbriet and a CYP1A2 inducer may decrease the exposure of Esbriet and decrease efficacy; this interaction may be particularly important for smokers. Hydrocarbons found in cigarettes are potent CYP1A2 inducers, and for smokers, the AUC and Cmax of Esbriet were 46% and 68% that of non-smokers (respectively). Patients should be instructed to stop smoking prior to and during treatment with Esbriet.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PIRFENIDONE

RATIONALE (CONTINUED)

Increases in ALT and AST greater than three times the upper limit of normal have been reported, with rare occasions of concomitant elevations in bilirubin. Increases in these liver enzymes were reversible with dose medication or treatment discontinuation. Prior to starting Esbriet, patients should obtain liver function tests.

The most common adverse reactions ($\geq 10\%$) are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastro-esophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia.

DOSAGE

The recommended daily maintenance dose of Esbriet is 801mg (three 267mg capsules, three 267mg tablets, or one 801mg tablet) three times a day with food for a total of 2403mg/day. Doses should be taken at the same time each day.

Upon initiation of treatment, titrate to the full dosage of 2403 mg per day over a 14-day period as follows:

TREATMENT DAYS	DOSAGE
Days 1 through 7	267 mg three times a day with food
Days 8 through 14	534 mg three times a day with food
Days 15 onward	801 mg three times a day with food

Patients who miss 14 or more days of Esbriet should re-initiate treatment by undergoing the initial 2-week titration regimen up to the full maintenance dosage.

Temporary dosage reductions or interruptions of Esbriet may be considered if patients experience significant adverse reactions or elevations in liver enzyme and bilirubin. Modifications in dosage should also be considered when Esbriet is administered concurrently with CYP1A2 inhibitors.

FDA APPROVED INDICATION

Esbriet is a pyridine indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PIRFENIDONE

REFERENCES

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- J FDA News Release on Oct 15, 2014: FDA approves Esbriet to treat idiopathic pulmonary fibrosis. [Accessed Oct 27, 2014]. Available online at:
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418991.htm>
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Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/01/17

Created: 02/15

Client Approval: 05/17

P&T Approval: 02/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PONATINIB

Generic	Brand	HICL	GCN	Exception/Other
PONATINIB HCL	ICLUSIG	39859		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of T315I-positive chronic myeloid leukemia (CML), or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)?

If yes, **approve for 12 fills by GPID as requested with the following quantity limits:**

) **45mg: #30 tablets per 30 days;**

) **15mg: #60 tablets per 30 days.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #2.

2. Does the patient have a diagnosis of chronic myeloid leukemia (CML), or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient previously tried or does the patient have a contraindication to Gleevec, Sprycel, Tasigna, or Bosulif?

If yes, **approve for 12 fills by GPID as requested with the following quantity limits:**

) **45mg: #30 tablets per 30 days;**

) **15mg: #60 tablets per 30 days.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires that one of the following conditions are met: 1) a diagnosis of T315I-positive chronic myeloid leukemia (CML), or T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL); or 2) a diagnosis of chronic myeloid leukemia (CML), or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) with a previous trial of Gleevec, Sprycel, Tasigna, or Bosulif, which may also require prior authorization.

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PONATINIB

RATIONALE

Ensure appropriate utilization of ponatinib based on FDA approved indication and dosage. The recommended dosage is 45mg once daily with or without food. Tablets should be swallowed whole. Continue treatment as long as the patient does not show evidence of disease progression or unacceptable toxicity. Dose modifications to 30mg and then 15mg daily are recommended for neutropenia and thrombocytopenia unrelated to leukemia; hepatic toxicity; or pancreatitis and lipase elevation. The recommended dose should be reduced to 30 mg once daily when administering Iclusig with strong CYP3A inhibitors.

Iclusig (ponatinib) is the fifth tyrosine kinase inhibitor (TKI) approved for the treatment of CML. It blocks the activity of ABL (including the T315I mutation) to treat CML and Ph+ALL. Iclusig also inhibited the in vitro activity of additional kinases involved in the growth and development of cancer cells. These include members of the VEGFR, PDGFR, FGFR, EPH receptors, the SRC families of kinases, and KIT, RET, TIE2, and FLT3.

CML is a malignant clonal disorder that results in rapid growth of myeloid stem cells in the bone marrow. It is usually associated with a chromosomal abnormality that results from the fusion of the BCR and ABL1 genes, called the Philadelphia (Ph) chromosome. Normally, the ABL1 gene produces a protein with tyrosine kinase catalytic activity that is tightly regulated. The fused BCR-ABL1 gene in the Ph chromosome however, produces a protein with deregulated and constitutively active kinase activity that is fundamental to the pathogenesis of CML. The presence of the T315I "gatekeeper" mutation has been associated with resistance to currently approved TKIs including Gleevec, Sprycel, Tasigna, and Bosulif.

The mainstay of treatment in CML over the last decade has been inhibition of the enzymatic activity of those proteins, and thus the TKIs Gleevec, Sprycel, and Tasigna are designated as first line treatment of CML in the National Comprehensive Cancer Network clinical practice guidelines. NCCN recommends that Bosulif, another TKI, be considered as a second line treatment. It is currently being studied in the phase III open-label BELA trial versus Gleevec for patients with newly diagnosed CML. Synribo, a first-in-class cephalotaxine that inhibits protein synthesis independently of direct BCR-ABL1 binding, was also approved in 2012 for patients that fail, cannot tolerate, or are resistant to TKI therapy. NCCN recommends its use for patients who failed two or more TKIs or have a T315I mutation. EPIC is an ongoing randomized trial comparing Iclusig to Gleevec in patients with newly diagnosed CML. EPIC began in June 2012 and has an estimated study completion date of June 2021. Initially Iclusig will likely be used as a second line agent (similar to Bosulif) except for those patients with the T315I mutation where it may be considered as a first line therapy (similar to Synribo). Depending on the results of the EPIC trial, Iclusig may be considered a first line agent for all patients regardless of mutation type.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****PONATINIB****RATIONALE (CONTINUED)**

The PACE trial (n=444) studied Iclusig in patients with CML and Ph+ALL whose disease was considered to be resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy. This was a single-arm, open-label, international, multicenter trial. All patients were administered a starting dose of 45 mg of Iclusig once daily. Patients were assigned to one of six cohorts based on disease phase (chronic phase CML [CP-CML]; accelerated phase CML [AP-CML]; or blast phase CML [BP-CML]/Ph+ALL), resistance or intolerance (R/I) to prior TKI therapy, and the presence of the T315I mutation. All patients had previously been on at least one FDA approved or investigational TKI therapy: 7% had 1 TKI therapy, 37% had 2 TKI therapies, and 56% had 3 or more TKI therapies.

Resistance in CP-CML while on prior TKI therapy, was defined as failure to achieve either a complete hematologic response (by 3 months), a minor cytogenetic response (by 6 months), or a major cytogenetic response (by 12 months). Patients with CP-CML who experienced a loss of response or development of a kinase domain mutation in the absence of a complete cytogenetic response or progression to AP-CML or BP-CML at any time on prior TKI therapy were also considered resistant. Resistance in AP-CML, BP-CML, and Ph+ALL was defined as failure to achieve either a major hematologic response (by 3 months in AP-CML, and by 1 month in BP-CML and Ph+ALL), loss of major hematologic response (at any time), or development of a kinase domain mutation in the absence of a complete major hematologic response while on prior TKI therapy. Intolerance was defined as the discontinuation of prior TKI therapy due to toxicities despite optimal management in the absence of a complete cytogenetic response in patients with CP-CML or major hematologic response for patients with AP-CML, BP-CML, or Ph+ALL.

The primary endpoint of major cytogenetic response (which combines both complete (no detectable Ph+ cells) and partial (1% to 35% Ph+ cells in at least 20 metaphases) cytogenetic responses) for CP-CML was 54% overall and 70% in the T315I cohort. At the time of analysis, the median duration of Iclusig treatment was 281 days in patients with CP-CML and the median duration of major cytogenetic response was not reached.

The results of the primary endpoint of overall major hematologic response (which combines complete hematologic responses and no evidence of leukemia) for AP-CML, BP-CML, and Ph+ALL were 52%, 31% and 41%, respectively. At the time of analysis, the median duration of Iclusig treatment was 286 days in patients with AP-CML, 89 days in patients with BP-CML, and 81 days in patients with Ph+ALL. The median time to overall, major hematologic response in patients with AP-CML, BP-CML, and Ph+ALL was 21 days, 29 days, and 20 days, respectively. The median duration of overall major hematologic response for patients with AP-CML, BP-CML, and Ph+ALL was 9.5 months, 4.7 months, and 3.2 months, respectively.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PONATINIB

RATIONALE (CONTINUED)

Iclusig has a boxed warning for vascular occlusion, heart failure and hepatotoxicity. Patients should be monitored for signs and symptoms of congestive heart failure, hypertension, pancreatitis, hemorrhage, fluid retention, cardiac arrhythmias, myelosuppression, tumor lysis syndrome, gastrointestinal perforation, and compromised wound healing. The most common non-hematologic adverse reactions (20%) were hypertension, rash, abdominal pain, fatigue, headache, dry skin, constipation, arthralgia, nausea, and pyrexia. Hematologic adverse reactions included thrombocytopenia, anemia, neutropenia, lymphopenia, and leukopenia. Iclusig is pregnancy category D and can cause fetal harm.

FDA APPROVED INDICATIONS

Iclusig (ponatinib) is a kinase inhibitor indicated for the:

-) Treatment of adult patients with T315I-positive chronic myeloid leukemia (CML) (chronic phase, accelerated phase, or blast phase) and T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL).
-) Treatment of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia or Ph+ ALL for whom no other tyrosine kinase inhibitor (TKI) therapy is indicated.

These indications are based upon response rate [see Clinical Studies (14)]. There are no trials verifying an improvement in disease-related symptoms or increased survival with Iclusig.

REFERENCES

-) Iclusig [Prescribing Information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; December 2013.
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-) Center for Drug Evaluation and Research. Application Number: 203469Orig1s000 Summary Review. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203469Orig1s000SumR.pdf [Accessed January 2, 2013].
-) Ariad Investors/News. ASH 2012 PACE 12-Month Update on Ponatinib. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT01650805?term=ponatinib+imatinib&rank=1> <http://phx.corporate-ir.net/phoenix.zhtml?c=118422&p=irol-IRhome> [Accessed January 2, 2013]
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-) Van Etten, RA. Clinical manifestations and diagnosis of chronic myeloid leukemia. In: UpToDate, Larson, RA (Ed), UpToDate, Waltham, MA, 2012.
-) Tefferi, A. Overview of the myeloproliferative neoplasms. In: UpToDate, Schrier, SL (Ed), UpToDate, Waltham, MA, 2012.
-) Negrin, RS., Schiffer, CA. Overview of the treatment of chronic myeloid leukemia. In: UpToDate, Larson, RA (Ed), UpToDate, Waltham, MA, 2012.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PONATINIB

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/14

Created: 01/13
Client Approval: 03/14

P&T Approval: 02/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RALOXIFENE

Generic	Brand	HICL	GCN	Exception/Other
RALOXIFENE HCL	EVISTA	16917		

Please note this is a copay override criteria to cover at no cost preventative medicine for breast cancer for those who are at increased risk per the Affordable Care Act. Generic tamoxifen is covered at zero copay for those using it as a preventative medicine for breast cancer. This guideline applies to generic raloxifene only.

GUIDELINES FOR USE

1. Is the request for the prevention (risk reduction) of breast cancer?

If yes, continue to #2.

If no, **approve for lifetime by HICL for #1 tablet per day for generic raloxifene.**

(NOTE: Override the PA edit only, no change in copay.)

2. Does the physician consider the patient to be at an increased risk for breast cancer?

If yes, continue to #3.

If no, do not approve. **Please enter a partial approval as follows: Approve for lifetime by HICL for #1 tablet per day for generic raloxifene. (NOTE: Override the PA edit only, no change in copay.)**

NOTE: If a proactive PA is entered then please add **FREE TEXT:** (A partial fill has been approved.)

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried or does the patient have a contraindication to Tamoxifen?

If yes, **approve for 5 years by HICL with a quantity limit of #1 tablet per day for generic raloxifene. (Note: Override the PA edit and update the copay amount field with zero copay.)**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: In order to qualify for zero dollar copay, our guideline for **RALOXIFENE** requires a diagnosis of breast cancer prevention in those who are at an increased risk, and a trial or contraindication to tamoxifen. Tamoxifen is available at zero copay for those at an increased risk for breast cancer.

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RALOXIFENE

RATIONALE

To be compliant with the Affordable Care Act and cover at no cost preventative medicine for breast cancer in women who are at increased risk.

For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.

The USPSTF recommends that clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. For women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. **(B recommendation)**

The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction of primary breast cancer in women who are not at increased risk for breast cancer. **(D recommendation)**

Breast cancer is the most common non-skin cancer in women. An estimated 232,340 new cases will be diagnosed in 2013, and 39,620 women will die of the disease (1). In the United States, mortality rates are highest among African American women. Screening for breast cancer may allow for early detection but does not prevent the development of the disease.

CLINICAL CONSIDERATIONS

The National Cancer Institute has developed a Breast Cancer Risk Assessment Tool (available at www.cancer.gov/bcrisktool) that is based on the Gail model and estimates the 5-year incidence of invasive breast cancer in women on the basis of characteristics entered into a risk calculator. This tool helps identify women who may be at increased risk for the disease. Other risk assessment models have been developed by the Breast Cancer Surveillance Consortium (BCSC), Rosner and Colditz, Chlebowski, Tyrer and Cuzick, and others (5-7).

Examples of risk factors elicited by risk assessment tools include patient age, race or ethnicity, age at menarche, age at first live childbirth, personal history of DCIS or LCIS, number of first-degree relatives with breast cancer, personal history of breast biopsy, body mass index, menopause status or age, breast density, estrogen and progestin use, smoking, alcohol use, physical activity, and diet.

These models are not recommended for use in women with a personal history of breast cancer, a history of radiation treatment to the chest, or a possible family history of mutations in the BRCA1 or BRCA2 genes. Only a small fraction of women are at increased risk for breast cancer. Most who are at increased risk will not develop the disease, and most cases will arise in women who are not identified as being at increased risk. Risk assessment should be repeated when there is a significant change in breast cancer risk factors.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RALOXIFENE

RATIONALE (CONTINUED) - CLINICAL CONSIDERATIONS (CONTINUED)

There is no single cutoff for defining increased risk. Most clinical trials defined increased risk as a 5-year risk for invasive breast cancer of 1.66% or greater, as determined by the BCPT (Breast Cancer Prevention Trial). At this cutoff, however, many women would not have a net benefit from risk-reducing medications. Freedman and colleagues (8) developed risk tables that incorporate the BCPT estimate of a woman's breast cancer risk as well as her age, race or ethnicity, and presence of uterus.

On the basis of the Freedman risk–benefit tables for women aged 50 years or older (Figures 1 to 4), the USPSTF concludes that many women with an estimated 5-year breast cancer risk of 3% or greater are likely to have more benefit than harm from using tamoxifen or raloxifene, although the balance depends on age, race or ethnicity, the medication used, and whether the patient has a uterus (8).

Supporting Clinical Data

To understand the effectiveness of risk-reducing medications for breast cancer, the USPSTF reviewed 7 large randomized, controlled trials of breast cancer outcomes in women without preexisting breast cancer. Other relevant study outcomes included death, fractures, thromboembolic events, cardiovascular disease events, uterine abnormalities, cataracts, and other adverse effects.

STAR (Study of Tamoxifen and Raloxifene) was a head-to-head comparison of tamoxifen versus raloxifene with more than 9800 patients in each study group. Four studies compared tamoxifen with placebo: NSABP-1 (National Surgical Adjuvant Breast and Bowel Project), IBIS-I, the Royal Marsden Hospital trial and the Italian Tamoxifen Prevention Study. Two studies compared raloxifene with placebo: the Multiple Outcomes of Raloxifene Evaluation study, with long-term follow-up in the Continuing Outcomes Relevant to Evista study, and the Raloxifene Use for the Heart trial. These were all multicenter trials that were relevant to primary care. They enrolled between 2471 and 19,747 women, predominantly in North America, Europe, and the United Kingdom. All trials met criteria for fair or good quality as well as high applicability to the U.S. primary care population.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RALOXIFENE

RATIONALE (CONTINUED) - CLINICAL CONSIDERATIONS (CONTINUED)

For STAR, eligibility criteria included having a 5-year predicted breast cancer risk of 1.66% or greater; median follow-up was 81 months. For the placebo-controlled trials involving tamoxifen, eligibility criteria and duration of follow-up varied. Eligibility criteria for NSABP-1 included having a 5-year predicted breast cancer risk of 1.66% or greater, and median follow-up was about 7 years. Eligibility criteria for IBIS-I included having an estimated 10-year risk of 5% or greater; median follow-up was 96 months. For the Royal Marsden Hospital and Italian Tamoxifen Prevention trials, eligibility criteria did not include a pre-specified breast cancer risk threshold, and median follow-up was 13 and 11 years, respectively. For placebo-controlled trials involving raloxifene (Multiple Outcomes of Raloxifene Evaluation and Continuing Outcomes Relevant to Evista), eligibility criteria did not include a pre-specified breast cancer risk threshold; together, these trials provided 8 years of follow-up.

In placebo-controlled trials, tamoxifen and raloxifene significantly reduced the risk for invasive breast cancer (tamoxifen RR, 0.70 [95% CI, 0.59 to 0.82] raloxifene RR, 0.44 [95% CI, 0.27 to 0.71]. In STAR, tamoxifen reduced breast cancer more than raloxifene (raloxifene RR, 1.24 [95% CI, 1.05 to 1.47]).

Both medications reduced breast cancer in all subgroups studied, although trial data for racial subgroups were not available. Tamoxifen reduced breast cancer outcomes in subgroups based on age, menopausal status, estrogen use, family history of breast cancer, and history of LCIS or atypical ductal hyperplasia. In NSABP-1, tamoxifen was most effective in preventing invasive breast cancer in high-risk groups, including women with LCIS, atypical ductal hyperplasia, the highest Gail risk scores, and the greatest number of relatives with breast cancer. Raloxifene reduced breast cancer outcomes in subgroups based on age, age at menarche, parity, age at first live childbirth, and body mass index. Effect estimates for raloxifene were limited by small sample size for subgroups based on prior estrogen use, family history of breast cancer, and prior hysterectomy or oophorectomy. Specific risk factors may be more useful than risk calculators in certain clinical settings.

Both medications reduced breast cancer risk in postmenopausal women. Tamoxifen also reduced the incidence of invasive breast cancer in premenopausal women who were at increased risk for the disease. Risk reduction with tamoxifen was greatest in women with 3 or more first-degree relatives with breast cancer, LCIS, or atypical hyperplasia.

Reduction of invasive breast cancer continued for at least 3 to 5 years after discontinuation of tamoxifen in the 2 trials providing post treatment follow-up data. Neither medication significantly reduced the risk for ER-negative breast cancer, noninvasive breast cancer, or all-cause mortality. In the placebo-controlled trials and STAR, raloxifene reduced vertebral fractures (RR, 0.61 [95% CI, 0.54 to 0.69]), whereas tamoxifen reduced non-vertebral fractures (RR, 0.66 [95% CI, 0.45 to 0.98]). Tamoxifen and raloxifene had similar effects on vertebral fractures in STAR.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RALOXIFENE

RATIONALE (CONTINUED) - CLINICAL CONSIDERATIONS (CONTINUED)

The USPSTF could not assess the effect of these medications on mortality attributed to breast cancer or other causes. The effects of tamoxifen and raloxifene on mortality were not statistically significant in the clinical trials, which did not have sufficient long-term follow-up for this outcome. Although there is convincing evidence that these medications can reduce the incidence of invasive breast cancer (predominantly ER-positive cancer), whether reductions in breast cancer incidence lead to a corresponding reduction in mortality is unclear.

The USPSTF also considered meta-analysis summary calculations of the number of events reduced per 1000 women in placebo-controlled trials, assuming 5 years of treatment. Both medications reduced the incidence of invasive breast cancer, with 7 fewer events per 1000 women for tamoxifen (4 trials) and 9 fewer events per 1000 women for raloxifene (2 trials). When compared head-to-head in STAR, tamoxifen reduced breast cancer incidence by 5 more events per 1000 women than raloxifene. Compared with placebo, raloxifene reduced the incidence of vertebral fractures by 7 events per 1000 women (2 trials), whereas tamoxifen reduced the incidence of non-vertebral fractures by 3 events per 1000 women (1 trial). There were no significant differences in vertebral fractures when the drugs were compared head-to-head in STAR.

FDA APPROVED INDICATIONS

Tamoxifen and raloxifene are selective estrogen receptor modulators that have been shown in randomized, controlled trials to reduce the risk for estrogen receptor (ER)-positive breast cancer. They have been approved by the U.S. Food and Drug Administration (FDA) for this indication.

Tamoxifen and raloxifene have multiple FDA approved indications, please see prescribing information for further information.

SAFETY

The USPSTF found adequate evidence that tamoxifen and raloxifene increase risk for venous thromboembolic events (VTEs) by 4 to 7 events per 1000 women over 5 years and that tamoxifen increases risk more than raloxifene. The USPSTF found that potential harms from thromboembolic events are small to moderate, with increased potential for harms in older women.

The USPSTF also found adequate evidence that tamoxifen but not raloxifene increases risk for endometrial cancer (4 more cases per 1000 women). Potential harms from tamoxifen-related endometrial cancer are small to moderate and depend on hysterectomy status and age. The potential risks for tamoxifen-related harms are higher in women older than 50 years and in women with a uterus. Tamoxifen may also increase the incidence of cataracts.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RALOXIFENE

FDA APPROVED INDICATIONS (CONTINUED) - SAFETY (CONTINUED)

Vasomotor symptoms (hot flashes) are a common adverse effect of both medications that is not typically classified as serious, but these symptoms may affect a patient's quality of life and willingness to use or adhere to these medications.

Tamoxifen is not recommended for use in combination with hormone therapy or hormonal contraception or in women who are pregnant, those who may become pregnant, or breastfeeding mothers.

DOSAGE

Selective estrogen receptor modulators (tamoxifen and raloxifene) have been shown to reduce the incidence of invasive breast cancer in several randomized, controlled trials. Tamoxifen has been approved for this use in women aged 35 years or older, and raloxifene has been approved for this use in postmenopausal women.

The usual daily doses for tamoxifen and raloxifene are 20 mg and 60 mg, respectively, for 5 years.

REFERENCES

-) Nolvadex [Prescribing Information]. Wilmington, DE: Astra Zeneca Pharmaceuticals.; September 2005.
-) Evista [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company.; September 2007.
-) The Center for Consumer Information & Insurance Oversight.
http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html
[Accessed on 4/25/14].
-) Medications for Risk Reduction of Primary Breast Cancer in Women: U.S. Preventive Service Task Force Recommendation Statement.
<http://www.uspreventiveservicestaskforce.org/uspstf13/breastcanmeds/breastcanmedsrs.htm>
[Accessed on 4/25/14].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/10/15

Created: 05/14

Client Approval: 09/15

P&T Approval: 08/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

REGORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
REGORAFENIB	STIVARGA	39665		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (CRC)?

If yes, continue to #2.

If no, continue to #5.

2. Is the colorectal cancer KRAS wild type (i.e., not KRAS mutation)?

If yes, continue to #3.

If no, continue to #4.

3. Has the patient tried or does the patient have a contraindication to an anti-EGFR therapy (such as Erbitux [cetuximab] or Vectibix [panitumumab])?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient tried, or does the patient have a contraindication to **ALL** of the following preferred therapies?

-) An anti-VEGF therapy (such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept])
-) A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine)

If yes, **approve for 12 months by HICL with a quantity limit of #84 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST)?

If yes, continue to #6.

If no, continue to #7.

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REGORAFENIB

GUIDELINE FOR USE (CONTINUED)

6. Has the patient tried or does the patient have a contraindication to Gleevec (imatinib) **AND** Sutent (sunitinib)?

If yes, **approve for 12 months by HICL with a quantity limit of #84 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

7. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) and has been previously treated with Nexavar (sorafenib)?

If yes, **approve for 12 months by HICL with a quantity limit of #84 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **REGORAFENIB (Stivarga)** requires a diagnosis of metastatic colorectal cancer (CRC), hepatocellular carcinoma (HCC), or locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST). In addition, the following criteria must be met:

For the diagnosis of metastatic colorectal cancer (CRC), approval requires a trial with ALL of the following preferred therapies:

-) An anti-VEGF therapy (such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept])
-) A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine)

For wild type KRAS (no mutation) CRC only, a trial of an anti-EGFR therapy (such as Erbitux [cetuximab] or Vectibix [panitumumab]) is also required.

For the diagnosis of locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST), approval requires a trial with Gleevec (imatinib) and Sutent (sunitinib).

For the diagnosis of hepatocellular carcinoma (HCC), approval requires previous treatment with Nexavar (sorafenib).

These prior therapies may be covered under the medical benefit and/or may require prior authorization.

RATIONALE

To ensure appropriate use of Stivarga consistent with FDA approved indication and dosing.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

REGORAFENIB

FDA APPROVED INDICATIONS

Stivarga is a kinase inhibitor indicated for the treatment of patients with:

-) Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy.
-) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
-) Hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

DOSAGE AND ADMINISTRATION

The recommended dose is 160 mg Stivarga (four 40 mg tablets) taken orally once daily for the first 21 days of each 28-day cycle. Continue treatment until disease progression or unacceptable toxicity. Take Stivarga at the same time each day. Swallow tablet whole with water after a low-fat meal that contains less than 600 calories and less than 30% fat. Do not take two doses of Stivarga on the same day to make up for a missed dose from the previous day.

REFERENCES

-) Stivarga [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc, April 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 10/12

Client Approval: 08/17

P&T Approval: 07/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RILUZOLE SUSPENSION

Generic	Brand	HICL	GCN	Exception/Other
RILUZOLE	TIGLUTIK		44091	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meets **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has had a trial of riluzole tablets
- ☐ Physician attestation that patient is unable to take riluzole tablet formulation

If yes, **approve for 12 months by GPID with a quantity limit of #20mL per day (#600 mL [2 bottles] per 30 days).**

If no, do not approve.

DENIAL TEXT: The guideline named **RILUZOLE SUSPENSION (Tiglutik)** requires a diagnosis of amyotrophic lateral sclerosis (ALS) and ALL the following criteria:

- ☐ The patient is 18 years of age or older
- ☐ The patient has had a trial of riluzole tablets
- ☐ Physician attestation that patient is unable to take riluzole tablet formulation

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tiglutik.

REFERENCES

- ☐ Tiglutik. [Prescribing Information]. Berwyn, PA: ITF Pharma, Inc.; September 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RUXOLITINIB

Generic	Brand	HICL	GCN	Exception/Other
RUXOLITINIB PHOSPHATE	JAKAFI	38202		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis?

If yes, continue to #2.

If no, continue to #4.

2. Has the patient been taking the requested medication for at least 6 months?

If yes, continue to #3.

If no, **approve for 6 months by HICL for #2 tablets per day.**

3. Did the patient experience or maintain symptom improvement [such as a 50 percent or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0], 50 percent or greater reduction in palpable spleen length, or spleen reduction of 35 percent or greater from baseline spleen volume after 6 months of therapy?

If yes, **approve for 12 months by HICL for #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of polycythemia vera?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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RUXOLITINIB

GUIDELINE FOR USE (CONTINUED)

5. Has the patient tried hydroxyurea?

If yes, **approve for 12 months by HICL for #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **RUXOLITINIB** requires a diagnosis of intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis OR a diagnosis of polycythemia vera after a trial of hydroxyurea. Renewal for intermediate or high-risk myelofibrosis requires symptom improvement [such as a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0], 50% or greater reduction in palpable spleen length, or spleen reduction of 35% or greater from baseline spleen volume after 6 months of therapy.

RATIONALE

Promote appropriate utilization and dosing of Jakafi for its FDA approved indication.

FDA APPROVED INDICATIONS

-) Jakafi is a kinase inhibitor indicated for treatment of patients with:
Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.
-) Polycythemia vera who have had an inadequate response to or are intolerant of hydroxyurea.

DOSAGE

Doses should be individualized based on safety and efficacy. Starting doses per indication are noted below.

Myelofibrosis

-) The starting dose of Jakafi is based on patient's baseline platelet count:
-) Greater than $200 \times 10^9/L$: 20 mg given orally twice daily
-) $100 \times 10^9/L$ to $200 \times 10^9/L$: 15 mg given orally twice daily
-) $50 \times 10^9/L$ to less than $100 \times 10^9/L$: 5 mg given orally twice daily
-) Monitor complete blood counts every 2 to 4 weeks until doses are stabilized, and then as clinically indicated. Modify or interrupt dosing for thrombocytopenia.

Polycythemia Vera

The starting dose of Jakafi is 10 mg given orally twice daily.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RUXOLITINIB

REFERENCES

) Incyte Corporation. Jakafi package insert. Wilmington, DE. December 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/01/15

Created: 12/11

Client Approval: 02/15

P&T Approval: 02/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SACROSIDASE

Generic	Brand	HICL	GCN	Exception/Other
SACROSIDASE	SUCRAID	18554		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of genetically determined sucrose deficiency, or congenital sucrase-isomaltase deficiency (CSID)?

If yes, **approve for 12 months for #8mL per day.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of genetically determined sucrose deficiency, or congenital sucrase-isomaltase deficiency (CSID).

RATIONALE

To ensure use of Sucraid based on its FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Sucraid oral solution is indicated as oral replacement therapy of the genetically determined sucrose deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

REFERENCES

) QOL Medical, LLC. Sucraid package insert. Vero Beach, FL. June 2011.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 12/14/12

Created: 05/12

Client Approval: 05/12

P&T Approval: 05/12



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SAPROPTERIN DIHYDROCHLORIDE

Generic	Brand	HICL	GCN	Exception/Other
SAPROPTERIN DIHYDROCHLORIDE	KUVAN	35266		ROUTE = ORAL

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) and follows a phenylalanine-restricted diet?

If yes, **approve for 1 month by HICL.**

APPROVAL TEXT: Renewal of **SAPROPTERIN DIHYDROCHLORIDE** requires that the patient experiences a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride) and follows a phenylalanine-restricted diet.

If no, do not approve.

DENIAL TEXT: Our guideline for **SAPROPTERIN DIHYDROCHLORIDE** requires a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) and that the patient follows a phenylalanine-restricted diet.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) and meets the following criteria?
 -) The patient experienced a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride).
 -) The patient follows a phenylalanine-restricted diet.

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **SAPROPTERIN DIHYDROCHLORIDE** renewal requires a diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU), in addition to the patient experiencing a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride) and continuing to follow a phenylalanine-restricted diet.

RATIONALE

Promote appropriate utilization of sapropterin dihydrochloride based on FDA approved indication and dosing.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SAPROPTERIN DIHYDROCHLORIDE

RATIONALE (CONTINUED)

Phenylketonuria (PKU), in most cases, is caused by deficiency of phenylalanine hydroxylase (PAH). PAH is a hepatic enzyme that catalyzes the conversion of the essential amino acid phenylalanine to tyrosine. Tetrahydrobiopterin (BH4) is a cofactor required for PAH activity. PKU results in elevated blood and urine concentrations of phenylalanine and its metabolites, phenylacetate and phenyllactate. Tyrosine concentration is normal or low normal. Occasionally tyrosine concentrations are low.

Complete enzyme deficiency results in classic PKU, in which serum phenylalanine concentration exceeds 20 mg/dL (1200 micromol/L). Residual enzyme activity causes mild PKU (phenylalanine concentration 10 to 20 mg/dL, 600 to 1200 micromol/L) and hyperphenylalaninemia (HPA, phenylalanine concentration 2.5 to 10 mg/dL, 150 to 600 micromol/L).

Kuvan is a synthetic form of the cofactor BH4 (tetrahydrobiopterin) for the enzyme phenylalanine hydroxylase (PAH). BH4 activates residual PAH enzyme, improving normal phenylalanine metabolism and decreasing phenylalanine levels in Kuvan responders. Response to Kuvan treatment was defined in clinical trials as a 30% decrease in blood Phe from baseline. Approximately 25% to 50% of patients with PAH deficiency are responsive to sapropterin. The prevalence of responsiveness was 79 to 83% in patients with mild HPA, 49 to 60% in patients with mild PKU, and 7 to 10% in patients with classic PKU. Before routine treatment with Kuvan is initiated, a test should be conducted to determine if the patient is responsive.

DOSAGE

Patients 1 month to 6 years

) The recommended starting dose of Kuvan is 10 mg/kg taken once daily.

Patients 7 years and older

) The recommended starting dose of Kuvan is 10 to 20 mg/kg taken once daily.

Blood Phe levels should be checked after 1 week of Kuvan treatment and periodically for up to a month. If blood Phe does not decrease from baseline at 10 mg/kg per day, the dose may be increased to 20 mg/kg per day. Patients whose blood Phe does not decrease after 1 month of treatment at 20 mg/kg per day are nonresponders and treatment with Kuvan should be discontinued in these patients.

Once responsiveness to Kuvan has been established, the dosage may be adjusted within the range of 5 to 20 mg/kg per day according to response to therapy. Periodic blood Phe monitoring is recommended to assess blood Phe control.

FDA APPROVED INDICATION

Kuvan is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SAPROPTERIN DIHYDROCHLORIDE

REFERENCES

-) Kuvan [Prescribing Information]. BioMarin Pharmaceutical Inc. Novato, CA. May 2015.
-) UpToDate, Inc. Overview of phenylketonuria. UpToDate [database online]. Waltham, MA. Available at: <http://www.uptodate.com/home/index.html>. Updated March 20, 2015.
-) Kuvan. [Online Drug Database]. Available at: www.factsandcomparisons.com. Updated January 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/15

Created: 01/08

Client Approval: 08/15

P&T Approval: 08/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SARGRAMOSTIM

Generic	Brand	HICL	GCN	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication prescribed by or currently being supervised by a Hematologist or Oncologist?

If yes, **approve for 3 months or requested duration of treatment up to 1 year.**

If no, continue to #2.

2. Is the request for **ONE** of the following indications?

-) To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years or older
-) For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years or older
-) For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years or older
-) For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years or older
-) For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years or older
-) To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

If yes, **approve for 3 months or requested duration of treatment up to 1 year.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SARGRAMOSTIM

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **SARGRAMOSTIM (Leukine)** requires that the requested medication is prescribed by or currently being supervised by a hematologist or oncologist, OR is being used for **ONE** of the following indications:

-) To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years or older
-) For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years or older
-) For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years or older
-) For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years or older
-) For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years or older
-) To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

RATIONALE

Ensure appropriate utilization of sargramostim based on its FDA approved indications.

FDA APPROVED INDICATIONS

LEUKINE is a leukocyte growth factor indicated:

-) To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML)
-) For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in adult patients
-) For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation in adult and pediatric patients 2 years of age and older
-) For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older
-) For treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older
-) To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SARGRAMOSTIM

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

-) Acute Myeloid Leukemia (AML), Neutrophil recovery following chemotherapy:
 - o 250 mcg/m²/day administered intravenously over a 4-hour period
-) Mobilization of peripheral blood progenitor cells:
 - o 250 mcg/ m²/day administered intravenously over 24 hours or subcutaneous injection once daily
-) Post peripheral blood progenitor cell transplantation:
 - o Autologous peripheral blood progenitor cell transplantation:
 - 250 mcg/ m²/day administered intravenously over 24 hours or subcutaneous injection once daily
 - o Autologous bone marrow transplantation:
 - 250 mcg/ m²/day administered intravenously over 2 hours
-) Myeloid reconstitution after autologous or allogeneic BMT:
 - o 250 mcg/ m²/day administered intravenously over a 2-hour period
-) BMT failure or engraftment delayed:
 - o 250 mcg/ m²/day for 14 days as a 2-hour intravenous infusion
-) Patients acutely exposed to myelosuppressive doses of radiation, administer once daily as subcutaneous injection:
 - o Adults and pediatric patients weighing >40 kg: 7 mcg/kg
 - o Pediatric patients 15 kg to 40 kg: 10 mcg/kg
 - o Pediatric patients <15 kg: 12 mcg/kg

REFERENCES

-) Leukine [Prescribing Information] Bridgewater, NJ: Sanofi-aventis U.S. LLC. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 02/03

Client Approval: 05/18

P&T Approval: 04/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SECUKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
SECUKINUMAB	COSENTYX	41715		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) without psoriatic arthritis involvement and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a dermatologist
 -) The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
 -) The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 -) The patient is 18 years of age or older

If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**

Approve for 1 month as follows:

-) **150mg every week dosing: 5mL (5 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
-) **300mg every week dosing: 10mL (10 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

Approve for 5 months as follows:

-) **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
-) **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis without psoriatic arthritis involvement requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #2.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- ☐ Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - ☐ The patient has had a previous trial of or has a contraindication to at least one of the following DMARDs (disease-modifying anti-rheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - ☐ The patient is 18 years of age or older

If yes, continue to #3.

If no, continue to #6.

3. Does the patient have coexistent moderate to severe plaque psoriasis (PsO)? (**Note:** For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.)

If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**

Approve for 1 month as follows:

- ☐ **150mg every week dosing: 5mL (5 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
- ☐ **300mg every week dosing: 10mL (10 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

Approve for 5 months as follows:

- ☐ **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
- ☐ **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

APPROVAL TEXT: Renewal requires that the patient has met **ONE** of the following criteria:

- ☐ For the diagnosis of psoriatic arthritis (PsA), the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
- OR**
- ☐ For the diagnosis of moderate to severe plaque psoriasis (PsO), the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #4.

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SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Is the request for treatment of psoriatic arthritis (PsA) with a loading dose?

If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**

Approve for 1 month as follows:

-) **150mg every week dosing: 5mL (5 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

Approve for 5 months as follows:

-) **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
) **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #5.

5. Is the request for treatment of psoriatic arthritis (PsA) without a loading dose?

If yes, **approve the requested strength and dosage form by NDC for a total of 6 months as follows:**

-) **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
) **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient is 18 years of age or older

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Is the request for the treatment of ankylosing spondylitis (AS) with a loading dose?

If yes, **approve by NDC for a total of 6 months as follows:**

Approve for 1 month as follows:

- ☐ **150mg every week dosing: 5mL (5 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

Approve for 5 months as follows:

- ☐ **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, continue to #8.

8. Is the request for treatment of ankylosing spondylitis (AS) without a loading dose?

If yes, **approve by NDC for a total of 6 months as follows:**

- ☐ **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SECUKINUMAB

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT: The guideline named **SECUKINUMAB (Cosentyx)** requires a diagnosis of moderate to severe plaque psoriasis, psoriatic arthritis, or ankylosing spondylitis. In addition, the following criteria must also be met:

For patients with moderate to severe plaque psoriasis (PsO), approval requires the following:

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
-) The patient is 18 years of age or older

For patients with psoriatic arthritis (PsA), approval requires the following:

-) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-) The patient has had a previous trial at least one of the following DMARDs (disease-modifying anti-rheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 18 years of age or older

For patients with ankylosing spondylitis (AS), approval requires the following:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient is 18 years of age or older

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy?

If yes, **approve the requested strength and dosage form by NDC for 12 months with the following quantity limits:**

-) **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
-) **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

If no, continue to #2.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SECUKINUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

If yes, **approve the requested strength and dosage form by NDC for 12 months with the following quantity limits:**

-) **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**
-) **300mg every 4 weeks dosing: 2mL (2 syringes/pens) per 28 days (PAC NOTE: Enter NDC 00078-0639-41 or 00078-0639-98 only)**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and has experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy?

If yes, **approve by NDC for 12 months with the following quantity limits:**

-) **150mg every 4 weeks dosing: 1mL (1 syringe/pen) per 28 days (PAC NOTE: Enter NDC 00078-0639-68 or 00078-0639-97 only)**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline named **SECUKINUMAB (Cosentyx)** requires a diagnosis of moderate to severe plaque psoriasis, psoriatic arthritis, or ankylosing spondylitis for renewal. In addition, the following criteria must also be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires that the patient has achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

For the diagnosis of psoriatic arthritis (PsA), approval requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

For the diagnosis of ankylosing spondylitis (AS), approval requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

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SECUKINUMAB

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Cosentyx.

FDA APPROVED INDICATIONS

Cosentyx is a human interleukin-17A antagonist indicated for the treatment of:

-) Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.
-) Adult patients with active psoriatic arthritis.
-) Adult patients with active ankylosing spondylitis.

DOSAGE AND ADMINISTRATION

Cosentyx is administered by subcutaneous injection.

Plaque Psoriasis

The recommended dose is 300 mg subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300mg every 4 weeks; for some patients 150mg may be acceptable.

Psoriatic Arthritis

For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.

For other psoriatic arthritis patients, administer Cosentyx with or without a loading dose by subcutaneous injection. The recommended dosage:

-) With a loading dose is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
-) Without a loading dose is 150 mg every 4 weeks.
-) If the patient continues to have active psoriatic arthritis, consider a dosage of 300 mg.

Ankylosing Spondylitis

Administer Cosentyx with or without a loading dose by subcutaneous injection. The recommended dosage:

-) With a loading dose is 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter.
-) Without a loading dose is 150 mg every 4 weeks.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SECUKINUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE FORMS AND STRENGTHS

Cosentyx Sensoready pen:

- ⌋ NDC 0078-0639-41: Carton of two 150mg/ml (300mg) Sensoready pens (injection)
- ⌋ NDC 0078-0639-68: Carton of one 150mg/ml (300mg) Sensoready pens (injection)

Cosentyx prefilled syringe:

- ⌋ NDC 0078-0639-98: Carton of two 150mg/ml (300mg) single-use prefilled syringes (injection)
- ⌋ NDC 0078-0639-97: Carton of one 150mg/ml (300mg) single-use prefilled syringes (injection)

For injection: 150mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use

REFERENCES

- ⌋ Cosentyx [Prescribing Information]. Novartis Pharmaceuticals Corporation. East Hanover, NJ: January 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/15

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SELEXIPAG

Generic	Brand	HICL	GCN	Exception/Other
SELEXIPAG	UPTRAVI	42922		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meets **ALL** of the following criteria?
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) of 15 mmHg
 - o Pulmonary vascular resistance (PVR) of > 3 Wood units
 -) Patient has NYHA-WHO Functional Class II-IV symptoms

If yes, approve for 12 months by GPID for the requested strength with the following quantity limits:

-) **Uptravi 200mcg tablets (GPID: 40355):** #8 tablets per day
-) **Uptravi 400mcg tablet (GPID: 40356):** #2 tablets per day
-) **Uptravi 600mcg tablet (GPID: 40357):** #2 tablets per day
-) **Uptravi 800mcg tablet (GPID: 40358):** #2 tablets per day
-) **Uptravi 1,000mcg tablet (GPID: 40359):** #2 tablets per day
-) **Uptravi 1,200mcg tablet (GPID: 40374):** #2 tablets per day
-) **Uptravi 1,400mcg tablet (GPID: 40375):** #2 tablets per day
-) **Uptravi 1,600mcg tablet (GPID: 40376):** #2 tablets per day
-) **Uptravi 200-800 Titration pack (GPID: 40378):** #1 pack per 12 months

If no, do not approve.

DENIAL TEXT: The guideline for **SELEXIPAG (Uptravi)** requires a diagnosis of pulmonary arterial hypertension. The following criteria must also be met:

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SELEXIPAG

INITIAL CRITERIA (CONTINUED)

-)] The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-)] Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) of ≥ 15 mmHg
 - o Pulmonary vascular resistance (PVR) of > 3 Wood units
-)] The patient has NYHA-WHO Functional Class II-IV symptoms

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

- | | |
|---|---------------------------|
|)] Uptravi 200mcg tablets (GPID: 40355): | #8 tablets per day |
|)] Uptravi 400mcg tablet (GPID: 40356): | #2 tablets per day |
|)] Uptravi 600mcg tablet (GPID: 40357): | #2 tablets per day |
|)] Uptravi 800mcg tablet (GPID: 40358): | #2 tablets per day |
|)] Uptravi 1,000mcg tablet (GPID: 40359): | #2 tablets per day |
|)] Uptravi 1,200mcg tablet (GPID: 40374): | #2 tablets per day |
|)] Uptravi 1,400mcg tablet (GPID: 40375): | #2 tablets per day |
|)] Uptravi 1,600mcg tablet (GPID: 40376): | #2 tablets per day |

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SELEXIPAG

RENEWAL CRITERIA (CONTINUED)

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patients WHO functional class remained stable or has improved?

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**

) Uptravi 200mcg tablets (GPID: 40355):	#8 tablets per day
) Uptravi 400mcg tablet (GPID: 40356):	#2 tablets per day
) Uptravi 600mcg tablet (GPID: 40357):	#2 tablets per day
) Uptravi 800mcg tablet (GPID: 40358):	#2 tablets per day
) Uptravi 1,000mcg tablet (GPID: 40359):	#2 tablets per day
) Uptravi 1,200mcg tablet (GPID: 40374):	#2 tablets per day
) Uptravi 1,400mcg tablet (GPID: 40375):	#2 tablets per day
) Uptravi 1,600mcg tablet (GPID: 40376):	#2 tablets per day

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline for **SELEXIPAG (Uptravi)** requires a diagnosis of pulmonary arterial hypertension for renewal. The following criteria must also be met:

-) The patient has shown improvement from baseline in the 6-minute walk distance test **OR**
-) The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class

RATIONALE

Promote appropriate utilization of **SELEXIPAG** based on FDA approved indication.

Pulmonary arterial hypertension (PAH) is a chronic, progressive, and debilitating rare lung disease that can lead to death or the need for lung transplantation. The currently available therapeutic options to treat patients with PAH include endothelin receptor antagonists (ERAs), phosphodiesterase-5 inhibitors (PDE-5i), soluble guanylate cyclase stimulators, and prostacyclin receptor agonists. Uptravi will be the second oral prostacyclin agent for PAH, joining Orenitram (treprostinil), although unlike the other prostacyclin agents it is selective for the IP receptor. Inhaled, subcutaneous and intravenously administered forms of prostacyclins are often reserved for more severe/progressive PAH patients.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SELEXIPAG

RATIONALE (CONTINUED)

Guidelines recommend a confirmatory diagnosis of PAH based on right heart catheterization. Optimal therapy for a PAH patient is a highly individualized clinical decision considering several factors such as severity of illness, route of administration, side effects, comorbidities, treatment goals. Baseline severity should be determined prior to initiation of therapy and this is done using the World Health Organization functional classifications (WHO-FC), which categorizes patients into four classes (I-IV) based on symptoms and tolerance of physical activity. The overall treatment goals are to address underlying etiology, improve symptoms/exercise capacity (achieve a low risk status [FC I or II]), prevent progression of disease, and improve survival and quality of life. The currently available oral therapeutic options to treat patients with PAH include endothelin receptor antagonists (ERAs), phosphodiesterase-5 inhibitors (PDE-5i), soluble guanylate cyclase stimulators, and prostacyclin receptor agonists (Orenitram). Monotherapy with an oral drug is recommended for initial treatment of PAH and this can include an ERA or PDE-5i, which are typically first line, or a soluble guanylate cyclase stimulator. For those patients with advanced disease (WHO-FC III- IV), an inhaled, subcutaneous or intravenous prostacyclin may also be considered. Current US guidelines recommend treatment with two or more classes of PAH drugs only when the response is inadequate or the patient deteriorates on monotherapy, but recently published European guidelines include recommendations for initial combination therapy. Although there is limited data available on the effectiveness of combination therapy for initial treatment of PAH, the combination therapy of agents with different mechanisms of action may become preferred over monotherapy due to recent data demonstrating a benefit in morbidity/mortality.

The efficacy of Uptravi was demonstrated in the Phase III GRIPHON trial that showed Uptravi significantly reduced the risk of morbidity/mortality events versus placebo by 40% (HR 0.60; 99% CI: 0.46,0.78, $p < 0.001$) primarily attributable to a reduction in hospitalization and a reduction in other disease progression events (worsening FC, decrease in 6MWD, or need for other PAH therapy). The treatment effect was consistent across baseline functional class, background PAH therapy subgroups, and regardless of dose achieved.

DOSAGE

The starting dose of Uptravi is 200mcg by mouth twice daily and increased in increments of 200 mcg twice daily, usually at weekly intervals, to the highest tolerated dose up to 1600mcg twice daily. The target dose will be individualized based on patient tolerability and tolerability may be improved with food. In addition, a dose reduction should be made in patients that reach a dose that cannot be tolerated.

For patients with moderate hepatic impairment (Child-Pugh class B), the starting dose of Uptravi is 200 mcg once daily. Increase in increments of 200 mcg once daily at weekly intervals, as tolerated.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SELEXIPAG

FDA APPROVED INDICATION

Uptravi is a prostacyclin receptor agonist indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.

AVAILABLE STRENGTHS

- | | |
|--|-------------------------|
|) 200 microgram tablet |) 1000 microgram tablet |
|) 400 microgram tablet |) 1200 microgram tablet |
|) 600 microgram tablet |) 1400 microgram tablet |
|) 800 microgram tablet |) 1600 microgram tablet |
|) Titration pack: 140 count bottle of 200 microgram tablets and a 60 count bottle of 800 microgram tablets | |

REFERENCES

-) Uptravi [Prescribing Information]; San Francisco, CA: Actelion Pharmaceuticals US, Inc.; December 2017.
-) FDA Press Release [Online Press Release]: FDA approves new orphan drug to treat pulmonary arterial hypertension. Access here:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm478599.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
-) PAH Info. How common is PAH (2013). Actelion Pharmaceuticals. Access here:
http://www.pah-info.com/How_common_is_PAH
-) Taichman DB, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. CHEST 2014 Aug; 146(2):449-75.
-) Galie N, et al. Updated treatment algorithm of pulmonary arterial hypertension. J Am Coll Cardiol. 2013 Dec 24; 62(25 Suppl): D60-72.
-) Galie N, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Eur Respir J. 2015 Dec; 46(6):1855-6.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 01/16

Client Approval: 02/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMEPREVIR

Generic	Brand	HICL	GCN	Exception/Other
SIMEPREVIR	OLYSIO	40771		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient meet ALL of the following?
 -) A diagnosis of chronic hepatitis C, genotype 1
 -) Patient has a recent HCV infection documented by one detectable HCV RNA level within the past 6 months
 -) Age of at least 18 years old
 -) This medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Has the patient completed a prior full course of therapy with 1) any HCV protease inhibitor [for example, telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis)] OR 2) regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen) and has not achieved a sustained virologic response (SVR)?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
If no, continue to #3.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMEPREVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet at least **ONE** of the following criteria?

-) Decompensated or compensated cirrhosis
-) Limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
-) The requested medication is being used with ribavirin **AND** peginterferon alfa
-) Patient is taking any of the following medications that are not recommended for concurrent use with Olysio:
 - o Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
 - o Any of the following HIV medications:
 - A cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcoibix, or Tybost)
 - An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)
 - Delavirdine, etravirine, nevirapine, or efavirenz

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

4. Is the request for a combination regimen with Sovaldi plus Olysio for 12 weeks?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following?

-) The patient has contraindications to Epclusa, Harvoni and Mavyret
-) The patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., inability to tolerate, adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved]

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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SIMEPREVIR

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ONE** of the following?

- ☐ Treatment naïve
- ☐ Treatment experienced with prior treatment with peginterferon/ribavirin

If yes, **approve for 12 weeks by HICL for #1 capsule per day.**

CLINICAL PHARMACISTS: Please review Sovaldi prior authorization guideline, member history, and hepatitis C MRF if available to ensure appropriate length of approval.

APPROVAL TEXT: Regimen approved: Sovaldi + Olysio for 12 weeks.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **SIMEPREVIR (Olysio)** requires a diagnosis of chronic hepatitis C, genotype 1. The following criteria must also be met:

- ☐ Concurrent use of Olysio with Sovaldi
- ☐ Patient is 1) treatment naïve or 2) treatment-experienced with prior treatment with peginterferon/ribavirin
- ☐ Patient is at least 18 years old
- ☐ Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Patient must have documentation of recent HCV infection by at least one detectable HCV RNA level within the past 6 months
- ☐ Patient must have had a short trial of Harvoni, Mavyret or Epclusa (e.g., adverse effect or intolerance early in therapy) **OR** contraindications to ALL three agents; [an individual who has completed a full course of therapy that did not achieve sustained virologic response (SVR) will not be approved]

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMEPREVIR

GUIDELINES FOR USE (CONTINUED)

Olysio will not be approved for the following patients:

-) Patients who have failed a full course of treatment with 1) any HCV protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek] or boceprevir [Victrelis]) **OR** 2) a regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
-) Patients with compensated cirrhosis or decompensated cirrhosis
-) Patients with a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
-) Patients who are using Olysio with ribavirin and peginterferon alfa
-) Patients who are taking any of the following medications that are not recommended for concurrent use with Olysio:
 - o Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
 - o Any cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcoibx, or Tybost)
 - o Delavirdine, etravirine, nevirapine, or efavirenz
 - o Any HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

RATIONALE

Ensure appropriate utilization of Olysio based on FDA approved indication.

FDA APPROVED INDICATIONS

For the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen.

Limitations:

-) Olysio with peginterferon alfa (IFN) and ribavirin (RBV): Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.
-) Olysio must not be used as monotherapy
-) Olysio is not recommended in patients who have previously failed a regimen that included Olysio or any other HCV protease inhibitor.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMEPREVIR

FDA APPROVED INDICATIONS (CONTINUED)

FDA APPROVED DOSAGE

Olysio 150mg once daily is added to peginterferon alfa and ribavirin for the first twelve weeks of therapy for genotype 1 or genotype 4 infection. Olysio is a component of triple therapy with peginterferon and ribavirin that will require a total treatment duration of 24 or 48 weeks.

-) All treatment-naïve and prior relapser patients not co-infected with HIV, with or without cirrhosis, should receive an additional 12 weeks of peginterferon alfa and ribavirin after completing 12 weeks of treatment with Olysio, peginterferon alfa and ribavirin; (total treatment duration of peginterferon/ribavirin is 24 weeks).
-) All treatment-naïve and prior relapser patients *co-infected with HIV with cirrhosis*, should receive an additional 36 weeks of peginterferon alfa and ribavirin after completing 12 weeks of treatment with Olysio, peginterferon alfa and ribavirin; (total treatment duration of peginterferon/ribavirin is 24 weeks).
-) All prior non-responder patients (including partial and null-responders), with or without cirrhosis and with or without HIV should receive an additional 36 weeks of peginterferon alfa and ribavirin after completing 12 weeks of treatment with Olysio, peginterferon alfa and ribavirin (total treatment duration of peginterferon/ribavirin is 48 weeks).

Olysio 150mg once daily can also be used with sofosbuvir 400mg once daily in an all-oral regimen for patients with genotype 1 infection. This regimen is administered for a duration of 12 or 24 weeks:

Duration of therapy:	
Treatment naïve or treatment experienced, without cirrhosis	12 weeks
Treatment naïve or treatment experienced, with cirrhosis	24 weeks

For peginterferon alfa/ribavirin and Sovaldi (sofosbuvir) specific dosage instructions, refer to their respective prescribing information.

No dosage recommendations can be made for patients of East Asian ancestry or for patients with severe hepatic impairment.

OTHER INFORMATION

Olysio is FDA-approved to treat HCV genotypes 1 and 4, but AASLD recommends use of Olysio only for genotype 1 infection. See hcvguidelines.org for most recent recommendations.

SAFETY

Common adverse reactions (incidence in greater than 20% of clinical trial participants and at least 3% higher frequency than those receiving placebo with ribavirin and peginterferon alfa) occurring in those receiving Olysio in combination with ribavirin and peginterferon alfa include rash (including photosensitivity), pruritus, and nausea.

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SIMEPREVIR

FDA APPROVED INDICATIONS (CONTINUED)

SAFETY

Concurrent use of Olysio with another agent such as Sovaldi and amiodarone may increase the risk of symptomatic bradycardia.

Patients should be counseled regarding the risk of photosensitivity reactions while taking Olysio. Patients must use sun protection measures and limit sun exposure during Olysio therapy. Consider discontinuation of therapy if a photosensitivity reaction occurs.

Contraindications include all contraindications known for peginterferon alfa and ribavirin since Olysio is administered in combination with these agents.

Patients with genotype 1a NS3 Q80K polymorphism are likely to experience a significant reduction in efficacy and/or treatment failure when taking Olysio. Patients with genotype 1a should be screened at baseline for the NS3 Q80K polymorphism, and alternative therapy should be considered for any patient infected with a virus that contains the NS3 Q80K polymorphism.

Strong CYP 3A4 inducers and inhibitors may affect Olysio serum levels, and should be avoided when possible in patients taking Olysio. CYP3A4 inducers, including phenytoin, carbamazepine, oxcarbazepine, phenobarbital and rifampin may increase serum levels, while CYP3A4 inhibitors, including erythromycin, clarithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, darunavir/ritonavir and ritonavir, may decrease Olysio serum levels. Olysio may increase levels of HMG CoA reductase inhibitors, including rosuvastatin, atorvastatin, and simvastatin and others, and may require statin dose reduction. Olysio may increase digoxin levels and affect serum levels of certain immunosuppressants, including cyclosporine, tacrolimus, and sirolimus. See prescribing information for a full description of all significant drug interactions.

Olysio is pregnancy category C; however, when administered in regimens with peginterferon alfa and ribavirin (pregnancy category X), avoid use during pregnancy in females receiving therapy and female partners of males receiving therapy. Patients must have a negative pregnancy test before starting therapy, use two methods of contraception during therapy, and have a monthly pregnancy test.

The safety and efficacy of Olysio has not been studied in liver transplant patients or patients with severe renal impairment, end-stage renal disease, or those requiring dialysis.

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SIMEPREVIR

FDA APPROVED INDICATIONS (CONTINUED)

SAFETY

Concurrent Sovaldi and Olysio therapy +/- ribavirin (12 or 24 week treatment)

-) Results from the COSMOS trial showed excellent SVR rates from an all-oral combination of Olysio 150 mg once daily plus Sovaldi 400 mg once daily when used for patients infected with HCV genotype 1. Patients were randomized to 12 or 24 weeks of the Olysio plus Sovaldi combination, with or without ribavirin. Results were similar in groups treated with or without ribavirin. Results were similar for 12 or 24 weeks of treatment, and high SVR rates were seen regardless of Metavir fibrosis stage or status of previous treatment (prior null responders to peginterferon/ribavirin versus treatment naïve).
-) Patients were either treatment experienced (prior null responders to peginterferon/ribavirin) with Metavir fibrosis stage of 0 or 2 (n=80, Cohort 1) or a treatment naïve or prior null responders with Metavir fibrosis stage of 3 or 4 (n=87, Cohort 2).
-) The two-drug combination treatment for 12 weeks showed an SVR12 rate of 93% in previously treated patients (Cohort 1) , and SVR of 96% when used in combination with ribavirin as triple therapy. The two-drug combination treatment for 24 weeks showed an SVR12 rate of 79% and 93%, with and without ribavirin, respectively. Cohort 1 had no viral breakthrough during therapy, although 3 patients with genotype 1a and Q80K polymorphism experienced viral relapse after completing therapy.
-) Cohort 2 has SVR4 results available at the time of AASLD/IDSA guideline publication. The 12-week treatment group demonstrated a 100% SVR in treatment naïve patients with and without ribavirin. The prior null responders in cohort 2 also showed excellent SVR rates with 100% and 93% with or without ribavirin, respectively. Again, no viral breakthrough was observed during treatment and after therapy one patient with genotype 1a and Q80K polymorphism experienced viral relapse after completing therapy.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMEPREVIR

REFERENCES

-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed November 3, 2017.
-) Jacobson I. SVR results of a once-daily regimen of simeprevir (TMC-438) plus sofosbuvir (GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: the COSMOS study. Program and abstracts of American Association for the Study of Liver Diseases The Liver Meeting® 2013; November 1-5, 2013. Abstract LB-3.
-) Lawitz E, Sulkowski M, Ghalib R, Rodriguez-Torres M, Younossi Z, et al. Simeprevir plus sofosbuvir with or without ribavirin, to treat chronic infection with hepatitis C virus genotype 1 in non-responders to pegylated interferon and ribavirin and treatment-naïve patients: the COSMOS randomized study. Lancet 2014; Jul 26. pii: S0140-6736(14)61036-9. doi: 10.1016/S0140-6736(14)61036-9. [Epub ahead of print]
-) Olysio [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals; November 2014.
-) Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; December 2013.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 02/14

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMVASTATIN ORAL SUSPENSION

Generic	Brand	HICL	GCN	Exception/Other
SIMVASTATIN	FLOLIPID		41189 41192	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?

-) Previous trial of or contraindication to simvastatin tablets
-) Prescriber documentation that the patient has dysphagia, difficulty swallowing tablets, or has a feeding tube (e.g., G-tube or J-tube)

If yes, continue to #2.

If no, do not approve

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient also requesting a zero dollar cost share exception (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

If yes, continue to #3.

If no, **approve for 12 months by GPID with the following quantity limits (NOTE: Override the PA edit only, no change in copay):**

-) Flolipid 20mg/5mL (GPID 41189): 150mL (#1 bottle) per 30 days.
-) Flolipid 40mg/5mL (GPID 41192): 150mL (#1 bottle) per 30 days.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMVASTATIN ORAL SUSPENSION

GUIDELINES FOR USE (CONTINUED)

3. Is the patient between 40-75 years of age without a history of cardiovascular disease and has **NOT** used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records?

- ☐ Aspirin/dipyridamole (Aggrenox)
- ☐ Clopidogrel (Plavix)
- ☐ Dipyridamole
- ☐ Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
- ☐ Prasugrel (Effient)
- ☐ Praluent Pen
- ☐ Repatha
- ☐ Ticagrelor (Brilinta)
- ☐ Ticlopidine
- ☐ Vorapaxar sulfate (Zontivity)

If yes, **approve for 12 months by GPID at zero cost share with the following quantity limits (NOTE: Override the PA edit and update the copay amount field with ZERO copay):**

- ☐ **Flolipid 20mg/5mL (GPID 41189): 150mL (#1 bottle) per 30 days.**
- ☐ **Flolipid 40mg/5mL (GPID 41192): 150mL (#1 bottle) per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires that the patient had a previous trial of or contraindication to simvastatin tablets and prescriber documentation that the patient has dysphagia, difficulty swallowing tablets, or has a feeding tube (e.g., G-tube or J-tube).

Requests for zero dollar cost share also requires that the patient is between 40-75 years of age without a history of cardiovascular disease and has not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records:

- ☐ Aspirin/dipyridamole (Aggrenox)
- ☐ Clopidogrel (Plavix)
- ☐ Dipyridamole
- ☐ Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
- ☐ Prasugrel (Effient)
- ☐ Praluent Pen
- ☐ Repatha
- ☐ Ticagrelor (Brilinta)
- ☐ Ticlopidine
- ☐ Vorapaxar sulfate (Zontivity)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMVASTATIN ORAL SUSPENSION

RATIONALE

Ensure appropriate utilization of SIMVASTATIN ORAL SUSPENSION based on FDA approved indication and dosage.

ACA/EHB

In November 2016, the US Preventive Services Task Force (USPSTF) issued its final recommendations on statin use for the primary prevention of cardiovascular disease (CVD) in adults. CVD is a broad term that includes a number of conditions such as coronary heart disease and cerebrovascular disease, which ultimately manifest as heart attack and stroke, respectively. CVD is the leading cause of morbidity and mortality in the US, accounting for one out of every three deaths among adults.

Based on the well-established benefit of statin therapy in reducing the risk of CVD events and mortality, the USPSTF now recommends that adults without a history of CVD use a low- to moderate-dose statin for the primary prevention of CVD events and mortality when all of the following criteria are met (Grade B recommendation):

- (1) Age 40 to 75 years
- (2) One or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking)
- (3) Calculated 10-year risk of a cardiovascular event of 10% or greater

Under the Affordable Care Act (ACA), plans are required to cover USPSTF preventive recommendations that have an A or B rating.

FDA APPROVED INDICATIONS

Flolipid is indicated as an adjunctive therapy to diet to:

-) Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events.
-) Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia.
-) Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbetalipoproteinemia.
-) Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia.
-) Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.
-) Limitations of Use Simvastatin has not been studied in Fredrickson Types I and V dyslipidemias.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SIMVASTATIN ORAL SUSPENSION

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The usual dosage range of Flolipid is 5 to 40mg/day. Flolipid should be taken in the evening on an empty stomach. The recommended usual starting dose is 10 or 20mg once a day.

For patients at high risk for a CHD event due to existing CHD, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease, the recommended starting dose is 40 mg/day. It is recommended to use Flolipid 40 mg/5 mL for dosages greater than or equal to 40 mg.

Due to the increased risk of myopathy, including rhabdomyolysis, associated with an 80-mg dose of Flolipid, patients unable to achieve their LDL-C goal utilizing the 40-mg dose of FLOLIPID should not be titrated to an 80-mg dose, but should be placed on alternative LDL-C-lowering treatment(s) that provides greater LDL-C lowering.

DOSAGE FORMS AND STRENGTHS

-) Flolipid is available in 150mL bottles in the following strengths: 20mg/5mL oral suspension and 40mg/5mL oral suspension

REFERENCES

-) Flolipid [Prescribing Information]. Brooksville, FL: Salerno Pharmaceuticals LP; October 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 03/18

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SOFOSBUVIR

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR	SOVALDI	40795		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Is the patient **ONE** of the following?
 -) Age of at least 18 years old and has a diagnosis of chronic hepatitis C, genotype 1 or 3
 -) Pediatric patient, age 12-17 years old **OR** weighs at least 77 pounds (35kg), with a diagnosis of chronic hepatitis C, genotype 2 or 3

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Does the patient meet at least **ONE** of the following?
 -) The patient has severe renal impairment (estimated glomerular filtration rate (GFR) less than 30 mL/min/1.73m²), end stage renal disease, or requires dialysis
 -) The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
 -) The patient is currently taking any of the following medications: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
 -) The patient is using Sovaldi with a direct acting antiviral (e.g., Olysio or Daklinza) **AND** is concurrently taking amiodarone

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
If no, continue to #3.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?

-) Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Patient has evidence of current HCV infection and chronic HCV infection as documented by one detectable HCV RNA level within the last 6 months

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient under age 18?

If yes, continue to #17.

If no, continue to #5.

5. Does the patient meet **ALL** of the following?

-) Treatment naïve **OR** treatment experienced (prior treatment with peginterferon/ribavirin)
-) Patient is without cirrhosis **OR** has decompensated cirrhosis **OR** is post-liver transplant (with or without cirrhosis)

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Has the patient failed a short trial of the preferred formulary agent or has a contraindication to therapy with the preferred formulary agents? (see criteria below)

-) For genotype 1 HCV infection: a short trial of Epclusa, Harvoni or Mavyret (e.g., adverse effect early in therapy to Mavyret, Harvoni or Epclusa) or contraindication to all three agents
-) For genotype 3 HCV infection: a short trial of Epclusa or Mavyret (e.g., adverse effect early in therapy to Epclusa or Mavyret) or contraindication to both agents
(**NOTE:** An individual who has completed a full course of therapy with the preferred agent that did not achieve SVR will not be approved)

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have decompensated cirrhosis?

If yes, continue to #12.

If no, continue to #8.

8. Is the requested medication being used with 1) ribavirin **OR** 2) peginterferon alfa and ribavirin?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #9.

9. Is this request for Sovaldi use in combination with Daklinza?

CLINICAL PHARMACISTS: Patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

If yes, continue to #13.

If no, continue to #10.

10. Is the request for a combination regimen with Sovaldi plus Olysio in a patient with genotype 1 hepatitis C infection?

If yes, continue to #11.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

11. Does the patient meet **ONE** or more of the following?

-) The patient has cirrhosis
-) Patient completed a prior full course of therapy with 1) any HCV protease inhibitor [for example, Incivek (telaprevir), Olysio (simeprevir), or Victrelis (boceprevir)] and has not achieved a sustained virologic response (SVR) **OR** 2) a regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
-) Patient is concurrently using any of the following medications with Sovaldi/Olysio which are not recommended by the manufacturer of Olysio:
 - o Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
 - o Any of the following HIV medications: delavirdine, efavirenz, nevirapine, or efavirenz
 - o A cobicistat-containing medication (e.g., Stribild or Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir), Evotaz, Prezcoibix, or Tybost)
 - o An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 12 weeks by HICL for #1 tablet per day. Maximum duration of sofosbuvir therapy is not to exceed 84 days (12 weeks). (NOTE: Regimen approved for genotype 1 patient without cirrhosis: Olysio and Sovaldi for 12 weeks)**

CLINICAL SPECIALISTS: Patient is on combination therapy with Olysio; please also view Olysio prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Olysio.

APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Olysio and Sovaldi.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

12. Is this request for Sovaldi use in combination with Daklinza?

CLINICAL PHARMACISTS: Patient must also meet all criteria in Daklinza guideline to be approvable for both agents. Review hepatitis C MRF and Daklinza request to ensure patient meets criteria for both agents.

If yes, continue to #13.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

13. Is the patient concurrently using Sovaldi/Daklinza with any of the following (contraindicated or not recommended by the manufacturer, except specified HIV medications) medications: amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #14.

14. Does the patient have compensated cirrhosis?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #15.

15. Does the patient have decompensated cirrhosis or is post-liver transplant?

If yes, continue to #16.

If no, **approve for 12 weeks by HICL for #1 tablet per day (Sovaldi in combination with Daklinza).**

CLINICAL PHARMACISTS: Patient is on combination therapy with Daklinza; please also view Daklinza prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Daklinza.

APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi.

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SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

16. Is the patient using a regimen of Daklinza and Sovaldi (sofosbuvir) **WITH** ribavirin?

If yes, **approve for 12 weeks by HICL for #1 tablet per day (Sovaldi in combination with Daklinza and ribavirin).**

CLINICAL PHARMACISTS: Patient is on combination therapy with Daklinza; please also view Daklinza prior authorization guideline, member history, and hepatitis C MRF, if available to ensure appropriate length of approval and that the patient also meets approval for Daklinza.

APPROVAL TEXT: Prior authorization is approved for a 12-week combination regimen with Daklinza and Sovaldi with ribavirin.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

17. Does the patient have genotype 2 infection **AND** has compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

If yes, continue to #18.

If no, continue to #19.

18. Is the requested medication being used with ribavirin?

If yes, **approve for 12 weeks by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

19. Does the patient have genotype 3 infection **AND** has compensated cirrhosis (Child-Pugh A) or is without cirrhosis?

If yes, continue to #20.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

20. Is the requested medication being used with ribavirin?

If yes, **approve for 24 weeks by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **SOFOSBUVIR (Sovaldi)** requires a diagnosis of chronic hepatitis C. The following criteria must also be met:

-) Patient is at least 18 years old with a diagnosis of chronic hepatitis C genotype 1 or genotype 3, OR the request is for a pediatric patient (age 12-17 or weighing at least 77lb (35kg)) with a diagnosis of chronic hepatitis C genotype 2 or 3
-) Currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Evidence of current HCV infection and chronic HCV infection as documented by one detectable HCV RNA level within the last 6 months
-) Adults: Concurrent use of Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
-) Concurrent use of ribavirin (genotypes 2 and 3) for pediatric patients (under age 18)
-) Adult patients are 1) treatment-naïve or 2) treatment-experienced with prior treatment with peginterferon/ribavirin
-) Requests for pediatric patients must meet the FDA-approved indication (treatment naïve or treatment experienced patient with compensated cirrhosis (Child-Pugh A) or without cirrhosis)
-) Adult patients with genotype 1 infection: requires a previous short trial of Epclusa, Harvoni or Mavyret (e.g., intolerance, adverse effect early in therapy) or contraindication to all three agents; an individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved
-) Adult patients with genotype 3 infection: requires a previous short trial of Epclusa or Mavyret (e.g., intolerance, adverse effect early in therapy) or contraindication to both agents; an individual who has completed a full course of therapy that did not achieve SVR will not be approved

Sovaldi will not be approved for the following patients:

-) Patients with severe renal impairment (GFR less than 30 mL/min/1.73m²), end stage renal disease and/or those requiring dialysis
-) Patients with a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
-) Adult patients with compensated cirrhosis
-) Patients using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
-) Patients who are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
-) Adult patients who are using Sovaldi with 1) ribavirin OR 2) peginterferon alfa and ribavirin

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

For requests for Sovaldi/Olysio regimen for genotype 1, the following criteria must be met:

-) Patient is at least 18 years old
-) Patient does not have cirrhosis
-) No previous failure of a prior full course of therapy with 1) any HCV protease inhibitor (e.g., Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir]) **OR** 2) a regimen containing NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
-) Patient is **NOT** concurrently using any of the following medications (contraindicated or not recommended by the manufacturer):
 - o Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
 - o Any of the following HIV medications: delavirdine, etravirine, nevirapine, or efavirenz
 - o A cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcoibix, or Tybost)
 - o An HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

For patients using Sovaldi with Daklinza, the following criteria must be met:

-) Patient is at least 18 years old
-) Genotype 1 or 3 hepatitis C
-) Patient must not have concurrent use with any of the following medications (contraindicated or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
-) Concurrent ribavirin use is required for patients with decompensated cirrhosis or who are post-liver transplant

RATIONALE

Ensure appropriate utilization of sofosbuvir.

FDA APPROVED INDICATIONS

Sovaldi is a hepatitis C virus nucleotide analog NS5B polymerase inhibitor indicated for the treatment of:

-) Adult patients with genotype 1,2,3 or 4 chronic hepatitis C virus infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen
-) Pediatric patients 12 years of age and older or weighing at least 35kg with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****SOFOSBUVIR****FDA APPROVED INDICATIONS (CONTINUED)**

Adult patient population	
Genotype	FDA-approved dosing regimen for Sovaldi (for HCV monoinfected or HIV-1/HCV co-infected patients)
Genotype 1	Sovaldi + peginterferon + ribavirin for 12 weeks
	Sovaldi + Daklinza for 12 weeks (ribavirin required for decompensated cirrhosis or post-liver transplant)
	Sovaldi + Olysio for 12 weeks (24 weeks if cirrhosis)
Genotype 1: interferon ineligible	Sovaldi + ribavirin for 24 weeks
Genotype 2	Sovaldi + ribavirin for 12 weeks
Genotype 3	Sovaldi + ribavirin for 24 weeks
	Sovaldi + Daklinza for 12 weeks (ribavirin required for cirrhosis (compensated or decompensated) or post-liver transplant)
Genotype 4	Sovaldi + peginterferon + ribavirin for 12 weeks

Pediatric patient population		
Genotype	Pediatric patient population 12 years of age and older or weighing at least 35 kg	FDA-approved dosing regimen for Sovaldi
Genotype 2	Treatment naïve or treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin for 12 weeks
Genotype 3	Treatment naïve and treatment experienced, without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin for 24 weeks

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SOFOSBUVIR

FDA APPROVED INDICATIONS (CONTINUED)

FDA APPROVED DOSAGE

-) One 400mg tablet taken once daily with or without food.
-) Sovaldi should be used in combination with ribavirin or in combination with pegylated interferon and ribavirin for the treatment of chronic hepatitis C (see chart above for FDA approved regimens and AASLD chart below for FDA approved and non-approved recommended regimens for hepatitis C). Sovaldi in combination with ribavirin for 24 weeks can be considered for chronic hepatitis C patients with genotype 1 infection who are interferon ineligible.
-) Sovaldi should be used in combination with ribavirin for treatment of chronic hepatitis C in patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation, whichever occurs first.
-) A dose recommendation cannot be made for patients with severe renal impairment or end stage renal disease.

SAFETY

Common adverse reactions (incidence in greater than 20% of clinical trial) occurring in those receiving Sovaldi in combination with ribavirin were fatigue and headache. Common adverse reactions occurring in those receiving Sovaldi as a component of triple therapy (in combination with peginterferon alfa and ribavirin) were fatigue, headache, nausea, insomnia, and anemia.

Contraindications include all contraindications known for peginterferon alfa and ribavirin when Sovaldi is administered in combination with these agents. Sovaldi is contraindicated in pregnant women and men whose female partners are pregnant. Sovaldi is pregnancy category B; however, due to required co-administration of peginterferon alfa and/or ribavirin (pregnancy category X), avoid use during pregnancy in females receiving therapy and female partners of males receiving therapy. Patients must have a negative pregnancy test before starting therapy, use two methods of contraception during therapy, and have a monthly pregnancy test.

Potent P-gp inducers such as rifampin and St. John's wort may decrease serum levels and efficacy of Sovaldi; avoid concurrent use of potent P-gp inducers with Sovaldi when possible. Sovaldi is not known to have drug interactions related to CYP450. Concurrent use of Harvoni and amiodarone may increase the risk of symptomatic bradycardia.

The safety and efficacy of Sovaldi have not been studied in patients post-liver transplant, patients with severe renal impairment or end-stage renal disease, or those requiring dialysis.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SOFOSBUVIR

REFERENCES

-) Daklinza [Prescribing Information]. Princeton, NJ: Bristol Myers Squibb; February 2016.
-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, and Managing, Accessed February 25, 2016.
-) Jacobson I. SVR results of a once-daily regimen of simeprevir (TMC-438) plus sofosbuvir (GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: the COSMOS study. Program and abstracts of American Association for the Study of Liver Diseases The *Liver Meeting® 2013; November 1-5, 2013. Abstract LB-3.*
-) Olysio [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals; November 2014.
-) Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 01/14

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SONIDEGIB

Generic	Brand	HICL	GCN	Exception/Other
SONIDEGIB	ODOMZO	42369		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced basal cell carcinoma (BCC) and has the following criteria been met?
 -) This is a recurrence of BCC after the patient has already had surgery or radiation therapy or the patient is not a candidate for surgery or radiation therapy

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at end of the guideline.

2. Has the patient obtained the following tests prior to initiating therapy?
 -) Baseline serum creatinine kinase (CK) level
 -) Baseline serum creatinine
 -) Pregnancy status of females of reproductive potential

If yes, **approve for 12 months by HICL with a quantity limit of #1 capsule per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at end of the guideline.

DENIAL TEXT: Our guideline for **SONIDEGIB** requires a diagnosis of locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or that the patient not be a candidate for surgery or radiation therapy. In addition, the patient must have obtained baseline serum creatine kinase (CK) and serum creatinine levels, and females of reproductive potential must verify their pregnancy status prior to initiating therapy.

RATIONALE

Promote appropriate utilization of Sonidegib based on FDA approved indication.

Skin cancer is the most common cancer and basal cell carcinoma accounts for approximately 80 percent of non-melanoma skin cancers. The vast majority of patients can be successfully managed with a variety of simple procedures, such as cryotherapy, curettage and electrodesiccation, topical treatments (5-fluorouracil, imiquimod), or simple surgical excision. When lesions are more advanced, Mohs micrographic surgery, more extensive surgical resection, or radiation therapy generally are generally sufficient to control locoregional disease. The use of systemic therapy is limited to patients with distant metastases or locally advanced disease that cannot be adequately managed with surgical or radiotherapeutic techniques.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SONIDEGIB

RATIONALE (CONTINUED)

The Hedgehog (Hh) signaling pathway plays a key role in directing growth and patterning during embryonic development and is required in vertebrates for the normal development of many structures, including the skin. Signaling in this pathway is initiated by the cell surface receptor smoothened homolog (SMO). In adults, this pathway normally is inhibited by another cell surface receptor, the patched homolog 1 (PTCH1). In the pathogenesis of basal cell carcinoma, either SMO or PTCH1 could have a mutation resulting in aberrant cell proliferation.

Odomzo works by binding to and inhibiting SMO protein, thereby blocking activation of the Hh pathway and the proliferation of tumor cells. It offers an alternative to Erivedge (vismodegib) with a similar safety profile for patients who have a recurrence of BCC following surgery or radiation therapy, or for those patients who are not candidates for surgery or radiation.

The safety and effectiveness of Odomzo was evaluated in a single clinical trial conducted in patients with locally advanced basal cell carcinoma (laBCC) or metastatic basal cell carcinoma who received Odomzo 200 mg orally, once daily, until disease progression or intolerable toxicity. A total of 66 patients randomized to Odomzo 200 mg daily had laBCC and were followed for at least 12 months unless discontinued earlier. Seventy-six percent of patients had prior therapy for treatment of BCC; this included surgery (73%), radiotherapy (18%), and topical/photodynamic therapies (21%). Approximately half of these patients (56%) had aggressive histology. The ORR was 58% (95% confidence interval: 45, 70), consisting of 3 (5%) complete responses and 35 (53%) partial responses. Among the 38 patients with an objective response, 7 (18%) patients experienced subsequent disease progression with 4 of these 7 patients having maintained a response of 6 months or longer. The remaining 31 patients (82%) have ongoing responses ranging from 1.9+ to 18.6+ months and the median duration of response has not been reached.

The most common adverse effects seen while using Odomzo were muscle spasms, alopecia, dysgeusia, fatigue, nausea, musculoskeletal pain, diarrhea, decreased weight, decreased appetite, myalgia, abdominal pain, headache, pain, vomiting, and pruritus. It is recommended that baseline serum CK and creatinine levels be obtained prior to initiating Odomzo, periodically during treatment, and as clinically indicated (e.g., if muscle symptoms are reported). Obtain serum creatinine and CK levels at least weekly in patients with musculoskeletal adverse reactions with concurrent serum CK elevation greater than 2.5 times ULN until resolution of clinical signs and symptoms. Depending on the severity of symptoms, temporary dose interruption or discontinuation may be required for musculoskeletal adverse reactions or serum CK elevation.

There is a **black box warning** for embryo-fetal death and severe birth defects. Pregnancy Category D.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SONIDEGIB

DOSAGE

Odomzo is taken as a single 200 mg capsule, once daily, on an empty stomach, at least 1 hour before or 2 hours after a meal. Odomzo therapy should be continued until disease progression or unacceptable toxicity.

FDA APPROVED INDICATION

Treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

REFERENCES

-) Odomzo [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals, Corp. July 2015.
-) FDA [Online Press Release]. Available at:
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm455862.htm> Updated: July 24, 2015.
-) UpToDate, Inc. Systemic treatment of advanced cutaneous squamous and basal cell carcinomas. UpToDate [database online]. Waltham, MA. Available at
<http://www.uptodate.com/home/index.html>. Updated July 28, 2015.
-) Hedgehog Signaling Pathway. CST Cell Signaling Technology. 2015. Available at:
<http://www.cellsignal.com/contents/science-cst-pathways-stem-cell-markers/hedgehog-signaling-pathway/pathways-hedgehog>. Accessed August 24, 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/16

Created: 10/15

Client Approval: 11/15

P&T Approval: 11/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SORAFENIB

Generic	Brand	HICL	GCN	Exception/Other
SORAFENIB TOSYLATE	NEXAVAR	33400		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**
If no, continue to #2.

2. Does the patient have a diagnosis of unresectable hepatocellular carcinoma?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**
If no, continue to #3.

3. Does the patient have a diagnosis of locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**
If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of advanced renal cell carcinoma (RCC), unresectable hepatocellular carcinoma, or locally recurrent/metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

RATIONALE

Ensure appropriate utilization of sorafenib based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATION

Sorafenib is indicated for the treatment of unresectable hepatocellular carcinoma, advanced renal cell carcinoma and locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SORAFENIB

REFERENCES

-) Bayer HealthCare Pharmaceuticals Inc. Nexavar package insert. Wayne, NJ. November 2013.
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. (Version 1.2011).
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. (Version 2.2011).

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/14

Created: 05/11

Client Approval: 03/14

P&T Approval: 02/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SUNITINIB

Generic	Brand	HICL	GCN	Exception/Other
SUNITINIB MALATE	SUTENT	33445		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #2.

2. Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST) **AND** meet the following criterion?

) The patient has had a previous trial of or contraindication to imatinib mesylate (Gleevec)

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #3.

3. Does the patient have a diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET) **AND** meet the following criterion?

) The patient's tumor is progressive and well-differentiated

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #4.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SUNITINIB

GUIDELINES FOR USE (CONTINUED)

4. Is the request for adjuvant treatment of renal cell carcinoma and meet **ALL** of the following criteria?

- ☐ Patient is at least 18 years old
- ☐ Patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: The guideline named **SUNITINIB (Sutent)** requires a diagnosis of advanced renal cell carcinoma (RCC), gastrointestinal stromal tumor (GIST), unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), or for adjuvant treatment of renal cell carcinoma. In addition, the following must be met:

For diagnosis of gastrointestinal stromal tumor (GIST), approval requires:

- ☐ The patient has had a previous trial of or contraindication to imatinib mesylate (Gleevec)

For diagnosis of unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval requires:

- ☐ The patient's tumor is progressive and well-differentiated

For adjuvant treatment of renal cell carcinoma, approval requires:

- ☐ Patient is at least 18 years old
- ☐ Patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

RATIONALE

Ensure appropriate utilization of sunitinib based on FDA approved indication.

FDA APPROVED INDICATIONS

Sutent is a kinase inhibitor indicated for the treatment of:

- ☐ Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
- ☐ Advanced renal cell carcinoma (RCC)
- ☐ Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease
- ☐ Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SUNITINIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

GIST and Advanced RCC:

) 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off.

Adjuvant RCC:

) 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off for nine 6-week cycles.

pNET:

) 37.5 mg orally once daily, with or without food, continuously without a scheduled off-treatment period.

Dose Modification:

) Dose interruptions and/or dose adjustments of 12.5 mg recommended based on individual safety and tolerability.

REFERENCES

) Pfizer Labs. Sutent package insert. New York, NY. November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 05/11

Client Approval: 12/17

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TAVABOROLE

Generic	Brand	HICL	GCN	Exception/Other
TAVABOROLE	KERYDIN	41353		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of onychomycosis (fungal infection) of the toenails?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of diabetes, peripheral vascular disease (PVD), or immunosuppression?

If yes, continue to #4.

If no, continue to #3.

3. Does the patient have pain surrounding the nail or soft tissue involvement?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Has the patient previously tried or have a contraindication to oral terbinafine **OR** oral itraconazole **AND** ciclopirox topical solution?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Are five or less toenails affected?

If yes, **approve for 48 weeks by HICL with a quantity limit of 10mL (1 bottle) per 60 days.**

If no, **approve for 48 weeks by HICL with a quantity limit of 10mL (1 bottle) per 30 days.**

DENIAL TEXT: The guideline named **TAVABOROLE (Kerydin)** requires the following: a diagnosis of onychomycosis of the toenails; presence of complicating factors such as diabetes, peripheral vascular disease, a suppressed immune system, or pain surrounding the nail or soft tissue; and previous trial or contraindication to oral terbinafine or oral itraconazole and ciclopirox topical solution.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TAVABOROLE

RATIONALE

To promote clinically appropriate utilization of Kerydin (tavaborole) based on its FDA approved indication and dosing.

Kerydin is an oxaborole antifungal. Onychomycosis refers to nail infections caused by any fungus, including yeasts and non-dermatophyte molds. Although onychomycosis is usually a cosmetic concern to patients, it also causes physical discomfort for some, particularly with more severe or advanced disease. Patients may experience chronic pain or acute pain exacerbated by nail cutting, footwear, or pressure from bedclothes. Additionally, in patients with diabetes or other immunocompromised states, onychomycosis may increase the risk of bacterial infections such as cellulitis.

Kerydin may not be as efficacious as oral antifungals (e.g. terbinafine and itraconazole) in the treatment of onychomycosis, but its safety profile is improved. The most common adverse reactions associated with Kerydin are ingrown toenails, application site reactions (i.e. dermatitis, exfoliation, erythema). Additionally, Kerydin neither interacts with cytochrome P450 enzymes nor is associated with hepatotoxicity, as seen with oral antifungals.

DOSAGE AND ADMINISTRATION

Apply enough medication to cover the entire toenail surface and under the tip of each affected toenail once daily for 48 weeks. Use the dropper tip to gently spread Kerydin to the entire toenail up to the edges of the toenail as well as under the tip of the toenail.

For topical use only and not for oral, ophthalmic, or intravaginal use.

FDA APPROVED INDICATIONS

For the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*.

REFERENCES

) Kerydin [Prescribing Information]. Palo Alto, CA: Anacor Pharmaceuticals; July 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 11/14

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TELAPREVIR

Generic	Brand	HICL	GCN	Exception/Other
TELAPREVIR	INCIVEK	37629		

This drug requires a written request for prior authorization. All requests for hepatitis C medications require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

1. Is the requested medication being used with ribavirin **AND** peginterferon alfa; (**NOTE:** The patient must have an active prior authorization for ribavirin and peginterferon alfa before proceeding.)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

2. Is the patient currently taking the requested medication as indicated on the MRF, claims history, or prior authorization history?

If yes, continue to #11.

If no, continue to #3.

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TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of chronic hepatitis C, genotype 1?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

4. Is the patient at least 18 years old?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

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TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

5. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

6. Has the patient completed a prior course of therapy with a protease inhibitor (for example, telaprevir [Incivek], simeprevir [Olysio], or boceprevir [Victrelis]) and has not achieved a sustained virologic response (SVR)?

If yes, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

If no, continue to #7.

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TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

7. Is the patient currently taking rifampin?

If yes, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

If no, continue to #8.

8. Does the patient have a coinfection with hepatitis B?

If yes, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

If no, continue to #9.

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TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have a history of a previous organ transplant?

If yes, continue to #10.

If no, **approve #6 tablets per day for 8 weeks.**

PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 6 tablets and a duration of 56 days.

APPROVAL TEXT: Renewal requires HCV RNA level at baseline and at 4 weeks of telaprevir therapy (level 1,000 IU/mL or less). Please also document if the patient is one of these treatment groups: prior relapse patient, prior partial responder, prior null responder patients, or a treatment-naïve patients with cirrhosis. Drugs that are contraindicated with Incivek include alfuzosin, rifampin, ergot derivatives, cisapride, St. John's wort, atorvastatin, lovastatin, simvastatin, pimozide, sildenafil or tadalafil (when used for pulmonary arterial hypertension [PAH]), orally administered midazolam and triazolam. Incivek may increase serum levels of immunosuppressants such as cyclosporine, sirolimus, and tacrolimus; anticipate significant dose reduction and prolongation of dosing interval of immunosuppressants for transplant patients that are taking Incivek.

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TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

10. Is this a patient with a history of liver transplant and hepatitis C medications (triple therapy) being prescribed by a transplant center and transplant physician?

If yes, **approve #6 tablets per day for 8 weeks.**

PAC: The days supply is based on the benefit structure. Enter the Maximum Daily Dose (MDD) = 6 tablets and a duration of 56 days.

APPROVAL TEXT: Renewal requires HCV RNA level at baseline and at 4 weeks of telaprevir therapy (level 1,000 IU/mL or less). Please also document if the patient is one of these treatment groups: prior relapse patient, prior partial responder, prior null responder patients, or a treatment-naïve patients with cirrhosis. Drugs that are contraindicated with Incivek include alfuzosin, rifampin, ergot derivatives, cisapride, St. John's wort, atorvastatin, lovastatin, simvastatin, pimozide, sildenafil or tadalafil (when used for pulmonary arterial hypertension [PAH]), orally administered midazolam and triazolam. Incivek may increase serum levels of immunosuppressants such as cyclosporine, sirolimus, and tacrolimus; anticipate significant dose reduction and prolongation of dosing interval of immunosuppressants for transplant patients that are taking Incivek.

If no, do not approve.

DENIAL TEXT: Approval requires that patient has no history of solid organ transplant, except in the case of liver transplant patients managed by a transplant center. Other approval criteria include: concurrent use of ribavirin and peginterferon alfa and a diagnosis of chronic hepatitis C, genotype 1 without a coinfection with hepatitis B for a patient with a minimum age of 18 years who is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model and the patient has not failed therapy with telaprevir (Incivek), simeprevir (Olysio), or boceprevir (Victrelis) and is not currently taking rifampin.

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TELAPREVIR

GUIDELINES FOR USE (CONTINUED)

- 11. Renewal criteria for treatment week 9, the patient has an approved PA for telaprevir:** Did the patient have a HCV RNA level/viral load of 1,000 IU/mL or less at 4 weeks of telaprevir therapy?

If yes, **approve #6 tablets per day for 4 weeks. Maximum telaprevir therapy is not to exceed 12 weeks.**

PAC: The days supply is based on the benefit structure. Enter the **Maximum Daily Dose (MDD) = 6 tablets and a duration of 28 days; total telaprevir therapy duration not to exceed 84 days (12 weeks).**

APPROVAL TEXT: Drugs that are contraindicated with Incivek include alfuzosin, rifampin, ergot derivatives, cisapride, St. John's wort, atorvastatin, lovastatin, simvastatin, pimozi, sildenafil or tadalafil (when used for pulmonary arterial hypertension [PAH]), orally administered midazolam and triazolam. Incivek may increase serum levels of immunosuppressants such as cyclosporine, sirolimus, and tacrolimus; anticipate significant dose reduction and prolongation of dosing interval of immunosuppressants for transplant patients that are taking Incivek.

If no, do not approve.

DENIAL TEXT: Renewal requires HCV RNA level/viral load of less than 1,000 IU/mL at 4 weeks of telaprevir therapy.

CLINICAL SPECIALISTS: If HCV RNA level greater than 1,000 IU/mL at week 4, triple therapy will be discontinued at this time. Review the prior authorization history and close peginterferon PA (and ribavirin PA, if applicable).

CLINICAL SPECIALISTS: Please review peginterferon/ribavirin dosing regimens:

-) For treatment-naïve and prior relapse patients with undetectable HCV-RNA at weeks 4 and 12, dual therapy is for a total treatment duration of 24 weeks.
-) For treatment-naïve and prior relapse patients with detectable (1,000 IU/mL or less) HCV-RNA at weeks 4 and/or 12, dual therapy is for a total duration of 48 weeks.
-) For prior partial and null responder patients dual therapy is for a total duration of 48 weeks.
-) For treatment-naïve patients with cirrhosis who have undetectable HCV-RNA levels at week 4 and 12, dual therapy for a total duration of 48 weeks would be beneficial.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****TELAPREVIR**

From the Incivek package insert (Vertex):

Table 1: Recommend Treatment Duration (See also Table 2 for Treatment Futility Rules)

Treatment-Naïve and Prior Relapse Patients			
HCV RNA*	Triple Therapy INCIVEK, peginterferon alfa and ribavirin	Dual Therapy Peginterferon alfa and ribavirin	Total Treatment Duration
Undetectable (Target Not Detected) at Weeks 4 and 12	First 12 weeks	Additional 12 weeks	24 weeks
Detectable (1000 IU/mL or less) at Weeks 4 and/or 12	First 12 weeks	Additional 36 weeks	48 weeks
Prior Partial and Null Responder Patients			
	Triple Therapy INCIVEK, peginterferon alfa and ribavirin	Dual Therapy Peginterferon alfa and ribavirin	Total Treatment Duration
All Patients	First 12 weeks	Additional 36 weeks	478 weeks

*In clinical trials, HCV RNA in plasma was measured using a COBAS® TaqMan® assay with a lower limit of quantification of 25 IU/mL and a limit of detection of 10 IU/mL. See *Laboratory Tests (5.6)* for a description of HCV-RNA assay recommendations.

Table 2: Treatment Futility Rules: All Patients

HCV RNA	Action
Week 4 or Week 12: Greater than 1000 IU/mL	Discontinue INCIVEK and peginterferon alfa and ribavirin (INCIVEK treatment complete at 12 weeks)
Week 24: Detectable	Discontinue peginterferon alfa and ribavirin

If peginterferon alfa or ribavirin is discontinued for any reason, INCIVEK must also be discontinued.

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TELAPREVIR

RATIONALE

Ensure appropriate utilization of telaprevir based on FDA approved indication.

FDA APPROVED INDICATIONS

Incivek, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve (patients who have not received interferon-based drug therapy for their infection) or who have previously been treated with interferon-based treatment and not responded adequately, including prior null responders, partial responders, and relapsers.

FDA APPROVED DOSAGE

Incivek 1125mg (three 375mg tablets) orally twice daily is added to peginterferon alfa and ribavirin for the first twelve weeks of therapy.

OTHER INFORMATION

Currently AASLD treatment guidelines recommend that any use of telaprevir in HIV co-infected or transplant populations infected with HCV should be done with caution and under close clinical monitoring. A clinical trial evaluating use of telaprevir triple therapy in HCV/HIV co-infected patients showed significantly higher rates of SVR than in patients treated with peginterferon/ribavirin alone.

Note on HCV RNA levels defined by lab as undetectable versus detectable but not quantifiable: Commercially available quantitative HCV RNA assays may have differing limits for quantification and detection. The lower limit of detection is 10 or 50 IU/mL HCV RNA (depends on assay used by lab). The FDA suggests that labs testing HCV RNA levels for patients taking protease inhibitors must use an assay with a lower limit of quantification of 25 IU/mL or less, and a lower limit of detection of 10-15 IU/mL. Generally, patients with detectable but not quantifiable levels of HCV RNA will have lower SVR rates with triple therapy; a detectable but not quantifiable HCV RNA level should not be considered equivalent to an undetectable level. When the product package insert (or MedImpact PA guideline) specifies 'undetectable HCV RNA level', generally an undetectable HCV RNA result is required.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TELAPREVIR

REFERENCES

-) Arora S, Thornton K, Murata G, et al. Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers. NEJM 364; 23: 2199-2207.
-) Dietrich D, et al. 19th Conference on Retroviruses and Opportunistic Infections (CROI): Abstract 47: Presented March 6, 2012.
-) Ghany M, Nelson D, Strader D, Thomas D, and Seeff L. An Update on Treatment of Genotype I Chronic Hepatitis C Virus Infection: 2011 Practice Guidelines by the American Association for the Study of Liver Diseases. Hepatology 2011; 54 (4): 1433-1443. Accessed online March 9, 2012 at: <http://www.aasld.org/practiceguidelines/Documents/2011UpdateGenotype1HCVbyAASLD24641.pdf>
-) Harrington P, Zeng W, and Naeger L. Clinical relevance of detectable but not quantifiable hepatitis C virus RNA during boceprevir or telaprevir treatment. Hepatology 2012; Apr 55 (4): 1048-1057.
-) Vertex Pharmaceuticals. Incivek package insert. Cambridge, MA. May 2011.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/14

Created: 05/11

Client Approval: 03/14

P&T Approval: 02/14



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TELOTRISTAT

Generic	Brand	HICL	GCN	Exception/Other
TELOTRISTAT	XERMELO	44132		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea and meet **ALL** of the following criteria?
 -) The medication will be used in combination with a somatostatin analog (e.g., octreotide)
 -) The patient is 18 years of age or older
 -) The medication is being prescribed by or given in consultation with an oncologist or gastroenterologist
 -) Documentation that the patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
 -) Physician attestation that the patient's diarrhea is inadequately controlled as defined by the presence of at least four bowel movements per day

If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **TELOTRISTAT (Xermelo)** requires a diagnosis of carcinoid syndrome diarrhea. In addition, the following criteria must be met:

-) The medication will be used in combination with a somatostatin analog (e.g., octreotide)
-) The patient is 18 years of age or older
-) The medication is being prescribed by or given in consultation with an oncologist or gastroenterologist
-) Documentation that the patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
-) Physician attestation that the patient's diarrhea is inadequately controlled as defined by the presence of at least four bowel movements per day

RATIONALE

Promote appropriate utilization of **TELOTRISTAT (Xermelo)** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TELOTRISTAT

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dosage of Xermelo in adult patients is 250 mg three times daily for patients whose diarrhea is inadequately controlled by SSA therapy. Take Xermelo with food. When short-acting octreotide is used in combination with Xermelo, administer short-acting octreotide at least 30 minutes after administering Xermelo.

AVAILABLE STRENGTHS

Tablets: 250 mg

REFERENCES

-) Xermelo [Prescribing Information]. The Woodlands, Texas. Lexicon Pharmaceuticals, Inc; February 2017.
-) Kulke MH, Hörsch D, Caplin M, et al. Telotristat Ethyl, a Tryptophan Hydroxylase Inhibitor for the Treatment of Carcinoid Syndrome. *J Clin Oncol*. 2017 Jan; 35(1):14-23.
-) Kulke MH, Shah M, Benson A, et al. Neuroendocrine Tumors. NCCN Clinical Practice Guidelines in Oncology. Updated February 21, 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/17

Created: 03/17

Client Approval: 05/17

P&T Approval: 04/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TEMOZOLOMIDE - PO

Generic	Brand	HICL	GCN	Exception/Other
TEMOZOLOMIDE - PO	TEMODAR - PO		92903 92893 92933 92913 98310 98311	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have one of the following diagnoses: metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC)?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC).

RATIONALE

Based on FDA approved indications and NCCN recommendations. Temodar is approved for the treatment of newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment; and refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine. NCCN recommends Temodar for SCLC patients with relapse <2-3 months, performance status 0-2 or relapse >2-3 up to 6 months (most useful if brain metastases are present); and for the treatment of metastatic melanoma. NCCN considers temozolomide to be a systemic therapy option for advanced or metastatic melanoma. No quantity limit is included within this guideline since there are multiple dosing regimens available, all of which are based on body surface area.

FDA APPROVED INDICATIONS

Temodar is an alkylating drug indicated for the treatment of adult patients with:

- 1. Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment.
- 2. Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TEMOZOLOMIDE - PO

REFERENCES

- J National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology Melanoma. (Version 3.2012).
- J National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Small Cell Lung Cancer Version 2.2014. [Online] September 17, 2013. [Cited: September 25, 2013.] http://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf
- J Schering Corporation, a subsidiary of Merck & Co., Inc. Temodar package insert. Whitehouse Station, NJ. February 2011.
- J Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: January 24, 2012].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/27/15

Created: 02/12

Client Approval: 01/15

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TESAMORELIN

Generic	Brand	HICL	GCN	Exception/Other
TESAMORELIN	EGRIFTA	37268		

GUIDELINES FOR USE

1. Is the requested drug being used for the reduction of excess abdominal fat in an HIV-infected patient who has lipodystrophy syndrome?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient currently receiving treatment with a protease inhibitor (PI), PI combination (i.e., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), or an NRTI combination (i.e., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir)?

If yes, **approve for 3 months by HICL with a quantity limit of #60 vials per month.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **TESAMORELIN (Egrifta)** requires that the drug is being used for the reduction of excess abdominal fat in HIV-infected patients who have lipodystrophy syndrome. In addition, patients must be receiving treatment with a protease inhibitor (PI), PI combination (i.e., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), or an NRTI combination (i.e., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir).

RATIONALE

Ensure that tesamorelin is used solely for its FDA approved indication.

FDA APPROVED INDICATION

Tesamorelin is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

REFERENCES

) EMD Serono, Inc. Egrifta package insert. Rockland, MA. November 2010.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TESAMORELIN

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/17

Created: 02/11
Client Approval: 02/17

P&T Approval: 02/11



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TETRABENAZINE

Generic	Brand	HICL	GCN	Exception/Other
TETRABENAZINE	XENAZINE	07350		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the request for a tetrabenazine dosage that exceeds 50mg?

If yes, continue to #2.

If no, continue to #3.

2. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets the following criteria?

) The prescription has been prescribed or recommended by a neurologist

) The patient has been genotyped for CYP2D6 and is identified as an extensive metabolizer (EM) or intermediate metabolizer (IM) of CYP2D6

If yes, **approve for 12 months by GPID with the following quantity limits:**

) **12.5mg tablet: #3 tablets per day**

) **25mg tablet: #4 tablets per day**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of chorea (involuntary movements) associated with Huntington's disease and meets the following criteria?

) The prescription has been prescribed or recommended by a neurologist

If yes, **approve for 12 months by GPID with the following quantity limits:**

) **12.5mg tablet: #3 tablets per day**

) **25mg tablet: #2 tablets per day**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **TETRABENAZINE (Xenazine)** requires a diagnosis of chorea (involuntary movements) associated with Huntington's disease and that the medication has been prescribed or recommended by a neurologist. Request for a tetrabenazine dosage that exceeds 50mg requires that the patient has been genotyped for CYP2D6 and is identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

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TETRABENAZINE

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for tetrabenazine management.

FDA APPROVED INDICATION

Xenazine is indicated for the treatment of chorea associated with Huntington's disease.

DOSAGE

The dose of Xenazine should be individualized.

Dosing Recommendations Up to 50 mg per day

The starting dose should be 12.5 mg per day given once in the morning. After one week, the dose should be increased to 25 mg per day given as 12.5 mg twice a day. Xenazine should be titrated up slowly at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. If a dose of 37.5 to 50 mg per day is needed, it should be given in a three times a day regimen. The maximum recommended single dose is 25 mg. If adverse reactions such as akathisia, restlessness, parkinsonism, depression, insomnia, anxiety or sedation occur, titration should be stopped and the dose should be reduced. If the adverse reaction does not resolve, consideration should be given to withdrawing Xenazine treatment or initiating other specific treatment.

Dosing Recommendations Above 50 mg per day

Patients who require doses of Xenazine greater than 50 mg per day should be first tested and genotyped to determine if they are poor metabolizers (PMs) or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6. The dose of Xenazine should then be individualized accordingly to their status as PMs or EMs.

Extensive and Intermediate CYP2D6 Metabolizers

Genotyped patients who are identified as extensive (EMs) or intermediate metabolizers (IMs) of CYP2D6, who need doses of Xenazine above 50 mg per day, should be titrated up slowly at weekly intervals by 12.5 mg daily, to allow the identification of a tolerated dose that reduces chorea. Doses above 50 mg per day should be given in a three times a day regimen. The maximum recommended daily dose is 100 mg and the maximum recommended single dose is 37.5 mg. If adverse reactions such as akathisia, parkinsonism, depression, insomnia, anxiety or sedation occur, titration should be stopped and the dose should be reduced. If the adverse reaction does not resolve, consideration should be given to withdrawing Xenazine treatment or initiating other specific treatment (e.g., antidepressants).

Poor CYP2D6 Metabolizers

In PMs, the initial dose and titration is similar to EMs except that the recommended maximum single dose is 25 mg, and the recommended daily dose should not exceed a maximum of 50 mg.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TETRABENAZINE

REFERENCES

) Lundbeck Pharmaceuticals, Inc. Xenazine package insert. Deerfield, IL. June, 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/01/16

Created: 02/09

Client Approval: 05/16

P&T Approval: 11/15



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

THALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
THALIDOMIDE	THALOMID	11465		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma?

If yes, continue to #2.

If no, continue to #3.

2. Is Thalomid being used in combination with dexamethasone or prednisone?

If yes, **approve for 12 months by HICL for #1 capsule per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erythema nodosum leprosum (ENL)?

If yes, **approve for 12 months by HICL for #2 capsules per day.**

If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to myelodysplastic syndrome that has been previously treated?

If yes, **approve for 12 months by HICL for #2 capsules per day.**

If no, continue to #5.

5. Does the patient have a diagnosis of Waldenström's Macroglobulinemia?

If yes, **approve for 12 months by HICL for #1 capsule per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of multiple myeloma and that Thalomid is being used in combination with dexamethasone or prednisone; or a diagnosis of erythema nodosum leprosum (ENL); or a diagnosis of anemia due to myelodysplastic syndrome that has been previously treated; or a diagnosis of Waldenström's Macroglobulinemia.

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THALIDOMIDE

RATIONALE

To ensure appropriate use aligned with FDA approved indications and NCCN guidelines.

The FDA approved dose for multiple myeloma is 200mg once daily along with dexamethasone 40mg daily on days 1-4, 9-12, and 17-20 every 28 days. For cutaneous erythema nodosum leprosum the dosage is 100 to 300mg daily and up to 400mg daily for severe cases.

NCCN multiple myeloma treatment guidelines consider primary induction therapy for stem cell transplant candidates with lenalidomide in combination with dexamethasone, and thalidomide in combination with bortezomib and dexamethasone to have the strongest evidence. Other combinations involving bortezomib, lenalidomide or thalidomide are also considered effective. For primary induction therapy for non-transplant candidates in patients with newly diagnosed multiple myeloma, NCCN considers thalidomide and melphalan in combination prednisone, melphalan in combination with prednisone and bortezomib, and lenalidomide in combination with low-dose dexamethasone to have the strongest evidence. Other combinations involving melphalan, lenalidomide or thalidomide are also considered effective. For maintenance therapy following disease response in patients with newly diagnosed multiple myeloma who undergo stem cell transplant, NCCN considers thalidomide monotherapy to have the strongest evidence. Lenalidomide monotherapy, thalidomide in combination with prednisone and interferon monotherapy are also considered effective. For salvage therapy in patients who did not respond to or were ineligible for stem cell transplant, re-induction with the same regimen can be considered if the relapse occurs at greater than 6 months after completion of the initial induction therapy. NCCN considers lenalidomide in combination with dexamethasone to have the best evidence. Other therapies involving lenalidomide, thalidomide or bortezomib may be considered.

The NCCN myelodysplastic syndrome guidelines recognize thalidomide as a non-chemotherapy, low-intensity agent that has demonstrated efficacy in a phase II trial.

NCCN guidelines for Waldenström's Macroglobulinemia state that primary treatment options include oral alkylators, nucleoside analogs, rituximab alone or in combination with cyclophosphamide, bortezomib, nucleoside analogues, thalidomide, or bendamustine.

FDA APPROVED INDICATIONS

Thalomid in combination with dexamethasone is indicated for the treatment of patients with newly diagnosed multiple myelomas. Thalomid is indicated for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL). Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Thalomid is also indicated as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

THALIDOMIDE

REFERENCES

-) Celgene Corporation. Thalomid package insert. Summit, NJ. February 2012.
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Multiple Myeloma. (Version 1.2012).
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. (Version 1.2012).
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Waldenström's Macroglobulinemia / Lymphoplasmacytic Lymphoma. (Version 1.2012).

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/07/13

Created: 08/12

Client Approval: 08/12

P&T Approval: 08/12



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRAMETINIB

Generic	Brand	HICL	GCN	Exception/Other
TRAMETINIB DIMETHYL SULFOXIDE	MEKINIST	40361		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
- ☐ The medication will be used as a single agent **OR** in combination with Tafenlar (dabrafenib)
- ☐ The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafenlar)

If yes, **approve for 12 months by GPID with the following quantity limits:**

- ☐ **2mg tablets (GPID 34727): #30 tablets per 30 days.**
- ☐ **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E mutation as detected by an FDA-approved test
- ☐ The medication will be used in combination with Tafenlar (dabrafenib)

If yes, **approve for 12 months by GPID with the following quantity limits:**

- ☐ **2mg tablets (GPID 34727): #30 tablets per 30 days.**
- ☐ **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of melanoma and meet **ALL** of the following criteria?

- ☐ The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
- ☐ The medication has not previously been used for more than one year
- ☐ The medication will be used in combination with Tafenlar (dabrafenib) in the adjuvant setting
- ☐ There is involvement of lymph node(s), following complete resection
- ☐ The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafenlar)

If yes, **approve for 12 months by GPID with the following quantity limits:**

- ☐ **2mg tablets (GPID 34727): #30 tablets per 30 days.**
- ☐ **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

If no, continue to #4.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRAMETINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) and meet **ALL** of the following criteria?

-)] The patient has BRAF V600E mutation
-)] The medication will be used in combination with Tafenlar (dabrafenib)
-)] The patient has no satisfactory locoregional treatment options available

If yes, **approve for 12 months by GPID with the following quantity limits:**

-)] **2mg tablets (GPID 34727): #30 tablets per 30 days.**
-)] **0.5mg tablets (GPID 34726): #90 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **TRAMETINIB (Mekinist)** requires a diagnosis of unresectable or metastatic melanoma, metastatic non-small cell lung cancer (NSCLC), melanoma, or locally advanced or metastatic anaplastic thyroid cancer (ATC). In addition, the following criteria must be met:

For diagnosis of unresectable or metastatic melanoma, approval requires:

-)] The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
-)] The medication will be used as a single agent **OR** in combination with Tafenlar (dabrafenib)
-)] The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafenlar)

For diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

-)] The patient has BRAF V600E mutation as detected by an FDA-approved test
-)] The medication will be used in combination with Tafenlar (dabrafenib)

For diagnosis of melanoma, approval requires:

-)] The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
-)] The medication has not previously been used for more than one year
-)] The medication will be used in combination with Tafenlar (dabrafenib) in the adjuvant setting
-)] There is involvement of lymph node(s), following complete resection
-)] The patient has not experienced disease progression while on prior BRAF inhibitor therapy (e.g., Zelboraf, Tafenlar)

For diagnosis of locally advanced or metastatic anaplastic thyroid cancer, approval requires:

-)] The patient has BRAF V600E mutation
-)] The medication will be used in combination with Tafenlar (dabrafenib)
-)] The patient has no satisfactory locoregional treatment options available

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRAMETINIB

RATIONALE

Ensure appropriate use of Mekinist based on FDA-approved indications and dosing.

FDA APPROVED INDICATIONS

-) Mekinist is a kinase inhibitor indicated as a single agent or in combination with dabrafenib, for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
-) Mekinist is used in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection
-) Mekinist is used in combination with dabrafenib, for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
-) Mekinist is used in combination with dabrafenib, for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options

Limitation of use: Mekinist is not indicated for treatment of patients with melanoma who have progressed on prior BRAF-inhibitor therapy.

DOSAGE AND ADMINISTRATION

Confirm the presence of BRAF V600E or BRAF V600K mutation in tumor specimens prior to initiation of treatment with Mekinist and dabrafenib.

Unresectable or Metastatic Melanoma: The recommended dose is 2 mg orally taken once daily as a single agent or in combination with dabrafenib, until disease progression or unacceptable toxicity.

NSCLC: The recommended dose is 2 mg orally taken once daily in combination with dabrafenib, until disease recurrence or unacceptable toxicity.

Melanoma: The recommended dose is 2 mg orally taken once daily in combination with dabrafenib, until disease recurrence or unacceptable toxicity for up to 1 year.

Locally advanced or metastatic ATC: The recommended dose is 2 mg orally taken once daily in combination with dabrafenib, until disease recurrence or unacceptable toxicity.

Recommended Dose Reductions For Adverse Reactions Associated with MEKINIST

Action	Recommended Dosage
First Dose Reduction	1.5 mg orally once daily
Second Dose Reduction	1 mg orally once daily
Subsequent Modification	Permanently discontinue if unable to tolerate MEKINIST 1 mg orally once daily

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRAMETINIB

REFERENCES

) Mekinist [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/15/18

Created: 07/13

Client Approval: 05/18

P&T Approval: 07/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TREPROSTINIL

Generic	Brand	HICL	GCN	Exception/Other
TREPROSTINIL SODIUM	REMODULIN	23650		
TREPROSTINIL	TYVASO	36537 36539 36541		
TREPROSTINIL	ORENITRAM	40827		

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

REMODULIN

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
 -) The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III to IV symptoms
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) The patient had a previous trial of or contraindication to a phosphodiesterase-5 inhibitor (e.g., Adcirca or Revatio) **OR** an endothelin receptor antagonist (e.g., Tracleer, Letairis, Opsumit)
 -) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **TREPROSTINIL (Remodulin)** requires a diagnosis of pulmonary arterial hypertension. In addition, the following criteria must also be met:

-) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood unit

(Remodulin initial denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TREPROSTINIL

INITIAL CRITERIA - REMODULIN (CONTINUED)

-)] The patient has NYHA-WHO Functional Class III to IV symptoms
-)] The patient had a previous trial of or contraindication to a phosphodiesterase-5 inhibitor (e.g., Adcirca or Revatio) or an endothelin receptor antagonist (e.g., Tracleer, Letairis, Opsumit)

TYVASO

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
 -)] The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -)] Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 -)] Mean pulmonary artery pressure (PAP) of 25 mmHg
 -)] Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 -)] Pulmonary vascular resistance (PVR) > 3 Wood units
 -)] The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III to IV symptoms

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **TREPROSTINIL (Tyvaso)** requires a diagnosis of pulmonary arterial hypertension. In addition, the following criteria must also be met:

-)] The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-)] Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 -)] Mean pulmonary artery pressure (PAP) of 25 mmHg
 -)] Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 -)] Pulmonary vascular resistance (PVR) > 3 Wood units
-)] The patient has NYHA-WHO Functional Class III to IV symptoms

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TREPROSTINIL

INITIAL CRITERIA (CONTINUED)

ORENITRAM

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 -) Mean pulmonary artery pressure (PAP) of 25 mmHg
 -) Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 -) Pulmonary vascular resistance (PVR) > 3 Wood units
 -) The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms
 -) The patient does not have severe hepatic impairment
 -) The patient has tried a preferred formulary phosphodiesterase-5 inhibitor (e.g., sildenafil [generic for Revatio] or Adcirca [tadalafil]) **OR** an endothelin receptor antagonist (e.g., Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **TREPROSTINIL (Orenitram)** requires a diagnosis of pulmonary arterial hypertension. In addition, the following criteria must also be met:

-) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
-) The patient has NYHA-WHO Functional Class II to IV symptoms
-) The patient does not have severe hepatic impairment
-) The patient has tried a preferred formulary phosphodiesterase-5 inhibitor (e.g., sildenafil [generic for Revatio] or Adcirca [tadalafil]) **OR** an endothelin receptor antagonist (e.g., Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TREPROSTINIL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
 -) The patient has shown improvement or has remained stable from baseline in the 6-minute walk distance test
 -) The patient's World Health Organization (WHO) functional class has improved or remained stable

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Is the request for Tyvaso or Orenitram?

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Is the request for Remodulin and the patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline named **TREPROSTINIL (Remodulin, Tyvaso, Orenitram)** requires for renewal a diagnosis of pulmonary arterial hypertension. In addition, the following criteria must also be met:

-) The patient has shown improvement or has remained stable from baseline in the 6-minute walk distance test
-) The patient's World Health Organization (WHO) functional class has improved or remained stable

Requests for treprostinil (Remodulin) also require that the patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms

RATIONALE

Ensure appropriate use of Remodulin, Tyvaso and Orenitram.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TREPROSTINIL

FDA APPROVED INDICATION

Remodulin

Remodulin is indicated as a continuous subcutaneous infusion or intravenous infusion for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise. Although injectable treprostinil is FDA-approved for use in functional class II patients, it would rarely be recommended for these patients due to its complex administration, cost, safety concerns and adverse effects. Thus, a trial of an oral Phosphodiesterase-5 inhibitor or an Endothelin receptor antagonist is required prior to approval for functional class II PAH.

Tyvaso

Tyvaso is indicated to increase walk distance in patients with WHO Group I pulmonary arterial hypertension and NYHA Class III symptoms.

Orenitram

Orenitram is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%).

When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this. Orenitram is probably most useful to replace subcutaneous, intravenous, or inhaled treprostinil, but this use has not been studied.

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (e.g. diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TREPROSTINIL

REFERENCES

-) United Therapeutics. Remodulin package insert. Research Triangle Park, NC. January 2010.
-) Badesch D, Abman S, Simonneau G, Rubin L, and McLaughlin V. American College of Chest Physicians Evidence Based Clinical Practice Guidelines: Medical Therapy for Pulmonary Arterial Hypertension. Chest 2007; 131: 1917-1928. Available at: <http://chestjournal.chestpubs.org/content/131/6/1917.full.pdf+html> [Accessed December 23, 2010].
-) Barst R, Gibbs, S, Ghofrani H, Hooper M, et al. Updated Evidence Based Treatment Algorithm in Pulmonary Arterial Hypertension. Journal of American College of Cardiology 2009; 54; S78-S84. Available at: http://content.onlinejacc.org/cgi/reprint/54/1_Suppl_S/S78.pdf [Accessed January 17, 2011].
-) United Therapeutics. Tyvaso package insert. Research Triangle Park, NC. Available at: <http://tyvaso.com/pdf/tyvasopi.pdf> [Accessed December 2010].
-) United Therapeutics. Orenitram Package Insert. Research Triangle Park, NC. December 2013.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 09/05

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRIENTINE

Generic	Brand	HICL	GCN	Exception/Other
TRIENTINE	SYPRINE	01109		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a known family history of Wilson's disease or physical examination consistent with Wilson's disease and meet **ONE** of the following criteria?
 - ☐ Plasma copper-protein ceruloplasmin less than 20mg/dL
 - ☐ Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
 - ☐ Diagnosis has been confirmed by genetic testing for ATP7B mutations

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
 - ☐ The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
 - ☐ The medication is prescribed by or given in consultation with a hepatologist
 - ☐ The patient has had a previous trial of or contraindication to Depen (penicillamine)

If yes, **approve for 12 months by HICL with a quantity limit of #8 capsules per day.**

APPROVAL TEXT: Renewal requires a diagnosis of Wilson's disease.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **TRIENTINE (Syprine)** will allow for approval for patients with a known family history of Wilson's disease or physical examination consistent with Wilson's disease and who meet ONE of the following criteria:

- ☐ Plasma copper-protein ceruloplasmin less than 20mg/dL
- ☐ Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
- ☐ Diagnosis has been confirmed by genetic testing for ATP7B mutations

In addition, the following criteria must also be met:

- ☐ The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
- ☐ The medication is prescribed by or given in consultation with a hepatologist
- ☐ The patient has had a previous trial of or contraindication to Depen (penicillamine)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRIENTINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease?

If yes, **approve for 12 months by HICL with a quantity limit of #8 capsules per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TRIENTINE (Syprine)** will allow for renewal for patients with a diagnosis of Wilson's disease.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Syprine.

REFERENCES

) Syprine [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals. June 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 08/16

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

URIDINE TRIACETATE

Generic	Brand	HICL	GCN	Exception/Other
URIDINE TRIACETATE	XURIDEN		39481	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of hereditary orotic aciduria as confirmed by **ALL** of the following criteria?
 -) Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
 -) Patient has an elevated urinary orotic acid level according to an age-specific reference range

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at end of the guideline.

2. Is this medication being prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases?

If yes, **approve for 6 months by GPID up to #4 packets per day.**

APPROVAL TEXT: Renewal requires that the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) has stabilized or improved from baseline while on treatment with uridine triacetate.

If no, do not approve.

DENIAL TEXT: The guideline named **URIDINE TRIACETATE (Xuriden)** requires a diagnosis of hereditary orotic aciduria as confirmed by the presence of a mutation in the uridine monophosphate synthase (UMPS) gene and elevated urinary orotic acid levels according to an age-specific reference range. In addition, the medication must be prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases.

RENEWAL CRITERIA

1. Has the patient's age dependent hematologic parameters (e.g., neutrophil count, neutrophil percent, white blood cell count, mean corpuscular volume) stabilized or improved from baseline while on treatment with uridine triacetate?

If yes, **approve for 12 months by GPID up to #4 packets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **URIDINE TRIACETATE (Xuriden)** requires improvement from baseline or stabilized hematologic parameters while on treatment with uridine triacetate for renewal.

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URIDINE TRIACETATE

RATIONALE

Promote appropriate utilization of **URIDINE TRIACETATE** based on FDA approved indication.

Xuriden (uridine triacetate) is the first FDA-approved treatment for patients with hereditary orotic aciduria (HOA), an ultra-rare metabolic disorder affecting approximately 20 patients worldwide. HOA is caused by a defect in uridine-5'-monophosphate (UMP) synthase, an enzyme which converts orotic acid to UMP, a pyrimidine nucleotide. When patients lack UMP synthase, they are unable to synthesize pyrimidine nucleotides and accumulate orotic acid that otherwise would have been converted to UMP and excreted in the urine. Xuriden provides uridine for patients with HOA who cannot synthesize sufficient quantities of uridine. Prior to the approval of Xuriden, HOA was treated with oral uridine monophosphate, a similar pyrimidine analog.

Pyrimidines are heterocyclic organic compounds that are crucial for key functions in cell physiology. Pyrimidines form nucleotides that supply the building blocks for DNA (cytosine and thymine) and RNA (cytosine and uracil). Additionally, pyrimidine-activated sugars are involved in the synthesis of polysaccharides and phospholipids, glycosylation of proteins and lipids, and vasoregulation of novel endothelium-derived vasoactive compounds. Pyrimidine nucleotide synthesis occurs either by the de novo pathway (built from simple precursor molecules) or by the salvage pathway (recycled from the degradation of other compounds).

Signs and symptoms of HOA include the following:

-) Blood abnormalities (e.g., anemia, decreased white blood cell and neutrophil counts) due to instability of red blood cells (RBC) and white blood cells (WBC) from lack of pyrimidine nucleotides
-) Urinary tract obstruction due to the formation of orotic acid crystals in the urinary tract
-) Developmental delays and failure to thrive
-) Congenital malformations and immune deficiencies (in rare instances)

Disorders of pyrimidine metabolism are often misdiagnosed or remain undiagnosed due to limited clinical awareness and considerable variability in disease presentation. Unfortunately, there are no readily measurable end products that can be used to screen for HOA. Macrocytic hypochromic megaloblastic anemia refractory to standard therapies (e.g., iron, folic acid, B12) and elevated levels of urinary orotic acid and orotidine should alert providers to evaluate for HOA.

Xuriden is an acetylated prodrug of uridine. Following oral administration, esterase enzymes deacetylate Xuriden to yield uridine, which is then utilized for nucleotide synthesis, thereby reducing the accumulation and urinary excretion of orotic acid. Because of the lipophilic properties of its triacetate form, Xuriden crosses the gastrointestinal mucosa more readily than uridine monophosphate, resulting in eight-fold higher bioavailability.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

URIDINE TRIACETATE

EFFICACY

The efficacy of Xuriden was evaluated in a single open-label study in four patients with HOA (3 males, 1 female; age range 3 – 19 years old). The study assessed changes in the patients' pre-specified hematologic parameters during the 6-week trial period. The primary endpoint was stability of a pre-specified hematologic parameter for the three patients who were previously receiving treatment with oral uridine (Patients 1, 2, and 3), whereas the primary endpoint was improvement in the hematologic parameter for the treatment-naïve patient (Patient 4). The pre-specified hematologic parameters were neutrophil count and percent neutrophils (Patient 1), WBC count (Patient 2), and mean corpuscular volume (Patients 3 and 4). Secondary endpoints were urine orotic acid and orotidine levels, and growth (height and weight) for all four patients.

After six weeks of treatment, Patients 1 and 3 met the pre-specified criteria for stability of the hematologic parameter. When Patient 2 was switched from uridine to Xuriden, the pre-specified criteria for WBC count remained stable; however documentation of a low WBC count prior to uridine initiation was not available. Patient 4 did not meet the pre-specified endpoint of improvement of the hematologic parameter. Table 1 summarizes the primary efficacy results from the study.

Table 1. Primary Efficacy Results [from Xuriden Prescribing Information]

Patient	Pre-specific hematologic parameter (age-specific reference range)	Primary endpoint	Baseline (day 0)	Week 6 (day 42)	% change from baseline
Patient 1	Neutrophil count (1.5-8.0 x 10 ³ /mm ³)	Stable hematologic value	0.95	0.81	-15%
	Neutrophil % (26-48%)		21	23	10%
Patient 2	White blood cell count (3.8-10.6 x 10 ⁹ /L)	Stable hematologic value	7.8	7.4	-5%
Patient 3	Mean corpuscular volume (75-91 fL)	Stable hematologic value	109.9	108.5	-1%
Patient 4	Mean corpuscular volume (72-90 fL)	Improved hematologic value	114.6	113.4	-2%

The treatment effect of Xuriden on growth was assessed in the three pediatric patients (Patients 1, 3, and 4). For Patients 1 and 4, weight and height measurements at baseline were at or below the lower limit of normal for age (below 5th percentile for age); height and weight measurements were within the normal range for age for Patient 3. After 6 months of treatment, Patients 1 and 3 experienced improved weight growth, as reflected in increases in their weight-for-age percentiles and weight velocity percentiles; Patient 4's weight growth remained stable (i.e., weight percentile for age and weight velocity percentile for age was unchanged). Height growth remained stable in all three patients (i.e., height percentiles for age and height velocity percentiles for age were unchanged).

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

URIDINE TRIACETATE

EFFICACY (CONTINUED)

During an extension phase of the trial, patients continued to receive Xuriden. Dosing during the extension phase ranged from 60 mg/kg to 120 mg/kg once daily. After six months of treatment, the neutrophil count and neutrophil percent values normalized in Patient 1; hematologic parameters for the other three patients remained stable. Orotic acid and orotidine levels also remained stable for all four patients.

SAFETY

There are no contraindications or warnings and precautions for Xuriden treatment.

The safety of Xuriden was assessed in four patients with HOA ranging in age from 3 to 19 years (3 male, 1 female) who received 60 mg/kg of Xuriden once daily for six weeks. The patients continued to receive Xuriden for at least nine months at dosages of up to 120 mg/kg once daily. No adverse reactions were reported with Xuriden.

There are no available data on Xuriden use in pregnant women. When administered orally to pregnant rats during the period of organogenesis, Xuriden at doses similar to the maximum recommended human dose (MRHD) of 120 mg/kg per day was not teratogenic and did not produce adverse effects on embryo-fetal development. There are no data on the presence of Xuriden in human milk, the effect on the breastfed infant, or the effect on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Xuriden and any potential adverse effects on the breastfed infant from Xuriden or from the underlying maternal condition.

DOSAGE

The recommended starting dose of Xuriden is 60 mg/kg once daily. The dose may be increased to 120 mg/kg once daily (not to exceed 8 grams per day) for insufficient efficacy, which may be evidenced by one of the following:

-] Levels of orotic acid in urine remain above normal or increase above the usual or expected range
-] Laboratory values (e.g., RBC or WBC indices) affected by HOA show evidence of worsening
-] Worsening of other signs or symptoms of the disease

Each 2 gram packet of Xuriden contains approximately $\frac{3}{4}$ teaspoon of Xuriden. Please refer to prescribing information for dosing tables. The tables provide gram and teaspoon dosing guidance with regards to the 60 mg/kg and 120 mg/kg daily doses.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****URIDINE TRIACETATE****DOSAGE (CONTINUED)**

Doses should be measured using either a scale accurate to at least 0.1 gram or a graduated teaspoon accurate to the fraction of the dose to be administered. Xuriden should be mixed with soft food (e.g., applesauce, pudding, yogurt), but the granules should not be chewed. Xuriden may also be mixed with milk or infant formula. Any unused granules from an opened packet should be discarded after the dose has been measured. If a patient requires a dose in multiples of 2 grams ($\frac{3}{4}$ teaspoon), an entire packet(s) may be administered without weighing or measuring.

FDA APPROVED INDICATION

Xuriden (uridine triacetate) is a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria.

REFERENCES

-) Xuriden [Prescribing Information]. Gaithersburg, MD: Wellstat Therapeutics Corporation. September 2015.
-) FDA. [Press Release]. FDA approves new orphan drug to treat rare autosomal recessive disorder. Available at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm457867.htm>. Updated September 4, 2015.
-) Balasubramaniam S, Duley JA, Christodoulou J. Inborn errors of pyrimidine metabolism: clinical update and therapy. *J Inherit Metab Dis* 2014;37:687-98.
-) McEvilly M, Popelas C, Tremmel B. Use of uridine triacetate for the management of fluorouracil overdose. *AJHP* 2011;68:1806-09.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/31/17

Created: 02/16

Client Approval: 09/17

P&T Approval: 05/16



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VANDETANIB

Generic	Brand	HICL	GCN	Exception/Other
VANDETANIB	CAPRELSA	37531		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient currently stable on the requested medication?

If yes, **approve for 12 months by GPID as follows:**

) If the request is for 300mg tablets: **#1 tablet per day.**

) If the request is for 100mg tablets: **for up to #2 tablets per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #2.

2. Does the patient have diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease?

If yes, **approve for 12 months by GPID as follows:**

) If the request is for 300mg tablets: **#1 tablet per day.**

) If the request is for 100mg tablets: **for up to #2 tablets per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.

RATIONALE

Ensure appropriate utilization of vandetanib based on FDA approved indication and NCCN guidelines. Vandetanib is recommended as an option for the treatment of recurrent or persistent medullary thyroid carcinoma.

FDA APPROVED INDICATIONS

Vandetanib is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VANDETANIB

REFERENCES

-) AstraZeneca Pharmaceuticals LP. Vandetanib package insert. Wilmington, DE. April 2011.
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. (Version 2.2011).
-) Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: June 22, 2011].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 05/11

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VEMURAFENIB

Generic	Brand	HICL	GCN	Exception/Other
VEMURAFENIB	ZELBORAF	37837		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet the following criterion?

) The patient has a genetic mutation called BRAF V600E as detected by an FDA-approved test

If yes, **approve for 12 months with a quantity limit of #8 tablets per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease and meet the following criterion?

) The patient has a genetic mutation called BRAF V600

If yes, **approve for 12 months with a quantity limit of #8 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **VEMURAFENIB (Zelboraf)** requires a diagnosis of unresectable or metastatic melanoma with a BRAF V600E mutation as detected by an FDA-approved test or Erdheim-Chester Disease with a BRAF V600 mutation.

RATIONALE

Ensure appropriate use of vemurafenib based on FDA approved indication.

FDA APPROVED INDICATIONS

Zelboraf is a kinase inhibitor indicated for:

-) Treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
-) Treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation

Limitation of Use: Zelboraf is not recommended for use in patients with wild-type BRAF melanoma.

DOSAGE AND ADMINISTRATION

Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with ZELBORAF.

Recommended dose: 960 mg orally twice daily taken approximately 12 hours apart with or without a meal.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VEMURAFENIB

REFERENCES

) Genentech, Inc. Zelboraf package insert. South San Francisco, CA. November 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 12/01/17

Created: 08/11

Client Approval: 11/17

P&T Approval: 01/18



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VISMODEGIB

Generic	Brand	HICL	GCN	Exception/Other
VISMODEGIB	ERIVEDGE	38455		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic basal cell carcinoma?

If yes, **approve for 12 months with a quantity limit of #1 capsule per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or is the patient not a candidate for surgery or radiation?

If yes, **approve for 12 months with a quantity limit of #1 capsule per day.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic basal cell carcinoma or locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation.

RATIONALE

To promote appropriate utilization of Erivedge based on its FDA approved indication.

Vismodegib is an inhibitor of the Hedgehog signaling pathway. This pathway is important in embryonic development and becomes reactivated in cancer. Because this pathway is not required in most adult tissues, inhibitors selectively attack tumor cells. Vismodegib is the first drug approved for advanced BCC. BCC is the most common type of skin cancer and is typically localized, slow-growing and painless. Localized disease is usually curable by surgery and radiation treatment. Advanced disease is more deadly and has no other FDA approved treatment options.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VISMODEGIB

RATIONALE (CONTINUED)

A single-arm, open-label trial was conducted in patients with either mBCC (n=33) or laBCC (n=71) who received 150mg vismodegib daily until disease progression or unacceptable toxicity. Objective response rates were 30.3% for mBCC and 42.9% for laBCC. No mBCC patients achieved complete response, while 20.6% of laBCC patients had a complete response. Median response duration was 7.6 months for both mBCC and laBCC.

The common adverse reactions are muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia.

There is a **black box warning** for embryo-fetal death and severe birth defects. Pregnancy Category D.

Dosage: One 150mg capsule once daily with or without food.

FDA APPROVED INDICATION

Erivedge is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

REFERENCES

) Genentech, Inc. Erivedge package insert. South San Francisco, CA. January 2012.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/12

Client Approval: 11/13

P&T Approval: 11/13



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BRENTUXIMAB VEDOTIN	ADCETRIS	37879		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of classical Hodgkin lymphoma and meet **ONE** of the following criteria?

-) Has failed an autologous hematopoietic stem cell transplant (auto-HSCT)
-) Has failed at least two multi-agent chemotherapy regimens (potential regimens include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of classical Hodgkin lymphoma and is considered high risk for relapse or disease progression post-auto-HSCT, as defined according to status following frontline therapy: refractory, relapse within 12 months, or relapse 12 months with extranodal disease?

If yes, continue to #4.

If no, continue to #5.

4. Did the patient obtain a complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy?

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of relapsed systemic anaplastic large cell lymphoma (sALCL) and meet the following criterion?

) Has failed at least one multi-agent chemotherapy regimen (potential regimens include but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #6.

6. Does the patient have a diagnosis of systemic anaplastic large cell lymphoma (sALCL) OR other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, and meet ALL of the following criteria?

) The patient has not received treatment for sALCL or other CD30-expressing PTCL
) The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

If yes, **approve for 12 months with a total fill count of 8 and a quantity limit of #4 vials per 21 days.**

If no, continue to #7.

7. Does the patient have a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) **AND** meet the following criterion?

) The patient has received prior systemic therapy

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #8.

8. Does the patient have a diagnosis of Stage III or IV classical Hodgkin lymphoma (cHL) and meet **ALL** of the following criteria?

) The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
) The patient has not received treatment for Stage III or IV classical Hodgkin lymphoma (cHL)

If yes, **approve for 12 months with a total fill count of 12 and a quantity limit of #3 vials per 14 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **BRENTUXIMAB (Adcetris)** requires a diagnosis of classical Hodgkin lymphoma, Stage III or IV classical Hodgkin lymphoma (cHL), systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), primary cutaneous anaplastic large cell lymphoma (pcALCL), or CD30-expressing mycosis fungoides (MF). In addition, the patient must be 18 years of age or older. The following criteria must also be met:

For the diagnosis of classical Hodgkin lymphoma, approval requires ONE of the following:

-) The patient has failed autologous hematopoietic stem cell transplant (auto-HSCT)
-) The patient has failed at least two multi-agent chemotherapy regimens (potential regimens include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])
-) The patient is considered high risk of relapse or disease progression post-auto-HSCT **AND** the patient has obtained complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy

For the diagnosis of relapsed systemic anaplastic large cell lymphoma (sALCL), approval requires:

-) The patient has failed at least one multi-agent chemotherapy regimen (potential regimens include but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

For the diagnosis of systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, approval requires:

-) The patient has not received treatment for sALCL or other CD30-expressing PTCL
-) The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

For the diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), approval requires:

-) The patient has received prior systemic therapy

For the diagnosis of Stage III or IV classical Hodgkin lymphoma (cHL), approval requires:

-) The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
-) The patient has not received treatment for Stage III or IV classical Hodgkin lymphoma (cHL)

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

BRENTUXIMAB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcetris.

REFERENCES

) Adcetris [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/10/18

Created: 09/11

Client Approval: 11/18

P&T Approval: 01/19



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

CEMPIPLIMAB-RWLC (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
CEMPIPLIMAB-RWLC	LIBTAYO	45284		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) and meet the following criteria?

) The patient is not a candidate for curative surgery or curative radiation

If yes, **approve for 12 months by HICL with a quantity limit of 7ml (1 vial) per 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CEMPIPLIMAB-RWLC (Libtayo)** requires a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) in patients who are not candidates for curative surgery or curative radiation.

RATIONALE

For further information, please refer to the Prescribing Information for Libtayo.

REFERENCES

-) Libtayo [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/08/18

Created: 10/18

Client Approval: 10/18

P&T Approval: 10/18



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

CONTOUR TEST STRIPS (INSULIN PUMP)

Generic	Brand	HICL	GCN	NDC
BLOOD SUGAR DIAGNOSTIC BLOOD SUGAR DIAGNOSTIC, DISC BLOOD SUGAR DIAGNOSTIC, DRUM	CONTOUR TEST STRIPS			193730850, 193708050 193709021, 193182050 193731025, 193731150 193731221, 193707025

CSR NOTE: Requests for blood glucose (diabetic) test strips manufactured by Kroger and Roche (Accu-Chek) will adjudicate at the point of service with no restrictions. Contour test strips will require prior authorization.

GUIDELINES FOR USE

1. Does the patient require the use of CONTOUR blood glucose test strips based on his/her use of a companion insulin pump?

If yes, **approve open-ended by GPID.**

APPROVAL TEXT: Your request for a non-preferred blood glucose test strip has been approved.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **CONTOUR TEST STRIPS** requires that this product is only covered for patients who have a companion insulin pump. The preferred meters and test strips are by Kroger or Roche (Accu-Chek). Your physician did not indicate that you are using this product with a companion insulin pump and therefore your request was not approved.

RATIONALE

The intent of this prior authorization is to encourage the use of cost-effective formulary preferred glucose testing strips before considering coverage of non-preferred alternatives.

FDA APPROVED INDICATIONS

REFERENCES

- 1 Drug Facts and Comparisons (online version), Blood Glucose Meters. Available at <http://online.factsandcomparisons.com>.
- 2 American Diabetes Association. Standards of Medical Care in Diabetes- 2017. Diabetes Care 2017; 40 (suppl 1): S11-S135.

Library	Commercial	NSA
Yes	Yes	No

Commercial Effective: 01/1/18

Client Approval: 01/18

P&T Approval: 01/18



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

LACOSAMIDE

Generic	Brand	HICL	GCN	Exception/Other
LACOSAMIDE	VIMPAT	35872		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of partial-onset seizures **AND** meet the following criterion?
J The patient has had a trial of or contraindication to at least **TWO** of the following: divalproex, valproic acid, gabapentin, lamotrigine, oxcarbazepine, carbamazepine, levetiracetam, levetiracetam ER, topiramate or zonisamide

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vimpat injection **AND** the patient is 17 years of age or older?

If yes, **approve for one time by GPID (14344) with a quantity limit of #2 vials per day for up to 5 days.**

If no, continue to #3.

3. Is the request for Vimpat tablets or oral solution **AND** the patient is 4 years of age or older?

If yes, **approve for 12 months by GPID for all of the following:**

- J **Vimpat 50mg tablets (GPID 14338): #2 tablets per day.**
- J **Vimpat 100mg tablets (GPID 14339): #2 tablets per day.**
- J **Vimpat 150mg tablets (GPID 14341): #2 tablets per day.**
- J **Vimpat 200mg tablets (GPID 14342): #2 tablets per day.**
- J **Vimpat 10mg/mL oral solution (GPID 28643): #40 mL per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **LACOSAMIDE (Vimpat)** requires a diagnosis of partial-onset seizures. The patient also must have had a trial of or contraindication to at least two of the following: divalproex, valproic acid, gabapentin, lamotrigine, oxcarbazepine, carbamazepine, levetiracetam, levetiracetam ER, topiramate or zonisamide. In addition, the following criteria must be met:

For requests of Vimpat injection, approval requires:

- J The patient is 17 years of age or older

For requests of Vimpat tablets or oral solution, approval requires:

- J The patient is 4 years of age or older

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

LACOSAMIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vimpat.

REFERENCES

) Vimpat [Prescribing Information]. UCB, Inc: Smyrna, GA; November 2017.

Library	Commercial	NSA
Yes	No	No

Part D Effective: N/A

Commercial Effective: 11/12/18

Created: 04/09

Client Approval: 11/18

P&T Approval: 08/12



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OCRELIZUMAB	OCREVUS	44178		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of primary progressive multiple sclerosis (PPMS)?

If yes, continue to #3.

If no, continue to #2.

2. Does the patient have a relapsing form of multiple sclerosis (MS), and has the patient tried **TWO** preferred MS agents (oral or injectable): Avonex, Gilenya, Plegridy, Rebif, Tecfidera, or glatiramer; (**Please note:** other MS agents may also require prior authorization)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: The guideline named **OCRELIZUMAB (Ocrevus)** requires a diagnosis of primary progressive multiple sclerosis (PPMS), or the patient has a relapsing form of multiple sclerosis (MS) and has tried TWO of the following preferred MS agents: Avonex, Gilenya, Plegridy, Rebif, Tecfidera, or glatiramer. Please note that other MS agents may also require prior authorization.

3. Is the patient requesting a starting dose?

If yes, **approve for 12 months by HICL with the following quantity limits:**

) **FIRST AUTHORIZATION:** approve one fill for a quantity of #20mL (two 300mg/10mL vials), override quantity limits for new start dose.

) **SECOND AUTHORIZATION:** approve #20mL (two 300mg/10mL vials) every 6 months.

If no, **approve for 12 months by HICL with a quantity limit of #20mL (two 300mg/10mL vials) every 6 months.**

RATIONALE

Promote appropriate utilization of Ocrevus (ocrelizumab) based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Ocrevus is a CD20-directed cytolytic antibody indicated for the treatment of patients with relapsing or primary progressive forms of multiple sclerosis.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

OCRELIZUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Administer Ocrevus under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage severe reactions such as serious infusion reactions.

-) Initial dose: 300 mg intravenous infusion, followed two weeks later by a second 300 mg intravenous infusion.
-) Subsequent doses: single 600 mg intravenous infusion every 6 months.

HOW SUPPLIED

Injection: 300 mg/10 mL (30 mg/mL) in a single-dose vial.

REFERENCES

-) Ocrevus [Prescribing Information]. Genentech, Inc.: San Francisco, CA. March 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 01/17

Client Approval: 12/17

P&T Approval: 01/17



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-CBQV (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
PEGFILGRASTIM-CBQV	UDENYCA	45445		

GUIDELINES FOR USE

1. Is Udenyca prescribed for the following indication?
J Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **PEGFILGRASTIM-CBQV (Udenyca)** requires that the medication is used in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Udenyca.

REFERENCES

Udenyca [Prescribing Information]. Redwood City, CA: Coherus BioSciences Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 12/14/18

Created: 12/18

Client Approval: 01/19

P&T Approval: 01/19



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB TOSYLATE

Generic	Brand	HICL	GCN	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?

- ✓ The patient is 18 years of age or older
- ✓ The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an FDA-approved test

If yes, **approve for 12 months by GPID with the following quantity limits:**

- ✓ **Talzenna 0.25mg (GPID 45595): #3 capsules per day**
- ✓ **Talzenna 1mg (GPID 45596): #1 capsule per day**

If no, do not approve.

DENIAL TEXT: The guideline named **TALAZOPARIB TOSYLATE (Talzenna)** requires a diagnosis of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. In addition, the following criteria must be met:

- ✓ The patient is 18 years of age or older
- ✓ The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an FDA-approved test

RATIONALE

For further information, please refer to the Prescribing Information for Talzenna.

REFERENCES

- ✓ Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/26/18

Created: 10/18

Client Approval: 10/18

P&T Approval: 01/19



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE ENANTHATE-XYOSTED (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
TESTOSTERONE ENANTHATE	XYOSTED		45519 45515 45517	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a condition associated with a deficiency or absence of endogenous testosterone and meet **ALL** of the following criteria?

- ☐ Patient is at least 18 years old
- ☐ Patient is a male
- ☐ The requested medication is used for testosterone replacement therapy

If yes, **approve the requested agent for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: The guideline named **TESTOSTERONE ENANTHATE** requires a diagnosis of a condition associated with a deficiency or absence of endogenous testosterone. The following criteria must also be met:

- ☐ Patient is at least 18 years old
- ☐ Patient is a male
- ☐ The requested medication is used for testosterone replacement therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xyosted.

REFERENCES

Xyosted [Prescribing Information] Ewing, NJ; Antares Pharma, Inc. November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/15/18

Created: 11/18
Client Approval: 11/18

P&T Approval: 1/1/19



SODIUM OXYBATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM OXYBATE	XYREM	12346		

GUIDELINES FOR USE

***** PLEASE NOTE: VERBAL RESPONSES ARE NOT ACCEPTED TO CONFIRM THE CRITERIA HAS BEEN MET *****

INITIAL CRITERIA

1. Is the patient currently on a sedative hypnotic agent (e.g., Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra)? PLEASE NOTE: Use of sodium oxybate (Xyrem) with sedative hypnotics is contraindicated.

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have a diagnosis of cataplexy in narcolepsy and meets **ALL** of the following criteria?

- ☐ The patient is 7 years of age or older
- ☐ Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
- ☐ Both the patient and physician are registered in the "Xyrem REMS Program" provided by the manufacture
- ☐ Provide clinical documentation of narcolepsy with cataplexy symptoms occurring for at least 3 months. **Please note: verbal responses are not accepted to confirm the criteria has been met.**
- ☐ Provide clinical documentation of functional impairment due to narcolepsy with cataplexy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **Please note: verbal responses are not accepted to confirm the criteria has been met.**

If yes, **approve for 6 months by HICL for #18mL per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, continue to #3.

3. Does the patient have a diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2) when **ALL** of the following are met:

- ☐ The patient is 7 years of age or older



- J Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
- J Both the patient and physician are registered in the “Xyrem REMS Program” provided by the manufacture
- J Diagnosis of narcolepsy, after evaluation including a sleep study which excludes other causes of chronic daytime sleepiness (unless the prescriber provides documentation that a sleep study would not be clinically appropriate)
- J Modafinil in doses up to 400 mg daily, OR armodafinil in doses up to 250 mg daily, has been ineffective, not tolerated, or contraindicated
- J At least one generic stimulant (e.g., methylphenidate, dextroamphetamine, or amphetamine) has been ineffective, not tolerated, or contraindicated
- J Provide clinical documentation of narcolepsy symptoms occurring for at least 3 months with ESS (Epworth Sleepiness Scale) scores > 10 confirmed by one of the following: **Please note: verbal responses are not accepted to confirm the criteria has been met.**
 - o MSLT mean sleep latency 8 minutes or less, including REM sleep episodes during 2* or more test periods (aka SOREMPs)
 - *Polysomnography demonstrating early-onset REM sleep of approximately 15 minutes the night before the MSLT may replace one mid-MSLT SOREMP but should rule out non-narcolepsy causes of EDS
 - o Alternately, low CSF orexin/hypocretin levels per assay
- J Provide clinical documentation of functional impairment due to narcolepsy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **Please note: verbal responses are not accepted to confirm the criteria has been met.**

If yes, **approve for 6 months by HICL for #18mL per day.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve. (**NOTE:** Please review the request for a proactive prior authorization of modafinil and armodafinil. Please enter proactive PA if criteria is met and modify denial text as needed.)

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **SODIUM OXYBATE (XYREM)** requires a diagnosis of cataplexy in narcolepsy OR excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2). Additional guideline requirements apply.

For the diagnosis of cataplexy in narcolepsy, the following criteria must be met:

- J The patient is 7 years of age or older
- J Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
- J Both the patient and physician are registered in the “Xyrem REMS Program” provided by the manufacture



- J Provide clinical documentation of narcolepsy with cataplexy symptoms occurring for at least 3 months. **Please note: verbal responses are not accepted to confirm the criteria has been met.**
- J Provide clinical documentation of functional impairment due to narcolepsy with cataplexy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **Please note: verbal responses are not accepted to confirm the criteria has been met.**
- J Patient is not currently on a sedative hypnotic agent (e.g., Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra)

For the diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2), the following criteria must be met:

- J The patient is 7 years of age or older
- J Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
- J Both the patient and physician are registered in the “Xyrem REMS Program” provided by the manufacture
- J Diagnosis of narcolepsy, after evaluation including a sleep study which excludes other causes of chronic daytime sleepiness (unless the prescriber provides documentation that a sleep study would not be clinically appropriate)
- J Modafinil in doses up to 400 mg daily, OR armodafinil in doses up to 250 mg daily, has been ineffective, not tolerated, or contraindicated
- J At least one generic stimulant (e.g., methylphenidate, dextroamphetamine, or amphetamine) has been ineffective, not tolerated, or contraindicated
- J Provide clinical documentation of narcolepsy symptoms occurring for at least 3 months with ESS (Epworth Sleepiness Scale) scores > 10 confirmed by one of the following: **Please note: verbal responses are not accepted to confirm the criteria has been met.**
 - o MSLT mean sleep latency 8 minutes or less, including REM sleep episodes during 2* or more test periods (aka SOREMPs)
 - *Polysomnography demonstrating early-onset REM sleep of approximately 15 minutes the night before the MSLT may replace one mid-MSLT SOREMP but should rule out non-narcolepsy causes of EDS
 - o Alternately, low CSF orexin/hypocretin levels per assay
- J Provide clinical documentation of functional impairment due to narcolepsy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **Please note: verbal responses are not accepted to confirm the criteria has been met.**
- J Patient is not currently on a sedative hypnotic agent (e.g., Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra)

RENEWAL CRITERIA



1. Does the patient have a diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness associated with narcolepsy without cataplexy and meet ONE of the following:
 -) Provide documentation of sustained improvement of cataplexy symptoms compared to baseline. **Please note: verbal responses are not accepted to confirm the criteria has been met.**
 -) Provide documentation of sustained EDS improvement as shown by sustained ESS improvement of at least 25% over baseline since initial authorization. **Please note: verbal responses are not accepted to confirm the criteria has been met.**

If yes, **approve for 12 months by HICL for #18 mL per day**

If no, do not approve.

DENIAL TEXT: Our guideline for **SODIUM OXYBATE (XYREM)** requires a diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2) for renewal. In addition, one of the following criteria must also be met:

-) Provide documentation of sustained improvement of cataplexy symptoms compared to baseline. **Please note: verbal responses are not accepted to confirm the criteria has been met.**
-) Provide documentation of sustained EDS improvement as shown by sustained ESS improvement of at least 25% over baseline since initial authorization. **Please note: verbal responses are not accepted to confirm the criteria has been met.**

RATIONALE

Based on recommended maximum dose of 9 g daily and FDA indications.

DOSAGE

Adults:

Initiate dose at 4.5 grams (g) per night administered orally in two equal, divided doses: 2.25 g at bedtime and 2.25 g taken 2.5 to 4 hours later. Titrate to effect in increments of 1.5 g per night at weekly intervals (0.75 g at bedtime and 0.75 g taken 2.5 to 4 hours later). Recommended dose range: 6 g to 9 g per night orally.

Pediatrics: Dose based on patient weight; dose may be titrated based on efficacy and tolerability.

Children \geq 7 years and adolescents:

<20 kg: There is no specific dosing provided in the manufacturer's labeling (insufficient information). consider lower initial dosage, lower maximum weekly dosage increases, and lower total maximum nightly dosage.



20 to <30 kg: Initial dose up to 1 g at bedtime after the patient is in bed, and up to 1 g 2.5 to 4 hours later (up to 2 g per night). Titrate dose by 1 g per night (0.5 g at bedtime and 0.5 g 2.5 to 4 hours later) in weekly intervals; maximum dose: 3 g/dose; 6 g per night.

30 to <45 kg: Initial dose up to 1.5 g at bedtime after the patient is in bed, and up to 1.5 g 2.5 to 4 hours later (up to 3 g per night). Titrate dose by 1 g per night (0.5 g at bedtime and 0.5 g 2.5 to 4 hours later) in weekly intervals; maximum dose: 3.75 g/dose; 7.5 g per night.

>45 kg: Initial dose up to 2.25 g at bedtime after the patient is in bed, and up to 2.25 g 2.5 to 4 hours later (up to 4.5 g per night). Titrate dose by 1.5 g per night (0.75 g at bedtime and 0.75 g 2.5 to 4 hours later) in weekly intervals; maximum dose: 4.5 g/dose; 9 g per night.

FDA APPROVED INDICATION

Xyrem is a central nervous system depressant indicated for the treatment of:

-) Cataplexy in narcolepsy.
-) Excessive daytime sleepiness (EDS) in narcolepsy.

Xyrem may only be dispensed to patients enrolled in the Xyrem Success Program.

REFERENCES

-) Jazz Pharmaceuticals, Inc. Xyrem package insert. Palo Alto, CA. December 2012.
-) Anon. Gamma hydroxybutyrate (Xyrem) for narcolepsy. Med Lett Drugs Ther 2002;44(1145): 103-105.
-) Anon. A new indication for gamma hydroxybutyrate (Xyrem) in narcolepsy. Med Lett Drugs Ther. 2006;48(1227):11-12.
-) Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep 2007;30(12):1705-1711.
-) Billiard M, Bassetti C, Dauvilliers Y, et al., for the EFNS Task Force. EFNS guidelines on management of narcolepsy. Eur J Neurol. 2006;13(10):1035-48.
-) Lemon M, Strain J, Farver D. Sodium oxybate for cataplexy. Ann Pharmacother. 2006;40:433-440.

DACLIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
DACLIZUMAB	ZINBRYTA	16921		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a relapsing form of multiple sclerosis (MS) and meet **ALL** of the following criteria?
 - Patient is 18 years of age and older
 - Trial of 2 preferred oral or injectable agents that have been FDA approved for the treatment of relapsing forms of multiple sclerosis (MS) (**Please note:** Other MS agents also require prior authorization [Tecfidera, Glatopa, glatiramer Avonex, Plegridy, Rebif] and may require a prior trial of other medications first [Extavia, Tysabri, Lemtrada])
 - Patient does not have pre-existing hepatic disease or impairment, including:
 - Active hepatitis B and C
 - Autoimmune hepatitis or other autoimmune conditions involving the liver
 - Baseline ALT and AST at least 2 times upper limit of normal (ULN)

If yes, **approve for 3 months by HICL for 1mL (one prefilled 150mg/mL syringe) per 28 days.**

APPROVAL TEXT: Renewal of **DACLIZUMAB (Zinbryta)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) and the following criteria must be met:

- Patient does not have autoimmune hepatitis
- Patient does not have hepatic injury
 - Defined as elevated ALT/AST (greater than 5x ULN), total bilirubin (greater than 2x ULN), or both (ALT/AST at least or greater than 3x ULN + total bilirubin greater than 1.5 ULN) with no other etiologies identified as a cause for the increases besides therapy with Zinbryta

If no, do not approve.

DENIAL TEXT: The guideline named **DACLIZUMAB (Zinbryta)** requires a diagnosis of a relapsing form of multiple sclerosis (MS). The following criteria must also be met:

- Patient is 18 years of age and older
- Trial of 2 preferred oral or injectable agents that have been FDA approved for the treatment of relapsing forms of multiple sclerosis (MS) (**Please note:** Other MS agents also require prior authorization [Tecfidera, Glatopa, glatiramer, Avonex, Plegridy, Rebif] and may require a prior trial of other medications first [Extavia, Tysabri, Lemtrada])
- Patient does not have pre-existing hepatic disease or impairment, including:
 - Active hepatitis B and C
 - Autoimmune hepatitis or other autoimmune conditions involving the liver
 - Baseline ALT and AST at least 2 times upper limit of normal (ULN)

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DACLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a relapsing form of multiple sclerosis (MS) and meet the following criteria?
 - Patient does not have autoimmune hepatitis
 - Patient does not have hepatic injury
 - Defined as elevated ALT/AST (greater than 5x ULN), total bilirubin (greater than 2x ULN), or both (ALT/AST at least or greater than 3x ULN + total bilirubin greater than 1.5 ULN) with no other etiologies identified as a cause for the increases besides therapy with Zinbryta

If yes, **approve for 12 months by HICL for 1mL (one prefilled 150mg/mL syringe) per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **DACLIZUMAB (Zinbryta)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) and the following criteria must be met:

- Patient does not have autoimmune hepatitis
- Patient does not have hepatic injury
 - Defined as elevated ALT/AST (greater than 5x ULN), total bilirubin (greater than 2x ULN), or both (ALT/AST at least or greater than 3x ULN + total bilirubin greater than 1.5 ULN) with no other etiologies identified as a cause for the increases besides therapy with Zinbryta.

RATIONALE

Promote appropriate utilization of **DACLIZUMAB** based on FDA approved indication, labeled contraindications and dosing. The rationale behind renewal criteria and approval duration are per REMS required monitoring (patient status form sent every 90 days) and labeled conditions for Zinbryta discontinuation.

DOSAGE

The recommended dosage of Zinbryta is 150 milligrams injected subcutaneously once monthly.

A missed dose should be injected as soon as possible but no more than two weeks late. After two weeks, skip the missed dose and take the next dose on schedule. Administer only one dose at a time.

FDA APPROVED INDICATIONS

Zinbryta is an interleukin-2 receptor blocking antibody indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Zinbryta should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

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DACLIZUMAB

FDA APPROVED INDICATIONS (CONTINUED)

HOW SUPPLIED

A carton containing a single-dose prefilled syringe providing 1 mL of 150 mg/mL of daclizumab.

REFERENCES

- Zinbryta [Prescribing Information]. Biogen Inc.: Cambridge, MA; May 2016.

Created: 03/18

Effective: 04/16/18

Client Approval: 03/29/18

P&T Approval: N/A

OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand	HICL	GCN	Exception/other
OPIOIDS	OPIOIDS			

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine equivalent dose [MED]) or hard-stop threshold (120 mg morphine equivalent dose)?

NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with Soft_DENY_LIMIT= 90 or HARD_DENY_LIMIT= 120 (i.e., Cumulative morphine equivalent dose of [patient's current MED] = / exceeds threshold of [90 mg MED or 120 mg MED per day]).

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have one of the following conditions?

- Diagnosis of cancer
- Diagnosis of palliative care
- Diagnosis of sickle cell disease
- Patients enrolled in hospice

If yes, **approve as follows:**

- **For drugs with clinical prior authorization criteria, approval duration should match clinical prior authorization criteria (i.e., same duration and dosage formulation [HICL or GPID] as the clinical prior authorization criteria).**
- **For drugs without clinical prior authorization criteria, the approval duration should be for 12 months by HICL.**
- **NOTE: Please enter a class override to override the MED cumulative dosing for the duration of approval.**
- **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

If no, continue to #3.

3. Is the prescriber aware of multiple prescribers for opioid prescriptions?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline. (**NOTE:** An optional operational denial text is also provided for an approval of the clinical PA with an opioid safety edit denial).

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

4. Have **TWO** of the following criteria been met?

- There is documentation that the member's current level of opioid utilization is necessary and required for the level of pain management needed
- Member has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
- Member has a pain contract in place
- Member does not have a history of substance abuse or addiction
- Provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

If yes, **approve as follows:**

- **For drugs with clinical prior authorization criteria, approval duration should match clinical prior authorization criteria (i.e., same duration and dosage formulation [HICL or GPID] as the clinical prior authorization criteria)**
- **For drugs without clinical prior authorization criteria, the approval duration should be for 12 months by HICL.**
- **NOTE: Please analyze claims and override the hard_deny_limit edit.**
- **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline. (NOTE: An optional operational denial text is also provided for an approval of the clinical PA with an opioid safety edit denial).

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL PA, BUT DENIAL OF THE OPIOID SAFETY EDIT:

While your prior authorization for (enter requested drug) has been granted, the drug cannot be covered by your plan due to the amount of opiates prescribed and because multiple prescribers are writing opioid prescriptions for you. Your opiate amount exceeds or is equal to [90 mg morphine equivalent dose] or [120 mg morphine equivalent dose]. [Enter Denial Text Below]

CONTINUED ON NEXT PAGE

OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **Opioid Cumulative Dosing Override** allows for an override for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine equivalent dose) or hard-stop threshold (120mg morphine equivalent dose).

An override will be provided for patients with one of the following conditions:

- Diagnosis of cancer
- Diagnosis of palliative care
- Diagnosis of sickle cell disease
- Patients enrolled in hospice care

For all other patients, the prescriber must be aware that there is more than one provider prescribing opiates for the patient, and that **TWO** of the following criteria must be met:

- There is documentation that the member's current level of opioid utilization is necessary and required for the level of pain management needed
- Member has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
- Member has a pain contract in place
- Member does not have a history of substance abuse or addiction
- Provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record.

The Opioid Cumulative Dose safety edit will cause a claim for a pain medication to deny when there are two or more providers prescribing opioid agents for a patient who is receiving a high quantity of these agents. This guideline will allow you to receive a higher quantity of an opioid medication if certain criteria are met. Please consult your physician if you have any questions about this safety edit on prescription pain medications and the requirements needed for you to obtain an override for higher quantities of these agents.

CONTINUED ON NEXT PAGE

OPIOID CUMULATIVE DOSING OVERRIDE

RATIONALE

To align with opioid restrictions per CMS 2017 Call Letter. Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. MedImpact's standard soft opioid edit is set at ≥ 90 mg morphine equivalent dose (MED). MedImpact's standard hard opioid edit threshold is set at ≥ 120 mg MED. This requirement should not apply to patients with cancer, hospice patients, or patients approved by case management or retrospective DUR Programming. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be override by the pharmacy via DUR PPS codes or as part of coverage determination process. Hard-thresholds are only overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MED days criterion as it would not prevent beneficiaries from reaching high opioid doses.

REFERENCES

- Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.
- Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>. Available at <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>. [Assessed August 11, 2016].
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf> [Accessed August 11, 2016].
- CMS Medicare Benefit Policy Manual Chapter 9 – Coverage of Hospice Services Under Hospital Insurance. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf> [Accessed January 2, 2017].

Created: 02/18

Effective: 02/01/18

Client Approval: 02/02/18

P&T Approval: N/A



MYDAYIS ADHD AGE RESTRICTION OVERRIDE

Generic	Brand	HICL	GCN	Exception/Other
DEXTROAMPHETAMINE/ AMPHETAMINE	MYDAYIS		43538, 43539, 43542, 43543	

GUIDELINES FOR USE

1. Is the request for an age restriction override?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient previously been on **Mydayis** as a pediatric patient (i.e., the patient was on the product when the patient was under 18 years of age)?

If yes, **approve for 12 months by GPID with quantity limits. Do not override quantity limits.** (**NOTE:** Please analyze claim to verify allowable quantity limits per coding. If the request is for a quantity limit override, please defer to a pharmacist for further review. Quantity Exception overrides must be reviewed by a pharmacist.)

If no, continue to #4.

4. Has the patient had a previous trial of or contraindication to a generic immediate release stimulant (e.g., dextroamphetamine, methylphenidate or amphetamine/dextroamphetamine mixture)?

If yes, **approve for 12 months by GPID with quantity limits. Do not override quantity limits.** (**NOTE:** Please analyze claim to verify allowable quantity limits per coding. If the request is for a quantity limit override, please defer to a pharmacist for further review. Quantity Exception overrides must be reviewed by a pharmacist.)

If no, do not approve.

DENIAL TEXT: This medication is available on the formulary for the treatment of Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) in patients who are age 18 years and older who have been receiving the medication as a pediatric patient or had a previous trial or contraindication to a generic immediate-release stimulant.

CONTINUED ON NEXT PAGE

MYDAYIS ADHD AGE RESTRICTION OVERRIDE

RATIONALE

Ensure appropriate use of CNS stimulants.

FDA APPROVED INDICATIONS

All medications on this guideline have FDA approval for ADHD.

REFERENCES

- Micromedex Vol 126.
- Clinical Pharmacology
- Pliszka S. Practice parameter for the assessment and treatment of children and adolescents with attention deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry 2007; 46 (7): 894-921.

Created: 2/18

Effective: 02/09/18

Client Approval: 02/02/18

P&T Approval: N/A



TADALAFIL (CIALIS)

Generic	Brand	HICL	GCN	Exception/Other
TADALAFIL	CIALIS		18995 18996 20736 99409	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Benign Prostatic Hyperplasia (BPH)?

If yes, continue to #2.

If no, continue to #3.

2. Has the patient tried or had a contraindication to at least **TWO** preferred formulary agents, including **ONE** agent from **EACH** of the following classes?

- 5-alpha-reductase inhibitors (e.g., finasteride or dutasteride)
- Alpha blockers (e.g., doxazosin, terazosin, tamsulosin, or alfuzosin)

If yes, **approve Cialis 2.5mg or 5mg (whichever strength is requested) for 12 months by GPID with a quantity limit of #30 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of erectile dysfunction?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is erectile dysfunction a covered benefit?

If yes, **approve tadalafil (Cialis) for 12 months by GPID for the requested strength with the following quantity limits:**

- **Cialis 2.5mg: #30 tablets per 30 days.**
- **Cialis 5mg: #30 tablets per 30 days.**
- **Cialis 10mg: #6 tablets per 30 days, except KC464 #10 per 30 days.**
- **Cialis 20mg: #6 tablets per 30 days, except KC464 #10 per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

TADALAFIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline for **TADALAFIL (Cialis)** requires a diagnosis of benign prostatic hyperplasia (BPH) or a diagnosis of erectile dysfunction. The following criteria must also be met. **For the diagnosis of benign prostatic hyperplasia (BPH)**, approval requires a trial of at least two preferred formulary alternatives, including one agent from each of the following classes:

- 5-alpha-reductase inhibitors (e.g, finasteride or dutasteride)
- Alpha blockers (e.g., doxazosin, terazosin, tamsulosin, or alfuzosin)

For the diagnosis of erectile dysfunction, approval requires this to be a covered benefit.

RATIONALE

Ensure appropriate utilization based on FDA approved indication for benign prostatic hyperplasia (BPH). For plans that cover erectile dysfunction (ED), to ensure cost-effective treatment of erectile dysfunction.

FDA APPROVED INDICATIONS

Cialis is indicated for the treatment of ED, the signs and symptoms of BPH, and ED and the signs and symptoms of BPH. Cialis may be administered once daily or on an as needed basis for the treatment of ED. For the treatment of BPH, Cialis is recommended to be administered on a daily basis.

REFERENCES

- AUA practice guidelines Committee. AUA guideline on management of benign prostatic hyperplasia. Chapter 1: Guideline on the Management of Benign Prostatic Hyperplasia. 2010: American Urological Association Education and Research, Inc.
- Eli Lilly and Company. Cialis package insert. Indianapolis, IN. September 2015.
- MICROMEDEX® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare; Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: October, 31, 2014].

Created: 10/17

Effective: 04/16/18

Client Approval: 03/30/18

P&T Approval: N/A

TERIFLUNOMIDE

Generic	Brand	HICL	GCN	Exception/Other
TERIFLUNOMIDE	AUBAGIO	39624		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis and has the patient tried one of the following preferred agents?

- Rebif, Extavia, Copaxone 40mg, Avonex, Plegridy or Glatopa

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **TERIFLUNOMIDE (Aubagio)** requires a diagnosis of a relapsing form of multiple sclerosis and a trial of one of the following preferred agents: Rebif, Extavia, Copaxone 40mg, Avonex, Plegridy or Glatopa.

RATIONALE

To ensure appropriate use of Aubagio consistent with FDA approved indication.

Type of MS	Description	% MS population
Clinically Isolated Syndrome (CIS)	Single neurologic symptomatic attack compatible with MS. Clinically defined MS occurs in about 80% of patients who have demyelinating lesions on MRI.	MS Precursor
Relapsing Remitting MS (RRMS)	Clearly defined acute exacerbations, followed by partial or complete recovery of the deficits.	85%
Secondary Progressive MS (SPMS)	Initiates as RRMS before developing into a more steady disability progression, which may also include occasional relapses. The transition to SPMS generally occurs in people who have been living with RRMS for at least 10 years.	85% of RRMS patients
Primary Progressive MS (PPMS)	Progression of disability from onset without plateaus or remissions. Does not experience acute attacks.	10%
Progressive Relapsing MS (PRMS)	Continuous worsening neurologic function with occasional relapses.	5%

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TERIFLUNOMIDE

DOSING

The recommended dose of Aubagio is 7 mg or 14 mg orally once daily, with or without food.

FDA APPROVED INDICATIONS

Aubagio is indicated for the treatment of patients with the relapsing forms of multiple sclerosis.

REFERENCES

- Aubagio [Prescribing Information]. Cambridge, MA: Genzyme Corporation; September 2012.
- Goodin DS et al. Disease modifying therapies in multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. *Neurology*. 2002;58(2):169-178.
- National Clinical Advisory Board of the National Multiple Sclerosis Society. MS Disease Management Consensus Statement. 2007. Available at: <http://www.nationalmssociety.org/for-professionals/healthcare-professionals/publications/expert-opinion-papers/index.aspx> [Accessed October 1, 2012].

Created: 09/17

Effective: 10/01/17

Client Approval: 09/15/17

P&T Approval: N/A



PRIOR AUTHORIZATION GUIDELINES

AMINO ACID BASED AND ENTERAL FORMULAS

Generic	STC Description	HICL	GCN	Exception/Other
	PARENTERAL AMINO ACID SOLUTIONS AND COMBINATIONS			STC = C318
	PROTEIN REPLACEMENT			STC = 0181
	NUTRITIONAL THERAPY, MED COND SPECIAL FORMULATION			STC = 7896

GUIDELINES FOR USE

1. Is the request for an enteral formula?

If yes, continue to #2.

If no, continue to #4.

2. Does the patient have a diagnosis of phenylketonuria?

If yes, continue to #3.

If no, continue to #4.

3. Does the plan cover enteral formulas for the diagnosis of phenylketonuria?

If yes, **approve for 12 months by GPID to allow coverage at 20% coinsurance.**

If no, do not approve.

DENIAL TEXT: The plan does not cover enteral formulas for the diagnosis of phenylketonuria.

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PRIOR AUTHORIZATION GUIDELINES

AMINO ACID BASED AND ENTERAL FORMULAS

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of a severe-protein allergic condition or impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (immunoglobulin E and nonimmunoglobulin E-mediated allergies to multiple food proteins; severe food protein-induced enterocolitis syndrome; eosinophilic disorders as evidenced by the results of a biopsy; impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract)? This is not applicable to those persons having an intolerance for lactose or soy.

If yes, and the request is for an amino-acid formula, continue to #5.

If yes, and the request is for an enteral formula, do not approve.

DENIAL TEXT: The plan does not cover enteral formulas for the diagnosis of a severe-protein allergic condition or impaired absorption of nutrients caused by disorders affecting the absorptive surface function, length, and motility of the GI tract.

If no, do not approve.

DENIAL TEXT: The guideline named **AMINO ACID BASED AND ENTERAL FORMULAS** requires a diagnosis of phenylketonuria or a severe-protein allergic condition or impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (immunoglobulin E and nonimmunoglobulin E-mediated allergies to multiple food proteins; severe food protein-induced enterocolitis syndrome; eosinophilic disorders as evidenced by the results of a biopsy; impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract). In addition, the patient must be 20 years old or less if the diagnosis is not phenylketonuria.

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PRIOR AUTHORIZATION GUIDELINES

AMINO ACID BASED AND ENTERAL FORMULAS

GUIDELINES FOR USE (CONTINUED)

5. Does the plan cover amino-acid based formulas for the diagnosis of a severe-protein allergic condition or impaired absorption of nutrients caused by disorders affecting the absorptive surface function, length, and motility of the GI tract?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: The plan does not cover amino-acid based formulas for the diagnosis of a severe-protein allergic condition or impaired absorption of nutrients caused by disorders affecting the absorptive surface function, length, and motility of the GI tract.

6. Is the patient 20 years old or less?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: Coverage requires a diagnosis of a severe-protein allergic condition or impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract (immunoglobulin E and nonimmunoglobulin E-mediated allergies to multiple food proteins; severe food protein-induced enterocolitis syndrome; eosinophilic disorders as evidenced by the results of a biopsy; impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract). In addition, the patient must be 20 years old.

RATIONALE

Promote appropriate utilization of Amino Acid Based Formulas to achieve compliance with West Virginia Senate Bill 299.

FDA APPROVED INDICATION

REFERENCES

-) The PKU Foundation, Available at <https://www.pkufoundation.com>
-) West Virginia SB 299, January 2018

Created: 06/18

Effective: 08/01/18

Client Approval: 06/26/18



OPIOID CUMULATIVE DOSING OVERRIDE

Generic	Brand	HICL	GCN	Exception/other
OPIOIDS	OPIOIDS			

GUIDELINES FOR USE

1. Is the request for an opioid product equal to or exceeding the hard-stop threshold (90 mg morphine equivalent dose)?

NOTE: Claims should stop for DUR_MAX_CUMUL_DOSE 2 edit with HARD_DENY_LIMIT= 90 (i.e., Cumulative morphine equivalent dose of [patient's current MED] = / exceeds threshold of [90 mg MED per day]).

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have one of the following conditions?

- Diagnosis of cancer
- Diagnosis of palliative care
- Diagnosis of sickle cell disease
- Patients enrolled in hospice

If yes, **approve as follows:**

- **For drugs with clinical prior authorization criteria, approval duration should match clinical prior authorization criteria (i.e., same duration and dosage formulation [HICL or GPID] as the clinical prior authorization criteria).**
- **For drugs without clinical prior authorization criteria, the approval duration should be for 12 months by HICL.**
- **NOTE: Please enter a class override to override the MED cumulative dosing for the duration of approval.**
- **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

If no, continue to #3.

3. Is the prescriber aware of multiple prescribers for opioid prescriptions?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline. (**NOTE:** An optional operational denial text is also provided for an approval of the clinical PA with an opioid safety edit denial).

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

4. Have **TWO** of the following criteria been met?
- There is documentation that the member's current level of opioid utilization is necessary and required for the level of pain management needed
 - Member has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
 - Member has a pain contract in place
 - Member does not have a history of substance abuse or addiction
 - Provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record

If yes, **approve as follows:**

- **For drugs with clinical prior authorization criteria, approval duration should match clinical prior authorization criteria (i.e., same duration and dosage formulation [HICL or GPID] as the clinical prior authorization criteria)**
- **For drugs without clinical prior authorization criteria, the approval duration should be for 12 months by HICL.**
- **NOTE: Please analyze claims and override the hard_deny_limit edit.**
- **If the claim rejects after analyzing, then follow the clinical coverage determination process.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline. (NOTE: An optional operational denial text is also provided for an approval of the clinical PA with an opioid safety edit denial).

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL PA, BUT DENIAL OF THE OPIOID SAFETY EDIT:

While your prior authorization for (enter requested drug) has been granted, the drug cannot be covered by your plan due to the amount of opiates prescribed and because multiple prescribers are writing opioid prescriptions for you. Your opiate amount exceeds or is equal to [90 mg morphine equivalent dose]. [Enter Denial Text Below]

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OPIOID CUMULATIVE DOSING OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **Opioid Cumulative Dosing Override** allows for an override for an opioid product equal to or exceeding the hard-stop threshold (90 mg morphine equivalent dose).

An override will be provided for patients with one of the following conditions:

- Diagnosis of cancer
- Diagnosis of palliative care
- Diagnosis of sickle cell disease
- Patients enrolled in hospice care

For all other patients, the prescriber must be aware that there is more than one provider prescribing opiates for the patient, and that **TWO** of the following criteria must be met:

- There is documentation that the member's current level of opioid utilization is necessary and required for the level of pain management needed
- Member has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
- Member has a pain contract in place
- Member does not have a history of substance abuse or addiction
- Provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record.

The Opioid Cumulative Dose safety edit will cause a claim for a pain medication to deny when there are two or more providers prescribing opioid agents for a patient who is receiving a high quantity of these agents. This guideline will allow you to receive a higher quantity of an opioid medication if certain criteria are met. Please consult your physician if you have any questions about this safety edit on prescription pain medications and the requirements needed for you to obtain an override for higher quantities of these agents.

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OPIOID CUMULATIVE DOSING OVERRIDE

RATIONALE

To align with opioid restrictions per CMS 2017 Call Letter. Prior authorization will be required for opioid prescriptions in excess of hard opioid edit. Soft opioid edit thresholds may be overridden by a dispensing pharmacist or provider/patient may request a coverage determination. MedlmKPP's hard opioid edit threshold is set at ≥ 90 mg MED. This requirement should not apply to patients with cancer, hospice patients, or patients approved by case management or retrospective DUR Programming. Additional payment determination is required for patients identified as hospice. Soft-thresholds may also be override by the pharmacy via DUR PPS codes or as part of coverage determination process. Hard-thresholds are only overridable as part of the coverage determination process. The cumulative opioid edit minimizes false positives by accounting for known exceptions: 1) patients on hospice, have certain cancer diagnosis 2) overlapping dispensing dates for Rx refills and new Rx orders for continuing fills 3) high-dose opioid usage previously determined to be medically necessary (approved PAs, previous coverage determinations, case management) 4) no consecutive high-MED days criterion as it would not prevent beneficiaries from reaching high opioid doses.

REFERENCES

- Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.
- Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>. Available at <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>. [Assessed August 11, 2016].
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf> [Accessed August 11, 2016].
- CMS Medicare Benefit Policy Manual Chapter 9 – Coverage of Hospice Services Under Hospital Insurance. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf> [Accessed January 2, 2017].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/03/17

Created: 09/16

Client Approval: 02/17

P&T Approval: 11/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ALGLUCOSIDASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ALGLUCOSIDASE ALFA	LUMIZYME MYOZYME	33588		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Pompe's disease (acid alpha-glucosidase [GAA] deficiency)?

If yes, **approve for lifetime by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ALGLUCOSIDASE ALFA** requires a diagnosis of Pompe's disease (acid alpha-glucosidase deficiency).

RATIONALE

Promote appropriate utilization and dosing based on FDA approved indication.

FDA APPROVED INDICATIONS

Lumizyme is a hydrolytic lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (GAA deficiency).

Myozyme is a lysosomal glycogen-specific enzyme indicated for patients with Pompe disease (GAA deficiency).

DOSAGE AND ADMINISTRATION

20 mg per kg body weight administered every 2 weeks as an intravenous infusion

REFERENCES

-) Lumizyme [Prescribing Information]. Cambridge, MA:Genzyme Corporation; August 2014. Myozyme [Prescribing Information] , Cambridge, MA:Genzyme Corporation; May 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/15

Created: 08/14

Client Approval: 11/14

P&T Approval: 11/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AXICABTAGENE CILOLEUCEL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AXICABTAGENE CILOLEUCEL	YESCARTA	44577		

GUIDELINES FOR USE

1. Does the patient have **ONE** of the following diagnoses?

- ☐ Primary Central Nervous System Lymphoma (PCNSL)
- ☐ Mantle Cell Lymphoma (MCL)
- ☐ Burkitt's Lymphoma

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have **ONE** of the following diagnoses?

- ☐ Diffuse Large B-Cell Lymphoma (DLBCL) not otherwise specified
- ☐ Primary Mediastinal Large B-Cell Lymphoma (PMBCL)
- ☐ High grade B-Cell Lymphoma (e.g., double-hit or triple-hit lymphoma)
- ☐ Diffuse Large B-Cell Lymphoma (DLBCL) arising from Follicular lymphoma (FL) [i.e., transformed follicular Lymphoma (TFL)]

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ Treatment is prescribed by a Yescarta-certified hematologist or oncologist
- ☐ Yescarta will be administered at a treatment center that is certified to administer Yescarta
- ☐ The patient has not received a previous trial of Yescarta

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AXICABTAGENE CILOLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the physician attest that the patient meets **ONE** of the following criteria?
-) The patient has had disease progression or relapsed after stem cell transplantation (SCT)
 -) The patient has had disease progression or relapsed after two or more lines of systemic therapy

If yes, **approve 1 fill by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **AXICABTAGENE CILOLEUCEL (Yescarta)** requires that the patient has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma (e.g., double-hit or triple-hit lymphoma), or diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma (FL) [i.e., transformed follicular lymphoma (TFL)]. **AXICABTAGENE CILOLEUCEL (Yescarta)** is not FDA-approved for the treatment of Primary Central Nervous System Lymphoma (PCNSL), Mantle Cell Lymphoma (MCL), or Burkitt's lymphoma. In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) Treatment is prescribed by a Yescarta-certified hematologist or oncologist
-) Yescarta will be administered at a treatment center that is certified to administer Yescarta
-) The patient has not had a previous trial of Yescarta
-) Physician attestation of **ONE** of the following criteria:
 - o The patient has had disease progression or relapsed after stem cell transplantation (SCT)
 - o The patient has had disease progression or relapsed after two or more lines of systemic therapy

RATIONALE

Promote appropriate utilization of **YESCARTA** based on FDA approved indication, dosing and clinical trial design.

NOTE: Yescarta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological events. Healthcare facilities that dispense and administer Yescarta must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after Yescarta infusion, if needed for treatment of CRS.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AXICABTAGENE CILOLEUCEL (NSA)

RATIONALE (CONTINUED)

Yescarta is the second gene therapy to be approved by the FDA and was granted Priority Review, Breakthrough Therapy, and Orphan Drug designations. Yescarta is an engineered chimeric antigen receptor (CAR) product that targets CD19, a protein expressed on the surface of B cell leukemia and lymphoma cells. The CAR product is utilized in the process of autologous cell therapy in which a patient's own white blood cells are collected, T cells are isolated, the CAR gene is inserted into the T cells, the T cell colony is expanded, and then the engineered T cells are infused back into the patient. This process results in an expanded number of tumor-specific T cells that circulate throughout the body to target and kill cancer cells.

Diffuse large B-cell lymphoma (DLBCL) is the most common aggressive non-Hodgkin lymphoma (NHL), accounting for three out of every five cases. In the U.S. each year, there are approximately 7,500 patients with refractory DLBCL who are eligible for CAR T therapy. Historically, when treated with the current standard of care, patients with refractory large B-cell lymphoma had a median overall survival of approximately six months, with only 7% attaining a complete response. Currently, patients with large B-cell lymphoma in second or later lines of therapy have poor outcomes and greater unmet need, since nearly half of them either do not respond or relapse shortly after transplant.

FDA APPROVED INDICATIONS

Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitation of Use: Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.

DOSAGE AND ADMINISTRATION

- J Yescarta is supplied as a frozen cell suspension of genetically modified autologous T cells in one infusion bag labeled for the specific recipient. Yescarta is shipped directly to the cell lab associated with the infusion center and is administered in a certified health care facility.
- J Yescarta is for autologous use and is administered by intravenous infusion only.
- J Prior to infusion:
 - o Verify the patient's identity
 - o Premedicate with acetaminophen and an H1-antihistamine
 - o Confirm availability of tocilizumab
- J Yescarta dosing is based on the number of chimeric antigen receptor (CAR) positive viable T cells.
 - o The target Yescarta dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AXICABTAGENE CILOLEUCEL (NSA)

AVAILABLE STRENGTHS

Each single infusion bag of Yescarta contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

REFERENCES

-) Yescarta [Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc. October 2017.
-) ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT 02348216. A Phase 1-2 Multi-Center Study Evaluating KTE-C19 in Subjects With Refractory Aggressive Non-Hodgkin Lymphoma (ZUMA-1). Available at: <https://clinicaltrials.gov/ct2/show/NCT02348216>. Accessed October 18, 2017.
-) Kite Pharma [Press Release]. Kite's Yescarta (Axicabtagene Ciloleucel) Becomes First CAR T Therapy Approved by the FDA for the Treatment of Adult Patients With Relapsed or Refractory Large B-Cell Lymphoma After Two or More Lines of Systemic Therapy. Available at: http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle_Print&ID=2309672. Accessed October 18, 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 10/17

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELINOSTAT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BELINOSTAT	BELEODAQ	41264		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication being used for the treatment of a patient with relapsed or refractory peripheral T-cell lymphoma (PTCL)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **BELINOSTAT (Belinostat)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL).

RATIONALE

Promote appropriate utilization of Beleodaq based on FDA approved indication.

There is no consensus regarding the preferred induction chemotherapy for peripheral T-cell lymphoma (PTCL), and patients should be encouraged to participate in clinical trials whenever possible. Most of the treatment regimens that have been studied combine an anthracycline with an alkylating agent. Examples of regimens most commonly considered for the treatment of patients with PTCL not enrolled in clinical trials include:

-) CHOP ([cyclophosphamide](#), [doxorubicin](#), [vincristine](#), [prednisone](#)) with or without [etoposide](#)
-) EPOCH ([etoposide](#), [prednisone](#), [vincristine](#), [cyclophosphamide](#), [doxorubicin](#))

DOSAGE

The recommended dosage of Beleodaq is 1,000 mg/m² administered over 30 minutes by intravenous infusion once daily on Days 1-5 of a 21-day cycle. Cycles can be repeated every 21 days until disease progression or unacceptable toxicity.

FDA APPROVED INDICATION

Beleodaq is a histone deacetylase inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BELINOSTAT

REFERENCES

) Beleodaq [Prescribing Information]. Irvine, CA: Spectrum Pharmaceuticals; July 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 07/14

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BLINATUMOMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BLINATUMOMAB	BLINCYTO	41612		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)?

If yes, **approve for 3 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 2.**

APPROVAL TEXT: A prior authorization has been approved for two cycles of Blincyto. For renewal, please document the following:

-) Whether the patient has achieved complete remission (CR) or CR with partial hematological recovery of peripheral blood counts (CPh) after two cycles.
-) Whether the patient has received stem cell transplant after completion of Blincyto therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?

-) The patient is in first or second complete remission
-) The patient has minimal residual disease (MRD) greater than or equal to 0.1%

If yes, **approve for 2 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 1.**

APPROVAL TEXT: A prior authorization has been approved for one cycle of Blincyto. For renewal, please document that the patient has achieved undetectable minimal residual disease (MRD) within one cycle of Blincyto treatment and is relapse-free (i.e., hematological or extramedullary relapse, or secondary leukemia).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **BLINATUMOMAB (Blincyto)** requires a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) or minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met.

For diagnosis of minimal residual disease (MRD) - positive B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

-) The patient is in first or second complete remission
-) The patient has minimal residual disease (MRD) greater than or equal to 0.1%

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BLINATUMOMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
 -) The patient has achieved undetectable minimal residual disease (MRD) within one cycle of Blincyto treatment
 -) The patient is relapse-free (i.e., hematological or extramedullary relapse, or secondary leukemia)

If yes, **approve for 5 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 3.**

If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
 -) The patient has completed two cycles of induction treatment (cycle 1 and 2) with Blincyto
 -) The patient has achieved complete remission (CR) or CR with partial hematological recovery of peripheral blood counts (CPh) after two cycles

If yes, continue to #3.

If no, send to clinical pharmacist for review.

CLINICAL PHARMACIST: Please review initial criteria. If initial criteria were met, an additional cycle may be approved. Please check if initial therapy was interrupted for dose modification, and follow prescribing information regarding dose modification for toxicities due to Blincyto.

3. Has the patient obtained allogeneic hematopoietic stem-cell transplant?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #4.

4. Is the requested medication being used for consolidation therapy of cycles 3 - 5?

If yes, **approve for 5 months by HICL with a quantity limit of #28 vials per 42 days with a fill count of 3.**

APPROVAL TEXT: An approval has been entered for 3 cycles of Blincyto to complete 3 cycles of consolidation therapy.

If no, continue to #5.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BLINATUMOMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

5. Is the requested medication being used for continued therapy of cycles 6 - 9?

If yes, **approve for 12 months by HICL with a quantity limit of #28 vials per 84 days with a fill count of 4.**

APPROVAL TEXT: An approval has been entered for 4 cycles of Blincyto for continued therapy to complete 9 cycles of therapy. This medication has been FDA approved for a total of 9 cycles.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline named **BLINATUMOMAB (Blincyto)** requires a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) OR minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met.

For diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

-) The patient has achieved complete remission (CR) or CR with partial hematological recovery of peripheral blood counts (CPh) after two cycles of induction treatment (cycle 1 and 2) with Blincyto
-) The patient has not received allogeneic hematopoietic stem-cell transplant

For diagnosis of minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

-) The patient have achieved undetectable minimal residual disease (MRD) within one cycle of Blincyto treatment
-) The patient is relapse-free (i.e., hematological or extramedullary relapse, or secondary leukemia)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BLINATUMOMAB (NSA)

RATIONALE

To promote appropriate utilization of Blincyto based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATION

Blincyto is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of adults and children with

-) B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%.
 - o This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials
-) Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

DOSAGE & ADMINISTRATION

MRD-Positive B-cell Precursor ALL

-) A treatment course consists of 1 cycle of BLINCYTO for induction followed by up to 3 additional cycles for consolidation
-) A single cycle of treatment of Blincyto induction or consolidation consists of 28 days of continuous intravenous infusion, followed by a 14- day treatment-free interval (total 42 days)
-) The table below shows the recommended dose by patient weight and schedule.

Patient Weight	Induction Cycle 1		Consolidation Cycles 2 - 4	
	Days 1-28	Days 29-42	Days 1-28	Days 29-42
45 kg (fixed-dose)	28 mcg/day	14-day treatment-free interval	28 mcg/day	14-day treatment-free interval
<45 kg (BSA-based dose)	15 mcg/m ² /day (not to exceed 28 mcg/day)		15 mcg/m ² /day (not to exceed 28 mcg/day)	

Relapsed or Refractory B-cell Precursor ALL

A treatment course consists of up to 2 cycles for induction followed by 3 additional cycles for consolidation and up to 4 additional cycles of continued therapy.

A single cycle of treatment of Blincyto induction or consolidation consists of 28 days of continuous intravenous infusion, followed by a 14-day treatment-free interval (total 42 days).

A single cycle of treatment of Blincyto continued therapy consists of 28 days of continuous intravenous infusion followed by a 56-day treatment-free interval (total 84 days).

See the table below for the recommended dose by patient weight and schedule. Patients greater than or equal to 45 kg receive a fixed-dose, and for patients less than 45 kg, the dose is calculated using the patient's body surface area (BSA).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BLINATUMOMAB (NSA)****FDA APPROVED INDICATION (CONTINUED)****DOSAGE & ADMINISTRATION****Blincyto dosage and schedule for the treatment of Relapsed or Refractory B-cell Precursor ALL**

Patient Weight	Induction Cycle 1			Induction Cycle 2	
	Days 1-7	Days 8-28	Days 29-42	Days 1-28	Days 29-42
45 kg (fixed-dose)	9 mcg/day	28 mcg/day	14-day treatment-free interval	28 mcg/day	14-day treatment free interval
<45 kg (BSA-based dose)	5 mcg/m ² /day (not to exceed 9 mcg/day)	15 mcg/m ² /day (not to exceed 28 mcg/day)		15 mcg/m ² /day (not to exceed 28 mcg/day)	

Patient Weight	Consolidation Cycle 3 - 5		Continued Therapy Cycle 6 - 9	
	Days 1-28	Days 29-42	Days 1-28	Days 29-84
45 kg (fixed-dose)	28 mcg/day	14-day treatment-free interval	28 mcg/day	56-day treatment-free interval
<45 kg (BSA-based dose)	15 mcg/m ² /day (not to exceed 28 mcg/day)		15 mcg/m ² /day (not to exceed 28 mcg/day)	

If the interruption after an adverse event is no longer than 7 days, continue the same cycle to a total of 28 days of infusion inclusive of days before and after the interruption in that cycle. If the interruption after an adverse event is longer than 7 days, start a new cycle.

REFERENCES

) Blincyto [Prescribing Information]. Thousand Oaks, CA: Amgen Inc. March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 02/15

Client Approval: 05/18

P&T Approval: 04/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BORTEZOMIB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BORTEZOMIB	VELCADE, BORTEZOMIB	25202		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma?

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of mantle cell lymphoma?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received at least one prior therapy for mantle cell lymphoma?

If yes, **approve for 12 months by HICL.**

If no, **approve Velcade for 12 months by NDC 63020-0049-01. (Note: If the request is for bortezomib by Fresenius Kabi, do not approve since this is indicated for mantle cell lymphoma ONLY in patients who have received at least 1 prior therapy)**

DENIAL TEXT: The guideline named **BORTEZOMIB** requires a diagnosis of multiple myeloma or mantle cell lymphoma. In addition, the following criterion must be met:

For bortezomib (manufactured by Fresenius Kabi), approval requires the patient has received at least one prior therapy for mantle cell lymphoma.

RATIONALE

Ensure appropriate utilization of bortezomib based on FDA approved indication.

FDA APPROVED INDICATIONS

Velcade (Millennium) is a proteasome inhibitor indicated for:

-) Treatment of patients with multiple myeloma
-) Treatment of patients with mantle cell lymphoma

Bortezomib (Fresenius Kabi) is a proteasome inhibitor indicated for:

-) Treatment of patients with multiple myeloma
-) Treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BORTEZOMIB (NSA)

REFERENCES

-) Velcade [Prescribing Information]. Cambridge, MA: Millennium Pharmaceuticals; June 2017.
-) Bortezomib [Prescribing Information]. Lake Zurich, IL: Fresenius Kabi; November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/29/18

Created: 11/12

Client Approval: 01/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BRENTUXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BRENTUXIMAB VEDOTIN	ADCETRIS	37879		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of classical Hodgkin lymphoma and meet **ONE** of the following criteria?

) Has failed an autologous hematopoietic stem cell transplant (auto-HSCT)

) Has failed at least two multi-agent chemotherapy regimens (potential regimens include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of classical Hodgkin lymphoma and is considered high risk for relapse or disease progression post-auto-HSCT, as defined according to status following frontline therapy: refractory, relapse within 12 months, or relapse 12 months with extranodal disease?

If yes, continue to #4.

If no, continue to #5.

4. Did the patient obtain a complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy?

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of relapsed systemic anaplastic large cell lymphoma (sALCL) and meet the following criterion?

) Has failed at least one multi-agent chemotherapy regimen (potential regimens include but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #6.

6. Does the patient have a diagnosis of systemic anaplastic large cell lymphoma (sALCL) OR other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, and meet ALL of the following criteria?

) The patient has not received treatment for sALCL or other CD30-expressing PTCL
) The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

If yes, **approve for 12 months with a total fill count of 8 and a quantity limit of #4 vials per 21 days.**

If no, continue to #7.

7. Does the patient have a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) **AND** meet the following criterion?

) The patient has received prior systemic therapy

If yes, **approve for 12 months with a quantity limit of #4 vials per 21 days.**

If no, continue to #8.

8. Does the patient have a diagnosis of Stage III or IV classical Hodgkin lymphoma (cHL) and meet **ALL** of the following criteria?

) The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
) The patient has not received treatment for Stage III or IV classical Hodgkin lymphoma (cHL)

If yes, **approve for 12 months with a total fill count of 12 and a quantity limit of #3 vials per 14 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BRENTUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **BRENTUXIMAB (Adcetris)** requires a diagnosis of classical Hodgkin lymphoma, Stage III or IV classical Hodgkin lymphoma (cHL), systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), primary cutaneous anaplastic large cell lymphoma (pcALCL), or CD30-expressing mycosis fungoides (MF). In addition, the patient must be 18 years of age or older. The following criteria must also be met:

For the diagnosis of classical Hodgkin lymphoma, approval requires ONE of the following:

-) The patient has failed autologous hematopoietic stem cell transplant (auto-HSCT)
-) The patient has failed at least two multi-agent chemotherapy regimens (potential regimens include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])
-) The patient is considered high risk of relapse or disease progression post-auto-HSCT **AND** the patient has obtained complete remission (CR), partial remission (PR), or stable disease (SD) to most recent pre-auto-HSCT salvage therapy

For the diagnosis of relapsed systemic anaplastic large cell lymphoma (sALCL), approval requires:

-) The patient has failed at least one multi-agent chemotherapy regimen (potential regimens include but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone])

For the diagnosis of systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, approval requires:

-) The patient has not received treatment for sALCL or other CD30-expressing PTCL
-) The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

For the diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), approval requires:

-) The patient has received prior systemic therapy

For the diagnosis of Stage III or IV classical Hodgkin lymphoma (cHL), approval requires:

-) The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
-) The patient has not received treatment for Stage III or IV classical Hodgkin lymphoma (cHL)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BRENTUXIMAB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcetris.

REFERENCES

) Adcetris [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/10/18

Created: 09/11

Client Approval: 11/18

P&T Approval: 01/19



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE IMPLANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE	PROBUPHINE	01762		ROUTE= IMPLANT

GUIDELINES FOR USE

1. Has the patient previously received one Probuphine treatment course in **each** arm (for a maximum of **two** 6-month treatment courses)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have a diagnosis of opioid addiction/dependence and meets the following criteria?
 -) The patient has achieved and sustained clinical stability on low to moderate doses of transmucosal buprenorphine (defined as 8 mg per day or less of Subutex/Suboxone or its transmucosal buprenorphine product equivalent for a minimum of 3 months without any need for supplemental dosing or adjustments).
 - o Examples of acceptable doses of transmucosal buprenorphine include:
 - Subutex (buprenorphine) sublingual tablet (or its generic equivalent): 8mg or less
 - Suboxone (buprenorphine/naloxone) sublingual tablet (or its generic equivalent): 8mg/2 mg or less
 - Bunavail (buprenorphine/naloxone) buccal film: 4.2 mg/0.7 mg or less
 - Zubsolv (buprenorphine/naloxone) sublingual tablets: 5.7 mg/1.4 mg or less
 -) Therapy is prescribed by a physician certified with the Probuphine REMS program to prescribe, insert, and remove Probuphine implants as confirmed by checking probuphinerems.com.

If yes, **approve for 6 months by GPID with a quantity limit of #4 implantable rods.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **BUPRENORPHINE IMPLANT (Probuphine)** requires that the following criteria must also be met.

-) The patient has not previously received one Probuphine treatment course in each arm (for a maximum of **two** 6-month treatment courses)
-) The patient has achieved and sustained clinical stability on low to moderate doses of transmucosal buprenorphine (defined as 8 mg per day or less of Subutex/Suboxone or its transmucosal buprenorphine product equivalent for a minimum of 3 months without any need for supplemental dosing or adjustments)
-) Therapy is prescribed by a physician certified with the Probuphine REMS program to prescribe, insert, and remove Probuphine implants as confirmed by checking probuphinerems.com

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE IMPLANT (NSA)

RATIONALE

Under the Drug Addiction Treatment Act (DATA) codified at 21 United States Code (U.S.C.) 823(g), use of this product in the treatment of opioid dependence is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe or dispense this product for the treatment of opioid dependence and have been assigned a unique identification number that must be included on every prescription.

Probuphine implants should be used only in patients who are opioid tolerant. Each dose consists of four Probuphine implants inserted subdermally in the inner side of the upper arm. Probuphine subdermal implants are intended to be in place for 6 months of treatment. Remove Probuphine implants by the end of the sixth month.

New implants may be inserted subdermally in an area of the inner side of either upper arm that has not been previously used at the time of removal, if continued treatment is desired. If new implants are not inserted on the same day as the removal of implants, maintain patients on their previous dosage of transmucosal buprenorphine (i.e., the dose from which they were transferred to Probuphine treatment) prior to additional Probuphine treatment.

After one insertion in each arm, most patients should be transitioned back to a transmucosal buprenorphine-containing product for continued treatment. There is no experience with inserting additional implants into other sites in the arm to recommend an approach to a second insertion into a previously used arm. Neither re-insertion into previously used administration sites, nor into sites other than the upper arm, has been studied.

FDA APPROVED INDICATIONS

Indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine-containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Probuphine should be used as part of a complete treatment program to include counseling and psychosocial support. Probuphine is not appropriate for new entrants to treatment and patients who have not achieved and sustained prolonged clinical stability, while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.

DOSING

Four Probuphine implants are inserted subdermally in the upper arm for 6 months of treatment and are removed by the end of the sixth month. Probuphine implants should **not** be used for additional treatment cycles after one insertion in each upper arm. Probuphine implants must be inserted and removed by trained Healthcare Providers only.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BUPRENORPHINE IMPLANT (NSA)

REFERENCES

) Probuphine [Prescribing Information]. Braeburn Pharmaceuticals, Inc. Princeton, NJ. May 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/2016

Created: 06/20/2016

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARFILZOMIB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CARFILZOMIB	KYPROLIS	39338		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma (MM) and meets **ONE** of the following criteria?
 -) The patient has tried or has a contraindication to at least one prior multiple myeloma therapy and will be using Kyprolis as a single agent
 -) The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with Revlimid (lenalidomide) and dexamethasone
 -) The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with dexamethasone

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **CARFILZOMIB (Kyprolis)** requires a diagnosis of multiple myeloma and that the patient meets **ONE** of the following criteria:

-) The patient has tried or has a contraindication to at least one prior multiple myeloma therapy and will be using Kyprolis as a single agent
-) The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with Revlimid (lenalidomide) and dexamethasone
-) The patient has tried one to three lines of multiple myeloma therapy and will be using Kyprolis in combination with dexamethasone

RATIONALE

Ensure appropriate utilization of carfilzomib based on FDA approved indication.

FDA APPROVED INDICATIONS

Kyprolis is a proteasome inhibitor that is indicated for:

-) **Combination Therapy**
 -) In combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy
-) **Monotherapy**
 -) As a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARFILZOMIB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

Please note that doses may be modified based on toxicity. See the carfilzomib, lenalidomide, and dexamethasone prescribing Information respectively for dosing adjustment recommendations.

Combination Therapy

Administer Kyprolis intravenously as a 10-minute infusion on two consecutive days, each week for three weeks followed by a 12-day rest period. Each 28-day period is considered one treatment cycle. The recommended starting dose of Kyprolis is 20 mg/m² in Cycle 1 on Days 1 and 2. If tolerated, escalate to a target dose of 27 mg/m² on Day 8 of Cycle 1. From Cycle 13, omit the Day 8 and 9 doses of Kyprolis. Discontinue Kyprolis after Cycle 18. Lenalidomide 25 mg is taken orally on Days 1–21 and dexamethasone 40 mg by mouth or intravenously on Days 1, 8, 15, and 22 of the 28-day cycles. Continue treatment until disease progression or unacceptable toxicity occurs. Refer to the lenalidomide and dexamethasone prescribing information for other concomitant medications, such as the use of anticoagulant and antacid prophylaxis that may be required with those agents.

Table 1: Kyprolis in Combination with Lenalidomide and Dexamethasone

	Cycle 1										
	Week 1			Week 2			Week 3			Week 4	
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Days 23–28
Kyprolis (mg/m ²):	20	20	-	27	27	-	27	27	-	-	-
Dexamethasone	40 mg	-	-	40 mg	-	-	40 mg	-	-	40 mg	-
Lenalidomide	25 mg daily									-	-
	Cycles 2 to 12										
	Week 1			Week 2			Week 3			Week 4	
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Days 23–28
Kyprolis (mg/m ²):	27	27	-	27	27	-	27	27	-	-	-
Dexamethasone	40 mg	-	-	40 mg	-	-	40 mg	-	-	40 mg	-
Lenalidomide	25 mg daily									-	-
	Cycles 13 on ^a										
	Week 1			Week 2			Week 3			Week 4	
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Day 22	Days 23–28
Kyprolis (mg/m ²):	27	27	-	-	-	-	27	27	-	-	-
Dexamethasone	40 mg	-	-	40 mg	-	-	40 mg	-	-	40 mg	-
Lenalidomide	25 mg daily										

^a Kyprolis is administered through Cycle 18, lenalidomide and dexamethasone continue thereafter.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CARFILZOMIB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Monotherapy

Administer Kyprolis intravenously as a 10-minute infusion on two consecutive days, each week for three weeks followed by a 12-day rest period. Each 28-day period is considered one treatment cycle. The recommended starting dose of Kyprolis is 20 mg/m² in Cycle 1 on Days 1 and 2. If tolerated, escalate to a target dose of 27 mg/m² on Day 8 of Cycle 1. From Cycle 13, omit the Day 8 and 9 doses of Kyprolis. Continue treatment until disease progression or unacceptable toxicity occurs.

Table 2: Kyprolis Monotherapy

Kyprolis (mg/m ²):	Cycle 1									
	Week 1			Week 2			Week 3			Week 4
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Days 22–28
	20	20	-	27	27	-	27	27	-	-
Kyprolis (mg/m ²):	Cycles 2 to 12									
	Week 1			Week 2			Week 3			Week 4
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Days 22–28
	27	27	-	27	27	-	27	27	-	-
Kyprolis (mg/m ²):	Cycles 13 on									
	Week 1			Week 2			Week 3			Week 4
	Day 1	Day 2	Days 3–7	Day 8	Day 9	Days 10–14	Day 15	Day 16	Days 17–21	Days 22–28
	27	27	-	-	-	-	27	27	-	-

REFERENCES

) Kyprolis [Prescribing Information]. Thousand Oaks, CA: Onyx Pharmaceuticals; June 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 09/01/18

Created: 11/12

Client Approval: 08/18

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CEMPIIMAB-RWLC (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CEMPIIMAB-RWLC	LIBTAYO	45284		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) and meet the following criterion?

) The patient is not a candidate for curative surgery or curative radiation

If yes, **approve for 12 months by HICL with a quantity limit of 7mL (1 vial) per 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CEMPIIMAB-RWLC (Libtayo)** requires a diagnosis of metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) in patients who are not candidates for curative surgery or curative radiation.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Libtayo.

REFERENCES

-) Libtayo [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CERLIPONASE ALFA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CERLIPONASE ALFA	BRINEURA	44258		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient meet **ALL** of the following criteria?
 -) A diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
 -) The patient is ambulatory and experiencing symptoms (e.g., instability, intermittent falls, requires assistance to walk, or can crawl only)
 -) The patient has a documented CLN2 Clinical Rating Scale Score of 3 to 5, with a minimum score of 1 in each of the motor and language domains
 -) The patient is 3 years of age or older
 -) The medication is prescribed by or given in consultation with a neurologist or pediatric CLN2 specialist

If yes, **approve for 6 months with a quantity limit of #2 kits per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CERLIPONASE ALFA (Brineura)** requires the following criteria must be met:

-) A diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
-) The patient is ambulatory and experiencing symptoms (e.g., instability, intermittent falls, requires assistance to walk, or can crawl only)
-) The patient has a documented CLN2 Clinical Rating Scale Score of 3 to 5, with a minimum score of 1 in each of the motor and language domains
-) The patient is 3 years of age or older
-) The medication is prescribed by or given in consultation with a neurologist or pediatric CLN2 specialist

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CERLIPONASE ALFA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?

-) Patient has improved or maintained baseline motor function (e.g., ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (e.g., ambulation, walking or crawling) from baseline
-) CLN2 motor score must be at least 1 (e.g., patient is not bedridden or immobile)

If yes, **approve for 12 months with a quantity limit of #2 kits per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CERLIPONASE ALFA (Brineura)** requires for renewal the following criteria to be met:

-) Patient has improved or maintained baseline motor function (e.g., ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (e.g., ambulation, walking or crawling) from baseline
-) CLN2 motor score must be at least 1 (e.g., patient is not bedridden or immobile)

RATIONALE

Promote appropriate utilization of **CERLIPONASE ALFA** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Brineura is indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

DOSAGE AND ADMINISTRATION

The recommended dosage of Brineura in pediatric patients 3 years of age and older is 300 mg administered once every other week by intraventricular infusion. Administer Brineura first followed by infusion of the Intraventricular Electrolytes each at an infusion rate of 2.5 mL/hr. The complete Brineura infusion, including the required infusion of Intraventricular Electrolytes, is approximately 4.5 hours. Pre-treatment of patients with antihistamines with or without antipyretics or corticosteroids is recommended 30 to 60 minutes prior to the start of infusion.

AVAILABLE STRENGTHS

Injection: Brineura 150 mg/5 mL (30 mg/mL) solution, two single-dose vials per carton co-packaged with Intraventricular Electrolytes Injection 5 mL in a single-dose vial.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CERLIPONASE ALFA (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

CLN2 Disease Clinical Rating Scale

The CLN2 Disease Clinical Rating Scale is a standardized means of quantitatively assessing disease progression and tracks loss of function in 2 main functional domains: motor and language. Each domain is scored from 0 to 3 as described below in table 1. The scores of the two domains sum up to a total score of six, with 0 representing a complete loss of function, while a score of six represents normal function.

Table 1: CLN2 Disease Clinical Rating Scale

Motor function	Language function
3 Normal Grossly normal gait. No prominent ataxia, no pathologic falls.	3 Normal Apparently normal language. Intelligible and grossly age-appropriate. No decline noted yet.
2 Clumsy, falls Independent gait, as defined by ability to walk without support for 10 steps. Will have obvious instability, and may have intermittent falls.	2 Abnormal Language has become recognizably abnormal; some intelligible words; may form short sentences to convey concepts, requests, or needs.
1 No unaided walking Requires assistance to walk, or can crawl only.	1 Minimal Hardly understandable. Few intelligible words.
0 Immobile Can no longer walk or crawl.	0 Unintelligible No intelligible words or vocalizations.

REFERENCES

- Brineura [Prescribing Information]. Novato, CA: BioMarin Pharmaceutical Inc. April 2017.
- CLN2Connection. Natural History: CLN2 disease follows a devastatingly rapid course—symptoms and functional loss compound with age. Available at: <http://www.cln2connection.com/overview/natural-history>. Accessed April 28, 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/17

Created: 08/17
Client Approval: 08/17

P&T Approval: 07/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

COPANLISIB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
COPANLISIB	ALIQOPA	44503		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed follicular lymphoma (FL) and meet the following criteria?

-) The patient is 18 years of age or older
-) The patient has received at least two prior systemic therapies for follicular lymphoma (FL)

If yes, **approve for 12 months by HICL with a quantity limit of #3 vials per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **COPANLISIB (Aliqopa)** requires that the following criteria be met:

-) A diagnosis of relapsed follicular lymphoma (FL)
-) The patient is 18 years of age or older
-) The patient has received at least two prior systemic therapies for follicular lymphoma (FL)

RATIONALE

Promote appropriate utilization of COPANLISIB based on FDA approved indication and dosing.

FDA APPROVED INDICATION

ALIQOPA is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

DOSAGE AND ADMINISTRATION

ALIQOPA is administered as a 1-hour intravenous infusion of a 60 mg dose, on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (three weeks on and one week off), until disease progression or unacceptable toxicity.

AVAILABLE STRENGTHS

Injection: supplied as a sterile lyophilized solid, white to slightly yellowish in appearance, in a single-dose vial for reconstitution and further dilution. After reconstitution, the solution is colorless to slightly yellowish. Each vial contains 60 mg of ALIQOPA free base.

REFERENCES

-) Aliqopa [Prescribing Information]. Bayer HealthCare Pharmaceuticals Inc.: Whippany, NJ. August 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

COPANLISIB (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 01/01/18

Created: 09/17
Client Approval: 12/17

P&T Approval: 10/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CORTICOTROPIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CORTICOTROPIN	H.P. ACTHAR GEL	02830		ROUTE = INJECTION

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient less than two years old and diagnosed with infantile spasms?

If yes, **approve for 28 days with a maximum of #8 vials (each 5mL vial contains 400 units).**

If no, do not approve.

DENIAL TEXT: The guideline named **CORTICOTROPIN (H.P. Acthar Gel)** requires a diagnosis of infantile spasms in patients less than 2 years of age. For all other FDA indications, consider the use of IV corticosteroids.

FDA approved indications include: infantile spasm, acute multiple sclerosis, psoriatic arthritis, rheumatoid arthritis including juvenile rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus or systemic dermatomyositis (polymyositis), severe erythema multiforme, Stevens-Johnson syndrome, serum sickness, severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation), symptomatic sarcoidosis, or to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type, or that due to lupus erythematosus.

RATIONALE

Ensure appropriate therapeutic use of this long acting corticotropin formulation.

The recommended regimen for use in infantile spasms is a daily dose of 150 units/m² (divided into twice daily intramuscular injections of 75 units/ m²) then a gradual taper over a 2-week period. A suggested taper schedule is 30 units/ m² every morning for 3 days, 15 units/ m² every morning for 3 days, 10 units/ m² every morning for 3 days, and then 10 units/ m² every other morning for 6 days.

8 vials per 28 days supply based on dosage of 150 units/m²/day with an estimate of 0.7m² body surface area, estimated maximum for a child less than 40 pounds (two years old).

The American Academy of Neurology guidelines for treatment of infantile spasms state that response is usually within 2 weeks and current clinical data is insufficient to determine optimum dosage and duration.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CORTICOTROPIN (NSA)

RATIONALE (CONTINUED)

Questcor states that the H.P. Acthar Gel vial expires 28 days after initial puncture, when stored under ideal conditions (per USP standard guidelines).

FDA APPROVED INDICATIONS

Acthar Gel is indicated for the treatment of infantile spasms, for acute exacerbations of multiple sclerosis, and for numerous other diseases and disorders. (See below).

INFANTILE SPASMS: Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

MULTIPLE SCLEROSIS: Treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

RHEUMATIC DISORDERS: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), and ankylosing spondylitis.

COLLAGEN DISEASES: During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis).

DERMATOLOGIC DISEASES: Severe erythema multiforme (Stevens-Johnson syndrome).

ALLERGIC STATES: Serum sickness.

OPHTHALMIC DISEASES: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.

RESPIRATORY DISEASES: Symptomatic sarcoidosis.

EDEMATOUS STATE: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CORTICOTROPIN (NSA)

REFERENCES

- J Amphastar Pharmaceuticals, Inc. Cortrosyn package insert. Rancho Cucamonga, CA. September 2005.
- J Baram TZ, Mitchell WG et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms; a prospective, randomized, blinded study. Pediatrics 1996; 97:375–379.
- J CDC child growth charts (birth to 36 months for boys and girls). Last modified 4/20/2001. Accessible online at <http://www.cdc.gov/growthcharts/data/set2clinical/cj411067.pdf> [Accessed June 28, 2011].
- J Gettig J, Cummings J, and Matuszewski K. H.P. Acthar Gel and Cosyntropin Review. Pharmacy and Therapeutics 2009; 34 (5): 250-252.
- J Mackay MT, Weiss, SK, Adams-Webber, T et al. Practice Parameter: Medical Treatment of Infantile Spasms Report of the American Academy of Neurology and the Child Neurology Society. Neurology 2004; 62:1668–1681. Accessible online at <http://www.neurology.org/content/62/10/1668.full.pdf> [Accessed June 28, 2011].
- J Questcor Pharmaceuticals, Inc. HP Acthar Gel package insert. Hayward, CA. June 2011.
- J Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: <http://www.thomsonhc.com/micromedex2/librarian>. [Accessed: June 28, 2011].
- J Riikonen R. A long-term follow-up study of 214 children with the syndrome of infantile spasms. Neuropediatrics. 1982; 13:14–23.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 11/07

Client Approval: 08/17

P&T Approval: 07/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DAUNORUBICIN/ CYTARABINE LIPOSOME	VYXEOS	44461		ROUTE = INTRAVEN.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
 -) The patient has newly diagnosed therapy-related acute myeloid leukemia (t-AML) **OR** AML with myelodysplasia-related changes (AML-MRC)
 -) The patient is 18 years of age or older

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires a new diagnosis of therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes in adult patients.

RATIONALE

Promote appropriate utilization of DAUNORUBICIN/CYTARABINE LIPOSOME based on FDA approved indication.

DOSAGE

VYXEOS is a liposome available as a single-dose vial for reconstitution. VYXEOS is administered via intravenous infusion over 90 minutes. A full VYXEOS course consists of 1-2 cycles of Induction and up to 2 cycles of Consolidation:

-) First Induction Cycle: (daunorubicin 44 mg/m² and cytarabine 100 mg/m²) liposome days 1, 3, and 5
-) Second Induction Cycle: (daunorubicin 44 mg/m² and cytarabine 100 mg/m²) liposome days 1 and 3 [administered 2 to 5 weeks after the first induction cycle, only for those patients failing to achieve a response with the first induction cycle]
-) Consolidation Cycle: (daunorubicin 29 mg/m² and cytarabine 65 mg/m²) liposome days 1 and 3

For patients who do not achieve remission with the first induction cycle, a second induction cycle may be administered 2 to 5 weeks after the first if there was no unacceptable toxicity with VYXEOS. Administer the first consolidation cycle 5 to 8 weeks after the start of the last induction.

For hypersensitivity reactions of any grade/severity, interrupt VYXEOS infusion immediately and manage symptoms. Reduce the rate of infusion or discontinue treatment. Discontinue VYXEOS in patients who exhibit impaired cardiac function unless the benefit of continuing treatment outweighs the risk.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

FDA APPROVED INDICATION

VYXEOS is indicated for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes.

REFERENCES

) Vyxeos [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. August 2017.

Library	Commercial	NSA
No	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/17

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DENOSUMAB-XGEVA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	XGEVA		29261	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multiple myeloma OR bone metastases from a solid tumor **AND** meet the following criterion?
) Xgeva is being used to prevent skeletal-related events (e.g., bone fractures or bone pain requiring radiation)

 If yes, **approve for 12 months by GPID for #1 (1.7mL) vial per 28 days.**
 If no, continue to #2.
2. Does the patient have a diagnosis of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity?

 If yes, **approve and enter two authorizations as follows:**
) **Approve for 1 month by GPID for #3 (5.1mL) vials per 28 days.**
) **Approve for 11 months by GPID for #1 (1.7mL) vial per 28 days with a start date after the end date of the first authorization.**
 If no, continue to #3.
3. Does the patient have a diagnosis of hypercalcemia of malignancy **AND** meet the following criterion?
) The patient is refractory to bisphosphonate therapy (e.g., Fosamax, Actonel, or Boniva)

 If yes, **approve and enter two authorizations as follows:**
) **Approve for 1 month by GPID for #3 (5.1mL) vials per 28 days.**
) **Approve for 11 months by GPID for #1 (1.7mL) vial per 28 days with a start date after the end date of the first authorization.**
 If no, do not approve.
DENIAL TEXT: The guideline named **DENOSUMAB (Xgeva)** requires that ONE of the following criteria is met:
) Diagnosis of multiple myeloma OR bone metastases from solid tumors AND the requested medication is being used to prevent skeletal-related events (e.g., bone fractures or bone pain requiring radiation)
) Diagnosis of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
) Diagnosis of hypercalcemia of malignancy that is refractory to bisphosphonate therapy (e.g., Fosamax, Actonel, or Boniva)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DENOSUMAB-XGEVA (NSA)

RATIONALE

To ensure appropriate use of denosumab based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Xgeva is a RANK ligand (RANKL) inhibitor indicated for:

-) Prevention of skeletal-related events in patients with multiple myeloma and bone metastases from solid tumors
-) Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
-) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

DOSAGE AND ADMINISTRATION

Xgeva is intended for subcutaneous route only and should not be administered intravenously, intramuscularly, or intradermally.

-) Multiple Myeloma and Bone Metastasis from Solid Tumors: Administer 120 mg every 4 weeks as a subcutaneous injection in the upper arm, upper thigh, or abdomen. Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia
-) Giant Cell Tumor of Bone: Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen. Administer calcium and vitamin D as necessary to treat or prevent hypocalcemia
-) Hypercalcemia of Malignancy: Administer 120 mg every 4 weeks with additional 120 mg doses on Days 8 and 15 of the first month of therapy. Administer subcutaneously in the upper arm, upper thigh, or abdomen.

REFERENCES

-) Amgen. Xgeva package insert. Thousand Oaks, CA. January, 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/29/18

Created: 11/07

Client Approval: 01/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DINUTUXIMAB

Generic	Brand	HICL	GCN	Exception/Other
DINUTUXIMAB	UNITUXIN	42038		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of high-risk neuroblastoma and meets all the following criteria?
 -) Patient is 17 years of age or younger
 -) Patient has received an autologous stem cell transplant
 -) Patient achieved at least a partial response to chemotherapy given prior to autologous stem cell transplant
 -) Patient has not undergone 5 cycles of dinutuximab in the past

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Will the patient be receiving dinutuximab concurrently with isotretinoin and either Leukine (GM-CSF) or Proleukin (IL-2)?

If yes, **approve for 12 months by HICL with a fill limit of up to 5 fills.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **DINUTUXIMAB** requires a diagnosis of high-risk neuroblastoma. In addition, the following criteria must be met:

-) Patient is 17 years of age or younger
-) Patient has received an autologous stem cell transplant
-) Patient achieved a partial response to chemotherapy given prior to autologous stem cell transplant
-) Patient has not undergone 5 cycles of dinutuximab in the past
-) Dinutuximab will be used concurrently with isotretinoin and either Leukine or Proleukin

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DINUTUXIMAB

RATIONALE

Promote appropriate utilization of dinutuximab based on FDA approved indication and dosing.

Unituxin is the first FDA approved medication for the treatment of high-risk neuroblastomas after initial treatment with first-line multi-agent, multimodality therapy, which consists of induction chemotherapy, surgical resection accompanied with radiation, and myeloablative consolidation chemotherapy followed with an autologous stem cell transplant. Following these initial therapies, the prior standard of care was to initiate oral 13-cis-retinoic acid also known as the generic drug isotretinoin, to eradicate residual disease. Unituxin is approved to be given in combination with isotretinoin, IL-2 (marketed as Proleukin [aldesleukin]), and GM-CSF (available as the brand Leukine [sargramostim]) following the initial therapy.

Patients at the highest risk for disease progression and mortality (high-risk neuroblastomas) are those who are older than 18 months of age and have disseminated disease or those with localized disease with unfavorable markers such as MYCN amplification.

FDA APPROVED INDICATION

Unituxin is a GD2-binding monoclonal antibody indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

DOSAGE

The recommended daily dose of dinutuximab is 17.5 mg/m²/day as an intravenous infusion over 10 to 20 hours for four consecutive days for a maximum of 5 cycles.

Unituxin is to be used in a regimen containing isotretinoin and either Leukine or Proleukin depending on the cycle. Cycles 1, 3, and 5 are 24 days in duration and Unituxin is given in combination with GM-CSF and RA (see Table 1). Cycles 2 and 4 are 32 days in duration and Unituxin is given in combination with IL-2 and RA (see Table 2).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DINUTUXIMAB

DOSAGE (CONTINUED)

Table 1: Dosing Regimen for Cycles 1, 3, and 5 (from Unituxin Prescribing Information)

Cycle Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15-24
GM-CSF ¹	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Unituxin ²				X	X	X	X								
RA ³											X	X	X	X	X

¹ GM-CSF: 250 µg/m²/day, administered by either subcutaneous injection (recommended) or IV infusion administered over 2 hours.

² Unituxin: 17.5 mg/m²/day, administered by diluted IV infusion over 10–20 hours.

³ RA: for >12 kg body weight, 80 mg/m² orally twice daily for a total dose of 160 mg/m²/day; for ≤12 kg body weight, 2.67 mg/kg orally twice daily for a total daily dose of 5.33 mg/kg/day (round dose up to nearest 10 mg).

Table 2: Dosing Regimen for Cycles 2 and 4 (from Unituxin Prescribing Information)

Cycle Day	1	2	3	4	5	6	7	8	9	10	11	12-14	15-28	29-32
IL-2 ¹	X	X	X	X				X	X	X	X			
Unituxin ²								X	X	X	X			
RA ³													X	

¹ IL-2: 3 MIU/m²/day administered by continuous IV infusion over 96 hours on Days 1-4 and 4.5 MIU/m²/day on Days 8-11.

² Unituxin: 17.5 mg/m²/day, administered by diluted IV infusion over 10-20 hours.

³ RA: for >12 kg body weight, 80 mg/m² orally twice daily for a total dose of 160 mg/m²/day; for ≤12 kg body weight, 2.67 mg/kg orally twice daily for a total daily dose of 5.33 mg/kg/day (round dose up to nearest 10 mg).

HOW SUPPLIED

Dinutuximab is supplied in a carton containing one 17.5 mg/5 mL single use vial (NDC 66302-0014-01)

REFERENCES

- 1) Unituxin [Prescribing Information]. United Therapeutics Corp.: Silver Spring, MD. March 2015.
- 2) National Cancer Institution. Neuroblastoma Treatment. Cancer.gov, Available at http://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq#section/_214

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/15

Created: 07/15

Client Approval: 08/15

P&T Approval: 08/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DURVALUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DURVALUMAB	IMFINZI	44230		ROUTE = INTRAVEN.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma and meet **ONE** of the following criteria?

-) The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) **OR**
-) The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of unresectable Stage III non-small cell lung cancer (NSCLC) **AND** meet the following criterion?

-) The patient's disease has not progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **DURVALUMAB (Imfinzi)** requires a diagnosis of locally advanced or metastatic urothelial carcinoma **OR** unresectable Stage III non-small cell lung cancer (NSCLC). In addition, the following criteria must be met:

For the diagnosis of locally advanced or metastatic urothelial carcinoma, approval requires ONE of the following:

-) The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) **OR**
-) The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

For the diagnosis of unresectable Stage III non-small cell lung cancer (NSCLC), approval requires:

-) The patient's disease has not progressed following concurrent platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) and radiation therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DURVALUMAB (NSA)

RATIONALE

Promote appropriate utilization of Imfinzi based on FDA approved indication.

FDA APPROVED INDICATIONS

Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with:

-) Locally advanced or metastatic urothelial carcinoma who:
 - o Have disease progression during or following platinum-containing chemotherapy.
 - o Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
 - o This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
-) Unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy

DOSAGE AND ADMINISTRATION

Urothelial Carcinoma: The recommended dose of Imfinzi is 10 mg/kg via intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity occurs.

NSCLC: The recommended dose of Imfinzi is 10 mg/kg via intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity, or a maximum of 12 months.

No dose reductions are recommended for adverse reactions. Withhold or discontinue Imfinzi to manage adverse reactions.

REFERENCES

-) Imfinzi [Prescribing Information]. AstraZeneca Pharmaceuticals: Wilmington, DE; February 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 03/12/18

Created: 08/17
Client Approval: 02/18

P&T Approval: 04/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
EDARAVONE	RADICAVA	44252		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of amyotrophic lateral sclerosis (ALS) and meet **ALL** the following?
 -) The patient is currently taking riluzole (Rilutek) or has previously tried riluzole (Rilutek)
 -) Requested medication is prescribed by or given in consultation with a neurologist or ALS specialist at a ALS Specialty Center or Care Clinic
 -) Duration of disease (from onset of symptoms) is less than 2 years
 -) Normal Respiratory Function defined as a Forced Vital Capacity (FVC) greater than 80%
 -) Mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (e.g., speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

If yes, please enter **TWO** approvals by HICL as follows (total approval duration is 6 months):

-) **FIRST APPROVAL:** approve for 1 month for 1 fill with a quantity limit of #2800mL (twenty-eight 30mg/100mL single-dose bags)
-) **SECOND APPROVAL:** approve for 5 months with a quantity limit of #2000mL (twenty 30mg/100mL single dose bags) per 28 days (Please enter a start date after the end date of the first approval).

If no, do not approve.

DENIAL TEXT: The guideline named **EDARAVONE (Radicava)** requires a diagnosis of amyotrophic lateral sclerosis (ALS) and the following criteria to be met:

-) The patient is currently taking riluzole (Rilutek) or has previously tried riluzole (Rilutek)
-) Requested medication is prescribed by or given in consultation with a neurologist or ALS specialist at a ALS Specialty Center or Care Clinic
-) Duration of disease (from onset of symptoms) is less than 2 years
-) Normal Respiratory Function defined as a Forced Vital Capacity (FVC) greater than 80%
-) Mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (e.g., speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient meet **ALL** of the following criteria?

- ☐ Patient has improved or maintained baseline functional ability or demonstrated a less-than-expected decline in functional ability from baseline as measured by functional assessments (e.g., ALSFRS)
- ☐ Patient does not require invasive ventilation
- ☐ Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

If yes, **approve for 12 months with a quantity limit of #2000mL (twenty 30mg/100mL single dose bags) per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **EDARAVONE (Radicava)** requires a diagnosis of amyotrophic lateral sclerosis (ALS) for renewal and the following criteria to be met:

- ☐ Patient has improved or maintained baseline functional ability or demonstrated a less-than-expected decline in functional ability from baseline as measured by functional assessments (e.g., ALSFRS)
- ☐ Patient does not require invasive ventilation
- ☐ Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R

RATIONALE

Promote appropriate utilization of **EDARAVONE** based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Radicava is indicated for the treatment of amyotrophic lateral sclerosis (ALS).

DOSAGE AND ADMINISTRATION

The recommended dosage of Radicava is an intravenous infusion of 60 mg administered over a 60-minute period according to the following schedule:

- ☐ An initial treatment cycle with daily dosing for 14 days, followed by a 14-day drug-free period.
- ☐ Subsequent treatment cycles with daily dosing for 10 days out of 14-day periods, followed by 14-day drug-free periods.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

AVAILABLE STRENGTHS

Injection: 30 mg/100 mL in a single-dose polypropylene bag; two bags per carton.

The ALSFRS-R is a validated questionnaire-based scale designed to be a clinical rating tool to monitor the progression of patients in clinical practice as well as an outcome measure in clinical trials. The rate of progression of ALS patient population is typically linear, however it is not homogenous, therefore it is difficult to ascertain the general rate of progression for the patient population. The ALSFRS-R scale consists of 12 questions that evaluate the fine motor, gross motor, bulbar, and respiratory function of patients with ALS (speech, salivation, swallowing, handwriting, cutting food, dressing/hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency). There are four domains: bulbar, fine motor, gross motor and breathing. Each questionnaire item is scored from 0-4, with higher scores representing greater functional ability; the total possible score is 48 points.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Figure 1: ALSFRS-R Questionnaire

Bulbar	Fine Motor	Gross Motor	Breathing
<p>1. Speech</p> <ul style="list-style-type: none">4. Normal speech processes3. Detectable speech disturbance2. Intelligible with repeating1. Speech combined with nonvocal communication0. Loss of useful speech <p>2. Salivation</p> <ul style="list-style-type: none">4. Normal3. Slight but definite excess of saliva in mouth; may have nighttime drooling2. Moderately excessive saliva; may have minimal drooling1. Marked excess of saliva with some drooling0. Marked drooling; requires constant tissue or handkerchief <p>3. Swallowing</p> <ul style="list-style-type: none">4. Normal eating habits3. Early eating problems-occasional choking2. Dietary consistency changes1. Needs supplemental tube feeding0. NPO (exclusively parenteral or enteral feeding)	<p>4. Handwriting</p> <ul style="list-style-type: none">4. Normal3. Slow or sloppy; all words are legible2. Not all words are legible1. Able to grip pen but unable to write0. Unable to grip pen <p>5a. Cutting Food / Handling Utensils</p> <ul style="list-style-type: none">4. Normal3. Somewhat slow and clumsy, but no help needed2. Can cut most foods, although clumsy and slow; some help needed1. Food must be cut by someone, but can still feed slowly0. Needs to be fed <p>5b. Cutting Food / Handling Utensils (Alt. for patients with Gastrostomy)</p> <ul style="list-style-type: none">4. Normal3. Clumsy but able to perform all manipulations independently2. Some help needed with closures and fasteners1. Provides minimal assistance to caregiver0. Unable to perform any aspect of task <p>6. Dressing and hygiene</p> <ul style="list-style-type: none">4. Normal function3. Independent and complete self-care with effort or decreased efficiency2. Intermittent assistance or substitute methods1. Needs attendant for self-care0. Total dependence	<p>7. Turning in bed</p> <ul style="list-style-type: none">4. Normal3. Somewhat slow and clumsy, but no help needed2. Can turn alone or adjust sheets, but with great difficulty1. Can initiate, but not turn or adjust sheets alone0. Helpless <p>8. Walking</p> <ul style="list-style-type: none">4. Normal3. Early ambulation difficulties2. Walks with assistance1. Non-ambulatory functional movement only0. No purposeful leg movement <p>9. Climbing stairs</p> <ul style="list-style-type: none">4. Normal3. Slow2. Mild unsteadiness or fatigue1. Needs assistance0. Cannot do	<p>10. Dyspnea</p> <ul style="list-style-type: none">4. None3. Occurs when walking2. Occurs with one or more of the following: eating, bathing, dressing (ADL)1. Occurs at rest, difficulty breathing when either sitting or lying0. Significant difficulty, considering using mechanical respiratory support <p>11. Orthopnea</p> <ul style="list-style-type: none">4. None3. Some difficulty sleeping at night due to shortness of breath. Does not routinely use more than two pillows2. Needs extra pillow in order to sleep (more than two)1. Can only sleep sitting up0. Unable to sleep <p>12. Respiratory insufficiency</p> <ul style="list-style-type: none">4. None3. Intermittent use of BiPAP2. Continuous use of BiPAP1. Continuous use of BiPAP during the night and day0. Invasive mechanical ventilation by intubation or tracheostomy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EDARAVONE (NSA)

REFERENCES

-) Radicava [prescribing information]. Jersey City, NJ: MT Pharma America, Inc.; May 2017.
- Cedarbaum J, Stambler N, Malt E et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999 Oct 31;169(1-2):13-21.
-) Cedarbaum J, Mitsumoto H, Pestronk A, et al. The ALSFRS @ 20: Evolution of the ALSFRS-R, history, clinimetric properties and future directions [Poster]. Available at:
https://cytokinetix.com/wp-content/uploads/2015/10/2011ALS_MND_ALSFRS20.pdf

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/17

Created: 08/17

Client Approval: 08/17

P&T Approval: 07/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELOSULFASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
ELOSULFASE ALFA	VIMIZIM	40929		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)?

If yes, **approve for lifetime by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ELOSULFASE ALFA** requires a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

RATIONALE

Promote appropriate utilization of Vimizim based on FDA approved indication.

Vimizim is the first agent approved to treat Morquio A syndrome. Prior to the approval of this medication, complications of Morquio A syndrome, such as, skeletal abnormalities, heart disease, hearing and vision loss, and breathing difficulties, are often treated medically and surgically as needed.

Morquio A syndrome, an autosomal recessive lysosomal storage disease, affects approximately 800 individuals in the United States. Morquio A syndrome is classified within a group of diseases called mucopolysaccharidoses (MPS) as MPS IV. Patients with Morquio A syndrome are deficient in the N-acetylgalactosamine-6-sulfate sulfatase (GALNS) enzyme. The first symptoms usually occur at 2-3 years of age. This enzyme deficiency causes difficulties in skeletal development and growth, and patients will typically exhibit symptoms such as abnormal bone development (including the spine), bell-shaped chest with flared ribs at bottom, coarse facial features, widely spaced teeth, hypermobile joints, knock knees, macrocephaly, and short stature. The patient with Morquio A syndrome may have physical exam abnormalities such as kyphoscoliosis, cloudy cornea, aortic regurgitation, enlarged liver, inguinal hernia, and paralysis below the neck due to underdeveloped upper vertebrae.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ELOSULFASE ALFA****RATIONALE (CONTINUED)**

The most common adverse events observed in clinical trials (occurring in 10% or greater of Vimizim patients) were nausea, vomiting, abdominal pain, chills, headache, pyrexia, and fatigue. In clinical trials 7.7% of patients had anaphylactic reactions and 18.7% had hypersensitivity reactions during or after Vimizim administration.

Vimizim contains a boxed warning regarding the risk of life-threatening anaphylactic reactions that may occur during infusion. Patients must be observed during and after Vimizim infusion by a health care provider trained to manage medical emergencies. Patients with acute febrile or respiratory conditions may be at increased risk due to potential for respiratory compromise during a hypersensitivity reaction; the healthcare provider must carefully consider the patient's clinical condition prior to infusion and consider delaying treatment with Vimizim when appropriate.

The safety and efficacy of Vimizim have not been established in patients less than 5 years old.

DOSAGE

The recommended dose of Vimizim is 2mg per kilogram of body weight administered once weekly as an intravenous infusion. Administer Vimizim over a minimum of 3.5 to 4.5 hours (based on infusion volume). Patients should receive pretreatment with antihistamines, with or without antipyretics, 30 to 60 minutes before administration of Vimizim. If a hypersensitivity reaction occurs during the infusion, administration may be slowed, temporarily stopped or discontinued based on the severity of the reaction. Vimizim should be infused using a low-protein binding infusion set with a low-protein binding 0.2 micrometer in-line filter.

FDA APPROVED INDICATION

Vimizim is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

REFERENCES

-) Vimizim [Prescribing Information]. Novato, CA: Biomarin Pharmaceutical Inc; February 2014.
-) FDA Press Announcement on 2/14/14: FDA approves Vimizim to treat rare congenital disorder. Available online at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm386008.htm> Accessed February 24, 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/14

Created: 03/14

Client Approval: 05/14

P&T Approval: 05/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELOTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ELOTUZUMAB	EMPLICITI	42842		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of multiple myeloma and meet **ONE** of the following criteria?
-) Empliciti (elotuzumab) will be used in combination with lenalidomide and dexamethasone in patient who has received one to three prior therapies for the treatment of multiple myeloma such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation **OR**
 -) Empliciti (elotuzumab) will be used in combination with pomalidomide and dexamethasone in patient who has received at least two prior therapies including lenalidomide and a proteasome inhibitor

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ELOTUZUMAB (Empliciti)** requires a diagnosis of multiple myeloma in adult patients. In addition, ONE of the following must be met for approval:

-) Empliciti must be used in combination with lenalidomide and dexamethasone in patients who have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation **OR**
-) Empliciti must be used in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empliciti.

REFERENCES

-) Empliciti [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/19/18

Created: 12/15

Client Approval: 11/18

P&T Approval: 02/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE

Generic	Brand	HICL	GCN	Exception/Other
IMIGLUCERASE	CEREZYME	09022		
TALIGLUCERASE ALFA	ELELYSO	38937		
VELAGLUCERASE ALFA	VPRIV	36874		

GUIDELINES FOR USE

ELELYSO

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease and meets the following criteria?

☐ Patient 4 years of age and above

If yes, **approve for up to 12 months.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE** requires a diagnosis of type 1 Gaucher disease. In addition, the following criteria must be met:

☐ Patient 4 years of age and above

VPRIV

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease and meets the following criteria?

☐ Patient 4 years of age and above

☐ Previous trial (unless contraindicated) of Elelyso

If yes, **approve for up to 12 months.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE** requires a diagnosis of type 1 Gaucher disease. In addition, the following criteria must be met:

☐ Patient 4 years of age and above

☐ Previous trial (unless contraindicated) of Elelyso

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE

GUIDELINES FOR USE (CONTINUED)

CEREZYME

1. Is the patient being treated for type 1 (non-neuronopathic) Gaucher disease and meets the following criteria?

- ☐ Patient 18 years of age and above
- ☐ Previous trial (unless contraindicated) of Elelyso

If yes, **approve for up to 12 months.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE** requires a diagnosis of type 1 Gaucher disease. In addition, the following criteria must be met:

- ☐ Patient 18 years of age and above
- ☐ Previous trial (unless contraindicated) of Elelyso

RATIONALE

Ensure that Cerezyme, Elelyso, and Vpriv are being used to treat patients with type 1 Gaucher disease.

FDA APPROVED INDICATIONS

CEREZYME is indicated for long term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease resulting in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly.

ELELYSO is indicated for long term enzyme replacement therapy for adult patients and pediatric patients with type 1 Gaucher disease. Dosing information is available for 4 years of age and older.

VPRIV is indicated for long term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher disease. Dosing information is available for 4 years of age and older.

REFERENCES

- ☐ Genzyme Corporation, Cerezyme package insert. Cambridge, MA. December 2012.
- ☐ Pfizer Labs, Elelyso package insert. New York, NY. August 2014.
- ☐ Shire Human Genetic Therapies, Inc., Vpriv package insert. Cambridge, MA. April 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/15

Created: 05/05

Client Approval: 05/15

P&T Approval: 05/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EPOPROSTENOL IV

Generic	Brand	HICL	GCN	Exception/Other
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN	07323		
EPOPROSTENOL SODIUM (ARGININE)	VELETTRI	37762		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meets **ALL** of the following criteria?
 -) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 -) Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
 -) The patient has NYHA/WHO Functional Class III-IV symptoms

If yes, **approve up to 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **EPOPROSTENOL (Flolan, Velettri)** requires a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1). The following criteria must also be met.

-) The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
-) Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters:
 - o Mean pulmonary artery pressure (PAP) of 25 mmHg
 - o Pulmonary capillary wedge pressure (PCWP) 15 mmHg
 - o Pulmonary vascular resistance (PVR) > 3 Wood units
-) The patient has NYHA/WHO Functional Class III-IV symptoms

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EPOPROSTENOL IV

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: The guideline for **EPOPROSTENOL (Flolan, Veletri)** renewal requires a diagnosis of pulmonary arterial hypertension (PAH). The following criteria must also be met.

) The patient has shown improvement from baseline in the 6-minute walk distance test **OR**

) The patient has a stable 6-minute walk distance test with a stable or improved WHO functional class.

RATIONALE

Ensure appropriate use of Flolan and Veletri based on FDA approved indication.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EPOPROSTENOL IV

RATIONALE (CONTINUED)

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (e.g. diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

FDA APPROVED INDICATION

Epoprostenol is indicated for the long-term intravenous treatment of primary pulmonary hypertension and pulmonary hypertension associated with the scleroderma spectrum of disease in NYHA/WHO Class III and Class IV patients who do not respond adequately to conventional therapy.

Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

REFERENCES

-) GlaxoSmithKline. Flolan package insert. Research Triangle Park, NC. April 2015.
-) Actelion. Veletri package insert. South San Francisco, CA. June 2012.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 09/05

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ERIBULIN

Generic	Brand	HICL	GCN	Exception/Other
ERIBULIN MESYLATE	HALAVEN	37256		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meets the following criteria?
 -) The patient has received previous treatment with **TWO** chemotherapeutic regimens for the treatment of metastatic disease which should have included at least **ONE** agent from **EACH** of the following chemotherapeutic drug classes:
 - o An anthracycline [e.g., daunorubicin (Cerubidine), daunorubicin liposomal (DaunoXome), doxorubicin (Adriamycin), doxorubicin liposomal (Doxil), idarubicin (Idamycin), epirubicin (Ellence), mitoxantrone (Novantrone)]
 - o A taxane [e.g., docetaxel (Taxotere), paclitaxel (Taxol or Abraxane)]

If yes, **approve for 12 months by HICL with a quantity limit of #6 vials (maximum 3 vials per dose) per 21 days.**

If no, continue to #2.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of unresectable or metastatic liposarcoma and meets the following criteria?
 -) The patient has received previous treatment for liposarcoma, which included an anthracycline [e.g., daunorubicin (Cerubidine), daunorubicin liposomal (DaunoXome), doxorubicin (Adriamycin), doxorubicin liposomal (Doxil), idarubicin (Idamycin), epirubicin (Ellence), mitoxantrone (Novantrone)]?

If yes, **approve for 12 months by HICL with a quantity limit of #6 vials (maximum 3 vials per dose) per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **ERIBULIN (Halaven)** requires a diagnosis of metastatic breast cancer and previous treatment with an anthracycline and a taxane OR a diagnosis of unresectable or metastatic liposarcoma and previous treatment with an anthracycline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ERIBULIN

RATIONALE

To ensure appropriate use of Halaven based on FDA indication.

FDA APPROVED INDICATIONS

Halaven is a microtubule inhibitor indicated for the treatment of patients with:

-) Metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.
-) Unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

REFERENCES

-) Halaven [Prescribing Information]. Eisai Inc.: Woodcliff Lake, NJ. January 2016.
-) Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: <http://www.thomsonhc.com/hcs/librarian/>. [Accessed: June 28, 2011].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: NA

Commercial Effective: 05/01/16

Created: 11/10

Client Approval: 11/13

P&T Approval: 05/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETELCALCETIDE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ETELCALCETIDE	PARSABIV	44093		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of secondary hyperparathyroidism (HPT) and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has chronic kidney disease
- ☐ The patient is on hemodialysis
- ☐ The patient is NOT taking another calcimimetic agent (e.g., cinacalcet)

If yes, **approve for 12 months by HICL with a quantity limit of #36mL per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ETELCALCETIDE (Parsabiv)** requires a diagnosis of secondary hyperparathyroidism (HPT). The following criteria must also be met:

- ☐ The patient is 18 years of age or older
- ☐ The patient has chronic kidney disease
- ☐ The patient is on hemodialysis
- ☐ The patient is NOT taking another calcimimetic agent (e.g., cinacalcet)

RATIONALE

Promote appropriate utilization of **ETELCALCETIDE** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS

Parsabiv is a calcium-sensing receptor agonist indicated for secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis.

DOSAGE AND ADMINISTRATION

Parasabiv is available as single-dose vials. Single-dose vials are available in 2.5 mg/0.5mL, 5 mg/1mL, and 10 mg/2 mL strengths.

The recommended starting dose of PARSABIV is 5 mg administered by intravenous (IV) bolus injection three times per week at the end of hemodialysis treatment. Administer PARSABIV only at the end of hemodialysis treatment.

The lowest maintenance dose of PARSABIV is 2.5 mg three times per week, and the highest maintenance dose of PARSABIV is 15 mg three times per week. The maintenance dose of PARSABIV is individualized and determined by titration based on parathyroid hormone (PTH) and corrected serum calcium response. The maintenance dose is the dose that maintains PTH levels within the recommended target range and corrected serum calcium within the normal range.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETELCALCETIDE (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Ensure corrected serum calcium is at or above the lower limit of normal prior to PARSABIV initiation, a PARSABIV dose increase, or re-initiation of PARSABIV therapy after a dosing interruption.

If a regularly scheduled hemodialysis treatment is missed, DO NOT administer any missed doses. Resume PARSABIV at the end of the next hemodialysis treatment at the prescribed dose. If doses of PARSABIV are missed for more than 2 weeks, re-initiate PARSABIV at the recommended starting dose of 5 mg (or 2.5 mg if that was the patient's last dose).

Monitor corrected serum calcium and PTH levels during dose initiation, dose adjustment, and dose maintenance according to the schedule in Table 1.

Table 1: Recommended Schedule for Monitoring Corrected Serum Calcium and Parathyroid Hormone Levels during PARSABIV Treatment *(from Parasabiv prescribing information)*

	Dose Initiation or Dose Adjustment	Maintenance
Corrected Serum Calcium Levels	1 week after	Every 4 weeks
Parathyroid Hormone Levels	4 weeks after	Per clinical practice

Increase the dose of PARSABIV in 2.5 mg or 5 mg increments in individuals with corrected serum calcium within the normal range and PTH levels above the recommended target range based on the patient's PTH levels no more frequently than every 4 weeks up to a maximum dose of 15 mg three times per week.

Decrease or temporarily discontinue PARSABIV dosing in individuals with PTH levels below the target range. In individuals with a corrected serum calcium below the lower limit of normal but at or above 7.5 mg/dL without symptoms of hypocalcemia, consider decreasing or temporarily discontinuing PARSABIV or use concomitant therapies to increase corrected serum calcium. If the dose is stopped, then re-initiate PARSABIV at a lower dose when the PTH is within the target range and hypocalcemia has been corrected.

Stop PARSABIV and treat hypocalcemia if the corrected serum calcium falls below 7.5 mg/dL or patients report symptoms of hypocalcemia. When the corrected serum calcium is within normal limits, symptoms of hypocalcemia have resolved, and predisposing factors for hypocalcemia have been addressed, re-initiate PARSABIV at a dose 5 mg lower than the last administered dose. If the last administered dose of PARSABIV was 2.5 mg or 5 mg, re-initiate at a dose of 2.5 mg.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETELCALCETIDE (NSA)

REFERENCES

) Parsabiv [Prescribing Information]. Thousand Oaks, CA: Kai Pharmaceuticals; February 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 02/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

Generic	Brand	HICL	GCN	Exception/Other
ETEPLIRSEN	EXONDYS 51	43770		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meets **ALL** of the following criteria?
 -) Documented genetic testing that confirms mutation in DMD gene is amenable to exon 51 skipping
 -) Prescribed by or given in consultation with a neurologist specializing in treatment of DMD at a DMD treatment center
 -) Patient is ambulatory
 -) Patient is currently receiving treatment with or has contraindication to corticosteroids (e.g., prednisone or prednisolone)

If yes, **approve for 24 weeks by HICL.**

APPROVAL TEXT: Renewal requires that the patient has maintained or demonstrated a less than expected decline in ambulatory function as measured by muscle function tests **OR** has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function).

If no, do not approve.

DENIAL TEXT: The guideline named **ETEPLIRSEN (Exondys 51)** requires a diagnosis of Duchenne muscular dystrophy (DMD) and that **ALL** of the following criteria are met:

-) Documented genetic testing that confirms mutation in DMD gene is amenable to exon 51 skipping
-) Prescribed by or given in consultation with a neurologist specializing in treatment of DMD at a DMD treatment center
-) Patient is ambulatory
-) Patient is currently receiving treatment with or has contraindication to corticosteroids (e.g., prednisone or prednisolone).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

2. Over the past 24 weeks, has the patient maintained or demonstrated a less than expected decline in ambulatory ability in muscle function assessments (i.e., 6-minute walking, distance (6MWD), ascending 4 stairs, descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment (NSAA))?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Renewal requires that the patient has maintained or demonstrated a less than expected decline in ambulatory function as measured by muscle function tests **OR** has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function).

If no, continue to #2.

3. During the past 24 weeks, has the patient maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Renewal requires that the patient has maintained or demonstrated a less than expected decline in ambulatory function as measured by muscle function tests **OR** has maintained or demonstrated a less than expected decline in other muscle function (i.e., pulmonary or cardiac function).

If no, do not approve.

DENIAL TEXT: The guideline named **ETEPLIRSEN (Exondys 51)** renewal requires ONE of the following criteria has been met:

-) Over the past 24 weeks, the patient has maintained or demonstrated a less than expected decline in ambulatory ability in muscle function assessments (i.e., 6-minute walking, distance (6MWD), ascending 4 stairs, descending 4 stairs, rise from floor time, 10-meter run/walk time, North Star Ambulatory Assessment (NSAA))
-) **OR** during the past 24 weeks, the patient has maintained or demonstrated a less than expected decline in other muscle function (i.e. pulmonary or cardiac function).

RATIONALE

Promote appropriate utilization of **ETEPLIRSEN** based on FDA approved indication.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

RATIONALE (CONTINUED)

Exondys 51 (eteplirsen) is a phosphorodiamidate morpholino oligomer (PMO) that selectively binds to exon 51 of the dystrophin pre-mRNA, enabling the splicing mechanisms to skip exon 51 and restore the open reading frame of the dystrophin protein, which produces a truncated but functional dystrophin protein.

Duchenne muscular dystrophy (DMD) is a rare X-linked genetic disorder that results in progressive muscle weakness, loss of independence, and early mortality. DMD affects 1 in 3,000 to 1 in 6,000 live male births. DMD occurs when there is a mutation, mainly internal deletions in the dystrophin gene that results in a near absent production of the protein dystrophin. Dystrophin contributes to functional muscle integrity by connecting muscle fibers to the surrounding extracellular matrix. Dystrophin is present in muscles at birth but repeated muscle movement leads to breakdown of the protein and production of dystrophin is needed to replenish the degraded protein. Patients with DMD are unable to produce new dystrophin and without this protein, there is progressive muscle cell degeneration and muscle fiber loss. Functional muscle units are replaced by adipose and sclerosis. Additional inflammatory and immunological processes occur in conjunction with dystrophin deficiency, contributing to muscle pathology.

DMD is present at the time of birth, but the disorder does not become apparent until around age 3 – 5 years. Children with DMD may have delayed development including starting to walk at a later age than children without DMD. Normal childhood activities such as running, jumping, and stair climbing are abnormal and done with difficulty, and patients may experience frequent falls. As the child continues to age, they experience progressive muscle weakness and dysfunction. Many patients are wheelchair bound in their early teenage years and most patients succumb to cardiac and/or respiratory failure in their 20's.

The diagnosis of DMD is definitively confirmed by genetic testing. Confirmation of DMD by genetic testing is always required even if DMD is first diagnosed by a muscle biopsy. The genetic testing will identify the types of mutations in the DMD gene, and if no deletions or duplications are detected, DNA sequencing is performed to identify point mutations (including nonsense mutations) that alter the translation of the protein. A full characterization of the mutations is necessary to determine how the genetic reading frame is affected, which is the major determinant of the phenotypic variability of DMD. Knowing which exons of the DMD gene are affected or if there is premature termination of protein production can also determine eligibility for mutation specific treatment options.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

RATIONALE (CONTINUED)

The 6-minute walking distance test (6MWD) is a validated measure of integrated function that is dependent on respiratory, cardiovascular, and nutritional status, as well as skeletal muscle function, and has been used in several studies that measure functional capabilities. Baseline 6MWD is an important predictor of subsequent ambulatory status in patients with DMD, and a baseline 6MWD of 330m or less are correlated with an increased likelihood for future loss of ambulation. Changes in values of 6MWD of 30m (or 10%) from baseline are considered clinically significant. Growing boys with DMD maintain a stable or even improving 6MWD up to about 7 years of age. After age 7, these boys experience a significant decline in walking ability compared with healthy boys of the same age. As walking ability deteriorates, the 6MWD loses value as an appropriate endpoint to measure prognosis due to its dependence on muscle tissue. As such, other endpoints are needed to determine appropriate measures of therapeutic effect in these patients. Studies of patients with DMD has resulted in the observation that the percent predicted of forced vital capacity (FVC) declines at a rate of 5% per year in DMD patients who are 5 – 24 years of age.

There is currently no cure for DMD and treatment is mainly supportive and aimed at delaying disease progression. Corticosteroids such as prednisone and prednisolone have been shown to delay muscle dysfunction and loss of ambulation by several years. Even after the loss of ambulation, treatment with corticosteroid may help preserve respiratory and cardiac function. Despite this benefit, there is no consensus on what the optimal corticosteroid regimen should be, and their long-term use is attributed to detrimental side effects.

DOSAGE

The recommended dosing regimen for eteplirsen is 30mg/kg administered once weekly as a 35 – 60 minute intravenous infusion.

FDA APPROVED INDICATION

Exondys 51 (eteplirsen) is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the *DMD* gene that is amenable to exon 51 skipping.

This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51. A clinical benefit of Exondys 51 has not been established. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

AVAILABLE STRENGTHS

100mg/2mL vials (50mg/mL)
500mg/10mL vials (50mg/mL)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ETEPLIRSEN

REFERENCES

- J Exondys 51 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc. September 2016.
- J FDA grants accelerated approval to first drug for Duchenne muscular dystrophy [Press release]. Updated September 19, 2016. Available from: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm521263.htm>.
- J Sarepta Therapeutics. Duchenne Muscular Dystrophy. Disease resources. Available from: <http://www.sarepta.com/community/disease-resources>
- J Bushby K, Finkel R, Birnkrant DJ, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010 Jan; 9(1):77-93.
- J Kole R, Krieg AM. Exon skipping therapy for Duchenne muscular dystrophy. Adv Drug Deliv Rev. 2015 Jun 29;87:104-7.
- J Skipahead.com. Understanding exon skipping: let's skip ahead. 2016. Available from: <http://www.skipahead.com/>
- J Advances in Duchenne Muscular Dystrophy Natural History and Biomarkers. Industry Therapeutic Update from BioMarin Pharmaceutical Inc. and PTC Therapeutics Inc. Presented June 22, 2015. Available from: http://files.shareholder.com/downloads/PTCT/1345262988x0x836302/7DA38D13-28CC-4C56-8905-3AB6258984F4/PTCT_BMRN_June_22_DMD_Day_FINAL_updated.pdf.
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Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/01/16

Created: 01/16

Client Approval: 09/16

P&T Approval: 02/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
FULVESTRANT	FASLODEX	23523		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer and meet **ALL** of the following criteria?

- ☐ The patient is female and postmenopausal
- ☐ The patient has not previously been treated with endocrine therapy
- ☐ The requested medication will be used as monotherapy

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- ☐ **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- ☐ **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, continue to #2.

2. Does the patient have a diagnosis of hormone receptor (HR)-positive advanced breast cancer and meet **ALL** of the following criteria?

- ☐ The patient is female and postmenopausal
- ☐ The patient has experienced disease progression following endocrine therapy
- ☐ The requested medication will be used as monotherapy

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- ☐ **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- ☐ **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and meet **ALL** of the following criteria?

- ☐ The patient is female
- ☐ The patient has experienced disease progression following endocrine therapy
- ☐ The requested medication will be used concurrently with Ibrance (palbociclib) or Verzenio (abemaciclib)

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- ☐ **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- ☐ **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, continue to #4.

4. Does the patient have a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer and meet **ALL** of the following criteria?

- ☐ The patient is female and postmenopausal
- ☐ The requested medication will be used in combination with Kisqali (ribociclib)
- ☐ The patient has not received prior endocrine based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, exemestane) **OR** patient has experienced disease progression on endocrine therapy

If yes, **approve for 12 months by HICL. Enter two authorizations by HICL as follows:**

- ☐ **Approve for 1 month for #6 (250mg/5mL) syringes (Total 30mL) for the initial month.**
- ☐ **Approve for 11 months for #2 (250mg/5mL) syringes (Total 10mL) per month for every subsequent month.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **FULVESTRANT (Faslodex)** requires a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, HR-positive advanced breast cancer or HR-positive, HER2-negative advanced or metastatic breast cancer. In addition, the following criteria must be met:

For the diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, approval requires:

-) The patient is female and postmenopausal
-) The patient has not previously been treated with endocrine therapy
-) The requested medication will be used as monotherapy

For the diagnosis of hormone receptor (HR)-positive advanced breast cancer, approval requires:

-) The patient is female and postmenopausal
-) The patient has experienced disease progression following endocrine therapy
-) The requested medication will be used as monotherapy

For the diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, approval requires ONE of the following:

-) The requested medication will be used concurrently with Ibrance (palbociclib) or Verzenio (abemaciclib) and meet ALL of the following:
 - o The patient is female
 - o The patient has experienced disease progression following endocrine therapy
-) The requested medication will be used in combination with Kisqali (ribociclib) and meet ALL of the following:
 - o The patient is female and postmenopausal
 - o The patient has not received prior endocrine based therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, exemestane) **OR** patient has experienced disease progression on endocrine therapy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

RATIONALE

To ensure appropriate usage Faslodex (fulvestrant) based on FDA approved indications.

FDA APPROVED INDICATIONS

Faslodex is an estrogen receptor antagonist indicated for:

-) Treatment of hormone receptor (HR)-positive, human epidermal growth receptor 2 (HER2)-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy.
-) Treatment of HR-positive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
-) Treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with palbociclib or abemaciclib in women with disease progression after endocrine therapy.
-) Treatment of HR-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with ribociclib in postmenopausal women not previously treated with endocrine therapy or with disease progression after endocrine therapy.

DOSAGE AND ADMINISTRATION

The recommended monotherapy dose of FASLODEX and when used in combination with palbociclib, abemaciclib, or ribociclib is 500 mg to be administered intramuscularly into the buttocks (gluteal area) slowly (1 - 2 minutes per injection) as two 5 mL injections, one in each buttock, on days 1, 15, 29 and once monthly thereafter.

When Faslodex is used in combination with palbociclib, the recommended dose of palbociclib is a 125 mg capsule taken orally once daily for 21 consecutive days followed by 7 days off treatment to comprise a complete cycle of 28 days. Palbociclib should be taken with food. Please refer to the full prescribing information of palbociclib.

When Faslodex is used in combination with abemaciclib, the recommended dose of abemaciclib is 150 mg orally, twice daily. Abemaciclib may be taken with or without food. Please refer to the Full Prescribing Information for abemaciclib.

When Faslodex is used in combination with ribociclib, the recommended dose of ribociclib is 600mg (three 200mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days.

Pre/perimenopausal women treated with the combination Faslodex plus palbociclib or abemaciclib should be treated with luteinizing hormone-releasing hormone (LHRH) agonists according to current clinical practice standards.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FULVESTRANT (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

A dose of 250 mg is recommended for patients with moderate hepatic impairment (Child-Pugh class B) to be administered intramuscularly into the buttock (gluteal area) slowly (1 - 2 minutes) as one 5 mL injection on days 1, 15, 29 and once monthly thereafter.

For complete administration instructions, please see full prescribing information of Faslodex, Ibrance, Verzenio and Kisqali.

REFERENCES

) Faslodex [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/13

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

HYDROXYPROGESTERONE CAPROATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
HYDROXYPROGESTERONE CAPROATE	MAKENA		39946 40784 44459	
HYDROXYPROGESTERONE CAPROATE	HYDROXY- PROGESTERONE CAPROATE (GENERIC FOR DELALUTIN)		11180	

GUIDELINES FOR USE

1. Is the request for Makena?

If yes, continue to #2.
If no, continued to #3.

2. Is the request for the reduction of risk of preterm birth in women with a history of singleton spontaneous preterm birth and meets **ALL** of the following criteria?
-) The patient does **NOT** have multiple gestations (twins, triplets, etc.)
 -) The patient has a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes
 -) The patient is at least 16 weeks pregnant but less than 37 weeks pregnant

If yes, **approve Makena for 6 months by GPID with a fill count of 5 and the following quantity limits:**

-) **Makena 1,250mg/5mL (GPID 39946): #5mL per 28 days.**
-) **Makena 250mg/mL (GPID 40784): #4mL per 28 days.**
-) **Makena 275mg/1.1mL autoinjector (GPID 44459): #4.4mL per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **HYDROXYPROGESTERONE CAPROATE (Makena)** requires that the agent will be used for the reduction of risk of preterm birth in women with a history of singleton spontaneous preterm birth. The following criteria must also be met.

-) The patient does **NOT** have multiple gestations (twins, triplets, etc.).
-) The patient is at least 16 weeks pregnant but less than 37 weeks pregnant with a single gestation.
-) The patient has a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

HYDROXYPROGESTERONE CAPROATE (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for use in a non-pregnant female who meets **ONE** of the following criteria?
-) For treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV)
 -) For the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer
 -) As a test for endogenous estrogen production
 -) For the production of secretory endometrium and desquamation

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: The guideline named **HYDROXYPROGESTERONE CAPROATE (Generic Delalutin)** requires use in non-pregnant females for **ONE** of the following:

-) For treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV)
-) For the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer
-) As a test for endogenous estrogen production
-) For the production of secretory endometrium and desquamation

RATIONALE

Ensure appropriate use of Makena consistent with its FDA approved indication. Ensure appropriate use of hydroxyprogesterone caproate with its FDA approved indication.

FDA APPROVED INDICATIONS

Makena is a progestin indicated to reduce the risk of preterm birth in women with a singleton pregnancy that have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.

Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

HYDROXYPROGESTERONE CAPROATE (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

Hydroxyprogesterone caproate (generic for Delalutin) is indicated in non-pregnant women:

-) For the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV).
-) In the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.
-) As a test for endogenous estrogen production
-) For the production of secretory endometrium and desquamation.

DOSAGE AND ADMINISTRATION

MAKENA

-) Makena auto-injector: Administer subcutaneously using Makena auto-injector at a dose of 275 mg (1.1 mL) once weekly, in the back of either upper arm by a healthcare provider
-) Makena (single- and multi-dose vials): Administer intramuscularly at a dose of 250 mg (1 mL) once weekly in the upper outer quadrant of the gluteus maximus by a healthcare provider
-) Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation
-) Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

Hydroxyprogesterone caproate (generic for Delalutin)

-) Treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV)
 - o Dosage: 1-7 grams IM per week until relapse occurs or after 12 weeks with no objective response
-) Amenorrhea (primary or secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology
 - o Dosage: 375mg IM x 1. Then begin cyclic therapy schedule after 4 days of desquamation or, if there is no bleeding, 21 days after initial injection. Discontinue after 4 cycles
-) Test for endogenous estrogen production
 - o Dosage: 250mg IM once and repeated once for confirmation, 4 weeks after first injection
-) Production of secretory endometrium and desquamation
 - o Patients not on estrogen therapy – utilize cyclic therapy schedule.
 - o Patients currently on estrogen therapy
-) Dosage: 375mg IM x 1. Then begin cyclic therapy schedule after 4 days of desquamation or, if there is no bleeding, 21 days after initial injection
-) Cyclic therapy schedule
 - o 28-day cycle; repeated every four weeks
 - o Day 1 of each cycle: 20mg of estradiol valerate injection USP
 - o Day 14 of each cycle: 250mg IM of hydroxyprogesterone caproate and 5mg estradiol valerate injection USP

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

HYDROXYPROGESTERONE CAPROATE (NSA)

REFERENCES

-) Makena [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc. February 2018.
-) Hydroxyprogesterone caproate [Prescribing Information]. Santa Ana, CA: McGuff Pharmaceuticals, Inc. August 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 05/11

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INOTUZUMAB OZOGAMICIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
INOTUZUMAB OZOGAMICIN	BESPONSA	44438		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) and meet following criterion?

) The patient is 18 years of age or older

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received 6 cycles of Bepsonsa treatment previously?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 6 months by HICL.**

DENIAL TEXT: The guideline named **INOTUZUMAB OZOGAMICIN (Bepsonsa)** requires the following criteria be met:

-) A diagnosis of relapsed or refractory B-cell pre-cursor acute lymphoblastic leukemia (ALL)
) The patient is 18 years of age or older
) The patient has **NOT** received 6 cycles of Bepsonsa previously

RATIONALE

Promote appropriate utilization of INOTUZUMAB OZOGAMICIN based on FDA approved indication.

FDA APPROVED INDICATION

BESPONSA is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia

DOSAGE AND ADMINISTRATION

Bepsonsa is infused for 1 hour at a rate of 50 mL/h at room temperature. Dosing is based on body surface area (m²) and response to preceding therapy:

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INOTUZUMAB OZOGAMICIN (NSA)

FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION

Dosing regimens for Cycle 1 and subsequent cycles, depending on the response to treatment:

- J **For the first cycle:** the recommended total dose of Besponsa for all patients is 1.8 mg/m² per cycle, administered as 3 divided doses on Day 1 (0.8 mg/m²), Day 8 (0.5 mg/m²), and Day 15 (0.5 mg/m²). Cycle 1 is 3 weeks in duration, but may be extended to 4 weeks if the patient achieves a complete remission (CR) or complete remission with incomplete hematologic recovery (CRi), and/or to allow recovery from toxicity.
- J **For subsequent cycles:** In patients who achieve a CR or CRi, the recommended total dose of Besponsa is 1.5 mg/m² per cycle, administered as 3 divided doses on Day 1 (0.5 mg/m²), Day 8 (0.5 mg/m²), and Day 15 (0.5 mg/m²). Subsequent cycles are 4 weeks in duration.
- J **In patients who do not achieve a CR* or CRi**:**, the recommended total dose of Besponsa is 1.8 mg/m² per cycle given as 3 divided doses on Day 1 (0.8 mg/m²), Day 8 (0.5 mg/m²), and Day 15 (0.5 mg/m²). Subsequent cycles are 4 weeks in duration. Patients who do not achieve a CR or CRi within 3 cycles should discontinue treatment.

* **CR** is defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, full recovery of peripheral blood counts (platelets $\geq 100 \times 10^9/L$ and absolute neutrophil counts [ANC] $\geq 1 \times 10^9/L$) and resolution of any extramedullary disease.

** **CRi** is defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, incomplete recovery of peripheral blood counts (platelets $< 100 \times 10^9/L$ and/or ANC $< 1 \times 10^9/L$) and resolution of any extramedullary disease.

For patients proceeding to hematopoietic stem cell transplant (HSCT), the recommended duration of treatment with Besponsa is 2 cycles. A third cycle may be considered for those patients who do not achieve CR or CRi and minimal residual disease (MRD) negativity after 2 cycles.

For patients not proceeding to HSCT, additional cycles of treatment, up to a maximum of 6 cycles, may be administered.

Patients should be pre-medicated before each dose.

AVAILABLE STRENGTHS

Injection: supplied as a white to off-white lyophilized powder in a single-dose vial for reconstitution and further dilution. Each vial delivers 0.9 mg inotuzumab ozogamicin. Each carton contains one single-dose vial.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

INOTUZUMAB OZOGAMICIN (NSA)

REFERENCES

) Besponsa [Prescribing Information]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc. August 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/18

Created: 08/17

Client Approval: 12/17

P&T Approval: 10/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IOBENGUANE IODINE 131 (NSA)

Generic	Brand	HICL	GCN	Exception/Other
IOBENGUANE I 131	AZEDRA	25483		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma and meet ALL of the following criteria?
 - ☐ The patient is 12 years of age or older
 - ☐ The patient requires systemic anticancer therapy
 - ☐ The tumors are iobenguane scan positive
 - ☐ The patient has **NOT** previously received 1 dosimetric dose and 2 therapeutic doses of Azedra

If yes, **approve by GPID for 12 months for all dosages with the following quantity limits:**

- ☐ **Azedra Dosimetric (GPID 45058): #1 vial per 12 months.**
- ☐ **Azedra Therapeutic (GPID 45059): #4 vials per 12 months.**

If no, do not approve.

DENIAL TEXT: The guideline named **IOBENGUANE IODINE 131 (Azedra)** requires a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma. In addition, the following criteria must be met:

- ☐ The patient is 12 years of age or older
- ☐ The patient requires systemic anticancer therapy
- ☐ The tumors are iobenguane scan positive
- ☐ The patient has **NOT** previously received 1 dosimetric dose and 2 therapeutic doses of Azedra

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Azedra.

REFERENCES

- ☐ Azedra [Prescribing Information]. New York, NY: Progenics Pharmaceuticals, Inc. Pharmaceuticals Corporation. July 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IRINOTECAN LIPOSOMAL

Generic	Brand	HICL	GCN	Exception/Other
IRINOTECAN LIPOSOMAL	ONIVYDE	42715		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic adenocarcinoma of the pancreas and have **ALL** of the following criteria been met?

-) The patient has experienced disease progression despite a trial of gemcitabine-based therapy.
-) Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin.

If yes, **approve for 12 months by HICL for 2 fills per 28 day supply.**

If no, continue to #2.

DENIAL TEXT: Our guideline for **IRINOTECAN LIPOSOMAL** requires a diagnosis of metastatic adenocarcinoma of the pancreas. In addition, the following criteria must also be met:

-) The patient has experienced disease progression despite a trial of gemcitabine-based therapy.
-) Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin.

RATIONALE

Promote appropriate utilization of irinotecan liposomal based on FDA approved indication and dosing.

Onivyde is a nanoliposomal encapsulated preparation of irinotecan that enables it to remain in circulation for a longer duration compared with standard irinotecan; this allows for higher drug uptake within tumor cells and conversion of irinotecan to its active form, SN38.

Pancreatic cancer can be difficult to diagnose early and treatment options are limited, especially when the disease has spread to other parts of the body and surgery to remove the tumor is not possible. The majority of these tumors (85%) are adenocarcinomas arising from the ductal epithelium. The disease is rare before the age of 45, but the incidence rises sharply thereafter. On the basis of significant improvements in clinical benefit and survival, gemcitabine was approved for first-line therapy of metastatic pancreatic cancer.

DOSAGE

The recommended dose of Onivyde is 70 mg/m² administered by intravenous infusion over 90 minutes every 2 weeks, unless the patient is known to be homozygous for the UGT1A1*28 allele, in which case, the first dose should be 50 mg/m². Onivyde requires pre-medication with a corticosteroid and an anti-emetic 30 minutes prior to the Onivyde infusion. Once the Onivyde infusion is complete, it should be followed by leucovorin 400 mg/m² intravenously over 30 minutes and then by fluorouracil 2400 mg/m² intravenously over 46 hours, every 2 weeks.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IRINOTECAN LIPOSOMAL

FDA APPROVED INDICATION

Onivyde is a topoisomerase inhibitor indicated, in combination with fluorouracil and leucovorin, for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy.

Limitation of Use: Onivyde is not indicated as a single agent for the treatment of patients with metastatic adenocarcinoma of the pancreas.

REFERENCES

) Onivyde [Prescribing Information]. Merrimack Pharmaceuticals, Inc.: Cambridge, MA. October 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/16

Created: 11/15

Client Approval: 11/15

P&T Approval: 11/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXABEPILONE

Generic	Brand	HICL	GCN	Exception/Other
IXABEPILONE	IXEMPRA	35083		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced breast cancer?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic or locally advanced breast cancer and, 1) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) or, 2) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel), and being used in combination with Xeloda (capecitabine).

2. Has the patient tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

If no, continue to #3.

3. Is the requested medication being used in combination with Xeloda (capecitabine)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic or locally advanced breast cancer and, 1) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) or, 2) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel), and being used in combination with Xeloda (capecitabine).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXABEPILONE

GUIDELINES FOR USE (CONTINUED)

4. Has the patient tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic or locally advanced breast cancer and, 1) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) or, 2) trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) and a taxane (paclitaxel or docetaxel), and being used in combination with Xeloda (capecitabine).

RATIONALE

Coverage of Ixempria (ixabepilone) is based on FDA approved indications and NCCN recommendations.

The recommended dose of Ixempria is 40 mg/m² infused intravenously over 3 hours every 3 weeks. Dose reduction is required in certain patients with elevated AST, ALT, or bilirubin.

NCCN guidelines recognize multiple chemotherapy treatment options for recurrent or metastatic breast cancer. Ixempria is considered a nonpreferred single agent therapy. NCCN no longer recognizes Ixempria with Xeloda as a valid chemotherapy regimen for the treatment of recurrent or metastatic breast cancer.

Preferred Single Agents	Other Single Agents	Combination Regimens
doxorubicin	cyclophosphamide	cyclophosphamide, doxorubicin, fluorouracil (FAC/CAF)
pegylated liposomal doxorubicin	carboplatin	fluorouracil, epirubicin, cyclophosphamide (FEC)
paclitaxel	docetaxel	doxorubicin, cyclophosphamide (AC)
Xeloda	Abraxane	epirubicin, cyclophosphamide (EC)
gemcitabine	cisplatin	cyclophosphamide, methotrexate, fluorouracil (CML)
Halaven	Ixempria	docetaxel, Xeloda
vinorelbine	epirubicin	gemcitabine, paclitaxel
		gemcitabine carboplatin
		paclitaxel, Avastin

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IXABEPILONE

FDA APPROVED INDICATION

-) Ixempra, a microtubule inhibitor, in combination with capecitabine is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane.
-) Ixempra as monotherapy is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline, a taxane, and capecitabine.

REFERENCES

-) Bristol-Myers Squibb Company. Ixempra package insert. Princeton, NJ. October 2011.
-) National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer (Version 3.2013).

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 08/13

Client Approval: 08/13

P&T Approval: 08/13



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LETERMOVIR IV (NSA)

Generic	Brand	HICL	GCN	Exception/Other
LETERMOVIR	PREVYMIS		44062 44063	

GUIDELINES FOR USE

1. Is the patient undergoing an allogeneic hematopoietic stem cell transplant (HSCT) and meet **ALL** of the following criteria?

- ☐ The patient is at least 18 years of age or older
- ☐ The patient is CMV-seropositive [R+]
- ☐ Prevmis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
- ☐ Prevmis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
- ☐ Patient is not receiving the medication beyond 100 days post-transplantation

If yes, **approve for 4 months by GPID for all daily dosage strengths with the following quantity limits:**

- ☐ **240mg/12mL daily dose (GPID 44062): #12mL (one single dose vial) per day.**
- ☐ **480mg/24mL (GPID 44063): #24mL (one single dose vial) per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **LETERMOVIR IV (Prevmis)** requires the patient to be undergoing an allogeneic hematopoietic stem cell transplant (HSCT). In addition, the following criteria must also be met:

- ☐ The patient is at least 18 years of age or older
- ☐ The patient is CMV-seropositive [R+]
- ☐ Prevmis will be used for prophylaxis of cytomegalovirus (CMV) infection and disease
- ☐ Prevmis will be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment)
- ☐ Patient is not receiving the medication beyond 100 days post-transplantation

RATIONALE

Promote appropriate utilization of **LETERMOVIR** based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Prevmis is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LETERMOVIR IV (NSA)

FDA APPROVED INDICATION (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. Prevymis is recommended to be initiated between Day 0 and Day 28 post-transplantation (before or after engraftment), and continue through Day 100 post-transplantation. Dosage of Prevymis should be decreased to 240mg once daily when co-administered with cyclosporine.

-) If cyclosporine is initiated after starting Prevymis, the next dose of Prevymis should be decreased to 240mg once daily.
-) If cyclosporine is discontinued after starting Prevymis, the next dose of Prevymis should be increased to 480mg once daily.
-) If cyclosporine dosing is interrupted due to high cyclosporine levels, no dose adjustment of Prevymis is needed.

Prevymis injection, which contains hydroxypropyl betadex, should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis as soon as they are able to take oral medications. Prevymis tablet and injection may be used interchangeably at the discretion of the physician, and no dosage adjustment is necessary when switching formulations.

AVAILABLE STRENGTHS

Tablet: 240mg, 480mg tablets; Injection: 240mg/12 mL (20mg/mL), 480mg/24mL (20mg/mL) single dose vials

REFERENCES

-) Prevymis [Prescribing Information]. Merck & Co, Inc.; Whitehouse Station, NJ. November 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/18

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LUTETIUM LU 177 DOTATATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
LUTETIUM LU 177 DOTATATE	LUTATHERA	44750		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) The patient will be treated with long-acting octreotide as maintenance therapy in conjunction with the requested drug
 -) The patient has been previously treated with a long acting somatostatin analog (i.e., octreotide or lanreotide) prior to the request of this medication

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received 4 doses of Lutathera previously?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 8 months by HICL with a quantity limit of #1 vial per 56 days.**

DENIAL TEXT: The guideline named **LUTETIUM LU 177 DOTATATE (Lutathera)** requires a diagnosis of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) The patient will be treated with long-acting octreotide as maintenance therapy in conjunction with the requested drug
-) The patient has been previously treated with a long acting somatostatin analog (i.e., octreotide or lanreotide) prior to the request of this medication
-) The patient has **NOT** previously received 4 doses of Lutathera

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

LUTETIUM LU 177 DOTATATE (NSA)

RATIONALE

To promote appropriate utilization of Lutathera based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Lutathera is a radiolabeled somatostatin analog indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

DOSAGE AND ADMINISTRATION

The recommended Lutathera dose is 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. Administer pre- and concomitant medications and administer Lutathera as recommended.

Lutathera is a radiopharmaceutical; handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling Lutathera. Radiopharmaceuticals, including Lutathera, should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.

Verify pregnancy status of females of reproductive potential prior to initiating Lutathera.

REFERENCES

) Lutathera [Prescribing Information]. New York, NY: Advanced Accelerator Applications USA, Inc. February 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 05/18

Client Approval: 05/18

P&T Approval: 04/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MINOCYCLINE HCL MICROSPHERES	ARESTIN	25203		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

1. Is this medication excluded from coverage?

If yes, guideline does not apply.
If no, continue to #2.

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets **ALL** of the following criteria?
-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
 -) No history of minocycline or tetracycline sensitivity or allergy
 -) No history of candidiasis or active oral candidiasis
 -) Not being used for acutely abscessed periodontal pocket
 -) Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
 - o Uncontrolled diabetes mellitus
 - o Chemotherapy
 - o Radiation therapy
 - o HIV infection
 -) Not being used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants
 -) Age 18 years or older
 -) Prescribed and administered by an oral health care professional

If yes, **approve for 3 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing
-) No history of minocycline or tetracycline sensitivity or allergy
-) No history of candidiasis or active oral candidiasis
-) Not being used for acutely abscessed periodontal pocket
-) Not being used in an immunocompromised individual, such as those immunocompromised by any of the following conditions:
 - o Uncontrolled diabetes mellitus
 - o Chemotherapy
 - o Radiation therapy
 - o HIV infection
-) Not being used in the regeneration of alveolar bone, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants
-) Age 18 years or older
-) Prescribed and administered by an oral health care professional

RENEWAL CRITERIA

1. Is this medication excluded from coverage?

If yes, guideline does not apply.

If no, continue to #2.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have documentation of a confirmed diagnosis of periodontitis and meets the following criteria?

-) The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

If yes, **approve for 6 months by HICL for the quantity requested up to a maximum of 48 unit-dose cartridges per 3 months.**

If no, do not approve.

DENIAL TEXT: The guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** renewal requires documentation of a confirmed diagnosis of periodontitis. The following criteria must also be met.

- o The requested drug will be used as an adjunct to scaling and root planing procedures **OR** used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing

RATIONALE

Ensure appropriate use of ARESTIN consistent with its FDA approved indication, dosing, contraindications, and precautions. In clinical trials, an average of 29.5 (5-114), 31.7 (4-137), and 31 (5-108) sites were treated at baseline in the scaling and root planning (SRP) alone, SRP + vehicle, and SRP + ARESTIN groups, respectively.

FDA APPROVED INDICATIONS

ARESTIN is indicated as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with adult periodontitis. ARESTIN may be used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planing.

DOSAGE

ARESTIN is provided as a dry powder, packaged in a unit dose cartridge with a deformable tip, which is inserted into a spring-loaded cartridge handle mechanism to administer the product.

The oral health care professional removes the disposable cartridge from its pouch and connects the cartridge to the handle mechanism. ARESTIN is a variable dose product, dependent on the size, shape, and number of pockets being treated. In US clinical trials, up to 122 unit dose cartridges were used in a single visit and up to 3 treatments, at 3-month intervals, were administered in pockets with pocket depth of 5 mm or greater.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MINOCYCLINE HCL MICROSPHERES (NSA)

REFERENCES

) Arestin [Prescribing Information]. Bridgewater, NJ: OraPharma. August 2015.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 08/01/18

Created: 08/16

Client Approval: 07/18

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MITOXANTRONE

Generic	Brand	HICL	GCN	Exception/Other
MITOXANTRONE HCL	NOVANTRONE	03932		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the prescription written by or supervised by an oncologist?

If yes, continue to #4.
If no, continue to #2.
2. Is the patient being treated for pain related to advanced hormone refractory prostate cancer or acute nonlymphocytic leukemia?

If yes, continue to #4.
If no, continue to #3.
3. Is the patient being treated for secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: Approval requires supervision by an oncologist or a diagnosis of pain related to advanced refractory prostate cancer or acute nonlymphocytic leukemia or secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis.
4. **Approve open ended.**
APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.
5. **Approve for 12 months. (FDA dosing regimen is 12 mg/m² IV every 3 months)**
APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information please ask your doctor or pharmacist.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MITOXANTRONE

RATIONALE

To assure safe and appropriate use of mitoxantrone.

FDA APPROVED INDICATIONS

Mitoxantrone is indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis; in combination with corticosteroids to treat pain related to advanced hormone-refractory prostate cancer; initial therapy or in combination with other approved drugs for acute nonlymphocytic leukemia in adults.

REFERENCES

) EMD Serono, Inc. Novantrone product labeling. Rockland, MA. September 2009.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 08/08

Client Approval: 08/13

P&T Approval: 08/10



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOGAMULIZUMAB-KPKC (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOGAMULIZUMAB-KPKC	POTELIGEO	45153		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Mycosis Fungoides (MF) or Sézary syndrome and meet **ALL** of the following criteria?

- ☐ The patient has relapsed or refractory disease
- ☐ The patient has tried and failed at least one prior systemic therapy
- ☐ The patient is 18 years or older

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires a diagnosis of Mycosis Fungoides (MF) or Sézary syndrome. In addition, the following criteria must be met:

- ☐ The patient has relapsed or refractory disease
- ☐ The patient has tried and failed at least one prior systemic therapy
- ☐ The patient is 18 years or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Poteligeo.

REFERENCES

- ☐ Poteligeo [Prescribing Information]. Bedminster, NJ: Kyowa Kirin; August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 11/18

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOMETASONE SINUS IMPLANT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOMETASONE FUROATE	SINUVA		44214	

GUIDELINES FOR USE

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has had previous ethmoid sinus surgery (ESS)
- ☐ The medication is prescribed by or given in consultation with an otolaryngologist
- ☐ The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
- ☐ The patient had a previous trial of at least **TWO** intranasal corticosteroids (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

If yes, **approve #2 implants (1 per sinus) by GPID per lifetime.**

If no, do not approve.

DENIAL TEXT: The guideline named **MOMETASONE IMPLANT (Sinuva)** requires a diagnosis of nasal polyps. In addition, the following criteria must also be met:

- ☐ The patient is 18 years of age or older
- ☐ The patient has had previous ethmoid sinus surgery (ESS)
- ☐ The medication is prescribed by or given in consultation with an otolaryngologist
- ☐ The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
- ☐ The patient had a previous trial of at least **TWO** intranasal corticosteroids (e.g., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

MOMETASONE SINUS IMPLANT (NSA)

RATIONALE

To promote appropriate utilization of SINUVA based on FDA approved indication and dosing.

FDA APPROVED INDICATION

Sinuva Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients 18 years of age who have had ethmoid sinus surgery

DOSAGE & ADMINISTRATION

One Sinuva Sinus Implant containing 1350 mcg of mometasone furoate. There are no studies evaluating repeat implantation of the Sinuva Sinus Implant.

The Sinuva Sinus Implant is loaded into a delivery system and placed in the ethmoid sinus under endoscopic visualization. The Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The Implant can be removed at Day 90 or earlier at the physician's discretion using standard surgical instruments. Sinuva must be inserted by physicians trained in otolaryngology.

REFERENCES

) Sinuva [Prescribing Information]. Menlo Park, CA: Intersect ENT. December 2017.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A

Commercial Effective: 08/01/18

Created: 05/18

Client Approval: 07/18

P&T Approval: 04/18

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****NECITUMUMAB**

Generic	Brand	HICL	GCN	Exception/Other
NECITUMUMAB	PORTRAZZA	42835		

GUIDELINES FOR USE

1. Will necitumumab be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin?

If yes, **approve for 12 months by HICL with a quantity limit of #2 vials per 21 days.**

If no, do not approve.

DENIAL TEXT: Our guideline for **NECITUMUMAB (Portrazza)** requires that it be used as first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin.

RATIONALE

Promote appropriate utilization of **NECITUMUMAB** based on its FDA approved indication.

Lung cancer is the second most common cancer in the United States with about 220,000 new diagnoses each year and the leading cause of cancer-related mortality with an estimated 158,000 deaths per year. About 85% of lung cancers are classified as NSCLC, of which squamous cell carcinomas account for about 25-30%, making them the most common histological subtype after adenocarcinoma. Squamous cell carcinomas are often associated with a history of smoking and are more commonly seen in males.

Treatment selection depends upon tumor staging, histology, molecular profiling to identify driver mutations (e.g., EGFR, anaplastic lymphoma kinase [ALK]), and an evaluation of the patient's overall medical condition. Whereas patients without metastatic disease are treated with curative intent using surgery, chemotherapy, and/or radiation therapy, the primary approach for patients with metastatic disease is palliative systemic chemotherapy. The National Comprehensive Cancer Network (NCCN) Panel recommends targeted tyrosine kinase inhibitor (TKI) therapies such as EGFR inhibitors (Tarceva [erlotinib], Gilotrif [afatinib], Iressa [gefitinib]) or ALK inhibitors (Xalkori [crizotinib], Zykadia [ceritinib], Alecensa [alectinib]) as first-line for patients whose tumors contain a driver mutation; however, these mutations are typically observed with adenocarcinomas rather than with squamous cell carcinomas.

For patients whose mutation status is negative or unknown, the NCCN Panel recommends platinum-based two-drug combination regimens as first-line treatment. Platinum-based chemotherapy prolongs survival, improves symptom control, and yields superior quality of life compared to best supportive care. Based upon superior efficacy compared to cisplatin/pemetrexed, the NCCN Panel recommends cisplatin/gemcitabine as first-line therapy in patients with squamous NSCLC. Two-drug regimens are preferred; a third cytotoxic drug may increase response rate but not survival. As many of the platinum two-drug combinations yield similar objective response rates and survival and differ slightly for toxicity, convenience, and cost, clinicians can individualize therapy for their patients.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NECITUMUMAB

RATIONALE (CONTINUED)

In December 2015, NCCN updated its guideline to include cisplatin/gemcitabine/necitumumab as a first-line systemic therapy option for advanced or metastatic squamous NSCLC; however, this was designated as a category 3 recommendation, which indicates major NCCN disagreement on the appropriateness of the intervention. NCCN stated that the category 3 recommendation for this regimen is due to its toxicity, cost, and limited improvement in efficacy that is seen when necitumumab is added to cisplatin/gemcitabine. NCCN recommendations (category 1) for first-line treatment options are listed in Table 1.

Table 1. First-line systemic therapy options for advanced or metastatic squamous cell NSCLC

Carboplatin-based regimens	Cisplatin-based regimens	Non-platinum-based regimens
) Carboplatin/albumin-bound paclitaxel) Cisplatin/docetaxel) Gemcitabine/docetaxel
) Carboplatin/docetaxel) Cisplatin/etoposide) Gemcitabine/vinorelbine
) Carboplatin/etoposide) Cisplatin/gemcitabine	
) Carboplatin/gemcitabine) Cisplatin/paclitaxel	
) Carboplatin/paclitaxel) Cisplatin/vinorelbine	
) Carboplatin/vinorelbine		

Other monoclonal antibodies have been approved for the treatment of NSCLC, but they occupy different places in therapy from Portrazza. For instance, Avastin (bevacizumab) is indicated for the first-line treatment of advanced NSCLC but only in patients with non-squamous histology. Opdivo (nivolumab) and Cyramza (ramucirumab) are indicated only as subsequent-line therapy for patients who have progressed on or after platinum-based chemotherapy. Erbitux (cetuximab) is a monoclonal antibody that also targets EGFR but is not currently indicated for the treatment of NSCLC.

The SQUIRE trial was a phase 3, multicenter, open-label, randomized trial that evaluated the efficacy of Portrazza in 1,093 patients with squamous NSCLC. Previously untreated patients with stage IV squamous NSCLC and an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 were randomized 1:1 to receive Portrazza plus gemcitabine/cisplatin or to gemcitabine/cisplatin alone. Baseline characteristics included median age of 62 years, 83% male, 84% Caucasian, 91% smokers, 91% with baseline ECOG performance status of 0-1, and 91% with metastatic disease in at least two sites (most commonly lung and lymph nodes). Gemcitabine/cisplatin was given for up to six cycles; in patients demonstrating at least stable disease (51%), Portrazza was continued alone after the completion of chemotherapy as maintenance treatment until disease progression or toxicity. Blinding was not conducted in this trial because the expected occurrence of acne-like rash would have unmasked most patients and investigators to treatment. The primary endpoint was overall survival.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****NECITUMUMAB****RATIONALE (CONTINUED)**

Efficacy results are shown in Table 2.

Table 2. Efficacy results of the SQUIRE trial

Outcome	Portrazza + gemcitabine/cisplatin (n = 545)	Gemcitabine/cisplatin (n = 548)	Hazard ratio (95% CI) p-value
Overall survival (OS)			
Median OS – months	11.5	9.9	0.84 (0.74, 0.96) p = 0.01
Deaths – no. (%)	418 (77)	442 (81)	--
Progression-free survival (PFS)			
Median PFS – months	5.7	5.5	0.85 (0.74, 0.98) p = 0.02
Events – no. (%)	431 (79)	417 (76)	--
Response			
Objective response rate (ORR) – no. (%)	170 (31)	158 (29)	p = 0.40

Portrazza should not be used for the treatment of non-squamous NSCLC due to a risk for increased toxicity and mortality observed in the INSPIRE trial. The INSPIRE trial was a multicenter, open-label trial that evaluated Portrazza in 633 patients with metastatic non-squamous NSCLC. Patients were randomized 1:1 to receive Portrazza plus pemetrexed/cisplatin (n = 315) or pemetrexed/cisplatin alone (n = 318). There was no significant difference in OS (HR 1.01; 95% CI 0.84, 1.21), PFS (HR 0.96; 95% CI 0.80, 1.16), or ORR (31% vs. 32%, respectively). The study was terminated early due to increased all-cause mortality and thromboembolic-related mortality in the Portrazza treatment arm.

FDA APPROVED INDICATION

Portrazza is indicated, in combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer.

Limitation of Use: Portrazza is not indicated for treatment of non-squamous non-small cell lung cancer.

DOSAGE

The recommended dose of Portrazza is 800 mg administered as an intravenous (IV) infusion over 60 minutes on Days 1 and 8 of each 3-week cycle prior to gemcitabine and cisplatin infusion.

Gemcitabine/cisplatin chemotherapy is given for a maximum of six cycles, and Portrazza is continued thereafter as single-agent maintenance therapy until disease progression or unacceptable toxicity.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NECITUMUMAB

DOSAGE (CONTINUED)

Infusion rate should be reduced and pre-medication should be administered with all subsequent infusions for patients who have experienced a Grade 1 or 2 infusion-related reaction with previous Portrazza infusion: diphenhydramine (or equivalent) after the first occurrence; diphenhydramine (or equivalent), acetaminophen (or equivalent), and dexamethasone (or equivalent) after the second occurrence. Portrazza should be permanently discontinued for Grade 3 or 4 infusion-related reactions and certain dermatologic toxicities (e.g., rash that does not resolve, worsening or intolerable reactions at a reduced dose, Grade 3 skin induration/fibrosis, Grade 4).

REFERENCES

-) FDA Press Release [Online Press Release]: FDA approves Portrazza to treat advanced squamous non-small cell lung cancer. Available at: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm474131.htm>. Updated November 24, 2015.
-) National Comprehensive Cancer Network. NCCN Guidelines: Non-Small Cell Lung Cancer. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Updated December 22, 2015.
-) Paz-Ares K, Mezger J, Ciuleanu TE, et al. Necitumumab plus pemetrexed and cisplatin as first-line therapy in patients with stage IV non-squamous non-small-cell lung cancer (INSPIRE): an open-label, randomised, controlled phase 3 study. *Lancet Oncol.* 2015;16:328-37.
-) Portrazza [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. November 2015.
-) Thatcher N, Hirsch FR, Luft AV, et al. Necitumumab plus gemcitabine and cisplatin versus gemcitabine and cisplatin alone as first-line therapy in patients with stage IV squamous non-small-cell lung cancer (SQUIRE): an open-label, randomised, controlled phase 3 trial. *Lancet Oncol.* 2015;16:763-74.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 12/15

Client Approval: 02/16

P&T Approval: 2/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBINUTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OBINUTUZUMAB	GAZYVA	40703		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) and meet **ALL** of the following criteria?

- ☐ The patient has not received previous treatment for chronic lymphocytic leukemia (CLL)
- ☐ The requested medication will be used in combination with chlorambucil

If yes, **please enter two approvals as follows:**

- ☐ **Approve for 1 month by HICL for #4 (1000mg/40mL) vials per 28 days.**
- ☐ **Approve for 5 months by HICL for #1 (1000mg/40mL) vial per 28 days with a start date one day after the end date of the first approval.**

If no, continue to #2.

2. Does the patient have a diagnosis of follicular lymphoma (FL) and meet **ALL** of the following criteria?

- ☐ The patient has relapsed after, or is refractory to, a regimen containing Rituxan (rituximab)
- ☐ The requested medication will be used in combination with bendamustine for the initial six cycles **OR** as monotherapy thereafter

If yes, **please enter three approvals as follows:**

- ☐ **Approve for 1 month by HICL for #3 (1000mg/40mL) vials per 28 days.**
- ☐ **Approve for 5 months by HICL for #1 (1000mg/40mL) vial per 28 days with a start date one day after the end date of the first approval.**
- ☐ **Approve for 6 months by HICL for #1 (1000mg/40mL) vial per 56 days with a start date one day after the end date of the second approval.**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBINUTUZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of stage II bulky, III or IV follicular lymphoma (FL) and meet **ALL** of the following criteria?

-) The patient is at least 18 years old
-) The patient has not received previous treatment for stage II bulky, III or IV follicular lymphoma
-) The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [i.e., bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] **OR** as monotherapy thereafter

If yes, please enter three approvals as follows:

-) **Approve for 1 month by HICL for #3 (1000mg/40mL) vials per 28 days.**
-) **Approve for 7 months by HICL for #1 (1000mg/40mL) vial per 28 days with a start date one day after the end date of the first approval.**
-) **Approve for 4 months by HICL for #1 (1000mg/40mL) vial per 56 days with a start date one day after the end date of the second approval.**

If no, do not approve.

DENIAL TEXT: The guideline named **OBINUTUZUMAB (Gazyva)** requires a diagnosis of chronic lymphocytic leukemia (CLL), follicular lymphoma (FL), or stage II bulky, III or IV follicular lymphoma. In addition, the following must be met:

For the diagnosis of chronic lymphocytic leukemia (CLL), approval requires:

-) The patient has not received previous treatment for chronic lymphocytic leukemia (CLL)
-) The requested medication will be used in combination with chlorambucil

For the diagnosis of follicular lymphoma (FL), approval requires:

-) The patient has relapsed after, or is refractory to, a regimen containing Rituxan (rituximab)
-) The requested medication will be used in combination with bendamustine for the initial six cycles **OR** as monotherapy thereafter

For the diagnosis of stage II bulky, III or IV follicular lymphoma (FL), approval requires:

-) The patient is at least 18 years old
-) The patient has not received previous treatment for stage II bulky, III or IV follicular lymphoma
-) The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [i.e., bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] **OR** as monotherapy thereafter

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****OBINUTUZUMAB (NSA)****RATIONALE**

To promote appropriate utilization of Gazyva based on FDA approved indication.

FDA APPROVED INDICATIONS

Gazyva (obinutuzumab) is a CD20-directed cytolytic antibody and is indicated:

-) In combination with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL).
-) In combination with bendamustine followed by Gazyva monotherapy, for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen.
-) In combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission, for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma.

DOSAGE AND ADMINISTRATION

Each dose of Gazyva is 1000 mg, administered intravenously.

Chronic Lymphocytic Leukemia (CLL)

Recommended dose for 6 cycles (28-day cycles):

Day of Treatment Cycle		Dose of Gazyva
Cycle 1	Day 1	100 mg
	Day 2	900 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-6	Day 1	1000 mg

The dose for chronic lymphocytic leukemia is 100 mg on day 1 and 900 mg on day 2 of Cycle 1, 1000 mg on day 8 and 15 of Cycle 1, and 1000 mg on day 1 of Cycles 2-6.

Relapsed or Refractory Follicular Lymphoma

For patients with relapsed or refractory FL, administer Gazyva in combination with bendamustine in six 28-day cycles. Patients who achieve stable disease, complete response, or partial response to the initial 6 cycles should continue on Gazyva 1000 mg as monotherapy for up to two years.

Recommended dose for 6 treatment cycles:

Day of Treatment Cycle		Dose of Gazyva
Cycle 1	Day 1	1000 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-6	Day 1	1000 mg
Monotherapy	Every 2 months for up to 2 years	1000 mg

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****OBINUTUZUMAB (NSA)****FDA APPROVED INDICATIONS (CONTINUED)****DOSAGE AND ADMINISTRATION**

Recommended dose for 6 treatment cycles:

Day of Treatment Cycle		Dose of Gazyva
Cycle 1	Day 1	1000 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-6	Day 1	1000 mg
Monotherapy	Every 2 months for up to 2 years	1000 mg

Previously Untreated Stage II bulky, III, or IV Follicular Lymphoma

For patients with previously untreated FL, administer Gazyva with one of the following chemotherapy regimens:

-) Six 28-day cycles in combination with bendamustine
-) Six 21-day cycles in combination with CHOP, followed by 2 additional 21-day cycles of Gazyva alone
-) Eight 21-day cycles in combination with CVP

Patients with previously untreated FL who achieve a complete response or partial response to the initial 6 or 8 cycles should continue on Gazyva 1000 mg as monotherapy for up to two years.

Recommended dose for 8 treatment cycles:

-) The dose for follicular lymphoma is 1000 mg on day 1, 8, and 15 of Cycle 1, and 1000 mg on day 1 of Cycles 2-8, and then 1000 mg every 2 months for 2 years.

Day of Treatment Cycle		Dose of Gazyva
Cycle 1	Day 1	1000 mg
	Day 8	1000 mg
	Day 15	1000 mg
Cycles 2-8	Day 1	1000 mg
Monotherapy	Every 2 months for up to 2 years	1000 mg

Patients should be premedicated with glucocorticoids, acetaminophen, and an antihistamine before infusion. Dilute and administer as intravenous infusion. Do not administer as an intravenous push or bolus. Patients with neutropenia are strongly recommended to receive antimicrobial prophylaxis throughout the treatment period. Antiviral and antifungal prophylaxis should be considered.

REFERENCES

-) Genentech, Inc. Gazyva package insert. South San Francisco, CA. November 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OBINUTUZUMAB (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 02/05/18

Created: 11/13
Client Approval: 01/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OFATUMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OFATUMUMAB	ARZERRA	36708		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient previously untreated for chronic lymphocytic leukemia (CLL) and meets **ALL** of the following criteria?

-) Fludara (fludarabine)-based therapy is considered inappropriate in this patient
-) The requested medication will be used in combination with chlorambucil

If yes, **approve as follows by GPID and enter two prior authorizations:**

) **Approval #1: Approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials AND**

) **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**

- o **Approve 12 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 28 days (total fill count of 12) OR**
- o **Approve 12 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 28 days (total fill count of 12)**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment of **relapsed** chronic lymphocytic leukemia (CLL) and does the patient meet the following criteria?

- ☐ The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

If yes, **approve as follows by GPID and enter two prior authorizations:**

- ☐ **Approval #1:** approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials **AND**
- ☐ **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
- ☐ **Approve 6 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 28 days (total fill count of 6) OR**
 - ☐ **Approve 6 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 28 days (total fill count of 6)**

If no, continue to #4.

4. For extended treatment of chronic lymphocytic leukemia (CLL), does the patient meet **ALL** of the following criteria?

- ☐ The patient is in complete or partial response
- ☐ The patient has received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL)

If yes, **approve as follows by GPID and enter two prior authorizations:**

- ☐ **Approval #1:** approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials **AND**
- ☐ **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**
- ☐ **Approve 24 months of Arzerra 100mg/5mL with a quantity limit of #10 vials per 8 weeks (total fill count of 13) OR**
 - ☐ **Approve 24 months of Arzerra 1,000mg/50mL with a quantity limit of #1 vial per 8 weeks (total fill count of 13)**

If no, continue to #5.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. For refractory chronic lymphocytic leukemia (CLL), does the patient meet **ALL** of the following criteria?

) The patient is refractory to Fludara (fludarabine) and Campath (alemtuzumab)

 If yes, **approve as follows by GPID and enter three prior authorizations:**

) **Approval #1: approve one fill of Arzerra 100mg/5mL with a quantity limit of #3 vials AND**

) **Approval #2 (Please enter a start date of 1 WEEK AFTER the start date of the initial PA):**

- **Approve 7 weeks of Arzerra 100mg/5mL with a quantity limit of #20 vials per 7 days (total fill count of 7) OR**
- **Approve 7 weeks of Arzerra 1,000mg/50mL with a quantity limit of #2 vials per 7 days AND**

) **Approval #3 (Please enter a start date of 4 WEEKS AFTER the end date of the second approval):**

- **Approve 16 weeks of Arzerra 100mg/5mL with a quantity limit of #20 vials per 28 days (total fill count of 4) OR**
- **Approve 16 weeks of Arzerra 1,000mg/50mL with a quantity limit of #2 vials per 28 days (total fill count of 4)**

 If no, do not approve.

DENIAL TEXT: The guideline named **OFATUMUMAB (Arzerra)** requires a diagnosis of chronic lymphocytic leukemia (CLL). In addition, the following criteria must also be met.

For patients with previously untreated chronic lymphocytic (CLL), approval requires all of the following:

-) The patient has not received previous treatment for chronic lymphocytic (CLL)
-) Fludara (fludarabine)-based therapy is considered inappropriate in this patient
-) The requested medication will be used in combination with chlorambucil

For patients with relapsed chronic lymphocytic (CLL), approval requires all of the following:

-) The patient has relapsed chronic lymphocytic (CLL)
-) The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

(Denial text continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OFATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

For patients requesting extended treatment of chronic lymphocytic (CLL), approval requires all of the following:

- ⌋ The patient is in complete or partial response
- ⌋ The patient has received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL)

For patients with refractory chronic lymphocytic (CLL), approval requires all of the following:

- ⌋ The patient is refractory to Fludara (fludarabine) and Campath (alemtuzumab)

RATIONALE

Ensure appropriate utilization of Arzerra (ofatumumab) per FDA-approved indications and dosing.

FDA APPROVED INDICATION

Arzerra (ofatumumab) is a CD20-directed cytolytic monoclonal antibody indicated for the treatment of chronic lymphocytic leukemia (CLL):

- ⌋ in combination with chlorambucil, for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate
- ⌋ in combination with fludarabine and cyclophosphamide for the treatment of patients with relapse CLL
- ⌋ for extended treatment of patients who are in complete or partial response
- ⌋ for the treatment of patients with CLL refractory to fludarabine and alemtuzumab

FDA APPROVED DOSING

Previously untreated CLL in combination with chlorambucil recommended dosage and schedule is:

- ⌋ 300 mg on Day 1, followed by 1,000 mg on Day 8 (Cycle 1)
- ⌋ 1,000 mg on Day 1 of subsequent 28-day cycles for a minimum of 3 cycles until best response or a maximum of 12 cycles.

Relapsed CLL in combination with fludarabine and cyclophosphamide recommended dosage and schedule is:

- ⌋ 300 mg on Day 1 followed by 1,000 mg on Day 8 (Cycle 1)
- ⌋ 1,000 mg on Day 1 of subsequent 28-day cycles for a maximum of 6 cycles

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OFATUMUMAB (NSA)

FDA APPROVED INDICATION (CONTINUED)

Extended treatment in CLL recommended dosage schedule is:

-) 300 mg on Day 1, followed by
-) 1,000 mg 1 week later on Day 8, followed by
-) 1,000 mg 7 weeks later and every 8 weeks thereafter for up to a maximum of 2 years

Refractory CLL recommended dosage and schedule is:

-) 300 mg initial dose, followed 1 week later by
-) 2000 mg weekly for 7 doses, followed 4 weeks later by
-) 2000 mg every 4 weeks for 4 doses.

REFERENCES

-) Arzerra [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. August 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/17

Created: 11/09

Client Approval: 12/16

P&T Approval: 11/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMALIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OMALIZUMAB	XOLAIR	25399		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic idiopathic urticaria (CIU) and still experiences hives on most days of the week for at least 6 weeks **AND** meets all of the following criteria?

- ☐ The patient is 12 years of age or older
- ☐ The patient has tried a high dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) **AND** leukotriene antagonist for at least 2 weeks
- ☐ Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

If yes, **approve for 24 weeks by GPID for the requested product as follows:**

- ☐ **Xolair 150mg vial (GPID 19966) with a quantity limit of #2 vials per 28 days.**
- ☐ **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #2mL per 28 days.**
- ☐ **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #2mL per 28 days.**

APPROVAL TEXT: Renewal requires a diagnosis of chronic idiopathic urticaria (CIU).

If no, continue to #2.

2. Does the patient have moderate to severe persistent asthma and meet **ALL** the following criteria?

- ☐ The patient is 6 years of age or older
- ☐ The patient has a positive skin prick or RAST test to a perennial aeroallergen
- ☐ The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
- ☐ The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- ☐ The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)

(Initial criteria continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

-) The patient has **ONE** of the following:
 - o Asthma Control Test (ACT) score of less than 20
 - o Asthma Control Questionnaire (ACQ) score of at least 1.5
 - o Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
-) Xolair will be used as add-on maintenance treatment
-) The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
-) Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

If yes, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

APPROVAL TEXT: Renewal for the diagnosis of moderate to severe persistent asthma requires all of the following:

-) The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
-) The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
-) The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **OMALIZUMAB (Xolair)** requires a diagnosis of chronic idiopathic urticaria or moderate to severe persistent asthma. In addition, the following criteria must also be met:

For patients with chronic idiopathic urticaria (CIU), approval requires:

-] The patient is 12 years of age or older
-] The patient still experiences hives on most days of the week for at least 6 weeks
-] The patient has tried a high dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) **AND** leukotriene antagonist for at least 2 weeks
-] Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

For patients with moderate to severe persistent asthma, approval requires:

-] The patient is 6 years of age or older
-] The patient has a positive skin prick or RAST test to a perennial aeroallergen
-] The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
-] The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
-] The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
-] The patient has **ONE** of the following:
 - o Asthma Control Test (ACT) score of less than 20
 - o Asthma Control Questionnaire (ACQ) score of at least 1.5
 - o Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
-] Xolair will be used as add-on maintenance treatment
-] The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
-] Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic idiopathic urticaria (CIU)?

If yes, **approve for 12 months by GPID for the requested product as follows:**

-] **Xolair 150mg vial (GPID 19966) with a quantity limit of #2 vials per 28 days.**
-] **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #2mL per 28 days.**
-] **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #2mL per 28 days.**

If no, continue to #2.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?
-) The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
 -) The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), **OR** Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Was the patient treated with a maintenance therapy regimen of oral corticosteroids prior to initiation of Xolair?

If yes, continue to #4.

If no, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

5. Has the patient decreased their total daily dose of oral corticosteroids from baseline?

If yes, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OMALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **OMALIZUMAB (Xolair)** renewal requires a diagnosis of moderate to severe persistent asthma or chronic idiopathic urticaria. In addition, the following criteria must also be met:

For patients with moderate to severe persistent asthma, approval requires:

-) The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
-) The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
-) The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES

-) Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc. September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/19

Created: 08/03

Client Approval: 11/18

P&T Approval: 10/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PACLITAXEL PROTEIN-BOUND

Generic	Brand	HICL	GCN	Exception/Other
PACLITAXEL PROTEIN-BOUND	ABRAXANE	26856		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer?

If yes, continue to #2.

If no, continue to #3.

2. Has the patient previously tried a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) or paclitaxel?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) or Small Cell Lung Cancer (SCLC)?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

If no, continue to #4.

4. Does the patient have a diagnosis of metastatic adenocarcinoma of the pancreas?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PACLITAXEL PROTEIN-BOUND

GUIDELINES FOR USE (CONTINUED)

5. Is the requested medication being used in combination with gemcitabine?

If yes, **approve for 12 months by HICL.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more Information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of metastatic breast cancer and trial of a chemotherapy regimen containing an anthracycline (doxorubicin or epirubicin) or paclitaxel; or a diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) or Small Cell Lung Cancer (SCLC); or a diagnosis of metastatic adenocarcinoma of the pancreas and will be used in combination with gemcitabine.

RATIONALE

Based on FDA approved indications and NCCN recommendations. Abraxane is indicated for treatment of locally advanced or metastatic NSCLC as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy; metastatic breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy; and metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine. NCCN recommends Abraxane as a first line therapy for patients with advanced NSCLC with performance status of 0-1 and as a substitute for paclitaxel or docetaxel among patients who have experienced hypersensitivity reactions or in whom the standard premedications are contraindicated.

The recommended dose of Abraxane for metastatic breast cancer is 260 mg/m² intravenously over 30 minutes every 3 weeks. The recommended dosage for Non-Small Cell Lung Cancer is 100 mg/m² intravenously over 30 minutes on Days 1, 8, and 15 of each 21-day cycle; carboplatin AUC 6 mg•min/mL is given intravenously on Day 1 of each 21 day cycle immediately after Abraxane administration. The recommended dose for adenocarcinoma of the pancreas is 125 mg/m² intravenously over 30-40 minutes on Days 1, 8, and 15 of each 28-day cycle; administer gemcitabine on Days 1, 8, and 15 of each 28-day cycle immediately after Abraxane.

NCCN guidelines recognize multiple chemotherapy treatment options for recurrent or metastatic breast cancer. Abraxane is considered a nonpreferred single agent therapy.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****PACLITAXEL PROTEIN-BOUND****RATIONALE (CONTINUED)**

Preferred Single Agents	Other Single Agents	Combination Regimens
doxorubicin	cyclophosphamide	cyclophosphamide, doxorubicin, fluorouracil (FAC/CAF)
pegylated liposomal doxorubicin	carboplatin	fluorouracil, epirubicin, cyclophosphamide (FEC)
paclitaxel	docetaxel	doxorubicin, cyclophosphamide (AC)
Xeloda	Abraxane	epirubicin, cyclophosphamide (EC)
gemcitabine	cisplatin	cyclophosphamide, methotrexate, fluorouracil (CML)
Halaven	Ixempra	docetaxel, Xeloda
vinorelbine	epirubicin	gemcitabine, paclitaxel
		gemcitabine carboplatin
		paclitaxel, Avastin

Abraxane versus Paclitaxel: Advanced NSCLC

A phase 3 trial compared Abraxane (100mg/m² weekly) with carboplatin to traditional solvent bound paclitaxel (200 mg/m² weekly) with carboplatin in untreated patients with stage IIIB to IV NSCLC. Abraxane demonstrated a significantly higher ORR than paclitaxel (33 versus 25 percent). There was a non-significant approximately 10 percent improvement in progression-free survival (6.3 v 5.8 months; HR, 0.902) and overall survival (12.1 v 11.2 months; HR, 0.922) in the Abraxane arm versus the paclitaxel arm, respectively.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PACLITAXEL PROTEIN-BOUND

RATIONALE (CONTINUED)

**Efficacy Results from Randomized Non-Small Cell Lung Cancer Trial (Intent-to-Treat Population)
From Abraxane Prescribing Information**

	ABRAXANE (100mg/m² weekly) + carboplatin (N = 521)	Paclitaxel Injection (200mg/m² every 3 weeks) + carboplatin (N = 531)
Overall Response Rate (ORR)		
Confirmed complete or partial overall response, n (%)	107 (33%)	132 (25%)
95% CI	28.6,36.7	21.2,28.5
P-value (Chi-Square test)	0.005	
Median DoR in months (92% CI)	6.9 (5.6,8.0)	6.0 (5.6,7.1)
Overall Response Rate by Histology		
Carcinoma/Adenocarcinoma	66/254 (26%)	71/264 (27%)
Squamous Cell Carcinoma	94/229 (41%)	54/221 (24%)
Large Cell Carcinoma	3/9 (33%)	2/13 (15%)
Other	7/29 (24%)	5/33 (15%)

CI = confidence interval; DoR = Duration of response

FDA APPROVED INDICATION

Abraxane is a microtubule inhibitor indicated for the treatment of:

-) Metastatic Breast Cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
-) Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC), as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
-) Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PACLITAXEL PROTEIN-BOUND

REFERENCES

-) Celgene Corporation. Abraxane package insert. Summit, NJ. September 2013.
-) National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology. Breast Cancer. (Version 3.2013).
-) Celgene Corporation. Abraxane (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) Prescribing Information. Drugs at FDA. [Online] September 2013. [Cited: October 7, 2013.]
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name
-) Socinski MA, Bondarenko I, Karaseva NA, et al. Weekly nab-paclitaxel in combination with carboplatin versus solvent-based paclitaxel plus carboplatin as first-line therapy in patients with advanced non-small-cell lung cancer: final results of a phase III trial. J Clin Oncol. [Online] June 10, 2012. [Cited: October 7, 2013.] <http://www.ncbi.nlm.nih.gov/pubmed/22547591>
-) National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 1.2014. [Online] October 11, 2013. [Cited: October 29, 2013.]
http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
-) National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Small Cell Lung Cancer Version 2.2014. [Online] September 17, 2013. [Cited: September 25, 2013.]
http://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 08/13

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PALIVIZUMAB	SYNAGIS	18564		

This drug requires a written request for prior authorization. Please use the drug specific medication request form.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient under 12 months of age?

If yes, continue to #2.
If no, continue to #11.

2. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia (BPD) as defined below?
-) Gestational age < 32 weeks and
 -) Patient required greater than 21% supplemental oxygen for at least the first 28 days after birth
- (Note:** This does not include respiratory distress in the newborn, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)

If yes, continue to #13.
If no, continue to #3.

3. Is the patient profoundly immunocompromised during the RSV season?

If yes, continue to #13.
If no, continue to #4.

4. Did the patient undergo solid-organ transplantation during the RSV season?

If yes, continue to #13.
If no, continue to #5.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have **ONE** of the following congenital heart disease conditions?
-) acyanotic heart disease requiring medication to control chronic heart failure (for example, furosemide, epinephrine, dopamine, lidocaine, milrinone, atenolol, propranolol, amlodipine, clonidine) and will require cardiac surgical procedures, or
 -) patient has moderate or severe pulmonary hypertension, or
 -) cyanotic heart defect patient and medication made in consultation with a pediatric cardiologist
(**Note:** This does not include patients with hemodynamically insignificant heart disease, infants with lesions adequately corrected by surgery, infants with mild cardiomyopathy who are not receiving medical therapy for the condition.)
- If yes, continue to #13.
If no, continue to #6.
6. Was the patient born prematurely?
- If yes, continue to #8.
If no, continue to #7.
7. Does the patient have congenital abnormalities of the airways (anatomic pulmonary abnormalities) or neuromuscular disease that compromises the handling of respiratory secretions?
- If yes, continue to #13.
If no, continue to #8.
8. Was the patient born at less than 29 weeks gestational age?
- If yes, continue to #13.
If no, continue to #9.
9. Is the patient an American Navajo or American White Mount Apache infant?
- If yes, continue to #13.
If no, continue to #10.
10. Is the patient an Alaska native infant?
- If yes, continue to #13.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

11. Is the patient younger than 24 months of age?

If yes, continue to #12.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

12. Does the patient meet **ONE** of the following criteria?

-) profoundly immunocompromised during the RSV season
-) chronic lung disease of prematurity **AND** requires medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to the start of the second RSV season
-) undergo solid-organ transplantation during RSV season

If yes, continue to #13.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

13. **Approve for up to 5 months by HICL (do not enter quantity limit on number of vials) as follows: (Note: Enter the start date as requested, no earlier than October 1st of the current year. End date must be within 5 months and no later than April of the following year.)**

-) **Approve with a start date of October of current year and an end date in February of the following year (10 fill counts).**
-) **Approve with a start date of November of current year and an end date in March of the following year (10 fill counts).**
-) **Approve with a start date of December of current year and an end date in April of the following year (10 fill counts).**
-) **Approve with a start date of January of current year and an end date in April of current year (8 fill counts).**
-) **Approve with a start date of February of current year and an end date in April of current year (6 fill counts).**
-) **Approve with a start date of March of current year and an end date in April of current year (4 fill counts).**
-) **Approve with a start date of April of current year and approved for 1 month (2 fill counts).**

Note: For requests for start date, earlier than October of current year or with an end date after April of following year, please refer to the CDC website to verify the RSV season for the specified region.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **PALIVIZUMAB (Synagis)** requires that the patient be either less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV) season. In addition, the following criteria must be met:

For patients less than 12 months old, ONE of the following criteria must be met:

-] gestational age of less than 29 weeks
-] chronic lung disease of prematurity, as defined as gestational age of less than 32 weeks and requiring greater than 21% supplemental oxygen for at least the first 28 days after birth
-] profoundly immunocompromised during RSV season
-] underwent solid-organ transplantation during RSV season
-] congenital heart disease conditions such as acyanotic heart disease requiring medication to control chronic heart failure, moderate to severe pulmonary hypertension, or cyanotic heart defect and medication made in consultation with a pediatric cardiologist
-] congenital abnormalities of the airways or neuromuscular disorder that compromises the handling of respiratory secretions
-] American Navajo or American White Mount Apache infant, Alaska native infant born prematurely

For patients less than 24 months old, ONE of the following criteria must be met:

-] chronic lung disease of prematurity and require medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to start of the second RSV season
-] underwent Solid-organ transplantation during RSV season
-] profoundly immunocompromised during RSV season

RENEWAL CRITERIA

1. Is the patient younger than 24 months of age?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Did the patient undergo cardiopulmonary bypass surgery during their RSV prophylaxis season?

If yes, **approve for 1 month by HICL with a fill count of 2 (do not enter quantity limit on number of vials).**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Is this a request for a second year of coverage (e.g., a previous approval in the previous RSV season)?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have chronic lung disease of prematurity (previously called bronchopulmonary dysplasia (BPD) and requires medical support (oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to start of the second RSV season; (**Note:** This does not include respiratory distress in the newborn period, wheezing, reactive airway disease (RAD), asthma, or cystic fibrosis. Current data does not support the routine use of palivizumab prophylaxis in patients with cystic fibrosis.)?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

5. **Approve for up to 5 months by HICL (do not enter a quantity limit on the number of vials) as follows: (Note: Enter the start date as requested, no earlier than October 1st of the current year. End date must be within 5 months and no later than April of the following year.)**

-) Approve with a start date of October of current year and an end date in February of the following year (10 fill counts).**
-) Approve with a start date of November of current year and an end date in March of the following year (10 fill counts).**
-) Approve with a start date of December of current year and an end date in April of the following year (10 fill counts).**
-) Approve with a start date of January of current year and an end date in April of current year (8 fill counts).**
-) Approve with a start date of February of current year and an end date in April of current year (6 fill counts).**
-) Approve with a start date of March of current year and an end date in April of current year (4 fill counts).**
-) Approve with a start date of April of current year and approved for 1 month (2 fill counts).**

Note: For requests for start date earlier than October of current year or with an end date after April of following year, please refer to the CDC website to verify the RSV season for the specified region.

RENEWAL DENIAL TEXT: Renewal of **PALIVIZUMAB (Synagis)** requires that the patient is under 24 months of age and meets **ONE** of the following criteria:

-) Patient underwent cardiopulmonary bypass surgery during RSV prophylaxis season, or**
-) Patient has chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 month period before the start of the second RSV season**

RATIONALE

To ensure the optimal use of palivizumab in high-risk patients for the prophylaxis of RSV by following the most recent American Academy of Pediatrics guidelines for the use of palivizumab for the prevention of serious RSV infections. Variations in the onset and offset of the RSV season in different regions may affect the timing of palivizumab administration. A maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons. RSV seasons within the continental United States may start in October/November and end in March/April.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PALIVIZUMAB (NSA)

FDA APPROVED INDICATIONS

For the prevention of serious, lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease.

REFERENCES

-) MedImmune, Inc. Synagis package insert. Gaithersburg, MD. March 2009.
-) American Academy of Pediatrics, Committee on Infectious Diseases and Committee on Fetus and Newborn. Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. Pediatrics 2003; 112(6):1442-1446.
-) American Academy of Pediatrics. Policy statement – modified recommendations for use of palivizumab for prevention of respiratory syncytial virus infections. Pediatrics 2009;124:1694-1701.
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-) American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infections. Pediatrics 2014;134:415-420
-) Reducing RSV hospitalizations. AAP modifies recommendations for use of palivizumab in high-risk infants, young children. AAP News 2009; 30:1.
-) Thomas Healthcare. Palivizumab. DRUGDEX® System [database online]. Greenwood Village, CO. [Accessed: August 7 2009].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/01/18

Created: 08/09

Client Approval: 01/18

P&T Approval: 11/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PANITUMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PANITUMUMAB	VECTIBIX	34054		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) and meet **ONE** of the following criteria?
 -) Vectibix will be used as monotherapy **AND** the patient has been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy
 -) Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **PANITUMUMAB (Vectibix)** requires a diagnosis of metastatic colorectal cancer (mCRC) with wild-type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use). In addition, **ONE** of the following criteria must be met:

-) Vectibix will be used as monotherapy **AND** the patient has been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy
-) Vectibix will be used in combination with FOLFOX (leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

RATIONALE

To ensure appropriate use of Vectibix consistent with FDA approved indication.

The FOLFOX regimen includes leucovorin calcium (folinic acid), fluorouracil, oxaliplatin.

FDA APPROVED INDICATIONS

Vectibix is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild type RAS (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use) metastatic colorectal carcinoma (mCRC):

-) In combination with FOLFOX for first-line treatment. **OR**
-) As monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.

Limitation of Use: Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC or for whom RAS mutation status is unknown.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PANITUMUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

The recommended dose of Vectibix is 6 mg/kg every 14 days administered as an intravenous infusion over 60 minutes (≤ 1000 mg) or 90 minutes (> 1000 mg). Reduce infusion rate by 50% for mild reactions.

REFERENCES

) Vectibix [Prescribing Information]. Thousand Oaks, CA: Amgen Inc., June 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/01/18

Created: 02/13

Client Approval: 02/18

P&T Approval: 10/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PATISIRAN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PATISIRAN	ONPATTRO	45155		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) The patient has a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
 - o Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm the presence of TTR protein
 - o DNA genetic sequencing to confirm hATTR
 -) The requested medication is being prescribed by or given in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
 -) Physician attestation that the patient has Stage 1 or 2 polyneuropathy

If yes, **approve for 6 months by HICL with a quantity limit of 15mL (30mg) per 21 days.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PATISIRAN (Onpattro)** requires a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy. In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) The patient has a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
 - o Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm the presence of TTR protein
 - o DNA genetic sequencing to confirm hATTR
-) The requested medication is being prescribed by or given in consultation with a neurologist, cardiologist, physician at an amyloidosis treatment center, or medical geneticist
-) Physician attestation that the patient has Stage 1 or 2 polyneuropathy

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PATISIRAN (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary TTR amyloidosis (hATTR) **AND** meet the following criterion?

-) Physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (30mg) per 21 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PATISIRAN** requires a diagnosis of hereditary TTR amyloidosis (hATTR) and physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

RATIONALE

Promote appropriate utilization of PATISIRAN based on FDA approved indication and dosing and clinical trial data. A list of amyloidosis treatment centers can be viewed at the following link:

<http://amyloidosis.org/resources/#treatment-centers>.

FDA APPROVED INDICATIONS

Onpattro is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Hereditary transthyretin amyloidosis (hATTR) is a genetic, rare, severe, debilitating, multi-systemic, progressive, and fatal disorder involving the protein tetramer transthyretin (TTR). Instead of folding properly, production in the liver of TTR protein, due to a mutation, folds into amyloid fibrils that deposit throughout the body. These deposits lead to damage to tissue, resulting in a multitude of clinical signs and symptoms, but primarily affect the heart and nerves.

RNA interference (RNAi) utilizes the universal model for gene expression to influence and silence protein production, a target of disease. Onpattro, a small interfering ribonucleic acid (siRNA) utilizes the cell's endogenous ability for gene expression control and silencing by engaging RNA-induced silencing complex (RISC). TTR-specific mRNA is targeted, which leads to the reduced amount of transthyretin produced and the amount of misfolded monomer that is available to aggregate into amyloid fibrils and deposit in tissues. It is also theorized that the established amyloid deposits (located in tissues and organs) would gradually diminish after reduced rate of deposition (TTR knockdown) was achieved.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PATISIRAN (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSING & ADMINISTRATION

Onpattro is available as a lipid complex solution for intravenous infusion supplied as a 10 mg/5 mL solution in a single-dose vial, administered only by a healthcare professional. Dosing is based on actual body weight.

-) For patients weighing less than 100 kg, the recommended dosage is 0.3 mg/kg once every 3 weeks.
-) For patients weighing 100 kg or more, the recommended dosage is 30 mg once every 3 weeks.

All patients should receive pre-medications 60 minutes prior to Onpattro to reduce the risk of infusion-related reactions. The following pre-medications should be given (pre-medications not available or not tolerated intravenously may be administered as equivalents orally):

-) Intravenous corticosteroid (e.g., dexamethasone 10 mg, or equivalent)
-) Oral acetaminophen (500 mg)
-) Intravenous H1 blocker (e.g., diphenhydramine 50 mg, or equivalent)
-) Intravenous H2 blocker (e.g., ranitidine 50 mg, or equivalent)

REFERENCES

-) Onpattro [prescribing information]. Cambridge, MA: Alnylam; 2018.
-) Holmes R. Amyloidosis: Definition of Amyloid and Amyloidosis, Classification Systems, Systemic Amyloidosis. Available at: <https://emedicine.medscape.com/article/335414-overview>. Accessed May 10, 2018.
-) Coelho T, Ericzon B, Falk R, et al. A Guide to Transthyretin Amyloidosis. Available at: <http://www.amyloidosis.org/wp-content/uploads/2017/05/2017-ATTR-guide.pdf>. Accessed May 18, 2018.
-) Rambaran R, Serpell LC. Amyloid Fibrils. *Prion*. 2008;2(3):112-117.
-) A is for Amyloidosis: Facts. Available at: <http://amyloidosis.org/facts/>. Accessed May 18, 2018.
-) Gertz, M. Hereditary ATTR Amyloidosis: Burden of Illness and Diagnostic Challenges. *Am J Manag Care*. 2017;23:S107-S112.
-) Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. *NEJM*. 2018;379(1):11-21. doi:10.1056/NEJMoa1716153.
-) Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. *Orphanet J Rare Dis*. 2013;8(1):1-18. doi:10.1186/1750-1172-8-31.
-) Buxbaum J. Oligonucleotide Drugs for Transthyretin Amyloidosis. *NEJM*. 2018;379(1):82-85. doi:10.1056/NEJMe1805499.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PATISIRAN (NSA)

REFERENCES (CONTINUED)

-) What causes hereditary ATTR (hATTR) amyloidosis? Available at: <https://hattbridge.com/about-hattr-amyloidosis/cause-and-symptoms>. Accessed May 18, 2018.
-) Gonzalez-Duarte A, Adams D, O’Riordan W, et al. Changes in Neuropathy Stage in Patients with Hereditary Transthyretin-Mediated Amyloidosis Following Treatment with Patisiran, an Investigational RNAi Therapeutic: An Analysis from the Phase 3 APOLLO Study. Available at: http://www.alnylam.com/wp-content/uploads/2018/03/5.-APOLLO-PND-FAP_FINAL.pdf. Accessed May 18, 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 09/01/18

Created: 08/18

Client Approval: 08/18

P&T Approval: 07/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGAPTANIB

Generic	Brand	HICL	GCN	Exception/Other
PEGAPTANIB SODIUM	MACUGEN	26805		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is this medication being prescribed by an ophthalmologist and/or retina specialist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (AMD)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for duration of 12 months by HICL for up to 18 syringes (2 syringes per 6 weeks).**

If no, and a single eye is being treated, **approve for duration of 12 months by HICL for up to 9 syringes (1 syringe per 6 weeks).**

DENIAL TEXT: Our guideline for **PEGAPTANIB** requires a diagnosis of neovascular (wet) age-related macular degeneration (AMD) and that the medication is being prescribed by an ophthalmologist and/or retina specialist.

RATIONALE

To ensure appropriate use of MACUGEN consistent with FDA approved indication.

FDA-APPROVED INDICATIONS

Macugen is indicated for the treatment of neovascular (wet) age-related macular degeneration.

REFERENCES

) Macugen [Prescribing Information]. San Dimas, CA: Eyetech Inc.; October 2011.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGAPTANIB

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 07/01/14

Created: 05/14
Client Approval: 05/14

P&T Approval: 05/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGLOTICASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PEGLOTICASE	KRYSTEXXA	37154		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic gout that is refractory to conventional therapy and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) There is physician attestation of symptomatic gout as evidenced by **ONE** of the following:
 - o At least 3 or more gout flares in the previous 18 months
 - o History of at least 1 gout tophus
 - o Gouty arthritis
 -) The patient has a baseline serum uric acid levels 8 mg/dL while on conventional gout medications (e.g., allopurinol, lesinurad)
 -) The patient does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency
 -) The patient will not be on concurrent urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) while using pegloticase
 -) The patient has experienced failure, contraindication, intolerance or inadequate response to previous therapy with a maximum tolerated dose for **TWO** conventional gout medications for at least 3 months (e.g., allopurinol, probenecid, lesinurad)

If yes, approve for 6 months by HICL for #2mL per 28 days.

APPROVAL TEXT: Renewal requires sustained serum uric acid levels below 6 mg/dL.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PEGLOTICASE (Krystexxa)** requires a diagnosis of chronic gout that is refractory to conventional therapy. In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) There is physician attestation of symptomatic gout as evidenced by **ONE** of the following:
 - o At least 3 or more gout flares in the previous 18 months
 - o History of at least 1 gout tophus
 - o Gouty arthritis

(Initial denial text continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGLOTICASE (NSA)

INITIAL CRITERIA (CONTINUED)

-) The patient has a baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications (e.g., allopurinol, lesinurad)
-) The patient does not have glucose-6-phosphate dehydrogenase (G6PD) deficiency
-) The patient will not be on concurrent urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) while using pegloticase
-) The patient has experienced failure, contraindication, intolerance or inadequate response to previous therapy with a maximum tolerated dose for **TWO** conventional gout medications for at least 3 months (e.g., allopurinol, probenecid, lesinurad)

RENEWAL CRITERIA

1. Does the patient have sustained serum uric acid levels below 6 mg/dL?

If yes, **approve for 12 months by HICL for #2mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level below 6 mg/dL for renewal.

RATIONALE

To ensure appropriate utilization of Krystexxa based on the FDA approved indication and dosing.

FDA APPROVED INDICATIONS

Krystexxa is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Important Limitations of Use:

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

DOSAGE AND ADMINISTRATION

The recommended dose and regimen of Krystexxa for adult patients is 8 mg (uricase protein) given as an intravenous infusion every two weeks. Do not administer as an intravenous push or bolus. The pegloticase admixture should only be administered by intravenous infusion over no less than 120 minutes via gravity feed, syringe-type pump, or infusion pump.

It is recommended that before starting Krystexxa patients discontinue oral urate-lowering medications and not institute therapy with oral urate-lowering agents while patients are on Krystexxa therapy. Monitor serum uric acid levels before each infusion. Patients should be pre-medicated with antihistamines and corticosteroids.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEGLOTICASE (NSA)

REFERENCES

) Krystexxa [Prescribing Information]. Horizon Pharma Rheumatology LLC. Lake Forest, IL. Jul 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 08/18

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PERTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PERTUZUMAB	PERJETA	39102		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
- ☐ The patient's breast cancer is HER2- positive
 - ☐ The patient has not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease
 - ☐ The requested medication will be used in combination with trastuzumab and docetaxel; (**PAC NOTE:** The patient must have an active prior authorization for trastuzumab [Herceptin] before proceeding)

If yes, please enter two approvals as follows:

- ☐ Approve for 1 month by HICL for #28mL (two 420mg/14mL) vials per 21 days.
- ☐ Approve for 11 months by HICL for #14mL (one 420mg/14mL) vial per 21 days with a start date of 22 days post the first approval start date.

If no, continue to #2.

2. Does the patient have a diagnosis of locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) and meet ALL of the following criteria?
- ☐ The patient's breast cancer is HER2- positive
 - ☐ The requested medication will be used in the neoadjuvant setting
 - ☐ The requested medication will be used in combination with trastuzumab and chemotherapy as part of a complete treatment regimen for early breast cancer; (**PAC NOTE:** The patient must have an active prior authorization for trastuzumab [Herceptin] before proceeding)

If yes, please enter two approvals as follows:

- ☐ Approve for 1 month by HICL for #28mL (two 420mg/14mL) vials per 21 days.
- ☐ Approve for 5 months by HICL for #14mL (one 420mg/14mL) vial per 21 days with a start date of 22 days post the first approval start date.

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PERTUZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of early breast cancer and meet **ALL** of the following criteria?

- ☐ The patient's breast cancer is HER2- positive
- ☐ The patient is at a high risk of recurrence
- ☐ The requested medication will be used in the adjuvant setting
- ☐ The requested medication will be used in combination with trastuzumab and chemotherapy;
(PAC NOTE: The patient must have an active prior authorization for trastuzumab [Herceptin] before proceeding)

If yes, please enter two approvals as follows:

- ☐ Approve for 1 month by HICL for #28mL (two 420mg/14mL) vials per 21 days.
- ☐ Approve for 11 months by HICL for #14mL (one 420mg/14mL) vial per 21 days with a start date of 22 days post the first approval start date.

If no, do not approve.

DENIAL TEXT: The guideline named **PERTUZUMAB (Perjeta)** requires a diagnosis of HER2- positive metastatic breast cancer, OR HER2- positive locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), OR HER2- positive early breast cancer. In addition, the following criteria must be met:

For the diagnosis of metastatic breast cancer, approval requires:

- ☐ The patient has not received prior therapy with an anti-HER2 agent or chemotherapy for metastatic disease
- ☐ The requested medication will be used in combination with trastuzumab and docetaxel

For the diagnosis of locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), approval requires:

- ☐ The requested medication will be used in the neoadjuvant setting
- ☐ The requested medication will be used in combination with trastuzumab and chemotherapy as part of a complete treatment regimen for early breast cancer

For the diagnosis of early breast cancer, approval requires:

- ☐ The patient is at a high risk of recurrence
- ☐ The requested medication will be used in the adjuvant setting
- ☐ The requested medication will be used in combination with trastuzumab and chemotherapy

RATIONALE

To promote appropriate utilization of Perjeta based on FDA approved indication.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PERTUZUMAB (NSA)

FDA APPROVED INDICATIONS

Perjeta is a HER2/neu receptor antagonist indicated for:

-) Use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
-) Use in combination with trastuzumab and chemotherapy as:
 - o Neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer.
 - o Adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence.

DOSAGE AND ADMINISTRATION

The initial dose of Perjeta is 840 mg administered as a 60-minute intravenous infusion, followed every 3 weeks by a dose of 420 mg administered as an intravenous infusion over 30 to 60 minutes.

Metastatic Breast Cancer

When administered with Perjeta, the recommended initial dose of docetaxel is 75 mg/m² administered as an intravenous infusion. The dose may be escalated to 100 mg/m² administered every 3 weeks if the initial dose is well tolerated.

Neoadjuvant Treatment of Breast Cancer

Perjeta should be administered every 3 weeks for 3 to 6 cycles as part of one of the following treatment regimens for early breast cancer.

-) Four preoperative cycles of Perjeta in combination with trastuzumab and docetaxel followed by 3 postoperative cycles of fluorouracil, epirubicin, and cyclophosphamide (FEC) as given in NeoSphere.
-) Three or four preoperative cycles of FEC alone followed by 3 or 4 preoperative cycles of Perjeta in combination with docetaxel and trastuzumab as given in TRYPHAENA and BERENICE, respectively.
-) Six preoperative cycles of Perjeta in combination with docetaxel, carboplatin, and trastuzumab (TCH) (escalation of docetaxel above 75 mg/m² is not recommended) as given in TRYPHAENA.
-) Four preoperative cycles of dose-dense doxorubicin and cyclophosphamide (ddAC) alone followed by 4 preoperative cycles of Perjeta in combination with paclitaxel and trastuzumab as given in BERENICE. Following surgery, patients should continue to receive Perjeta and trastuzumab to complete 1 year of treatment (up to 18 cycles).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PERTUZUMAB (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Adjuvant Treatment of Breast Cancer

Perjeta should be administered in combination with trastuzumab every 3 weeks for a total of 1 year (up to 18 cycles) or until disease recurrence or unmanageable toxicity, whichever occurs first, as part of a complete regimen for early breast cancer, including standard anthracycline and/or taxane-based chemotherapy as given in APHINITY. Perjeta and trastuzumab should start on Day 1 of the first taxane-containing cycle.

Patients should be selected based on HER2 protein overexpression or HER2 gene amplification in tumor specimens. Assessment of HER2 protein overexpression and HER2 gene amplification should be performed using FDA-approved tests specific for breast cancer by laboratories with demonstrated proficiency.

For delayed or missed doses, if the time between two sequential infusions is less than 6 weeks, the 420 mg dose of Perjeta should be administered. Do not wait until the next planned dose. If the time between two sequential infusions is 6 weeks or more, the initial dose of 840 mg Perjeta should be re-administered as a 60-minute intravenous infusion followed every 3 weeks thereafter by a dose of 420 mg administered as an intravenous infusion over 30 to 60 minutes. Perjeta should be discontinued if trastuzumab treatment is discontinued. Dose reductions are not recommended for Perjeta.

REFERENCES

) Genentech, Inc. Perjeta package insert. South San Francisco, CA. December 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/15/18

Created: 08/12

Client Approval: 12/17

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PORFIMER

Generic	Brand	HICL	GCN	Exception/Other
PORFIMER SODIUM	PHOTOFRIN	11790		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication being used for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC)?

If yes, **approve once by HICL.**
If no, continue to #2.
2. Is the requested medication being used for the treatment of microinvasive endobronchial non-small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated?

If yes, **approve once by HICL.**
If no, continue to #3.
3. Is the requested medication being used for the palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy?

If yes, **approve once by HICL.**
If no, continue to #4.
4. Is the requested medication being used for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy?

If yes, **approve once by HICL.**
If no, do not approve.
DENIAL TEXT: Approval requires that requested medication is being used for, 1) the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or, 2) treatment of microinvasive endobronchial non small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated or, 3) the palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy or, 4) the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PORFIMER

RATIONALE

Based on FDA approved indications. Photofrin is indicated for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC; treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated; palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy; and ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

Photofrin versus Nd: YAG Laser Therapy: Endobronchial NSCLC

Two randomized studies were conducted to compare Photofrin versus Nd:YAG laser therapy for reduction of obstruction and palliation of symptomatic patients with partially or completely obstructing endobronchial NSCLC. A course of therapy consisted of one injection of Photofrin (2 mg/kg administered as a slow intravenous injection over 3–5 minutes) followed by up to two nonthermal applications of 630 nm laser light. Assessments were made at one week and at monthly intervals after treatment. Objective tumor response rates (CR + PR), which demonstrate reduction of obstruction, were 59 percent for PDT and 58 percent for Nd:YAG at Week 1. The response rate at 1 month or later was 60 percent for PDT and 41 percent for Nd:YAG.

From Photofrin Prescribing Information

TABLE 11. Efficacy Results from Studies in Late-stage Obstructing Endobronchial Cancer – All Randomized Patients^a

EFFICACY PARAMETER	PDT N=102	Nd:YAG N=109
	% Patients	% Patients
OBJECTIVE TUMOR RESPONSE^b		
Week 1	59%	58%
Month 1 or later	60%	41% ^a
ATELECTASIS IMPROVEMENT^c		
	n=60	N=71
Week 1	35%	18%
Month 1 or later	35%	20%

^a Statistical comparisons were precluded by the amount of missing data at Month 1 or later (e.g., for tumor response, PDT 28% missing, Nd:YAG 38%).

^b CR+PR where CR = complete response (absence of bronchoscopically visible tumor) and PR = partial response (increase of $\geq 50\%$ in the smallest luminal diameter; or any appearance of a lumen for completely obstructing tumors).

^c In patients with atelectasis at baseline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PORFIMER

FDA APPROVED INDICATIONS

Photofrin is a photodynamic therapy drug indicated for:

Esophageal Cancer

-) Palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy

Endobronchial Cancer

-) Treatment of microinvasive endobronchial non-small-cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated
-) Reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC

High-Grade Dysplasia in Barrett's Esophagus

-) Ablation of high-grade dysplasia (HGD) in Barrett's esophagus (BE) patients who do not undergo esophagectomy

REFERENCES

-) Axcan Scandipharm Inc. Photofrin (porfimer sodium) for Injection Prescribing Information. Drugs at FDA. [Online] June 2011. [Cited: October 14, 2013.]
[HTTP://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRUGSATFDA/](http://www.accessdata.fda.gov/scripts/cder/drugsatfda/)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 11/13

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PRALATREXATE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PRALATREXATE	FOLOTYN	36644		

GUIDELINES FOR USE

1. Will the requested medication be used for the treatment of a patient with relapsed or refractory peripheral T-cell lymphoma (PTCL)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline for **PRALATREXATE (Folotyn)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL).

RATIONALE

Promote appropriate utilization of **PRALATREXATE** based on FDA approved indication.

DOSAGE

The recommended dose of Folotyn is 30 mg/m² administered as an intravenous push over 3-5 minutes via the side port of a free-flowing 0.9% Sodium Chloride Injection, intravenous line once weekly for 6 weeks in 7-week cycles until progressive disease or unacceptable toxicity. The calculated dose of Folotyn should be aseptically withdrawn into a syringe for immediate use. Do not dilute Folotyn.

For patients with severe renal impairment (eGFR 15 to < 30 mL/min/1.73 m²), the recommended dose of Folotyn is 15 mg/m².

FDA APPROVED INDICATION

Folotyn is indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is based on overall response rate. Clinical benefit such as improvement in progression-free survival or overall survival has not been demonstrated.

REFERENCES

) Folotyn [Prescribing Information]. Westminster, CO: Spectrum Pharmaceuticals. May 2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 08/16

Client Approval: 08/16

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RANIBIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RANIBIZUMAB	LUCENTIS	33861		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is this medication being prescribed by an ophthalmologist or retina specialist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have one of the following diagnoses?

☐ Diabetic macular edema (DME)

☐ Diabetic retinopathy (DR)

If yes, continue to #5.

If no, continue to #3.

3. Does the patient have one of the following diagnoses?

☐ Neovascular (wet) age-related macular degeneration (AMD)

☐ Macular edema following retinal vein occlusion (RVO)

If yes, continue to #6.

If no, continue to #4.

4. Does the patient have a diagnosis of myopic choroidal neovascularization (mCNV)?

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RANIBIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 12 months by GPID with the following quantity limits:**

-) 0.3mg/0.05mL prefilled syringe (GPID 44547): #0.1mL (two 0.3mg prefilled syringes) per 4 weeks.**
-) 0.3mg/0.05mL vial (GPID 32959): #0.1mL (two 0.3mg vials) per 4 weeks.**

If no, and a single eye is being treated, **approve for 12 months by GPID with the following quantity limits:**

-) 0.3mg/0.05mL prefilled syringe (GPID 44547): #0.05mL (one 0.3mg prefilled syringes) per 4 weeks.**
-) 0.3mg/0.05mL (GPID 32959): #0.05mL (one 0.3mg vial) per 4 weeks.**

6. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 12 months by GPID (27289 or 37135) with a quantity limit of #0.1mL (two 0.5mg vials or prefilled syringes) per 4 weeks.**

If no, and a single eye is being treated, **approve for 12 months by GPID (27289 or 37135) with a quantity limit of #0.05mL (one 0.5mg vial or prefilled syringe) per 4 weeks.**

7. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 3 months by GPID (27289 or 37135) with a quantity limit of #0.1mL (two 0.5mg vials or prefilled syringes) per 4 weeks.**

If no, and a single eye is being treated, **approve for 3 months by GPID (27289 or 37135) with a quantity limit of #0.05mL (one 0.5mg vial or prefilled syringe) per 4 weeks.**

DENIAL TEXT: The guideline named **RANIBIZUMAB (Lucentis)** requires a diagnosis of neovascular (wet) age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), macular edema following retinal vein occlusion (RVO), or myopic choroidal neovascularization (mCNV), and that the medication is prescribed by an ophthalmologist or retina specialist.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RANIBIZUMAB (NSA)

RATIONALE

To ensure appropriate use of Lucentis consistent with its FDA approved indications and dosing.

FDA APPROVED INDICATIONS

Lucentis, a vascular endothelial growth factor VEGF inhibitor, is indicated for the treatment of patients with:

-) Neovascular (Wet) Age-related macular degeneration (AMD)
-) Macular Edema following Retinal Vein Occlusion (RVO)
-) Diabetic Macular Edema (DME)
-) Diabetic Retinopathy
-) Myopic Choroidal Neovascularization (mCNV)

DOSAGE AND ADMINISTRATION

-) Neovascular (Wet) Age-Related Macular Degeneration (AMD): Lucentis 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days).
-) Macular Edema following Retinal Vein Occlusion (RVO): Lucentis 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days).
-) Diabetic Macular Edema (DME) and Diabetic Retinopathy: Lucentis 0.3 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days).
-) Myopic Choroidal Neovascularization (mCNV): Lucentis 0.5 mg (0.05 mL) by intravitreal injection once a month (approximately 28 days) for up to 3 months. Patients may be retreated if needed.

AVAILABLE STRENGTHS

-) Single-use vials
 - o 10mg/mL solution (Lucentis 0.5 mg)
 - o 6mg/mL solution (Lucentis 0.3 mg)
-) Single-use prefilled syringe
 - o 10mg/mL solution (Lucentis 0.5 mg)
 - o 6mg/mL solution (Lucentis 0.3 mg)

REFERENCES

-) Lucentis [Prescribing Information]. South San Francisco, CA: Genentech; March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/16/18

Created: 05/14

Client Approval: 04/16

P&T Approval: 07/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RITUXIMAB/ HYALURONIDASE, HUMAN - SQ	RITUXAN HYCELA	44378		

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of the requested medication?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of Follicular Lymphoma (FL) and meet **ONE** of the following criteria?

- ☐ The medication will be used as a single agent for a patient with relapsed or refractory FL
- ☐ The medication will be used in combination with first line chemotherapy for a patient with previously untreated FL
- ☐ The medication will be used as a single-agent for maintenance therapy for a patient who has achieved a complete or partial response to rituximab in combination with chemotherapy
- ☐ The medication will be used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy in a patient with non-progressing (including stable disease) FL

If yes, **approve for 12 months by GPID (36469).**

If no, continue to #4.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of Diffuse Large B-cell Lymphoma (DLBCL) and meet the following criterion?

) The medication will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or other anthracycline-based chemotherapy regimens for previously untreated Diffuse Large B-cell Lymphoma (DLBCL)

If yes, **approve for 12 months by GPID (36469).**

If no, continue to #5.

5. Does the patient have a diagnosis of Chronic Lymphocytic Leukemia (CLL) and meet the following criterion?

) The medication will be used in combination with fludarabine and cyclophosphamide (FC)

If yes, **approve for 12 months by GPID (43561).**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires a diagnosis of Follicular Lymphoma (FL), Diffuse Large B-cell Lymphoma (DLBCL), or Chronic Lymphocytic Leukemia (CLL) in adult patients who have received or will receive at least one full dose of a rituximab product by intravenous infusion prior to the initiation of the requested medication. In addition, the following criteria must be met:

For patients with Follicular Lymphoma (FL), one of the following criteria must be met:

-) The medication will be used as a single agent for a patient with relapsed or refractory FL
-) The medication will be used in combination with first line chemotherapy for a patient with previously untreated FL
-) The medication will be used as a single-agent for maintenance therapy for a patient who has achieved a complete or partial response to rituximab in combination with chemotherapy
-) The medication will be used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy in a patient with non-progressing (including stable disease) FL

For patients with Diffuse Large B-cell Lymphoma (DLBCL):

-) The medication will be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP), or other anthracycline-based chemotherapy regimens for previously untreated Diffuse Large B-cell Lymphoma (DLBCL)

For patients with Chronic Lymphocytic Leukemia (CLL):

-) The medication will be used in combination with fludarabine and cyclophosphamide (FC)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

RATIONALE

Ensure appropriate utilization of Rituxan Hycela consistent with FDA approved indication.

Rituxan Hycela is for subcutaneous use only and should only be administered by a healthcare professional with appropriate be fatal if they occur.

All patients must first receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions before starting treatment with Rituxan Hycela. If patients are not able to receive one full dose by intravenous infusion, they should continue subsequent cycles with a rituximab product by intravenous infusion and not switch to Rituxan Hycela until a full intravenous dose is successfully administered.

FDA APPROVED INDICATIONS

Indicated for the treatment of adult patients with:

Follicular Lymphoma (FL)

-) Relapsed or refractory, follicular lymphoma as a single agent
-) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy
-) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

Diffuse Large B-cell Lymphoma (DLBCL)

-) Previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens

Chronic Lymphocytic Leukemia (CLL)

-) Previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC)

Limitations of Use:

-) Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.
-) Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

REFERENCES

-) Rituxan Hycela [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2017.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/17

Created: 08/17
Client Approval: 08/17

P&T Approval: 07/17



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ROMIDEPSIN

Generic	Brand	HICL	GCN	Exception/Other
ROMIDEPSIN	ISTODAX	36898		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cutaneous T-cell lymphoma (also known as Mycosis Fungoides/Sezary Syndrome) **AND** meet ONE of the following criteria?
 -) The patient has a trial of or contraindication to Zolinza (vorinostat) **AND** is not able to tolerate oral medications
 -) The patient has tried at least one form of systemic therapy (e.g., retinoids, interferons, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) **AND** is able to tolerate oral medications.

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Is the requested medication being used for the treatment of peripheral T-cell lymphoma in a patient who has received at least one prior therapy?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ROMIDEPSIN (Istodax)** requires a diagnosis of cutaneous T-cell lymphoma or peripheral T-cell lymphoma. The following criteria must also be met.

For patients with cutaneous T-cell lymphoma, approval requires the following criteria:

-) The patient has a trial of or contraindication to Zolinza (vorinostat) **AND** is not able to tolerate oral medications.
-) The patient has tried at least one form of systemic therapy (e.g., retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) **AND** is able to tolerate oral medications.

For patients with peripheral T-cell lymphoma, approval requires that the patient has received at least one prior treatment.

RATIONALE

Promote appropriate utilization of **ROMIDEPSIN** based on FDA approved indications.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ROMIDEPSIN

FDA APPROVED INDICATIONS

Isotodax is indicated for:

-) Treatment of cutaneous T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy
-) Treatment of peripheral T-cell lymphoma (PTCL) in patients who have received at least one prior therapy

These indications are based on response rate. Clinical benefit such as improvement in overall survival has not been demonstrated.

SYSTEMIC TREATMENT OPTIONS	
Retinoids (bexarotene, retinoic acid, isotretinoin, acitretin)	Chlorambucil (Leukeran)
Interferons (Intron A)	Pentostatin
Extracorporeal photopheresis	Etoposide (VePesid)
Denileukin diftitox (Ontak)	Cyclophosphamide (Cytosan)
Methotrexate	Temozolomide (Temodar)
Liposomal doxorubicin (Doxil)	Bortezomib (Velcade)
Gemcitabine (Gemzar)	

REFERENCES

-) Istodax [Prescribing Information]. Celgene Corporation: Summit, NJ. October 2014.
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 3.2016.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/16

Created: 02/10

Client Approval: 09/16

P&T Approval: 08/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SEBELIPASE ALFA

Generic	Brand	HICL	GCN	Exception/Other
SEBELIPASE ALFA	KANUMA	42747		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Was the medication prescribed by or in consultation with an endocrinologist, hepatologist, gastroenterologist, medical geneticist, or lipidologist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of rapidly progressive lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life (also known as Wolman Disease), as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) plus **ANY** of the following?

-) A blood test indicating low or absent levels of LAL enzyme activity
-) A dried blood spot test indicating low or absent LAL enzyme activity
-) A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SEBELIPASE ALFA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive (also known as cholesteryl ester storage disease (CESD)), as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) plus **ANY** of the following?

- ☐ A blood test indicating low or absent levels of LAL enzyme activity
- ☐ A dried blood spot test indicating low or absent LAL enzyme activity
- ☐ A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires that the patient has a documented improvement in any one of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency while on therapy with Kanuma:

- ☐ A relative reduction from baseline in any one of the following lipid levels (LDL-c, non-HDL-c, or triglycerides).
- ☐ Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges.
- ☐ A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI).

Any one of the following baseline measurements will be required to assess renewal criteria: lipids (LDL-c, Non-HDL-c, or triglycerides), aspartate aminotransferase (AST), or MEGE MRI.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **SEBELIPASE ALFA (Kanuma)** requires that the medication be prescribed by or in consultation with an endocrinologist, hepatologist, gastroenterologist, medical geneticist, or lipidologist, **AND** a diagnosis of lysosomal acid lipase (LAL) deficiency, as confirmed by the presence of clinical features (e.g., hepatomegaly, elevated serum transaminases, dyslipidemia, splenomegaly) plus **ANY** of the following:

- ☐ A blood test indicating low or absent levels of LAL enzyme activity
- ☐ A dried blood spot test indicating low or absent LAL enzyme activity
- ☐ A genetic test indicating the bi-allelic presence of altered LIPA gene(s)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SEBELIPASE ALFA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have documented improvement in any one of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
 -) A relative reduction from baseline in any one of the following lipid levels (LDL-c, Non-HDL-c, or triglycerides)
 -) Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges
 -) A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

DENIAL TEXT: Our guideline for **SEBELIPASE ALFA (Kanuma)** renewal requires a diagnosis of lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive, and that the patient have documented improvement in any one of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:

-) A relative reduction from baseline in any one of the following lipid levels (LDL-c, Non-HDL-c, or triglycerides)
-) Normalization of aspartate aminotransferase (AST) based on age- and gender-specific normal ranges
-) A decrease in liver fat content compared to baseline assessed by abdominal imaging (e.g., multi-echo gradient echo [MEGE] MRI)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SEBELIPASE ALFA

RATIONALE

To ensure appropriate use of Kanuma (sebelipase alfa) consistent with FDA approved indication.

Kanuma is a human therapeutic biologic and the first FDA-approved treatment for lysosomal acid lipase (LAL) deficiency. Kanuma was granted orphan drug designation, breakthrough therapy designation, FDA priority review, and the manufacturer of Kanuma was granted a rare pediatric disease voucher. Kanuma is a recombinant form of the human LAL enzyme which serves as a replacement for the lacking enzyme in patients with deficiency. Kanuma is to be administered as an intravenous infusion by a healthcare professional.

LAL deficiency is a rare, autosomal recessive, inherited genetic disorder in which patients have little or no LAL enzyme activity due to mutations in the Lipase A, Lysosomal Acid, Cholesterol Esterase (LIPA) gene which encodes the LAL enzyme. LAL deficiency can be divided into two major phenotypes which differ by rate of progression and severity. When LAL deficiency is diagnosed in infancy, it is referred to as Wolman disease and represents the more rapidly progressing phenotype of the disease. These patients historically have a life expectancy of 3-6 months with a disease course characterized by liver failure, malabsorption, and growth failure.

LAL deficiency presenting post-infancy is generally referred to as cholesteryl ester storage disease (CESD) and causes hepatic steatosis, hepatic fibrosis, and cirrhosis. These patients are also at increased risk for accelerated atherosclerosis and cardiovascular disease. It is estimated that Wolman disease affects 1-2 infants per million births and CESD affects 25 individuals per million births.

Diagnostic criteria for LAL includes the presence of clinical features, blood tests and dried blood spot test for LAL enzyme activity, and genetic testing. Testing for LAL without clinical features is not indicated and may result in false positives, whereas genetic testing shows that both alleles are affected by mutations.

The efficacy of Kanuma in pediatric and adult patients with LAL was assessed in the clinical trial, LAL-CL02. The primary endpoint was normalization of the alanine aminotransferase level (ALT) and secondary endpoints included LDL-c relative reduction, non-HDL-C relative reduction, normalization of aspartate aminotransferase (AST), and triglyceride (TG) relative reduction. Results are provided in Table 1 below. Baseline assessments conducted in participants revealed substantially elevated aminotransferase levels and high LDL-c levels (190 mg/dL) in 38 of 66 patients (58%). As the most frequently reported complications of LAL deficiency are hepatic manifestations, the trial addressed common markers of liver injury. Patients treated with Kanuma had a significant reduction in hepatic fat content as assessed by MRI (mean reduction: -32% in the Kanuma group vs. -4.2% in the placebo group). The significance of reductions in ALT values and liver fat content to disease progression has not been established.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****SEBELIPASE ALFA****RATIONALE (CONTINUED)****Table 1. Pediatric and Adult Patients with LAL Deficiency, Trial Results [NEJM. Burton et al 2015]**

Endpoint	Population	Sebelipase Alfa (n = 36)	Placebo (n = 30)	Treatment Difference (p-value)
PRIMARY ENDPOINT:				
Normalization of ALT, % (n/N)	All, N = 66	31% (11/36)	7% (2/30)	24% (0.0271)
SECONDARY ENDPOINTS:				
Relative reduction in LDL-c, Mean (SD)	All, N = 66	-28% (22.3)	-6% (13.0)	-22% (<0.0001)
Relative reduction in triglyceride, Mean (SD)	All, N = 66	-25% (29.4)	-11% (28.8)	-14% (0.0375)
Relative increase in HDL-c, Mean (SD)	All, N = 66	20% (16.8)	-0.3% (12.3)	20% (<0.0001)

The efficacy of Kanuma in patients with rapidly progressive LAL deficiency presenting within the first 6 months of life was assessed in the clinical trial, LAL-CL03, a multinational, single-arm, open label, Phase II/III study of nine infants (aged 1 – 6 months at trial entry). Efficacy was assessed by comparing the survival of Kanuma-treated patients at 12 months of age with a historical cohort of 21 untreated patients with similar clinical characteristics and age at onset. In LAL-CL03, improvement in survival was accompanied by substantial and rapid improvements in markers of hepatic injury (i.e., AST/ALT), growth, and hematological abnormalities.

FDA APPROVED INDICATION

Kanuma (sebelipase) is indicated for the treatment of patients with a diagnosis of lysosomal acid lipase (LAL) deficiency.

DOSAGE

Patients with rapidly progressive LAL deficiency presenting within the first 6 months of life:

The recommended starting dosage is 1mg/kg as an intravenous infusion once weekly. For patients who do not achieve an optimal clinical response, increase to 3mg/kg once weekly.

Pediatric and adult patients with LAL deficiency:

The recommended dosage is 1mg/kg as an intravenous infusion once every other week.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SEBELIPASE ALFA

AVAILABLE STRENGTH:

-) 20mg/10ml solution in a single-use vial

REFERENCES

-) Kanuma [Prescribing Information]. Cheshire, CT: Alexion Pharmaceuticals, Inc. December 2015.
-) Kanuma [AMCP Dossier]. Cheshire, CT: Alexion Pharmaceuticals, Inc. December 2015.
-) Burton, B.K., Balwani, M., Feillet, I., et.al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. *The New England Journal of Medicine*. Abstract (2015) 373:1010-20.
-) Jones, S.A., Rojas-Caro, S., Quinn, A.G., et.al. Impact of sebelipase alfa on survival and liver function in infants with rapidly progressive lysosomal acid lipase deficiency. *Journal of Inherited Metabolic Disease*. (2015) 38 (Suppl 1):S35–S378.
-) Lysosomal acid lipase deficiency testing. LabCorp. 2013.
<http://m3.wyanokecdn.com/8bf88c2ed28280df9ef39e5614da71177.pdf>

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/16

Created: 12/15

Client Approval: 02/16

P&T Approval: 02/16



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SILTUXIMAB

Generic	Brand	HICL	GCN	Exception/Other
SILTUXIMAB	SYLVANT	41101		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multi-centric Castleman's disease (MCD)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient positive for either human immunodeficiency virus (HIV) or human herpesvirus-8 (HHV-8)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 12 months by HICL.**

DENIAL TEXT: Our guideline for **SILTUXIMAB** requires a diagnosis of multi-centric Castleman's disease (MCD) and that the patient is negative for both human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).

RATIONALE

Promote appropriate utilization of Sylvant based on FDA approved indication.

Castleman's disease (CD), also known as angiofollicular lymph node hyperplasia, is comprised of two distinct diseases: unicentric and multicentric. Unicentric CD usually affects a single group of lymph nodes and removal of the mass cures 90-95% of cases. Multicentric CD (MCD) involves more than a single group of lymph nodes and can affect other organs containing lymphoid tissue. Patients with MCD often have serious infections, severe fatigue, night sweats, recurrent fever, and weight loss. Patients may also experience peripheral edema, anemia, hypoalbuminemia, peripheral neuropathy and hepatosplenomegaly. CD is not officially a cancer, but the multicentric disease form is more aggressive than unicentric CD and roughly 20% of patients with MCD develop lymphoma.

Because MCD is a rare disease and most cases are seen in patients who are HIV/HHV-8 positive, the utilization of Sylvant is expected to be relatively minimal given its specific FDA indication for HIV/HHV-8 negative MCD patients.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SILTUXIMAB

RATIONALE (CONTINUED)

DOSAGE

Sylvant 11 mg/kg is given over 1 hour as an intravenous infusion administered every 3 weeks until treatment failure (defined as disease progression based on increase in symptoms, radiologic progression or deterioration in performance status) or unacceptable toxicity.

FDA APPROVED INDICATION

Sylvant is indicated for the treatment of patients with Multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitation of Use: Sylvant was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

REFERENCES

) Sylvant [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc; May 2014.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/14

Created: 6/14

Client Approval: 08/14

P&T Approval: 08/14



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TALIMOGENE LAHERPAREPVEC

Generic	Brand	HICL	GCN	Exception/Other
TALIMOGENE LAHERPAREPVEC	IMLYGIC	42741		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable melanoma and have all of the following criteria been met?
 -) Patient has a recurrence of melanoma lesions after initial surgery.
 -) Patient does not have a history of primary or acquired immunodeficient states, leukemia, lymphoma, or AIDS.
 -) Patient is not currently receiving immunosuppressive therapy.
 -) The patient is not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy.

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Will Imlygic be injected into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance?

If yes, **approve for a total of 12 months and enter three prior authorizations (initial, second, and maintenance doses) by GPID as follows:**

-) **First authorization: approve for 1 fill of Imlygic 10⁶ (1 million) PFU/mL vial (GPID= 39983): 4mL (#4 vials)**
-) **Second authorization (starting 3 weeks after initial authorization): approve for 1 fill of Imlygic 10⁸ (100 million) PFU/mL vial (GPID= 39984): 4mL (#4 vials)**
-) **Third authorization (starting 5 weeks after initial authorization): approve for 11 months for Imlygic 10⁸ (100 million) PFU/mL vial (GPID= 39984): 8mL (#8 vials) every 28 days**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TALIMOGENE LAHERPAREPVEC

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline for **TALIMOGENE LAHERPAREPVEC** requires a diagnosis of unresectable melanoma. Additional guideline requirements apply.

-) Patient has a recurrence of melanoma lesions after initial surgery.
-) Patient does not have a history of primary or acquired immunodeficient states, leukemia, lymphoma, or AIDS.
-) Patient is not currently receiving immunosuppressive therapy.
-) The patient is not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy.
-) The request must be for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance.

RATIONALE

Promote appropriate utilization of Imlygic (talimogene laherparepvec) based on FDA-approved indications.

Imlygic is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery. Imlygic is a live, attenuated herpes simplex virus and may cause life-threatening disseminated herpetic infection in patients who are immunocompromised. Imlygic should not be administered to immunocompromised patients, including those with a history of primary or acquired immunodeficient states, leukemia, lymphoma, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy. Imlygic should be discontinued if there are no injectable lesions to treat or if other treatment is required for melanoma. Other melanoma treatments include pembrolizumab, nivolumab, ipilimumab, dabrafenib, trametinib, vemurafenib, dabrafenib, interleukin-2, interferon, dacarbazine, temozolomide, paclitaxel, carboplatin, imatinib, melphalan, imiquimod, or radiation therapy.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TALIMOGENE LAHERPAREPVEC

DOSAGE

Imlygic is administered by injection into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound guidance.

The total injection volume for each treatment visit should not exceed 4 mL for all injected lesions combined. It may not be possible to inject all lesions at each treatment visit or over the full course of treatment. Previously injected and/or uninjected lesion(s) may be injected at subsequent treatment visits. The initial recommended dose is up to 4 mL of Imlygic at a concentration of 10^6 (1 million) PFU per mL. The recommended dose for subsequent administrations is up to 4 mL of IMLYGIC at a concentration of 10^8 (100 million) PFU per mL. The recommended dosing schedule for Imlygic is shown in Table 1.

Table 1. Recommended Dose and Schedule for IMLYGIC

Treatment	Treatment Interval	Maximum Injection Volume per Treatment Visit (all lesions combined)	Dose Strength	Prioritization of Lesions to be Injected
Initial	–	4 mL	10^6 (1 million) PFU per mL	<ul style="list-style-type: none">• Inject largest lesion(s) first.• Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.
Second	3 weeks after initial treatment	4 mL	10^8 (100 million) PFU per mL	<ul style="list-style-type: none">• Inject any new lesion(s) (lesions that have developed since initial treatment) first.• Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.
All subsequent treatments (including reinitiation)	2 weeks after previous treatment	4 mL	10^8 (100 million) PFU per mL	<ul style="list-style-type: none">• Inject any new lesion(s) (lesions that have developed since previous treatment) first.• Prioritize injection of remaining lesion(s) based on lesion size until maximum injection volume is reached or until all injectable lesion(s) have been treated.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TALIMOGENE LAHERPAREPVEC

FDA APPROVED INDICATION

Imlygic (talimogene laherparepvec) is indicated for the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery.

AVAILABLE STRENGTHS:

-) 10⁶ (1 million) PFU/mL 1ml vial
-) 10⁸ (100 million) PFU/mL 1ml vial

REFERENCES

-) Imlygic [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc. October 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/09/15

Created: 11/15

Client Approval: 11/15

P&T Approval: 11/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TEMOZOLOMIDE - IV

Generic	Brand	HICL	GCN	Exception/Other
TEMOZOLOMIDE - IV	TEMODAR - IV		17724	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have one of the following diagnoses: metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC)?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC).

RATIONALE

Based on FDA approved indications and NCCN recommendations. Temodar is approved for the treatment of newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment; and refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine. NCCN recommends Temodar for SCLC patients with relapse <2-3 months, performance status 0-2 or relapse >2-3 up to 6 months (most useful if brain metastases are present); and for the treatment of metastatic melanoma. NCCN considers temozolomide to be a systemic therapy option for advanced or metastatic melanoma. No quantity limit is included within this guideline since there are multiple dosing regimens available, all of which are based on body surface area.

FDA APPROVED INDICATIONS

Temodar is an alkylating drug indicated for the treatment of adult patients with:

-) Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment.
-) Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TEMOZOLOMIDE - IV

REFERENCES

- J National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology Melanoma. (Version 3.2012).
- J National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Small Cell Lung Cancer Version 2.2014. [Online] September 17, 2013. [Cited: September 25, 2013.] http://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf
- J Schering Corporation, a subsidiary of Merck & Co., Inc. Temodar package insert. Whitehouse Station, NJ. February 2011.
- J Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: January 24, 2012].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/12

Client Approval: 11/13

P&T Approval: 11/13



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TEMSIROLIMUS

Generic	Brand	HICL	GCN	Exception/Other
TEMSIROLIMUS	TORISEL	34870		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

If yes, **approve for 12 months with a quantity limit of #4 kits (vials) per month.**

If no, do not approve.

DENIAL TEXT: Approval requires a diagnosis of advanced renal cell carcinoma (RCC).

RATIONALE

Ensure appropriate utilization of temsirolimus based on FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATION

Temsirolimus is indicated for the treatment of advanced renal cell carcinoma.

REFERENCES

-) Wyeth Pharmaceuticals Inc. Torisel package insert. Philadelphia, PA. September 2010.
-) National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Kidney Cancer. (Version 2.2011).

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/13

Created: 05/11

Client Approval: 08/13

P&T Approval: 05/11



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

THYROTROPIN ALFA FOR INJECTION

Generic	Brand	HICL	GCN	Exception/Other
THYROTROPIN ALFA FOR INJECTION	THYROGEN	18855		

GUIDELINES FOR USE

1. Is the requested product being used as diagnostic tool for serum thyroglobulin (Tg) testing?

If yes, do not approve.

DENIAL TEXT: The requested product is not covered for diagnostic purposes under the pharmacy benefit. This product may be covered under the medical benefit.

If no, continue to #2.

2. Is the requested product being used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease?

If yes, **approve one fill of #2 vials.**

If no, do not approve.

DENIAL TEXT: Approval requires that the requested product being used as adjunctive treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease.

RATIONALE

To ensure appropriate use of Thyrogen based on FDA approved indication and dosage. Limit diagnostic use to the medical benefit.

Two-injection regimen of Thyrogen 0.9 mg IM, followed by a second 0.9 mg IM injection 24 hours later.

FDA APPROVED INDICATION

Thyrogen (thyrotropin alfa for injection) is indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Thyrogen (thyrotropin alfa for injection) is indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

REFERENCES

1. Thyrogen (thyrotropin alfa for injection) [Prescribing Information]. Cambridge, MA: Genzyme Corporation.; July 2012.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

THYROTROPIN ALFA FOR INJECTION

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 10/01/13

Created: 08/13
Client Approval: 08/13

P&T Approval: 08/13



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TISAGENLECLEUCEL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TISAGENLECLEUCEL	KYMRIAH	44483		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient meet **ALL** of the following criteria?
 -) Treatment is prescribed by a Kymriah-certified hematologist or oncologist
 -) Kymriah will be administered at a treatment center that is certified to administer Kymriah
 -) The patient has not received a previous trial of Kymriah

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Is the patient 25 years of age or younger **AND** have a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL)?
 - If yes, continue to #3.
 - If no, continue to #4.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TISAGENLECLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

3. Does the physician attest that the patient meets **ONE** of the following criteria?

- ☐ The patient is in second or greater bone marrow relapse
- ☐ The patient is currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT)
- ☐ The patient has not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (i.e., primary refractory disease)
- ☐ The patient has not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
- ☐ The patient has Philadelphia chromosome positive (Ph+) ALL and meets at least **ONE** of the following:
 - ☐ The patient has had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
 - ☐ The patient is unable to tolerate TKI therapy
 - ☐ The patient has a contraindication to TKI therapy
- ☐ The patient is not eligible for allogeneic stem cell transplantation (SCT)

If yes, **approve GPID 43799 for 1 fill.**

APPROVAL TEXT: Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, the Risk Evaluation and Mitigation Strategy (REMS) program requires that certified healthcare facilities must have on-site, immediate access to tocilizumab (Actemra). The patient must also meet all criteria in the Actemra guideline to be approvable for both agents.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient 18 years of age or older **AND** have **ONE** of the following diagnoses?

- ☐ relapsed or refractory Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
- ☐ High grade B-cell lymphoma
- ☐ DLBCL arising from follicular lymphoma (FL) [i.e. transformed follicular lymphoma (TFL)]

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TISAGENLECLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the physician attest that the patient meets **ALL** of the following criteria?

-) The patient is refractory or has had disease progression (relapsed) after two or more lines of systemic therapy including rituximab and an anthracycline **AND**
-) The patient has had disease progression or relapsed after autologous hematopoietic stem cell transplantation (ASCT) **OR** the patient is not eligible for ASCT

If yes, **approve GPID 44689 for 1 fill.**

APPROVAL TEXT: Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, the Risk Evaluation and Mitigation Strategy (REMS) program requires that certified healthcare facilities must have on-site, immediate access to tocilizumab (Actemra). The patient must also meet all criteria in the Actemra guideline to be approvable for both agents

If no, do not approve.

DENIAL TEXT: The guideline named **TISAGENLECLEUCEL (Kymriah)** requires a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) OR relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma (FL) [i.e. transformed follicular lymphoma (TFL)]. In addition, the following criteria must be met:

-) Treatment is prescribed by a Kymriah-certified hematologist or oncologist
-) Kymriah will be administered at a treatment center that is certified to administer Kymriah
-) The patient has not had a previous trial of Kymriah

For diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL), approval requires:

-) The patient is 25 years of age or younger
-) Physician attestation of **ONE** of the following criteria:
 - o The patient is in second or greater bone marrow relapse
 - o The patient is currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT)
 - o The patient has not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (i.e., primary refractory disease)
 - o The patient has not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
 - o The patient has Philadelphia chromosome positive (Ph+) ALL and meets at least **ONE** of the following:
 - The patient has had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
 - The patient is unable to tolerate TKI therapy
 - The patient has a contraindication to TKI therapy
 - o The patient is not eligible for allogeneic stem cell transplantation (SCT)

(Denial text continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TISAGENLECLEUCEL (NSA)

GUIDELINES FOR USE (CONTINUED)

For diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma (FL) [i.e. transformed follicular lymphoma (TFL)], approval requires:

-) The patient is 18 years of age or older
-) Physician attestation of **ALL** of the following criteria:
 - o The patient is refractory or has had disease progression (relapsed) after two or more lines of systemic therapy including rituximab and an anthracycline **AND**
 - o The patient has had disease progression or relapsed after autologous hematopoietic stem cell transplantation (ASCT) **OR** the patient is not eligible for ASCT

RATIONALE

Promote appropriate utilization of **KYMRIAH** based on FDA approved indication, dosing, and clinical trial design.

NOTE: Kymriah is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) because of the risk of cytokine release syndrome (CRS) and neurological events. The FDA is requiring that hospitals and their associated clinics that dispense Kymriah be specially certified. As part of that certification, staff involved in the prescribing, dispensing, or administering of Kymriah are required to be trained to recognize and manage CRS and neurological events. Additionally, the certified health care settings are required to have protocols in place to ensure that Kymriah is only given to patients after verifying that tocilizumab is available for immediate administration.

BACKGROUND

Kymriah is the first gene therapy to be approved by the FDA and was granted Priority Review and Breakthrough Therapy designations. Kymriah is an engineered chimeric antigen receptor (CAR) product that targets CD19, a protein expressed on the surface of B cell leukemia and lymphoma cells. The CAR product is utilized in the process of autologous cell therapy in which a patient's own white blood cells are collected, T cells are isolated, the CAR gene is inserted into the T cells, the T cell colony is expanded, and then the engineered T cells are infused back into the patient. This process results in an expanded number of tumor-specific T cells that circulate throughout the body to target and kill cancer cells.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TISAGENLECLEUCEL (NSA)

FDA APPROVED INDICATIONS

Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

-) Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
-) Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Limitation of Use: KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma (PCNSL).

DOSAGE AND ADMINISTRATION

-) Kymriah is supplied as a frozen suspension of genetically modified autologous T cells in one infusion bag labeled for the specific recipient. Kymriah is shipped directly to the cell lab associated with the infusion center. Kymriah is given as a one-time treatment.
-) Kymriah is for autologous use and is administered by intravenous infusion only.
-) Prior to infusion:
 - o Verify the patient's identity
 - o Pre-medicate with acetaminophen and an H1-antihistamine
 - o Confirm availability of tocilizumab
-) Kymriah dosing is based on the number of chimeric antigen receptor (CAR) positive viable T cells.
-) **Pediatric and Young Adult Relapsed or Refractory B-Cell ALL (up to 25 years of age):**
 - o For patients 50 kg or less, administer 0.2 to 5.0×10^6 CAR-positive viable T cells per kg body weight intravenously.
 - o For patients above 50 kg, administer 0.1 to 2.5×10^8 CAR-positive viable T cells (non-weight based) intravenously.
-) **Adults with Relapsed or Refractory Diffuse Large B-Cell Lymphoma:**
 - o Administer 0.6 to 6.0×10^8 CAR-positive viable T cells intravenously.

AVAILABLE STRENGTHS

-) **Pediatric and Young Adult B-Cell ALL (up to 25 years of age):**
 - o A single-dose unit of Kymriah contains 0.2 to 5.0×10^6 CAR-positive viable T cells per kg of body weight for patients 50 kg or less, or 0.1 to 2.5×10^8 CAR-positive viable T cells for patients more than 50 kg, suspended in a patient-specific infusion bag.
-) **Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma:**
 - o A single-dose unit of Kymriah contains 0.6 to 6.0×10^8 CAR-positive viable T cells suspended in one or more patient-specific infusion bag.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****TISAGENLECLEUCEL (NSA)****FDA APPROVED INDICATIONS (CONTINUED)****AVAILABLE STRENGTHS**

The actual number of CAR-positive T cells in the product is reported on the Certificate of Analysis that is shipped with Kymriah. The volume in the infusion bag ranges from 10 mL to 50 mL.

REFERENCES

-) Kymriah [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. May 2018.
-) FDA approval brings first gene therapy to the United States. [Press release]. August 30, 2017. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm>. Accessed August 31, 2017.
-) ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT 02435849. Determine Efficacy and Safety of CTL019 in Pediatric Patients With Relapsed and Refractory B-cell ALL (ELIANA). Available at: <https://clinicaltrials.gov/ct2/show/NCT02435849?term=eliana&draw=1&rank=1>. Accessed October 18, 2017.
-) ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT 02445248. Study of Efficacy and Safety of CTL019 in Adult DLBCL Patients. Available at: <https://clinicaltrials.gov/ct2/show/NCT02445248?term=02445248&rank=1>. Accessed May 17, 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/18

Created: 10/17

Client Approval: 09/18

P&T Approval: 07/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE FORMS AND STRENGTHS

Single-use vials of ACTEMRA (20 mg per mL) are available for intravenous administration:

-) 80 mg per 4 mL
-) 200 mg per 10 mL
-) 400 mg per 20 mL

REFERENCE

) Actemra [Prescribing Information]. South San Francisco, CA: Genentech. August 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 02/10

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRABECTEDIN

Generic	Brand	HICL	GCN	Exception/Other
TRABECTEDIN	YONDELIS	35367		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma and meets the following criterion?

) The patient has received prior therapy with an anthracycline-containing regimen such as doxorubicin

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: Our guideline for **TRABECTEDIN (Yondelis)** requires a diagnosis of unresectable or metastatic liposarcoma or leiomyosarcoma. Additional guideline requirements apply.

) The patient must have received prior therapy with an anthracycline-containing regimen such as doxorubicin.

RATIONALE

Promote appropriate utilization of Yondelis based on FDA-approved indications.

DOSAGE

Administer at 1.5 mg/m² body surface area as a 24-hour intravenous infusion, every 3 weeks through a central venous line.

Yondelis requires premedication with dexamethasone 20 mg IV, 30 minutes before each infusion.

FDA APPROVED INDICATION

Yondelis is an alkylating drug indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.

AVAILABLE STRENGTHS

) 1 mg vial

REFERENCES

) Yondelis [Package Insert]. Janssen Products. Horsham, PA. November 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/16

Created: 11/15

Client Approval: 03/16

P&T Approval: 11/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRASTUZUMAB

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB	HERCEPTIN	18801		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer?

If yes, continue to #2.

If no, continue to #4.

2. Is the request for metastatic breast cancer and meets the following criteria?

-) The patient has HER-2 overexpressing metastatic breast cancer **AND**
-) Requested medication is being used in combination with paclitaxel for first-line treatment **OR**
-) The patient previously tried chemotherapy for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Is the request for adjuvant therapy for breast cancer and meets the following criteria?

-) The patient is HER2 positive **OR**
-) The patient is HER2 negative with one of the following high risk features:
 - o The patient has a T1c primary tumor (defined as tumor > 10 mm but ≤ 20mm in greatest dimension) **OR**
 - o Tumor size > 2 cm **OR**
 - o The patient's age < 35 years old **OR**
 - o The patient has histologic and/or nuclear Grade 2 or 3 breast cancer

AND meets one of the following criteria:

- o Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel **OR**
- o Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin **OR**
- o Requested medication is being used as a single agent following multi-modality anthracycline based therapy (examples include, daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRASTUZUMAB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric cancer and meets **ALL** the following criteria?

-) The patient has HER2 positive metastatic gastric cancer
-) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
-) The patient has not received prior treatment for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of gastroesophageal junction adenocarcinoma and meets **ALL** the following criteria?

-) The patient has HER2 positive metastatic gastric cancer
-) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
-) The patient has not received prior treatment for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRASTUZUMAB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline for **TRASTUZUMAB** requires a diagnosis of breast cancer, metastatic gastric cancer, or metastatic gastric cancer/gastroesophageal junction adenocarcinoma. Additional guideline requirements apply.

For the diagnosis of metastatic breast cancer, approval requires:

-) The patient has HER-2 overexpressing metastatic breast cancer **AND**
-) Requested drug is being used in combination with paclitaxel for first-line treatment **OR**
-) The patient previously tried chemotherapy for metastatic disease

For the use as adjuvant therapy for breast cancer, approval requires:

-) The patient is HER2 positive **OR**
-) The patient is HER2 negative with one of the following high risk features:
 - o The patient has a T1c primary tumor (defined as tumor > 10 mm but ≤ 20mm in greatest dimension) **OR**
 - o The patient's tumor size is > 2 cm **OR**
 - o The patient's age is < 35 years old **OR**
 - o The patient has histologic and/or nuclear Grade 2 or 3 breast cancer

AND meets one of the following criteria:

- o Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel **OR**
- o Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin **OR**
- o Requested medication is being used as a single agent following multi-modality anthracycline based therapy (examples include, daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

For the diagnosis of metastatic gastric cancer, approval requires:

-) The patient has HER2 positive metastatic gastric cancer
-) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
-) The patient has not received prior treatment for metastatic disease

For the diagnosis of gastroesophageal junction adenocarcinoma, approval requires:

-) The patient has HER2 positive metastatic gastric cancer
-) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
-) The patient has not received prior treatment for metastatic disease

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TRASTUZUMAB

RATIONALE

To ensure appropriate use aligned with FDA approved indications and NCCN guidelines.

FDA APPROVED INDICATIONS

Adjuvant Breast Cancer

Herceptin is indicated for adjuvant treatment of HER2 overexpressing node positive or node negative breast cancer (ER/PR negative or with one high risk feature breast cancer [see Clinical Studies (14.1)]):

-) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
-) with docetaxel and carboplatin
-) as a single agent following multi-modality anthracycline based therapy.

Metastatic Breast Cancer

Herceptin is indicated:

-) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
-) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

Metastatic Gastric Cancer

Herceptin is indicated in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

REFERENCES

-) Genentech, Inc. Herceptin package insert. South San Francisco, CA. April 2015.
-) National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer, Version 2.2015.
-) National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers, Version 3.2015.
-) National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer, Version 3.2015.
-) Breast Cancer Treatment (PDQ) at <http://www.cancer.gov/cancertopics/pdq/treatment/breast/healthprofessional/page3> [Accessed May 12, 2015]

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 06/01/15

Created: 08/12

Client Approval: 05/15

P&T Approval: 05/15



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VORETIGENE NEPARVOVEC-RZYL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
VORETIGENE NEPARVOVEC- RZYL	LUXTURNA	44720		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

**THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT
SUBMITTING FOR PHARMACIST REVIEW.**

GUIDELINES FOR USE

1. Does the patient have a diagnosis of biallelic RPE65 mutation-associated retinal dystrophy and meet **ALL** of the following criteria?
 -) Biallelic RPE65 mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
 -) The patient is 3 years of age or older
 -) The requested medication is prescribed by or in consultation with an ophthalmologist or retinal specialist
 -) The patient has a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
 -) The treating physician attests that the patient has sufficient retinal cells as demonstrated by sufficient retinal thickness
 -) The patient does NOT have pre-existing eye conditions that may lead to blindness independently of RPE65-mutation associated retinal dystrophy (e.g., leukemia with CNS/optic nerve involvement, macular edema or CMV retinitis)
 -) Patient has NOT previously received gene therapy (including Luxturna) for the treatment of vision loss
 -) The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

If yes, **approve for 1 fill per lifetime by HICL with a quantity limit of 0.5mL (one single dose vial) per affected eye.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VORETIGENE NEPARVOVEC-RZYL (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **VORETIGENE NEPARVOVEC-RZYL (Luxturna)** requires that the patient has a diagnosis of confirmed biallelic RPE65 mutation-associated retinal dystrophy. In addition, the following criteria must be met:

-) Biallelic RPE65 mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
-) The patient is 3 years of age or older
-) The requested medication is prescribed by or in consultation with an ophthalmologist or retinal specialist
-) The patient has a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
-) The treating physician attests that the patient has sufficient retinal cells as demonstrated by sufficient retinal thickness
-) The patient does NOT have pre-existing eye conditions that may lead to blindness independently of RPE65-mutation associated retinal dystrophy (e.g., leukemia with CNS/optic nerve involvement, macular edema or CMV retinitis)
-) Patient has NOT previously received gene therapy (including Luxturna) for the treatment of vision loss
-) The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

RATIONALE

Promote appropriate utilization of **LUXTURNA** based on FDA approved indication.

FDA APPROVED INDICATIONS

Luxturna is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

DOSAGE AND ADMINISTRATION

-) The recommended dose of Luxturna for each eye is 1.5×10^{11} vector genomes (vg), administered by subretinal injection in a total volume of 0.3 mL.
-) Luxturna is administered by a surgeon via subretinal injection.
 - o Perform subretinal administration of Luxturna to each eye on separate days within a close interval, but no fewer than 6 days apart.
 - o Recommend systemic oral corticosteroids equivalent to prednisone at 1 mg/kg/day (maximum of 40 mg/day) for a total of 7 days (starting 3 days before administration of Luxturna to each eye), and followed by a tapering dose during the next 10 days.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

VORETIGENE NEPARVOVEC-RZYL (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

AVAILABLE STRENGTH(S)

Luxturna is a suspension for subretinal injection, supplied in a 0.5 mL extractable volume in a single-dose 2 mL vial for a single administration in one eye. The supplied concentration (5×10^{12} vg/mL) requires a 1:10 dilution prior to administration.

REFERENCES

) Luxturna [Prescribing Information]. Spark Therapeutics, Inc: Philadelphia, PA. December 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/18

Created: 03/18

Client Approval: 03/18

P&T Approval: 01/18



**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ZIV-AFLIBERCEPT

Generic	Brand	HICL	GCN	Exception/Other
ZIV-AFLIBERCEPT	ZALTRAP		32988 32989	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient tried an oxaliplatin-containing regimen (such as FOLFOX)?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is Zaltrap being used in combination with FOLFIRI or irinotecan?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: Approval requires a diagnosis of metastatic colorectal cancer, a trial of an oxaliplatin-containing regimen (such as FOLFOX), and concurrent use with FOLFIRI or irinotecan.

RATIONALE

To ensure appropriate use of Zaltrap consistent with FDA approved indication and National Comprehensive Cancer Network (NCCN) recommendations.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ZIV-AFLIBERCEPT

RATIONALE (CONTINUED)

Zaltrap is a fully humanized recombinant fusion protein that inhibits angiogenesis by binding to the vascular endothelial growth factor (VEGF)-A receptor. In addition to blocking all human VEGF-A isoforms, Zaltrap also inhibits VEGF-B, and placental growth factor (PIGF) with a higher affinity than native receptors. Zaltrap is given as a 4mgg intravenous infusion over 1 hour every 2 weeks. It should not be given as an intravenous push or bolus. It is given in combination with the FOLFIRI chemotherapy regimen. Zaltrap therapy must be suspended for both 4 weeks prior to and 4 weeks following major surgery. Aflibercept, marketed as Eylea, is approved for the treatment of macular degeneration.

NCCN Guidelines Version 2.2013: Colon Cancer / NCCN Guidelines Version 3.2013 Rectal Cancer

Surgical removal is the preferred treatment for early stage disease. Surgery is accompanied by adjuvant chemotherapy for patients with high-risk features or more extensive cancer involvement.

Primary treatment options for resectable synchronous metastases are:

-) Chemotherapy (FOLFIRI, FOLFOX, or CapeOX) with or without Avastin
-) Chemotherapy (FOLFIRI or FOLFOX) with or without Vectibix (*KRAS* wild-type patients only)
-) Chemotherapy (FOLFIRI) with or without Erbitux (*KRAS* wild-type patients only)
-) Staged resection
-) Infusional IV 5-FU with radiation

Primary treatment options for unresectable metachronous metastases previously treated with adjuvant FOLFOX are:

-) FOLFIRI with or without Avastin
-) FOLFIRI with or without Zaltrap
-) Irinotecan with or without Avastin
-) Irinotecan with or without Zaltrap
-) FOLFIRI or irinotecan with Erbitux or Vectibix (*KRAS* wild-type patients only)

Initial therapy options for treatment of mCRC in patients appropriate for intensive therapy are:

-) FOLFOX, with or without Avastin
-) FOLFOX, with or without Vectibix (*KRAS* wild-type patients only)
-) CapeOX with or without Avastin
-) FOLFIRI with or without Avastin
-) FOLFIRI with or without Erbitux or Vectibix (*KRAS* wild-type patients only)
-) 5-FU/leucovorin or Xeloda with or without Avastin
-) FOLFOXIRI

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ZIV-AFLIBERCEPT

RATIONALE (CONTINUED)

Initial therapy options for treatment of mCRC in patients not appropriate for intensive therapy are:

- ✓ Infusional 5-FU with leucovorin or Xeloda with or without Avastin
- ✓ Erbitux (KRAS wild-type patients only)
- ✓ Vectibix (KRAS wild-type patients only)

Zaltrap in combination with FOLFIRI is a recommended therapeutic regimen following progression of mCRC after an oxaliplatin containing chemotherapy regimen. Stivarga is considered a treatment option in therapy after first, second, or third progression, depending on previous lines of therapy.

Other treatment options after first or second progression include:

- ✓ Erbitux or Vectibix with irinotecan (KRAS wild-type patients only)
- ✓ FOLFOX, FOLFIRI, CapeOX, or irinotecan with or without Avastin
- ✓ Irinotecan and oxaliplatin with or without Avastin

FDA APPROVED INDICATIONS

Zaltrap, in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI), is indicated for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

REFERENCES

- ✓ Zaltrap [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.
- ✓ National Comprehensive Cancer Network. Colon Cancer Guideline Version 2.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/colon.pdf [Accessed January 16, 2013].
- ✓ National Comprehensive Cancer Network. Rectal Cancer Guideline Version 3.2013. Available at: http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf [Accessed January 16, 2013].

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/01/14

Created: 02/13

Client Approval: 11/13

P&T Approval: 11/13

PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AGALSIDASE BETA	FABRAZYME	24861		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of Fabry disease and meet **ALL** of the following criteria?
 - The patient is 8 years of age or older
 - The requested medication is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
 - The patient is **NOT** concurrently using an alpha-galactosidase A (a-Gal A) pharmacological chaperone (i.e., migalastat)
 - The patient is symptomatic **OR** has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Is the request for a female patient who meets the following criterion?
 - Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following 1) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss), 2) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound), OR 3) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy).

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (NSA)

INITIAL CRITERIA (CONTINUED)

3. Is the request for a male patient who meets **ONE** of the following criteria?

- Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal-A)
- Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following 1) Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss), 2) Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound), OR 3) Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **AGALSIDASE BETA (Fabrazyme)** requires a diagnosis of Fabry disease. In addition, the following criteria must be met:

- The patient is 8 years of age or older
- The requested medication is prescribed by or in consultation with a nephrologist, cardiologist, or specialist physician in genetics or inherited metabolic disorders
- The patient is **NOT** concurrently using an alpha-galactosidase A (a-Gal A) pharmacological chaperone (i.e., migalastat)
- The patient is symptomatic **OR** has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings (e.g., decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI)
- The patient meets **ONE** of the following:
 - Female patients: Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation
 - Male patients: Confirmation of Fabry disease via enzyme assay indicating deficiency of alpha galactosidase A (a-Gal-A), **OR** genetic test documenting galactosidase alpha gene (GLA) mutation

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES

AGALSIDASE BETA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Fabry disease **AND** meet the following criterion?
 - The prescribing provider attests that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following:
 - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
 - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
 - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **AGALSIDASE BETA (Fabrazyme)** requires a diagnosis of Fabry disease for renewal. In addition, the following renewal criteria must be met:

- The prescribing provider attests that the patient has demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regards to at least **ONE** of the following:
 - Symptoms (e.g., pain, hypohidrosis/anhidrosis, exercise intolerance, GI symptoms, angiokeratomas, abnormal cornea, tinnitus/hearing loss)
 - Imaging (e.g., brain/cardiac MRI, DEXA, renal ultrasound)
 - Laboratory or histological testing (e.g., GL-3 in plasma/urine, renal biopsy)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fabrazyme.

REFERENCES

- Fabrazyme [Prescribing Information]. Cambridge, MA: Genzyme Corporation; January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 02/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG (NSA)

Generic	Brand	HICL	GCN	Exception/Other
EMAPALUMAB-LZSG	GAMIFANT	45503		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) and diagnosis is confirmed by **ONE** of the following criteria?
 - The patient has undergone a genetic test identifying HLH-associated gene mutation (e.g., PRF1, UNC13D)
 - The patient has at least **five** of the following eight diagnostic criteria for HLH:
 - Fever
 - Splenomegaly
 - Cytopenias (affecting ≥ 2 of 3 cell lineages)
 - Hypertriglyceridemia and/or hypofibrinogenemia
 - Hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy
 - Low or absent natural killer-cell activity
 - Ferritin level of ≥ 500 mcg/L
 - Soluble CD25 level of $\geq 2,400$ U/mL

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient meet **ONE** of the following criteria?
 - The patient has refractory, recurrent, or progressive disease
 - The patient has a trial or intolerance to conventional HLH therapy (e.g., chemotherapy, steroids, immunotherapy)

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

EMAPALUMAB-LZSG (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?

- The requested medication will be used concurrently with dexamethasone
- Therapy is prescribed by or in consultation with an immunologist, hematologist, or oncologist

If yes, **approve for 8 weeks by HICL.**

APPROVAL TEXT: Renewal requires that 1) patient has not received successful hematopoietic cell transplantation and 2) patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g. altered mental status), improved CBC, increased fibrinogen levels and/or reductions in D-dimer, ferritin, soluble CD25 levels.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **EMAPALUMAB-LZSG (Gamifant)** requires a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH). In addition, the following criteria must be met:

- Diagnosis is confirmed by ONE of the following:
 - The patient has undergone a genetic test identifying HLH-associated gene mutation (e.g., PRF1, UNC13D)
 - The patient has at least five of the following eight diagnostic criteria for HLH (fever, splenomegaly, cytopenias (affecting at least 2 of 3 cell lineages), hypertriglyceridemia and/or hypofibrinogenemia, hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy, low or absent natural killer-cell activity, ferritin level of at least 500 mcg/L, soluble CD25 level of at least 2,400 U/mL)
- The patient has refractory, recurrent, or progressive disease; **OR** the patient has a trial or intolerance to conventional HLH therapy (e.g., chemotherapy, steroids, immunotherapy)
- The requested medication will be used concurrently with dexamethasone
- Therapy is prescribed by or in consultation with an immunologist, hematologist, or oncologist

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PRIOR AUTHORIZATION GUIDELINES**EMAPALUMAB-LZSG (NSA)****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of hemophagocytic lymphohistiocytosis (HLH) and meet **ALL** of the following criteria?
 - The patient has not received successful hematopoietic stem cell transplantation
 - The patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g., altered mental status), improved CBC, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 levels

If yes, **approve for 8 weeks by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **EMAPALUMAB-LZSG (Gamifant)** requires a diagnosis of hemophagocytic lymphohistiocytosis (HLH). In addition, the following criteria must be met:

- The patient has not received successful hematopoietic stem cell transplantation
- The patient has demonstrated improved immune system response from baseline as manifested by any of the following: resolution of fever, decreased splenomegaly, improvement in CNS symptoms (e.g., altered mental status), improved CBC, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 levels

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Gamifant.

REFERENCES

- Gamifant [Prescribing Information]. Waltham, MA: Sobi Inc.; November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

MOXETUMOMAB PASUDOTOX (NSA)

Generic	Brand	HICL	GCN	Exception/Other
MOXETUMOMAB PASUDOTOX-TDFK	LUMOXITI	45363		

GUIDELINES FOR USE

- Does the patient have a diagnosis of hairy cell leukemia (HCL) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The disease is relapsed or refractory
 - The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Has the patient previously received 6 cycles of Lumoxiti?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 6 months by HICL.**

DENIAL TEXT: The guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires a diagnosis of hairy cell leukemia (HCL). In addition, the following must be met:

- The patient is 18 years of age or older
- The disease is relapsed or refractory
- The patient has received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA)
- The patient has NOT previously received 6 cycles of Lumoxiti

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lumoxiti.

REFERENCES

- Lumoxiti [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19

PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

Generic	Brand	HICL	GCN	Exception/Other
OMADACYCLINE	NUZYRA		45478	

GUIDELINES FOR USE

- Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae*

If yes, continue to #2.
If no, continue to #5.
- Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) with a quantity limit of #26 tablets per 13 days.**
If no, continue to #3.
- Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
 - The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
 - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) with a quantity limit of #26 tablets per 13 days.**
If no, continue to #4.
- Does the patient meet **ALL** of the following criteria?
 - Antimicrobial susceptibility results are unavailable
 - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) with a quantity limit of #26 tablets per 13 days.**
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**OMADACYCLINE****GUIDELINES FOR USE (CONTINUED)**

5. Does the patient have a diagnosis of an acute bacterial skin or skin structure infection (ABSSSI) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, or *Klebsiella pneumoniae*

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

6. Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) with a quantity limit of #30 tablets per 14 days.**

If no, continue to #7.

7. Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
- The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)
 - The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Nuzyra

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) with a quantity limit of #30 tablets per 14 days.**

If no, continue to #8.

8. Does the patient meet **ALL** of the following criteria?
- Antimicrobial susceptibility results are unavailable
 - The patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)

If yes, **approve Nuzyra 150mg tablet for one fill by GPID (45478) with a quantity limit of #30 tablets per 14 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES**OMADACYCLINE****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: The guideline named **OMADACYCLINE (Nuzyra)** requires a diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin or skin structure infection (ABSSSI). In addition, the following criteria must also be met:

For the diagnosis of community-acquired bacterial pneumonia (CABP), approval requires:

- The patient is 18 years of age or older
- The infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae*
- The patient meets **ONE** of the following criteria:
 - Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** 2) the culture is susceptible to Nuzyra
 - Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

For the diagnosis of acute bacterial skin or skin structure infection (ABSSSI), approval also requires all of the following:

- The patient is 18 years of age or older
- The infection is caused by any of the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (Includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, or *Klebsiella pneumoniae*
- The patient meets **ONE** of the following criteria:
 - Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for ABSSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin), **AND** 2) the culture is susceptible to Nuzyra
 - Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for ABSSI (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalixin, cefazolin)

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PRIOR AUTHORIZATION GUIDELINES

OMADACYCLINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nuzyra.

REFERENCES

- Nuzyra [Prescribing Information]. Boston, MA: Paratek Pharmaceuticals, Inc.; October 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19



ADALIMUMAB

Generic	Brand	HICL	GCN	Exception/Other
ADALIMUMAB	HUMIRA	24800		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient meets ONE of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

If yes, **approve for 6 months by GPID for Humira 40mg/0.4mL syringe/pen OR 40mg/0.8mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 2 years of age or older
 - Documentation of the patient's current weight

If yes, **approve for 6 months by GPID with a quantity limit of #1 kit (2 syringes/pens) per month based on patient weight as follows:**

- If 10kg to <15kg in weight: Approve Humira 10mg/0.2mL syringe OR 10mg/0.1mL syringe.
- If 15kg to <30kg in weight: Approve Humira 20mg/0.4mL syringe OR 20mg/0.2mL syringe.
- If 30kg or heavier: Approve Humira 40mg/0.8mL pen/syringe OR 40mg/0.4mL pen/syringe.

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APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older

If yes, **approve for 6 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient is 18 years of age or older

If yes, **approve for 6 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, continue to #5.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 18 years of age or older

If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**

- **Approve for 1 fill for #1 Humira Psoriasis Starter Package (containing four 40mg/0.8mL pens) OR #1 Humira Psoriasis Starter Package (containing one 80 mg/0.8 mL pen and two 40 mg/0.4 mL pen).**
- **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #6.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 6 years of age or older

If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**

- **Approve for 1 fill for #1 Humira Crohn's Disease Starter Package (containing six 40mg/0.8mL pens), OR #1 Humira Pediatric Crohn's Starter Package (containing either three or six 40mg/0.8mL syringes), OR #1 Humira Pediatric Crohn's Disease Starter Package (containing three 80mg/0.8mL syringes), OR #1 Humira Pediatric Crohn's Disease Starter Package (containing one 40mg/0.4mL syringe and one 80mg/0.8mL syringe) OR #1 Humira Crohn's Disease Starter Package (containing three 80 mg/0.8 mL pens).**
- **Approve for 5 months for Humira 40mg/0.8mL syringe/pen, OR Humira 40mg/0.4mL syringe/pen, OR Humira 20mg/0.4mL syringe, OR Humira 20mg/0.2mL syringe with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #7.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older

If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**

- **Approve for 1 fill for #1 Humira Pen Starter Package for Ulcerative Colitis (UC) (containing six single-use 40mg/0.8mL pens) OR #1 Humira Ulcerative Colitis Starter Package (containing three 80 mg/0.8 mL pens).**
- **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and is 12 years of age or older?

If yes, **approve for a total of 6 months by GPID. Please enter two authorizations as follows:**

- **Approve for 1 fill for #1 Humira Pen Starter Package for Hidradenitis Suppurativa (HS) (containing six single-use 40mg/0.8mL pens) OR #1 Humira Hidradenitis Suppurativa Starter Package (containing three 80 mg/0.8 mL pens).**
- **Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 kits (4 syringes/pens) per month.**

If no, continue to #9.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

9. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with an ophthalmologist
- The patient is 2 years of age or older
- The patient does not have isolated anterior uveitis
- Documentation of the patient's current weight if between 2 to 17 years of age

If yes, **approve for a total of 6 months by GPID as follows:**

- **For age 2 to 17 years, approve with a quantity limit of #1 kit (2 syringes/pens) per month based on patient weight as follows:**
 - If 10kg to <15kg in weight: Approve Humira 10mg/0.2mL syringe OR 10mg/0.1mL syringe.
 - If 15kg to <30kg in weight: Approve Humira 20mg/0.4mL syringe OR 20mg/0.2mL syringe.
 - If 30kg or heavier: Approve Humira 40mg/0.8mL pen/syringe OR 40mg/0.4mL pen/syringe.
- **For age 18 years and above, please enter two authorizations as follows:**
 - Approve for 1 fill for #1 Humira Uveitis Starter Package (containing four 40mg/0.8mL pens) OR #1 Humira Uveitis Starter Package (containing one 80 mg/0.8 mL pen and two 40 mg/0.4 mL pens).
 - Approve for 5 months for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.

APPROVAL TEXT: Renewal for Uveitis requires that the patient has not experienced treatment failure, defined as development of new inflammatory chorioretinal or retinal vascular lesions, a 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade, or a worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, or moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis. The following criteria must also be met:
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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient meets ONE of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

For patients with moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 2 years of age or older
- Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with ankylosing spondylitis (AS), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 18 years of age or older

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe Crohn's disease (CD), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older

For patients with moderate to severe ulcerative colitis (UC), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older

For patients with moderate to severe hidradenitis suppurativa (HS), approval requires:

- The patient is 12 years of age or older

For patients with non-infectious intermediate, posterior and panuveitis, approval requires:

- Therapy is prescribed by or given in consultation with an ophthalmologist
- The patient is 2 years of age or older
- The patient does not have isolated anterior uveitis
- Documentation of the patient's current weight if between 2 to 17 years of age

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?

If yes, continue to #2.

If no, continue to #4.

2. Is the request for Humira 40mg dosed **every other week** and has the following criteria been met?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #3.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

3. Is the request for Humira 40mg dosed **every week** and have **ALL** of the following criteria been met?
- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
 - The patient has had a trial of at least a 3-month regimen of Humira 40mg dosed every other week

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #2 kits (4 syringes/pens) per month.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

PAC NOTE: Please enter a proactive prior authorization for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID for Humira 10mg/0.1mL syringe, OR Humira 10mg/0.2mL syringe, OR Humira 20mg/0.2mL syringe, OR Humira 20mg/0.4mL syringe, OR Humira 40mg/0.4mL syringe/pen, OR Humira 40mg/0.8mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #5.

5. Does the patient a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #6.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen, OR Humira 40mg/0.4 mL syringe/pen, OR Humira 20mg/0.4mL syringe, OR Humira 20mg/0.2mL syringe with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, continue to #10.

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS)?

If yes, **approve for 12 months by GPID for Humira 40mg/0.8mL syringe/pen OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #2 kits (4 syringes/pens) per month.**

If no, continue to #11.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

11. Does the patient have a diagnosis of non-infectious intermediate, posterior and panuveitis **AND** meet the following criteria?

- The patient has not experienced treatment failure, defined as **ONE** of the following criteria:
 - Development of new inflammatory chorioretinal or retinal vascular lesions
 - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
 - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

If yes, **approve for 12 months by GPID for Humira 10mg/0.1mL syringe, OR Humira 10mg/0.2mL syringe, OR Humira 20mg/0.2mL syringe, OR Humira 20mg/0.4mL syringe, OR Humira 40mg/0.8mL syringe/pen, OR Humira 40mg/0.4mL syringe/pen with a quantity limit of #1 kit (2 syringes/pens) per month.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis for renewal. The following criteria must also be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- Requests for Humira weekly dosing requires that the patient has had a trial of at least a 3-month regimen of Humira 40mg every other week

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of psoriatic arthritis requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of ankylosing spondylitis requires:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

(Renewal denial text continued on next page)

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

Renewal for the diagnosis of moderate to severe plaque psoriasis requires:

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

Renewal for the diagnosis of non-infectious intermediate, posterior and panuveitis requires:

- The patient has not experienced treatment failure, defined as **ONE** of the following criteria:
 - Development of new inflammatory chorioretinal or retinal vascular lesions
 - A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
 - A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for Humira.

FDA APPROVED INDICATIONS

HUMIRA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HUMIRA can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

HUMIRA is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. HUMIRA can be used alone or in combination with methotrexate.

HUMIRA is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. HUMIRA can be used alone or in combination with non-biologic (DMARDs).

HUMIRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

HUMIRA is indicated for reducing signs and symptoms, inducing, and maintaining clinical remission in adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

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ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

HUMIRA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

HUMIRA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients.

DOSAGE AND ADMINISTRATION

Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis

40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

Juvenile Idiopathic Arthritis or Pediatric Uveitis

The recommended dose of HUMIRA for patients 2 years of age and older with polyarticular juvenile idiopathic arthritis (JIA) is based on weight as shown below:

10 kg (22 lbs.) to <15 kg (33 lbs.): 10 mg every other week

15 kg (33 lbs.) to <30 kg (66 lbs.): 20 mg every other week

≥30 kg (66 lbs.): 40 mg every other week

Adult Crohn's Disease and Ulcerative Colitis

Initial dose (Day 1) is 160 mg (four 40 mg injections in one day, two 80 mg injections in one day, or one 80 mg injection per day for two consecutive days, or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every other week.

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ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Adult Hidradenitis Suppurativa

Initial dose (Day 1) is 160 mg (four 40 mg injections in one day, two 80 mg injections in one day, or one 80 mg injection per day for two consecutive days, or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every week.

Plaque Psoriasis or Adult Uveitis

80 mg initial dose followed by 40 mg every other week starting one week after initial dose.

Pediatric Crohn's Disease

	17 kg to <40kg OR 37 lbs to <88 lbs	≥40kg OR ≥ 88 lbs
Day 1	80 mg x1 (Two 40mg injections in one day)	160mg x1 (Four 40mg injections in one day or two 40mg injections for 2 days)
Day 15	40 mg x1	80mg x1
Day 29	20 mg every other week	40mg every other week

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ADALIMUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE FORMS AND STRENGTHS

- 80 mg/0.8 mL in a single-use prefilled syringe of 3 (Humira Pediatric Crohn's starter kit)
- 80 mg/0.8 mL in a single-use prefilled pen of 3 (Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa starter pack)
- 80 mg – 40 mg in 2 single-use prefilled syringes (Humira Pediatric Crohn's starter kit)
- 80 mg/0.8 mL and two 40 mg/0.4 mL single-use prefilled pens (Humira Psoriasis/Uveitis starter pack)
- 80 mg/0.8 mL in a single-use prefilled pen (HUMIRA Pen)
- 80 mg/0.8 mL in a single-use prefilled glass syringe
- 40 mg/0.8 mL in a single-use prefilled pen (HUMIRA Pen)
- 40 mg/0.4 mL in a single-use prefilled pen (HUMIRA Pen)
- 40 mg/0.8 mL in a single-use prefilled glass syringe
- 40 mg/0.4 mL in a single-use prefilled glass syringe
- 20 mg/0.4 mL in a single-use prefilled glass syringe
- 20 mg/0.2 mL in a single-use prefilled glass syringe
- 10 mg/0.2 mL in a single-use prefilled glass syringe
- 10 mg/0.1 mL in a single-use prefilled glass syringe
- 40 mg/0.8 mL in a single-use glass vial for institutional use only

REFERENCES

- Humira [Prescribing Information]. North Chicago, IL: AbbVie Inc. October 2018.
- Cohen S, Mikuls TR. Initial treatment of rheumatoid arthritis in adults. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019)
- Cohen S, Cannella A. Treatment of rheumatoid arthritis in adults resistant to initial nonbiologic DMARD therapy. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019).

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/01/18
10/18

Created: 05/03
Client Approval: 10/18

P&T Approval:



ALIROCUMAB

Generic	Brand	HICL	GCN	Exception/Other
ALIROCUMAB	PRALUENT PEN, PRALUENT SYRINGE	42347		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.
2. Does the patient meet **ONE** of the following criteria?
 - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
 - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
If yes, continue to #3.
If no, continue to #4.
3. Will the patient continue statin treatment as described above in combination with Praluent?

If yes, continue to #5.
If no, do not approve.
DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALIROCUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has **ONE** of the following diagnoses:
 - Clinical atherosclerotic cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)
 - Heterozygous familial hypercholesterolemia (HeFH) as determined by meeting **ONE** of the following:
 - Simon Broome diagnostic criteria for HeFH (definite)
 - Dutch Lipid Network criteria for HeFH with a score of at least 6

If yes, **approve for 12 months by HICL with a quantity limit of 2 mL (2 syringes/pens) per 28 days.**

If no, do not approve

DENIAL TEXT: See the initial denial text at the end of the guideline.

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ALIROCUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ALIROCUMAB (Praluent)** requires a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD) (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis). The following criteria must also be met:

- The patient is 18 years of age or older
- The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
- The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment

For statin tolerant patients, approval also requires:

- The patient meets **ONE** of the following criteria:
 - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
 - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient will continue statin treatment in combination with Praluent

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

For patients with heterozygous familial hypercholesterolemia (HeFH), approval also requires:

- The patient has a diagnosis of heterozygous familial hypercholesterolemia (HeFH) as determined by meeting **ONE** of the following criteria:
 - Simon Broome diagnostic criteria for HeFH (definite)
 - Dutch Lipid Network criteria for HeFH with a score of at least 6

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ALIROCUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

- Does the patient have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) **AND** meet **ONE** of the following criteria?
 - The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
 - The patient has continued concurrent therapy with a maximally tolerated dose of any statin
 - The patient has an absolute contraindication to statin therapy
 - The patient has complete statin intolerance

If yes, **approve for 12 months by HICL with a quantity limit of 2 mL (2 syringes/pens) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ALIROCUMAB (Praluent)** requires a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH). In addition, **ONE** of the following must be met:

- The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient has continued concurrent therapy with a maximally tolerated dose of any statin
- The patient has an absolute contraindication to statin therapy
- The patient has complete statin intolerance

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Praluent.

REFERENCES

- Praluent [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; January 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/11/19

Created: 08/15

Client Approval: 02/19

P&T Approval: 04/18

EMAPALUMAB-LZSG (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
EMAPALUMAB-LZSG	GAMIFANT	45503		

GUIDELINES FOR USE

- Does the patient have a diagnosis of hemophagocytic lymphohistiocytosis (HLH) and meet **ONE** of following criteria?

- The patient has refractory, recurrent, or progressive disease
- The patient has intolerance to conventional HLH therapy

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **EMAPALUMAB-LZSG (Gamifant)** requires a diagnosis of hemophagocytic lymphohistiocytosis (HLH). In addition, ONE of the following must be met:

- The patient has refractory, recurrent, or progressive disease
- The patient has intolerance to conventional HLH therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gamifant.

REFERENCES

- Gamifant [Prescribing Information]. Waltham, MA: Sobi Inc., November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/07/19

Created: 01/19

Client Approval: 01/19

P&T Approval: 01/19



ECALLANTIDE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ECALLANTIDE	KALBITOR	36797		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of hereditary angioedema and meet **ALL** of the following criteria?
 - Diagnosis is confirmed via complement testing
 - The medication is being used for treatment of acute attacks of hereditary angioedema
 - The patient is 12 years of age or older
 - The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
 - The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and/or angioedema

If yes, **approve for 12 months (up to 12 fills) by HICL with a quantity limit of 12mL per fill.**

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

If no, do not approve.

DENIAL TEXT: The guideline named **ECALLANTIDE (Kalbitor)** requires a diagnosis of hereditary angioedema. In addition, all of the following criteria must be met:

- Diagnosis is confirmed via complement testing
- The medication is being used for treatment of acute attacks of hereditary angioedema
- The patient is 12 years of age or older
- The medication is prescribed by or given in consultation with an allergist/immunologist or hematologist
- The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and/or angioedema

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ECALLANTIDE (NSA)

RATIONALE

Ensure appropriate use of Kalbitor (ecallantide) based on FDA-approved indication and dosing/administration.

FDA APPROVED INDICATIONS

Kalbitor (ecallantide) is indicated for treatment of acute attacks of hereditary angioedema in patients 12 years of age and older.

DOSING & ADMINISTRATION

The recommended dose of Kalbitor (ecallantide) is 30mg (3 mL) administered subcutaneously in three 10 mg (1 mL) injections. If the attack persists, an additional dose of 30 mg may be administered within a 24-hour period.

Kalbitor (ecallantide) should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema.

BOXED WARNING FOR ECALLANTIDE:

Anaphylaxis has been reported after administration of Kalbitor (ecallantide). Because of the risk of anaphylaxis, Kalbitor (ecallantide) should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema. Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor (ecallantide) to patients with known clinical hypersensitivity to Kalbitor (ecallantide).

REFERENCES

- Kalbitor [Prescribing Information]. Dyax Corp.: Burlington, MA. March 2015.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 03/18/19

Created: 11/13

Client Approval: 03/19

P&T Approval: 07/18

TRASTUZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB	HERCEPTIN	18801		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer?

If yes, continue to #2.

If no, continue to #4.

2. Is the request for metastatic breast cancer **AND** the patient meets the following criteria?

- The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Is the request for adjuvant therapy for breast cancer **AND** the patient meets the following criteria?

- The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma **AND** meet **ALL** of the following criteria?
- The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
 - Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 - The patient has not received prior treatment for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **TRASTUZUMAB (Herceptin)** requires a diagnosis of breast cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. In addition, the following criteria must be met:

For the diagnosis of metastatic breast cancer, approval requires:

- The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

For use as adjuvant therapy for breast cancer, approval requires:

- The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

For the diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:

- The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
- Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
- The patient has not received prior treatment for metastatic disease

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TRASTUZUMAB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herceptin.

REFERENCES

- Genentech, Inc. Herceptin package insert. South San Francisco, CA. November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/25/19

Created: 08/12

Client Approval: 02/19

P&T Approval: 05/15

EVOLOCUMAB

Generic	Brand	HICL	GCN	Exception/Other
EVOLOCUMAB	REPATHA SYRINGE, REPATHA SURECLICK, REPATHA PUSHTRONEX	42378		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?

- The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
- The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

If yes, continue to #3.

If no, continue to #4.

3. Will the patient continue statin treatment as described above in combination with Repatha?

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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EVOLOCUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has **ONE** of the following diagnoses:
 - Established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)
 - Primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)) as determined by meeting **ONE** of the following:
 - Simon Broome diagnostic criteria (definite)
 - Dutch Lipid Network criteria with a score of 6 or greater

If yes, **approve for 12 months by GPID for the requested medication with the following quantity limits:**

- **Repatha 140mg (GPID 39363, 38178): 2mL per 28 days.**
- **Repatha 420mg (GPID 41834): 3.5mL per 28 days.**

If no, continue to #7.

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EVOLOCUMAB**INITIAL CRITERIA (CONTINUED)**

7. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by meeting **ONE** of the following criteria?
- Simon Broome diagnostic criteria (definite)
 - Dutch Lipid Network criteria with a score of 8 or greater
 - A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either:
 - (1) xanthoma before 10 years of age **OR**
 - (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

If yes, **approve Repatha 420mg (GPID 41834) for 12 months with a quantity limit of 3.5mL per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **EVOLOCUMAB (Repatha)** requires a diagnosis of established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis), **OR** primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), **OR** homozygous familial hypercholesterolemia (HoFH). In addition, the following criteria must be met:

- The agent is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
- The patient has a LDL-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment

For statin tolerant patients, approval also requires:

- The patient meets **ONE** of the following criteria:
 - The patient has been taking a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
 - The patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient will continue statin treatment in combination with Repatha

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EVOLOCUMAB

INITIAL CRITERIA (CONTINUED)

For statin intolerant patients, approval also requires ONE of the following:

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

For patients with established cardiovascular disease, approval also requires:

- The patient is 18 years of age or older

For patients with primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), approval also requires:

- The patient is 18 years of age or older
- The diagnosis is determined by meeting **ONE** of the following:
 - Simon Broome diagnostic criteria (definite)
 - Dutch Lipid Network criteria with a score of 6 or greater

For patients with homozygous familial hypercholesterolemia (HoFH), the diagnosis must be determined by meeting ONE of the following criteria:

- Simon Broome diagnostic criteria (definite)
- Dutch Lipid Network criteria with a score of 8 or greater
- A clinical diagnosis based on a history of an untreated LDL-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

RENEWAL CRITERIA

1. Does the patient meet **ONE** of the following criteria?

- The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient has continued concurrent therapy with a maximally tolerated dose of any statin
- The patient has an absolute contraindication to statin therapy
- The patient has complete statin intolerance

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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EVOLOCUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of established cardiovascular disease **OR** primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH))?

If yes, **approve for 12 months by GPID for the requested medication with the following quantity limits:**

- **Repatha 140mg (GPID 39363, 38178): 2mL per 28 days.**
- **Repatha 420mg (GPID 41834): 3.5mL per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of homozygous familial hypercholesterolemia (HoFH)?

If yes, **approve Repatha 420mg (GPID 41834) for 12 months with a quantity limit of 3.5mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **EVOLOCUMAB (Repatha)** requires a diagnosis of established cardiovascular disease, primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), or homozygous familial hypercholesterolemia (HoFH). In addition, **ONE** of the following must be met:

- The patient has continued concurrent therapy with a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
- The patient has continued concurrent therapy with a maximally tolerated dose of any statin
- The patient has an absolute contraindication to statin therapy
- The patient has complete statin intolerance

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Repatha.

REFERENCES

- Repatha [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; December 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/11/19

Created: 08/15

Client Approval: 02/19

P&T Approval: 04/18

INHALED INSULIN

Generic	Brand	HICL	GCN	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		ROUTE = INHALATION

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient meet any **ONE** of the following criteria?
 - Chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease)
 - Active lung cancer
 - Currently in diabetic ketoacidosis
 - Patient who smokes or who has quit smoking within the past 6 months

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

- Has baseline spirometry to measure FEV1 been performed?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis type 1 diabetes and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient is concurrently using a long-acting insulin
- The patient had a trial of a preferred formulary rapid acting insulin: Humalog

If yes, **approve for 12 months by GPID with the following quantity limits:**

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter, and concurrent use of a long acting insulin. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

If no, continue to #4.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient had a trial of a preferred formulary rapid acting insulin: Humalog
- The prescriber indicated that the patient is physically unable to or unwilling to administer injectable insulin

If yes, **approve for 12 months by GPID with the following quantity limits:**

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INHALED INSULIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **INHALED INSULIN (Afrezza)** requires a diagnosis of type 1 or type 2 diabetes, patient is 18 years of age or older, and a baseline spirometry to measure FEV1 is performed. In addition, the following criteria must be met:

For type 1 diabetes, approval requires:

- The patient is concurrently using a long-acting insulin
- The patient had a trial of a preferred formulary rapid acting insulin: Humalog

For type 2 diabetes, approval requires:

- The patient had a trial of a preferred formulary rapid acting insulin: Humalog
- The prescriber indicated that the patient is physically unable to or unwilling to administer injectable insulin

Afrezza will NOT be approved for patients with any of the following conditions:

- Chronic lung disease
- Active lung cancer
- Currently in diabetic ketoacidosis
- The patient is currently smoking or has quit smoking within the past 6 months

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes and currently on a long acting insulin?

If yes, continue to #3.

If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

3. Was follow-up spirometry to measure FEV1 performed after 6 months of treatment and annually thereafter?

If yes, continue to #4.

If no, **approve for 1 month by GPID (to allow for follow-up spirometry evaluation) with the following quantity limits:**

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

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INHALED INSULIN

RENEWAL CRITERIA (CONTINUED)

4. Has FEV1 declined 20% or more from baseline?

If yes, do not approve.

RENEWAL DENIAL TEXT: The guideline named **INHALED INSULIN (Afrezza)** requires a diagnosis of type 1 or type 2 diabetes, and a follow up spirometry to measure FEV1 after 6 months of treatment and annually thereafter. In addition, the following criteria must be met for renewal:

- **For type 1 diabetes**, approval requires concurrent use of a long acting insulin.
- **Afrezza will NOT be approved** for patients with a FEV1 that has declined 20% or more from baseline

If no, approve for 12 months by GPID with the following quantity limits:

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

REFERENCES

- Afrezza [Prescribing Information]. Danbury, CT: Mankind Corporation. October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/25/19

Created: 02/15

Client Approval: 02/19

P&T Approval: 07/17



ITRACONAZOLE-SPORANOX

Generic	Brand	HICL	GCN	Exception/Other
ITRACONAZOLE	SPORANOX		49101 49100	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of *tinea corporis*, *tinea cruris*, or *tinea pedis*?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have a diagnosis of onychomycosis (*tinea unguium*) **AND** meet the following criterion?

- There is documentation of a positive dermatophyte culture as indicated by a copy of the lab report

If yes, continue to #3.

If no, continue to #9.

3. Is the onychomycosis involving the toenails **AND** the patient meets the following criterion?

- The patient has **NOT** been treated for toenail onychomycosis in the last 12 months (per MRF or prior authorization history)

If yes, continue to #4.

If no, continue to #6.

4. Is the request for Sporanox capsules?

If yes, **approve Sporanox capsules (GPID 49101) for 12 weeks with a quantity limit of #2 capsules per day.**

If no, continue to #5.

5. Is the request for Sporanox solution **AND** the patient is unable to swallow capsules?

If yes, **approve Sporanox solution (GPID 49100) for 12 weeks with a quantity limit of #20mL per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



ITRACONAZOLE-SPORANOX

GUIDELINES FOR USE (CONTINUED)

6. Is the request for onychomycosis involving the fingernails **AND** the patient meets the following criterion?
- The patient has **NOT** been treated for fingernail onychomycosis in the last 6 months (per MRF or prior authorization history)

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the request for Sporanox capsules?

If yes, **approve Sporanox capsules (GPID 49101) up to #28 capsules per month for 2 months (56 x 100mg capsules for 5 weeks: #2 of 100mg capsules BID for one week, stop 3 weeks & repeat).**

If no, continue to #8.

8. Is the request for Sporanox solution **AND** the patient is unable to swallow capsules?

If yes, **approve Sporanox solution (GPID 49100) with a quantity limit of #560mL for 5 weeks.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient have a diagnosis of esophageal candidiasis **AND** meet the following criterion?
- The patient has had a trial of or contraindication to fluconazole

If yes, **approve Sporanox solution (GPID 49100) for course of treatment up to 20mL per day for up to 3 weeks.**

If no, continue to #10.

10. Does the patient have a diagnosis of a systemic infection such as pulmonary or extrapulmonary blastomycosis, histoplasmosis (including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis), or pulmonary or extrapulmonary aspergillosis **AND** meet the following criterion?

- The patient is intolerant or refractory to amphotericin B therapy

If yes, continue to #11.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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ITRACONAZOLE-SPORANOX**GUIDELINES FOR USE (CONTINUED)**

11. Is the request for Sporanox capsules?

If yes, **approve Sporanox capsules (GPID 49101) for course of treatment (200mg to 400mg daily for minimum of 3 months).**

If no, continue to #12.

12. Is the request for Sporanox solution **AND** the patient is unable to swallow capsules?

If yes, **approve Sporanox solution (GPID 49100) with a quantity limit of #40mL per day per course of treatment.**

If no, do not approve.

DENIAL TEXT: The guideline named **ITRACONAZOLE (Sporanox)** requires a diagnosis of onychomycosis of the toenails or fingernails (tinea unguium), esophageal candidiasis, systemic infection such as pulmonary or extrapulmonary blastomycosis, histoplasmosis (including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis), or pulmonary or extrapulmonary aspergillosis. In addition, the following criteria must be met:

For patients with onychomycosis of the toenails, approval requires:

- There is documentation of a positive dermatophyte culture as indicated by a copy of the lab report
- The patient has **NOT** been treated for toenail onychomycosis in the last 12 months (per MRF or prior authorization history)
- Requests for the Sporanox solution require the patient is unable to swallow capsules

For patients with onychomycosis of the fingernails, approval requires:

- There is documentation of a positive dermatophyte culture as indicated by a copy of the lab report
- The patient has **NOT** been treated for fingernail onychomycosis in the last 6 months (per MRF or prior authorization history)
- Requests for the Sporanox solution require the patient is unable to swallow capsules

For patients with esophageal candidiasis, approval requires:

- The patient has had a trial of or contraindication to fluconazole

For patients with a systemic infection such as pulmonary or extrapulmonary blastomycosis, histoplasmosis (including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis), or pulmonary or extrapulmonary aspergillosis, approval requires:

- The patient is intolerant or refractory to amphotericin B therapy
- Requests for the Sporanox solution require the patient is unable to swallow capsules

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sporanox.

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ITRACONAZOLE-SPORANOX**REFERENCES**

- Sporanox capsules [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. May 2018.
- Sporanox solution [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. October 2017.

Library	Commercial	NSA
Yes	No	No

Part D Effective: N/A

Commercial Effective: 01/14/19

Created: 05/95

Client Approval: 12/18

P&T Approval: 08/11

OLARATUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OLARATUMAB	LARTRUVO	43867		

GUIDELINES FOR USE

1. Is the request for continuation of Lartruvo therapy (i.e., patient is currently on Lartruvo)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of soft tissue sarcoma (STS) and meet **ALL** of the following criteria?

- The requested medication will be used in combination with doxorubicin for the first 8 cycles
- The histologic subtype of sarcoma (e.g., undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen
- The patient is not amenable to curative treatment with radiotherapy or surgery

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **OLARATUMAB (Lartruvo)** requires a diagnosis of soft tissue sarcoma. In addition, the following criteria must be met:

For the diagnosis of soft tissue sarcoma, approval requires:

- The request is for continuation of Lartruvo therapy (i.e., patient is currently on Lartruvo)
- The requested medication will be used in combination with doxorubicin for the first 8 cycles
- The histologic subtype of sarcoma (e.g., undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen
- The patient is not amenable to curative treatment with radiotherapy or surgery

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lartruvo.

REFERENCES

- Lartruvo [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. August 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/11/19

Created: 11/16

Client Approval: 02/19

P&T Approval: 11/16

PENICILLAMINE

Generic	Brand	HICL	GCN	Exception/Other
PENICILLAMINE	CUPRIMINE		7091	
PENICILLAMINE	DEPEN		7100	
PENICILLAMINE	D-PENAMINE		7101	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for D-Penamamine and the patient has an active prior authorization approval for Depen?

[Note: D-Penamamine is temporarily available to address a critical drug shortage of Depen. Patients previously approved for Depen will be allowed access without additional criteria during this shortage.]

If yes, **approve D-Penamamine for 12 months by GPID (7101) for the requested indication as follows:**

- **Wilson's Disease: #16 tablets per day**
- **Rheumatoid Arthritis: #12 tablets per day**
- **Cystinuria: #32 tablets per day**

If no, continue to #2.

2. Does the patient have a known family history of Wilson's disease or physical examination consistent with Wilson's disease and meet **ONE** of the following criteria?
 - Plasma copper-protein ceruloplasmin less than 20mg/dL
 - Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
 - The diagnosis has been confirmed by genetic testing for ATP7B mutations

If yes, continue to #3.

If no, continue to #6.

3. Does the patient meet **ALL** of the following criteria?
 - The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
 - The medication is prescribed by or given in consultation with a hepatologist

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

4. Is the request for Depen or D-Penamine?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Depen (GPID 7100): #8 tablets per day**
- **D-Penamine (GPID 7101): #16 tablets per day**

APPROVAL TEXT: Renewal requires a diagnosis of Wilson's disease.

If no, continue to #5.

5. Is the request for Cuprimine and the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

If yes, **approve Cuprimine for 12 months by GPID (7091) with a quantity limit of #8 capsules per day.**

APPROVAL TEXT: Renewal requires a diagnosis of Wilson's disease.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

6. Does the patient have a diagnosis of cystinuria and meet **ALL** of the following criteria?

- Presence of nephrolithiasis and at least **ONE** of the following:
 - Stone analysis positive for cystine
 - Urinalysis positive for pathognomonic hexagonal cystine crystals
 - Family history of cystinuria with a positive cyanide-nitroprusside screen
- Daily cystine output greater than 300mg per 24 hours following urine cystine excretion testing
- The patient has failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following (unless contraindicated): increased fluid intake, modest reductions in sodium and protein intake, and urinary alkalization
- The medication is prescribed by or given in consultation with a nephrologist

If yes, continue to #7.

If no, continue to #9.

7. Is the request for Depen or D-Penamine?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Depen (GPID 7100): #16 tablets per day.**
- **D-Penamine (GPID 7101): #32 tablets per day.**

If no, continue to #8.

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PENICILLAMINE

INITIAL CRITERIA (CONTINUED)

8. Is the request for Cuprimine and has the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin)?

If yes, **approve Cuprimine for 12 months by GPID (7091) with a quantity of #16 capsules per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of active rheumatoid arthritis and meet **ALL** of the following criteria?

- The medication is prescribed by or given in consultation with a rheumatologist
- The patient does not have a history of or other evidence of renal insufficiency
- The patient has failed to respond to an adequate trial of conventional therapy including at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

If yes, continue to #10.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

10. Is the request for Depen or D-Penamine?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Depen (GPID 7100): #6 tablets per day.**
- **D-Penamine (GPID 7101): #12 tablets per day.**

If no, continue to #11.

11. Is the request for Cuprimine and has the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)?

If yes, **approve Cuprimine for 12 months by GPID (7091) with a quantity of #6 capsules per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PENICILLAMINE



INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamamine)** will allow for approval for patients with a known family history of Wilson's disease or physical examination consistent with Wilson's disease, cystinuria, or active rheumatoid arthritis unresponsive to conventional therapy. The following criteria must also be met:

For patients with Wilson's disease, approval requires ONE of the following:

- Plasma copper-protein ceruloplasmin less than 20mg/dL
 - Liver biopsy positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings
 - The diagnosis has been confirmed by genetic testing for ATP7B mutations
- In addition, the following criteria must also be met:
- The patient has maintained a reduced copper dietary intake (less than 2mg copper per day)
 - The medication is prescribed by or given in consultation with a hepatologist
 - For Cuprimine requests, the patient had a previous trial of or contraindication to Depen or D-Penamamine (penicillamine)

For patients with cystinuria, approval requires:

- Presence of nephrolithiasis and at least **ONE** of the following:
 - Stone analysis positive for cystine
 - Urinalysis positive for pathognomonic hexagonal cystine crystals
 - Family history of cystinuria with a positive cyanide-nitroprusside screen
- Daily cystine output greater than 300mg per 24 hours following urine cystine excretion testing
- Patient has failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following (unless contraindicated):
 - Increased fluid intake
 - Modest reductions in sodium and protein intake
 - Urinary alkalinization
- The medication is prescribed by or given in consultation with a nephrologist
- For Cuprimine requests, the patient had a previous trial of or contraindication to Depen (penicillamine) or D-Penamamine (penicillamine) **AND** Thiola (tiopronin)

For patients with active rheumatoid arthritis unresponsive to conventional therapy, approval requires:

- The medication is prescribed by or given in consultation with a rheumatologist
- The patient does not have a history of or other evidence of renal insufficiency
- The patient has failed to respond to an adequate trial of conventional therapy including at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- For Cuprimine requests, the patient had a previous trial of or contraindication to Depen or D-Penamamine (penicillamine)

For patients with an active prior authorization approval for Depen, D-Penamamine will be approved without meeting additional criteria during the period of Depen shortage.

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PENICILLAMINE

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Wilson's disease?

If yes, **approve for 12 months by GPID for the requested drug as follows:**

- **Depen (GPID 7100): #8 tablets per day.**
- **Cuprimine (GPID 7091): #8 capsules per day.**
- **D-Penamine (GPID 7101): #16 tablets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** will allow for renewal for patients with a diagnosis of Wilson's disease.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for penicillamine.

REFERENCES

- Cuprimine [Prescribing Information]. Lawrenceville, NJ. Aton Pharma, a Division of Valeant Pharmaceuticals; March 2010.
- Thiola [Prescribing Information]. San Antonio, TX. Mission Pharmacal; November 2012.
- Depen [Prescribing Information]. Somerset, NJ. Meda Pharmaceuticals; April 2009.
- FDA Website: Penicillamine (Depen) Titratable Tablets Drug Shortage. Available at: [https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine%20\(Depen\)%20Titratable%20Tablets&st=c](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Penicillamine%20(Depen)%20Titratable%20Tablets&st=c). Accessed on January 21, 2019

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/21/19

Created: 05/16

Client Approval: 1/19

P&T Approval: 1/19

RAVULIZUMAB-CWVZ (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
RAVULIZUMAB-CWVZ	ULTOMIRIS	45548		

GUIDELINES FOR USE

- Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for a total of 12 months by HICL as follows:**

Patient's weighing 40kg to less than 60kg

Enter both of the following approvals:

- Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of 540 ml per 28 days for 1 fill**
- Maintenance dose: Approve for 11 months with a quantity limit of 300 ml per 8 weeks (Please enter a start date of 5 weeks from the end date of the first approval)**

Patient's weighing 60kg to less than 100kg

Enter both of the following approvals:

- Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of 600 ml per 28 days for 1 fill**
- Maintenance dose: Approve for 11 months with a quantity limit of 330 ml per 8 weeks (Please enter a start date of 5 weeks from the end date of the first approval)**

Patient's weighing greater than or equal to 100kg

Enter both of the following approvals:

- Loading dose plus 1st maintenance dose: Approve for 1 month with a quantity limit of 660 ml per 28 days for 1 fill**
- Maintenance dose: Approve for 11 months with a quantity limit of 360 ml per 8 weeks (Please enter a start date of 5 weeks from the end date of the first approval)**

If no, do not approve.

DENIAL TEXT: The guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH). In addition, the following must be met.

- The patient is 18 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ultomiris.

REFERENCES

Ultomiris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Created: 12/18

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Created: 12/31/2018

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Commercial Effective: 01/04/2019 Client Approval: 01/19

P&T Approval: 01/19

INFLIXIMAB-ABDA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
INFLIXIMAB-ABDA	RENFLEXIS	44432		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

- Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient is currently using or has a contraindication to methotrexate
 - The patient meets ONE of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - The patient has had a previous trial of the formulary preferred immunomodulators: Enbrel **AND** Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

- Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, or Otezla (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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INFLIXIMAB-ABDA (NSA)**INITIAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient is 18 years of age or older
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, **OR** Cosentyx (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a dermatologist
 - The patient is 18 years of age or older
 - The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
 - The patient has had a previous trial of at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, or Otezla (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #5.

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INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 6 years of age or older
 - The patient has had a previous trial of the formulary preferred immunomodulator(s): Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meets **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - The patient has had a previous trial of the formulary preferred immunomodulatory: Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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INFLIXIMAB-ABDA (NSA)**INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: The guideline named **INFLIXIMAB-ABDA (Renflexis)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis,

moderate to severe Crohn's disease, or moderate to severe ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is currently using or has a contraindication to methotrexate
- The patient meets ONE of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
- The patient has had a previous trial of the formulary preferred immunomodulators: Enbrel and Humira

For patients with psoriatic arthritis (PsA), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, **OR** Otezla

For patients with ankylosing spondylitis (AS), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, **OR** Cosentyx

For patients with severe plaque psoriasis (PsO), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient is 18 years of age or older
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient has had a previous trial of at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, **OR** Otezla

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INFLIXIMAB-ABDA (NSA)

INITIAL CRITERIA (CONTINUED)



For patients with moderate to severe Crohn's disease (CD), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 6 years of age or older
- The patient has had a previous trial of the formulary preferred immunomodulator(s): Humira

For patients with moderate to severe ulcerative colitis (UC), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient has had a previous trial of the formulary preferred immunomodulatory: Humira

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets **ALL** of the following criteria?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- The patient is currently using or has a contraindication to methotrexate

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets the following criteria?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

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INFLIXIMAB-ABDA (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets the following criteria?

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

If yes, **approve for 12 months by HICL.**



If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meets the following criteria?
- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

If yes, **approve for 12 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **INFLIXIMAB-ABDA (Renflexis)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires all of the following:

- That the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- The patient is currently using or has a contraindication to methotrexate

Renewal for the diagnosis of psoriatic arthritis requires:

- That the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Renewal denial text continued on next page)

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INFLIXIMAB-ABDA (NSA)

RENEWAL CRITERIA (CONTINUED)

Renewal for the diagnosis of ankylosing spondylitis requires:

- That the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

Renewal for the diagnosis of severe plaque psoriasis requires:

- That the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

RATIONALE

To ensure the appropriate use of Renflexis according to FDA-approved indications.

FDA APPROVED INDICATIONS

Renflexis is a tumor necrosis factor (TNF) blocker indicated for:

- **Crohn's Disease:**
 - reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
 - reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.
- **Pediatric Crohn's Disease:** reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- **Ulcerative Colitis:** reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- **Rheumatoid Arthritis in combination with methotrexate:** reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.
- **Ankylosing Spondylitis:** reducing signs and symptoms in patients with active disease.
- **Psoriatic Arthritis:** reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.
- **Plaque Psoriasis:** treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

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INFLIXIMAB-ABDA (NSA)**FDA APPROVED INDICATIONS (CONTINUED)****DOSING AND ADMINISTRATION**

Renflexis is administered by intravenous infusion.

- **Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.
- **Ulcerative Colitis:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
- **Rheumatoid Arthritis:** In conjunction with methotrexate, 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
- **Ankylosing Spondylitis:** 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.
- **Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
- **Plaque Psoriasis:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.

REFERENCES

- Renflexis [Prescribing Information]. Kenilworth, NJ: Merck & Co., Inc. April 2017.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A
Commercial Effective: 04/01/18

Created: 07/17
Client Approval: 03/18

P&T Approval: 01/18



RIFAXIMIN

Generic	Brand	HICL	GCN	Exception/Other
RIFAXIMIN 200 MG	XIFAXAN		93749	
RIFAXIMIN 550 MG			28530	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the 200 mg tablets?

If yes, continue to #2.

If no (request is for 550 mg tablets), continue to #3.

2. Does the patient meet all of the following criteria?

- Patient is greater than or equal to 12 years old.
- Patient has moderate to severe traveler’s diarrhea caused by noninvasive strains of E.coli.
- The patient has a contraindication to BOTH azithromycin and ciprofloxacin.

If yes, **approve for 6 months by GPID for a quantity limit of #9 tablets for 3 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of this guideline.

3. Is the patient being treated for the hepatic encephalopathy (HE) and meets the following criteria?

- The patient is at least 18 years old
- The medication is being prescribed by a hepatologist
- The patient had a trial of lactulose or currently on lactulose monotherapy

If yes, **approve for 12 months by GPID with a quantity limit of #2 tablets per day.**

If no, continue to #2.

4. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets the following criteria?

- The patient is at least 18 years old
- The medication is being prescribed by a gastroenterologist
- The patient had a trial of or contraindication to tricyclic anti-depressants or dicyclomine

If yes, **approve for 12 weeks by GPID for 1 fill of #42 tablets.**

If no, do not approve.

DENIAL TEXT:

Our guideline for RIFAXIMIN 200 mg (Xifaxan) requires a diagnosis of traveler’s diarrhea caused by non-invasive strains of E.coli. Additional guideline requirements apply.

- For the treatment of traveler’s diarrhea (TD), the following criteria must be met:
 - Age at least 12 years old
 - TD is caused by non-invasive strains of E.coli
 - Patient has a contraindication to BOTH azithromycin and ciprofloxacin



Our guideline for **RIFAXIMIN 550mg** (Xifaxan) requires a diagnosis of hepatic encephalopathy (HE) or irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply.

- **For the treatment of hepatic encephalopathy (HE)**, the following criteria must be met:
 - age at least 18 years old
 - trial of lactulose or concurrent lactulose therapy
 - prescriber is a hepatologist.
- **For the treatment of irritable bowel syndrome with diarrhea (IBS-D)**, the following criteria must be met:
 - age at least 18 years old
 - trial of or contraindication to tricyclic anti-depressants or dicyclomine
 - prescriber is a gastroenterologist.

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RIFAXIMIN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the patient being treated for hepatic encephalopathy (HE)?

If yes, **approve for 12 months by GPID with a quantity limit of #2 tablets per day.**

If no, continue to #2.

2. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets the following criteria?

- At least 10 weeks have passed since the last treatment course of rifaximin
- Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
- Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

If yes, **approve for 12 months by GPID up to 2 fills of #42 tablets each fill, separated by at least 12 weeks (total of 2 fills in 12 months).**

If no, do not approve.

DENIAL TEXT: Our guideline for **RIFAXIMIN 550mg** (Xifaxan) renewal requires a diagnosis of hepatic encephalopathy (HE) or irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply.

- **For the treatment of irritable bowel syndrome with diarrhea (IBS-D),** the following criteria must be met:
 - at least 10 weeks have passed since the last treatment course of rifaximin
 - patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
 - patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

RATIONALE

To ensure appropriate utilization of Xifaxan for traveler's diarrhea (TD), hepatic encephalopathy (HE) and irritable bowel syndrome with diarrhea (IBS-D).

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RIFAXIMIN

RATIONALE (CONTINUED)

Per the American College of Gastroenterology, there is high quality evidence that tricyclic antidepressants are effective in providing symptom relief in IBS-D. However, tolerance to these agents could be an issue for some patients.

Renewal criteria for IBS-D is based on the definition of a responder used in Trial 3 of the Xifaxan pivotal trials.

FDA APPROVED INDICATIONS

Xifaxan is a rifamycin antibacterial indicated for:

- Treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adult and pediatric patients 12 years of age and older
- Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults
- Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults

Limitations of Use

- TD: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli

DOSING

Condition	Recommended Dosage Regimen
TD	One 200 mg tablet 3 times a day for 3 days
HE	One 550 mg tablet 2 times a day
IBS-D	One 550 mg tablet 3 times a day for 14 days. Patients who experience recurrence can be retreated up to two times with the same regimen.

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RIFAXIMIN

EFFICACY

The efficacy of Xifaxan for the treatment of IBS-D was established in 3 randomized, multi-center, double-blind, placebo-controlled trials in adult patients. The first two trials, Trials 1 and 2 were of identical design. In these trials, a total of 1258 patients meeting Rome II criteria for IBS were randomized to receive Xifaxan 550 mg three times a day (n=624) or placebo (n=634) for 14 days and then followed for a 10-week treatment-free period. Trial 3 evaluated repeat treatment in adults with IBS-D meeting Rome III criteria for up to 46 weeks. A total of 2579 were enrolled to receive open-label Xifaxan for 14 days. Of 2438 evaluable patients, 1074 (44%) responded to initial treatment and were evaluated over 22 weeks for continued response or recurrence of IBS-symptoms. A total of 636 patients had symptom recurrence and were randomized into the double-blind phase of the study. These patients were scheduled to receive Xifaxan 550 mg three times a day (n=328) or placebo (n=308) for two additional 14-day repeat treatments courses separated by 10 weeks (i.e., total of 12 weeks apart between the start of each retreatment).

In Trials 1 and 2, adequate relief of IBS symptoms was experienced by more patients receiving Xifaxan than those receiving placebo during the month following 2 weeks of treatment (SGA-IBS Weekly Results: 41% vs.31%, p=0.0125; 41% vs. 32%, p=0.0263). More patients receiving Xifaxan were monthly responders for abdominal pain and stool consistency.

In Trial 3, 2579 patients were scheduled to receive an initial 14-day course of open-label Xifaxan followed by 4 weeks of treatment-free follow-up. At the end of the follow-up period, patients were assessed for response to treatment. Patients were considered a responder if they achieved both of the following:

- $\geq 30\%$ improvement from baseline in the weekly average abdominal pain score based on the daily question: *"In regards to your specific IBS symptoms of abdominal pain, on a scale of 0-10, what was your worst IBS-related abdominal pain over the last 24 hours? 'Zero' means you have no pain at all; 'Ten' means the worst possible pain you can imagine"*.
- at least a 50% reduction in the number of days in a week with a daily stool consistency of Bristol Stool Scale type 6 or 7 compared with baseline where 6=fluffy pieces with ragged edges, a mushy stool; 7=watery stool, no solid pieces; entirely liquid.

There were 1074 (44%) of 2438 evaluable patients who responded to initial treatment with improvement in abdominal pain *and* stool consistency. The response rate for each IBS symptom during the open-label phase of Trial 3 is similar to the rates seen in Trials 1 and 2. A total of 636 patients subsequently had sign and symptom recurrence and were randomized to the repeat treatment phase. The median time to recurrence for patients who experienced initial response during the open label phase with Xifaxan was 10 weeks (range 6 to 24 weeks). Thirty six of 308 (11.7%) of placebo patients and 56 of 328 (17.1%) of Xifaxan-treated patients responded to the first repeat treatment and did not have recurrence of signs and symptoms through the treatment-free follow-up period (10 weeks after first repeat treatment). The response rate difference was 5.4% with 95% confidence interval (1.2% to 11.6%).

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RIFAXIMIN 550MG

REFERENCES

- Salix Pharmaceuticals, Inc. Xifaxan package insert. Raleigh, NC. May 2015.
- Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology Monograph on the Management of Irritable Bowel syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol 2014; 109:S2-S26.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/16
02/16

Created: 02/05
Client Approval: 02/16

P&T Approval:



WELLFLEET
RX PLAN

SIPONIMOD

Generic	Brand	HICL	GCN	Exception/Other
SIPONIMOD	MAYZENT	45670		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of **ANY** of the following relapsing forms of multiple sclerosis?
 - Clinically isolated syndrome
 - Relapsing-remitting multiple sclerosis

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

- Does the patient have a diagnosis of relapsing forms of secondary progressive multiple sclerosis **AND** meet the following criterion?
 - The patient is 18 years of age or older

If yes, continue to #3.

If no, do not approve

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotypes?

If yes, **approve for 12 months by GPID for all strengths as follows:**

- Mayzent 0.25mg starter pack (GPID 46135): 1 pack (12 tablets) per fill**
- Mayzent 2mg (GPID 46133): 1 tablet per day**

If no, continue to #4.

- Does the patient have a CYP2C9 *1/*3 or *2/*3 genotypes?

If yes, **approve Mayzent 0.25mg tablet by GPID (46134) for 12 months with a quantity limit of 4 tablets per day.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **SIPONIMOD (Mayzent)** requires a diagnosis of relapsing forms of secondary progressive multiple sclerosis AND the patient must be 18 years of age or older.

Requests will NOT be approved for the diagnosis of any of the following relapsing forms of multiple sclerosis:

- Clinically isolated syndrome
- Relapsing-remitting multiple sclerosis

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SIPONIMOD**RENEWAL CRITERIA**

1. Does the patient have a diagnosis of relapsing forms of secondary progressive multiple sclerosis and meet **ALL** of the following criteria?

- Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
- The patient does not have lymphopenia

If yes, continue to #2.

If no, do not approve

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

If yes, **approve for 12 months by GPID for all strengths as follows:**

- **Mayzent 0.25mg starter pack (GPID 46135): 1 pack (12 tablets) per fill**
- **Mayzent 2mg (GPID 46133): 1 tablet per day**

If no, continue to #3.

3. Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

If yes, **approve Mayzent 0.25mg tablet by GPID (46134) for 12 months with a quantity limit of 4 tablets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **SIPONIMOD (Mayzent)** requires a diagnosis of relapsing forms of secondary progressive multiple sclerosis. In addition, the following criteria must be met.

- Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
- The patient does not have lymphopenia

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/05/19

Created: 04/19

Client Approval: 01/19

P&T Approval: 01/19

SIPONIMOD

Generic	Brand	HICL	GCN	Exception/Other
SIPONIMOD	MAYZENT	45670		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of **ANY** of the following relapsing forms of multiple sclerosis?
 - Clinically isolated syndrome
 - Relapsing-remitting multiple sclerosis

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

- Does the patient have a diagnosis of relapsing forms of secondary progressive multiple sclerosis **AND** meet the following criterion?
 - The patient is 18 years of age or older

If yes, continue to #3.

If no, do not approve

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotypes?

If yes, **approve for 12 months by GPID for all strengths as follows:**

- Mayzent 0.25mg starter pack (GPID 46135): 1 pack (#12 tablets) per fill.**
- Mayzent 2mg (GPID 46133): #1 tablet per day.**

If no, continue to #4.

- Does the patient have a CYP2C9 *1/*3 or *2/*3 genotypes?

If yes, **approve Mayzent 0.25mg tablet by GPID (46134) for 12 months with a quantity limit of #4 tablets per day.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **SIPONIMOD (Mayzent)** requires a diagnosis of relapsing forms of secondary progressive multiple sclerosis AND the patient must be 18 years of age or older.

Requests will NOT be approved for the diagnosis of any of the following relapsing forms of multiple sclerosis:

- Clinically isolated syndrome
- Relapsing-remitting multiple sclerosis

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SIPONIMOD

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

- Does the patient have a diagnosis of relapsing forms of secondary progressive multiple sclerosis and meet **ALL** of the following criteria?
 - Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
 - The patient does not have lymphopenia

If yes, continue to #2.

If no, do not approve

DENIAL TEXT: See the renewal denial text at the end of the guideline.

- Does the patient have a CYP2C9 *1/*1, *1/*2, or *2/*2 genotype?

If yes, **approve for 12 months by GPID for all strengths as follows:**

- Mayzent 0.25mg starter pack (GPID 46135): 1 pack (#12 tablets) per fill.**
- Mayzent 2mg (GPID 46133): #1 tablet per day.**

If no, continue to #3.

- Does the patient have a CYP2C9 *1/*3 or *2/*3 genotype?

If yes, **approve Mayzent 0.25mg tablet by GPID (46134) for 12 months with a quantity limit of #4 tablets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **SIPONIMOD (Mayzent)** requires a diagnosis of relapsing forms of secondary progressive multiple sclerosis. In addition, the following criteria must be met:

- Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
- The patient does not have lymphopenia

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mayzent.

REFERENCES

- Mayzent [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/15/19

Created: 04/19

Client Approval: 04/19

P&T Approval: 01/19

SUFENTANIL (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
SUFENTANIL CITRATE	DSUVIA		45928	

GUIDELINES FOR USE

1. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of acute pain and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient's pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate (e.g., non-opioid analgesic products or opioid combination products)
- The patient's treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

If yes, **approve for 3 days by GPID (45928) for one fill with a quantity limit of #12 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **SUFENTANIL (Dsuvia)** requires a diagnosis of acute pain. In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient's pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate (e.g., non-opioid analgesic products or opioid combination products)
- The patient's treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dsuvia.

REFERENCES

Dsuvia [Prescribing Information]. Redwood City, CA: AcclRx Pharmaceutical, Inc. November 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 2/4/19

Created: 2/4/19

Client Approval: 4/19

P&T Approval: 4/19

TAGRAXOFUSP-ERZS (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
TAGRAXOFUSP-ERZS	ELZONRIS	45555		

GUIDELINES FOR USE

- Does the patient have a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) **AND** meet the following criterion?

- The patient is 2 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #1 fill per 21 days (1 fill = 5 doses).**

If no, do not approve.

DENIAL TEXT: The guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN). In addition, the following criteria must be met.

- The patient is 2 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Elzonris.

REFERENCES

Elzonris [Prescribing Information]. New York, NY: Stemline Therapeutics, Inc., December 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 3/11/19

Created: 03/19

Client Approval: 04/19

P&T Approval: 04/19

TOREMIFENE

Generic	Brand	HICL	GCN	Exception/Other
TOREMIFENE CITRATE	FARESTON	11632		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?

- The patient is a postmenopausal female
- The patient has an estrogen-receptor positive or unknown tumor

If yes, **approve for 12 months by HICL with a quantity limit of #30 tablets per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **TOREMIFENE (Fareston)** requires a diagnosis of metastatic breast cancer. In addition, the following criteria must be met:

- The patient is a postmenopausal female
- The patient has an estrogen-receptor positive or unknown tumor

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fareston.

REFERENCES

- Fareston [Prescribing Information] Bedminster, NJ: Kyowa Kirin Inc. May 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/25/19

Created: 08/13

Client Approval: 02/19

P&T Approval: 08/13



VENETOCLAX

Generic	Brand	HICL	GCN	Exception/Other
VENETOCLAX	VENCLEXTA	43284		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL) **OR** small lymphocytic lymphoma (SLL) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has received at least one prior therapy

If yes, **approve for 12 months for the requested strength by GPID with the following quantity limits:**

- Venclexta Starting pack (GPID 41048): #42 tablets (1 pack) per 28 days.
- 10mg tablet (GPID 41049): #2 tablets per day.
- 50mg tablet (GPID 41051): #1 tablet per day.
- 100mg tablet (GPID 41052): #4 tablets per day.

If no, continue to #2.

2. Does the patient have newly-diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
 - The patient is 75 years of age or older, **OR** the patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy
 - The requested medication will be used in combination with azacitidine or decitabine

If yes, **approve for 12 months for the requested strength by GPID with the following quantity limits:**

- 10mg tablet (GPID 41049): #2 tablets per day.
- 50mg tablet (GPID 41051): #1 tablet per day.
- 100mg tablet (GPID 41052): #4 tablets per day.

If no, continue to #3.

CONTINUED ON NEXT PAGE

VENETOCLAX

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have newly-diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?

- The patient is 75 years of age or older, **OR** the patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy
- The requested medication will be used in combination with low-dose cytarabine

If yes, **approve for 12 months for the requested strength by GPID with the following quantity limits:**

- **10mg tablet (GPID 41049): #2 tablets per day.**
- **50mg tablet (GPID 41051): #1 tablet per day.**
- **100mg tablet (GPID 41052): #6 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **VENETOCLAX (Venclexta)** requires a diagnosis of chronic lymphocytic leukemia, small lymphocytic lymphoma, or newly-diagnosed acute myeloid leukemia (AML). In addition, the following must be met:

For patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval requires:

- The patient is 18 years of age or older
- The patient has received at least one prior therapy

For patients with newly-diagnosed acute myeloid leukemia (AML), approval requires:

- The patient is 75 years of age or older, **OR** the patient is 18 years of age or older with comorbidities that preclude the use of intensive induction chemotherapy
- The requested medication will be used in combination with azacitidine or decitabine or low-dose cytarabine

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Venclexta.

REFERENCES

- Venclexta [Prescribing Information]. North Chicago, IL: Abbvie Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/11/19

Created: 11/16

Client Approval: 01/19

P&T Approval: 07/18

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

VALBENAZINE

Generic	Brand	HICL	GCN	Exception/Other
VALBENAZINE	INGREZZA	44202		

GUIDELINES FOR USE

- Does the patient have a diagnosis of moderate to severe tardive dyskinesia and meet **ALL** of the following criteria?
 - Moderate to severe tardive dyskinesia has been present for at least 3 months
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
 - The patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

If yes, **approve for 12 months by GPID for all strengths as follows:**

- Ingrezza 40mg (GPID 43266): #1 capsule per day**
- Ingrezza 80mg (GPID 43934): #1 capsule per day**
- Ingrezza Initiation pack (GPID 46216): 1 pack (#28 capsules) per fill**

If no, do not approve.

DENIAL TEXT: The guideline named **VALBENAZINE (Ingrezza)** requires a diagnosis of moderate to severe tardive dyskinesia. In addition, the following criteria must be met:

- Moderate to severe tardive dyskinesia has been present for at least 3 months
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
- The patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if patient is 60 years of age or older) as documented in the prescription claims history

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ingrezza.

REFERENCES

- Ingrezza [Prescribing Information]. San Diego, CA. Neurocrine Biosciences, Inc; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/03/19

Created: 04/17

Client Approval: 02/18

P&T Approval: 01/18

OPIOID LONG-TERM USE GUIDELINE

Generic	Brand	HICL	GCN	Exception/other
OPIOIDS	OPIOIDS			

GUIDELINES FOR USE

****Documentation is required and may include, but is not limited to chart notes, laboratory results, and prescription claims history****

- Does the patient have an active diagnosis of chronic cancer pain due to an active malignancy?

If yes, **approve for 12 months by GPID.**

If no, continue to #2.

- Is the patient eligible for hospice care?

If yes, **approve for 12 months by GPID.**

If no, continue to #3.

- Is the request for continuation of treatment for a patient that has been established on treatment with opioid therapy?

If yes, continue to #9.

If no, continue to #4.

- Is the request for long-term use of immediate release (IR) or combination opioids for an extended duration?

If yes, continue to #5.

If no (i.e., the request is for extended-release opioids), continue to #6.

- Is the patient undergoing treatment of extended-duration (long-term) non-cancer pain and ALL of the following:

- i. The prescriber has provided documentation in support of use of immediate release (IR) or combination opioids for an extended duration
- ii. There is a formal, consultative evaluation including:
 - a. Diagnosis
 - b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy



- iii. Trial of other pain management treatments has been maximized and documented as insufficient for control of pain, unless use of the below therapies is documented as medically contraindicated, including both of the following:
 - a. Nonpharmacological therapy, such as:
 - 1. Exercise, such as regular walks, swimming, stretching, yoga, physical therapy, or physical rehabilitation
 - 2. Relaxation techniques, such as meditation, yoga, tai chi, deep breathing, visualization, listening to soothing music, or progressive muscle relaxation
 - 3. Other options (variable, depending on the type of pain): heat/cold therapy, massage, psychological therapy, cognitive behavioral therapy, weight loss, biofeedback
 - b. Non-opioid therapy (such as acetaminophen, NSAIDs, antiepileptics, or antidepressants)
- iv. The prescriber has confirmed that a patient-specific pain management plan is on file for the patient
- v. The prescriber documents safe amounts of opioids are being used and that the patient's controlled substance history is consistent with the prescribing record, including verification from the state's prescription monitoring database (PDMP), unless the state does NOT have a PDMP

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- 6. Is the patient undergoing treatment of chronic non-cancer pain and ALL of the following:
 - i. There is a formal, consultative evaluation including:
 - a. Diagnosis
 - b. A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
 - ii. Trial of other pain management treatments has been maximized and documented as insufficient for control of pain, unless use of step therapy is documented as medically contraindicated, including both of the following:
 - a. Nonpharmacological therapy, such as:
 - 1. Exercise, such as regular walks, swimming, stretching, yoga, physical therapy, or physical rehabilitation
 - 2. Relaxation techniques, such as meditation, yoga, tai chi, deep breathing, visualization, listening to soothing music, or progressive muscle relaxation
 - 3. Other options (variable, depending on the type of pain): heat/cold therapy, massage, psychological therapy, cognitive behavioral therapy, weight loss, biofeedback
 - b. Non-opioid therapy (such as acetaminophen, NSAIDs, antiepileptics, or antidepressants)
 - iii. The requested agent is not prescribed as an as-needed (prn) analgesic



- iv. The patient's medical history includes at least a 5-day trial of an immediate-release (IR) opioid
- v. The prescriber has confirmed that a patient-specific pain management plan is on file for the patient
- vi. The prescriber documents safe amounts of opioids are being used and that the patient's controlled substance history is consistent with the prescribing record, including verification from the state's prescription monitoring database (PDMP), unless the state does NOT have a PDMP

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

7. Will the patient be using buprenorphine or buprenorphine/naloxone concurrently with the opioid?

If yes, continue to #8.

If no, **approve for 12 months by GPID.**

8. Will this be used for opioid dependence treatment, also referred to as "Medication Assisted Treatment" (MAT) AND the prescriber has documentation in support of use of opioids with buprenorphine or buprenorphine/naloxone for opioid dependence treatment?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

9. Has a urine drug screening ("UTOX") been performed in the past 12 months?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT:

The guideline named **OPIOID LONG-TERM USE** requires a diagnosis of chronic cancer pain due to an active malignancy, being eligible for hospice care, or undergoing the treatment of long-term noncancer pain.

For the **initial treatment** of long-term noncancer pain, the following must also be met:

- Prescriber has provided documentation in support of use of immediate release (IR) or combination opioids for an extended duration
- A formal, consultative evaluation including:
 - Diagnosis



- A complete medical history which includes previous and current pharmacological and non-pharmacological therapy
- Trial of other pain management treatments has been maximized and documented as insufficient for control of pain, unless use of the below therapies is documented as medically contraindicated, including both of the following:
 - Nonpharmacological therapy, such as:
 - Exercise, such as regular walks, swimming, stretching, yoga, physical therapy, or physical rehabilitation
 - Relaxation techniques, such as meditation, yoga, tai chi, deep breathing, visualization, listening to soothing music, or progressive muscle relaxation
 - Other options (variable, depending on the type of pain): heat/cold therapy, massage, psychological therapy, cognitive behavioral therapy, weight loss, biofeedback
 - Non-opioid therapy (such as acetaminophen, NSAIDs, antiepileptics, or antidepressants)
- The prescriber has confirmed that a patient-specific pain management plan is on file for the patient
- The prescriber documents safe amounts of opioids are being used and that the patient's controlled substance history is consistent with the prescribing record, including verification from the state's prescription monitoring database (PDMP), unless the state does NOT have a PDMP
- One of the following is true:
 - The patient will not be using buprenorphine or buprenorphine/naloxone concurrently with the opioid OR
 - This be used for opioid dependence treatment, also referred to as "Medication Assisted Treatment" (MAT) AND the prescriber has documentation in support of use of opioids with buprenorphine or buprenorphine/naloxone for opioid dependence treatment

For **continuation of treatment**, coverage requires a urine drug screening has been performed in the past 12 months.

OPIOID LONG-TERM USE OVERRIDE

RATIONALE

To facilitate the best possible medical care for patients with non-cancer pain, prior authorization will be required for opioid prescription in excess of the quantity limit established. The long-term opioid prior authorization does not apply to restrict opioid therapy in patients with an active diagnosis of cancer-related pain or those who are in hospice care, or buprenorphine therapy as medication assisted therapy (MAT) for treatment of opioid addiction.

REFERENCES

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- Agency Medical Director's Group. Interagency Guideline on Prescribing Opioids for Pain 3rd Edition. AMDG. Olympia, WA. June 2015. Available at: <http://www.agencymeddirectors.wa.gov/guidelines.asp>
- Federation of State Medical Boards (FSMB). Model Policy for the Use of Controlled Substances for the Treatment of Pain. Washington, DC: The Federation, July 2013. Available at: http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf
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- Carson S, Thakurta S, Low A, et al. Drug Class Review: Long-Acting Opioid Analgesics: Final Update 6 Report [Internet]. Portland (OR): Oregon Health & Science University; 2011 Jul. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK62335/>
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- Washington State Health Care Authority. Opioid Policy Criteria, October 19, 2016. Available at: <https://www.hca.wa.gov/billers-providers/programs-and-services/opioids>

Created	FS Committee Approval	Effective
4/2019	4/2019	5/2019

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB

Generic	Brand	HICL	GCN	Exception/Other
ERDAFITINIB	BALVERSA	45687		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has susceptible Fibroblast growth factor receptor (FGFR3) or (FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ONE** of the following criteria?
 - The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by GPID for all strengths as follows:**

- **Balversa 3mg tablet (GPID 46189): #3 tablets per day.**
- **Balversa 4mg tablet (GPID 46192): #2 tablets per day.**
- **Balversa 5mg tablet (GPID 46193): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ERDAFITINIB (Balversa)** requires a diagnosis of locally advanced or metastatic urothelial carcinoma (i.e., bladder cancer). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The patient has susceptible Fibroblast growth factor receptor (FGFR3) or (FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
- The patient meets ONE of the following:
 - The patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ERDAFITINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Balversa.

REFERENCES

- Balversa [Prescribing Information]. Horsham, PA: Janssen Products, LP; April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/06/19

Created: 04/19

Client Approval: 04/19

P&T Approval: 04/19



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ROMOSOZUMAB-AQQG	EVENITY	45681		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of postmenopausal osteoporosis and meet **ONE** of the following criteria?

- The patient is at high risk for fractures defined as **ONE** of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score greater than or equal to 20% for any major fracture **OR** greater than or equal to 3% for hip fracture
- The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient received a total of 12 months of Evenity therapy?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 12 months by HICL with a quantity limit of #2.34mL per month.**

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ROMOSOZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **ROMOSOZUMAB (Evenity)** requires a diagnosis of postmenopausal osteoporosis and the patient has not received a total of 12 months or more of Evenity therapy. In addition, one of the following criteria must be met:

- The patient is at high risk for fractures defined as **ONE** of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score greater than or equal to 20% for any major fracture **OR** greater than or equal to 3% for hip fracture
- The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evenity.

REFERENCES

- Evenity [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/19

Created: 04/19

Client Approval: 04/19

P&T Approval: 02/17



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-HYALURONIDASE-SQ (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA	45653		

GUIDELINES FOR USE

1. Is the request for adjuvant therapy for breast cancer and the patient meets **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, **approve for 12 months by HICL with a quantity limit of #5mL per 21 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in a patient who has previously tried chemotherapy for metastatic disease

If yes, **approve for 12 months by HICL with a quantity limit of #5mL per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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TRASTUZUMAB-HYALURONIDASE-SQ (NSA) (INTERIM)

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **TRASTUZUMAB-HYALURONIDASE-SQ (Herceptin Hylecta)** requires a diagnosis of breast cancer. In addition, the following criteria must be met.

For use as adjuvant treatment for breast cancer, approval requires:

- The patient is 18 years of age or older
- The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

For the diagnosis of metastatic breast cancer, approval requires:

- The patient is 18 years of age or older
- The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test **AND ONE** of the following:
 - Requested medication is being used in combination with paclitaxel for first-line treatment
 - Requested medication is being used as a single agent in a patient who has previously tried chemotherapy for metastatic disease

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Herceptin Hylecta.

REFERENCES

Herceptin Hylecta [Prescribing Information]. San Francisco, CA: Genentech, Inc., February 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 4/19/19

Created: 04/19

Client Approval: 04/19

P&T Approval: 04/19

PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

Generic	Brand	HICL	GCN	Exception/Other
INFLIXIMAB-ABDA	RENFLEXIS	44432		

****Please apply the RENEWAL CRITERIA if the patient is currently receiving therapy with ANY infliximab product (Remicade, Inflectra, Renflexis) and is continuing infliximab therapy with Renflexis. ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient is currently using or has a contraindication to methotrexate
 -) The patient meets **ONE** of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 -) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 -) The patient is 18 years of age or older

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient is 18 years of age or older

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a dermatologist
- ☐ The patient is 18 years of age or older
- ☐ The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- ☐ The patient has had a previous trial of at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

If yes, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of **INFLIXIMAB-ABDA (Renflexis)** for severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #5.

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?

-) Therapy is prescribed by or given in consultation with a gastroenterologist
-) The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
-) The patient is 6 years of age or older

If yes, **approve for 6 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meets **ALL** of the following criteria?

-) Therapy is prescribed by or given in consultation with a gastroenterologist
-) The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
-) The patient is 18 years of age or older

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **INFLIXIMAB-ABDA (Renflexis)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient is currently using or has a contraindication to methotrexate
-) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

For patients with psoriatic arthritis (PsA), approval requires all of the following:

-) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 18 years of age or older

For patients with ankylosing spondylitis (AS), approval requires all of the following:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient is 18 years of age or older

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

INITIAL CRITERIA (CONTINUED)

For patients with severe plaque psoriasis (PsO), approval requires all of the following:

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient is 18 years of age or older
-) The patient has plaque psoriasis involving at least 10% body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient has had a previous trial of at least one or more forms of conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

For patients with moderate to severe Crohn's disease (CD), approval requires all of the following:

-) Therapy is prescribed by or given in consultation with a gastroenterologist
-) The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
-) The patient is 6 years of age or older

For patients with moderate to severe ulcerative colitis (UC), approval requires all of the following:

-) Therapy is prescribed by or given in consultation with a gastroenterologist
-) The patient has had a previous trial of one or more of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
-) The patient is 18 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets **ALL** of the following criteria?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
 -) The patient is currently using or has a contraindication to methotrexate

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets the following criteria?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets the following criteria?
 -) The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of severe plaque psoriasis (PsO) and meets the following criteria?
 -) The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

If yes, **approve for 12 months by HICL.**

If no, continue to #6.

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

RENEWAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **INFLIXIMAB-ABDA (Renflexis)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, severe plaque psoriasis, moderate to severe Crohn's disease, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires all of the following:

-) That the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
-) The patient is currently using or has a contraindication to methotrexate

Renewal for the diagnosis of psoriatic arthritis requires:

-) That the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of ankylosing spondylitis requires:

-) That the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

Renewal for the diagnosis of severe plaque psoriasis requires:

-) That the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

RATIONALE

To ensure the appropriate use of Renflexis according to FDA-approved indications.

FDA APPROVED INDICATIONS

Renflexis is a tumor necrosis factor (TNF) blocker indicated for:

-) **Crohn's Disease:**
 - o reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
 - o reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.
-) **Pediatric Crohn's Disease:** reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

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PRIOR AUTHORIZATION GUIDELINES

INFLIXIMAB-ABDA

FDA APPROVED INDICATIONS (CONTINUED)

-) **Ulcerative Colitis:** reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
-) **Rheumatoid Arthritis in combination with methotrexate:** reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.
-) **Ankylosing Spondylitis:** reducing signs and symptoms in patients with active disease.
-) **Psoriatic Arthritis:** reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.
-) **Plaque Psoriasis:** treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

DOSING AND ADMINISTRATION

Renflexis is administered by intravenous infusion.

-) **Crohn's Disease:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response.
-) **Ulcerative Colitis:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
-) **Rheumatoid Arthritis:** In conjunction with methotrexate, 3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.
-) **Ankylosing Spondylitis:** 5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks.
-) **Psoriatic Arthritis:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.
-) **Plaque Psoriasis:** 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks.

REFERENCES

-) Renflexis [Prescribing Information]. Kenilworth, NJ: Merck & Co., Inc. April 2017.

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
CERITINIB

Generic	Brand	HICL	GCN	Exception/Other
CERITINIB	ZYKADIA	41111		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND** meet the following criterion?

) Tumor is anaplastic lymphoma kinase (ALK) positive, as detected by an FDA-approved test

 If yes, **approve for 12 months by HICL with a quantity limit of #3 capsules/tablets per day.**

 If no, do not approve.

DENIAL TEXT: The guideline named **CERITINIB (Zykadia)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) with anaplastic lymphoma kinase (ALK)-positive tumor as detected by an FDA-approved test.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zykadia.

REFERENCE

-) Zykadia [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/01/19

Created: 05/14

Client Approval: 05/19

P&T Approval: 01/19

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

Generic	Brand	HICL	GCN	Exception/Other
IVOSIDENIB	TIBSOVO	45096		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?

- ☐ The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
- ☐ The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, continue to #2.

2. Does the patient have a new diagnosis of acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?

- ☐ The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
- ☐ The patient meets **ONE** of the following criteria:
 - The patient is 75 years of age or older
 - The patient is 18 years of age or older **AND** has comorbidities that preclude the use of intensive induction chemotherapy

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **IVOSIDENIB (Tibsovo)** requires a diagnosis of acute myeloid leukemia (AML). In addition, the following criteria must be met:

For patients with relapsed or refractory acute myeloid leukemia (AML), approval requires the following:

- ☐ The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
- ☐ The patient is 18 years of age or older

For patients with a new diagnosis of acute myeloid leukemia (AML), approval requires the following:

- ☐ The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
- ☐ The patient meets **ONE** of the following criteria:
 - The patient is 75 years of age or older
 - The patient is 18 years of age or older **AND** has comorbidities that preclude the use of intensive induction chemotherapy

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES

) Tibsovo [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals; May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/01/19

Created: 11/18

Client Approval: 05/19

P&T Approval: 10/18

ERENUMAB-AOOE

Generic	Brand	HICL	GCN	Exception/Other
ERENUMAB-AOOE	AIMOVIG	44923		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of episodic migraines and meet **ALL** the following criteria?
 -) The patient is 18 years of age or older
 -) Aimovig is prescribed for the preventive treatment of migraines
 -) The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

If yes, **approve for 6 months for the requested strength as follows:**

-) **Aimovig 70mg/mL autoinjector: #1mL (1 pack containing #1 70 mg/mL autoinjector, NDC 55513-0841-01) per 30 days.**
-) **Aimovig 140mg-Dose 2-autoinjectors: #2mL (1 pack containing #2 70mg/mL autoinjectors, NDC 55513-0841-02) per 30 days.**
-) **Aimovig 140 mg/mL autoinjector (GPID 46116): #1mL per 30 days.**

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, **OR** that the patient has experienced a reduction in migraine severity **OR** migraine duration with Aimovig therapy.

If no, continue to #2.

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ERENUMAB-AOOE**INITIAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** the following criteria?

-) The patient is 18 years of age or older
-) Aimovig is prescribed for the preventive treatment of migraines
-) The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox [**Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable**]

If yes, **approve for 6 months for the requested strength as follows:**

-) **Aimovig 70mg/mL autoinjector: #1mL (1 pack containing #1 70 mg/mL autoinjector, NDC 55513-0841-01) per 30 days.**
-) **Aimovig 140mg-Dose 2-autoinjectors: #2mL (1 pack containing #2 70mg/mL autoinjectors, NDC 55513-0841-02) per 30 days.**
-) **Aimovig 140 mg/mL autoinjector (GPID 46116): #1mL per 30 days.**

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, **OR** that the patient has experienced a reduction in migraine severity **OR** migraine duration with Aimovig therapy.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ERENUMAB-AOOE (Aimovig)** requires a diagnosis of migraines. The following criteria must also be met:

For episodic migraines, approval requires:

-) The patient is 18 years of age or older
-) Aimovig is prescribed for the preventive treatment of migraines
-) The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

For chronic migraines, approval requires:

-) The patient is 18 years of age or older
-) Aimovig is prescribed for the preventive treatment of migraines
-) The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox

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ERENUMAB-AOOE**GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Is Aimovig being prescribed for the preventive treatment of migraines **AND** does the patient meet at least **ONE** of the following criteria?

- ☐ The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy
- ☐ The patient has experienced a reduction in migraine severity with Aimovig therapy
- ☐ The patient has experienced a reduction in migraine duration with Aimovig therapy

If yes, **approve for 12 months for the requested strength as follows:**

- ☐ **Aimovig 70mg/mL autoinjector: #1mL (1 pack containing #1 70 mg/mL autoinjector, NDC 55513-0841-01) per 30 days.**
- ☐ **Aimovig 140mg-Dose 2-autoinjectors: #2mL (1 pack containing #2 70mg/mL autoinjectors, NDC 55513-0841-02) per 30 days.**
- ☐ **Aimovig 140 mg/mL autoinjector (GPID 46116): #1mL per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ERENUMAB-AOOE (Aimovig)** requires that Aimovig is being prescribed for preventive treatment of migraines. At least **ONE** of the following criteria must also be met:

- ☐ The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy
- ☐ The patient has experienced a reduction in migraine severity with Aimovig therapy
- ☐ The patient has experienced a reduction in migraine duration with Aimovig therapy

RATIONALE

Ensure appropriate criteria are used for the management of requests for AIMOVIG according to approved indication, dosing, and national treatment guidelines.

FDA APPROVED INDICATIONS

AIMOVIG is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults.

HOW SUPPLIED

70 mg/mL solution in a single-dose prefilled autoinjector.

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ERENUMAB-AOOE**FDA APPROVED INDICATIONS (CONTINUED)****DOSING & ADMINISTRATION**

AIMOVIG is for subcutaneous use only.

The recommended dosage of AIMOVIG is 70 mg injected subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly, which is administered as two consecutive subcutaneous injections of 70 mg each.

REFERENCES

) Aimovig [Prescribing Information]. Thousand Oaks, CA: Amgen/Novartis. May 2018.

Created	FS Committee Approval	Effective
4/2019	4/2019	

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ONASEMNOGENE ABEPARVOVEC-XIOI	ZOLGENSMA	45760		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of the limbs, permanent ventilator dependence)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Does the patient have a diagnosis of spinal muscular atrophy (SMA) and meet **ALL** of the following criteria?

-) The patient is less than 2 years of age
-) Therapy is prescribed by or in consultation with a neuromuscular specialist or SMA specialist at a SMA Specialty Center
-) The patient has documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (*SMN1*) mutations (i.e., deletions and/or point mutations)
-) The patient does **NOT** have anti-adeno-associated virus vector (anti-AAV9) antibody titers greater than 1:50 as determined by an enzyme-linked immunosorbent assay (ELISA)

If yes, **approve for one fill per lifetime.**

If no, do not approve.

DENIAL TEXT: The guideline named **ONASEMNOGENE ABEPARVOVEC-XIOI (Zolgensma)** requires a diagnosis of spinal muscular atrophy (SMA). In addition, the following criteria must be met.

-) The patient is less than 2 years of age
-) Therapy is prescribed by or in consultation with a neuromuscular specialist or SMA specialist at a SMA Specialty Center
-) The patient has documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (*SMN1*) mutations (i.e., deletions and/or point mutations)
-) The patient does **NOT** have anti-adeno-associated virus vector (anti-AAV9) antibody titers greater than 1:50 as determined by an enzyme-linked immunosorbent assay (ELISA)
-) The patient does NOT have advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of the limbs, permanent ventilator dependence)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zolgensma .

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)****REFERENCES**

Zolgensma [Prescribing Information]. Bannockburn, IL: AveXis, Inc., May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 06/07/19

Created: 06/19

Client Approval: 04/19

P&T Approval: 04/19

TILDRAKIZUMAB-ASMN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a dermatologist
 -) The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
 -) The patient had a previous trial of or contraindication to at least **ONE** or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 -) The patient is 18 years of age or older
 -) The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Enbrel, Renflexis, or Otezla [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by entering TWO approvals by HICL as follows:**

-) **FIRST APPROVAL: approve for 1 month with a quantity limit of #2mL (#2 100mg/mL syringes) per 28 days.**
-) **SECOND APPROVAL: approve for 5 months with a quantity limit of #1mL (#1 100mg/mL syringe) per 84 days (Please enter a start date of 1 WEEK AFTER the END date of the first approval).**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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TILDRAKIZUMAB-ASMN (NSA)**INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

- ⌋ Therapy is prescribed by or given in consultation with a dermatologist
- ⌋ The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- ⌋ The patient had a previous trial of or contraindication to at least ONE or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- ⌋ The patient is 18 years of age or older
- ⌋ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Enbrel, Renflexis, or Otezla

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
 - ⌋ The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL with a quantity limit of #1mL (#1 100mg/mL syringe) per 84 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) for renewal. The following criterion must also be met:

- ⌋ The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

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TILDRAKIZUMAB-ASMN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilumya.

REFERENCES

) Ilumya [Prescribing Information]. Whitehouse Station, NJ: Merck & Co.,Inc.; August 2018.

Created	FS Committee Approval	Effective
5/2019		

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

OPIOID-BENZODIAZEPINE CONCURRENT USE

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the claim rejecting with the following error code?

- **REJ- 433-1201: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY (H: DUR_CONCURRENT_USE)**

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient meet at least **ONE** of the following criteria?

- Patient has a diagnosis of active cancer
- Patient is in hospice care
- Patient is receiving palliative care or end-of-life care
- Patient is a resident of a long-term care facility
- Patient has a diagnosis of sickle cell disease

If yes, **approve for 12 months by HICL and set DUR_CONCURRENT_OVR to 'OP_BZD'.**

If no, continue to #3.

3. Has the prescriber provided attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication?

If yes, **approve for 12 months by HICL and set DUR_CONCURRENT_OVR to 'OP_BZD'.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON THE NEXT PAGE

OPIOID-BENZODIAZEPINE CONCURRENT USE**GUIDELINES FOR USE (CONTINUED)****OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT:**

While your request for **[enter requested drug]** has been granted, the drug cannot be covered by your plan due to the use of an opioid drug and a benzodiazepine drug together.

[Proceed to enter Denial Text below]

DENIAL TEXT: The guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval for patients who are receiving an opioid with a benzodiazepine. An approval for concurrent use will be provided when one of the following criteria is met:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility
- Diagnosis of sickle cell disease
- Prescriber attestation to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication.

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:

“We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019.” *CMS 2019 Call Letter, page 251*

The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.

This guideline allows an approval for patients with one of the following conditions:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility
- Diagnosis of sickle cell disease
- Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine

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OPIOID-BENZODIAZEPINE CONCURRENT USE

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf> [Accessed 4/2/18].
- Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Frequently-Asked-Questions-about-Contract-Year-2019-Formulary-Level-Opioid-Point-of-Sale-Safety-Edits.pdf> [Accessed 5/13/19].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 10/17

Client Approval: 06/19

P&T Approval: 07/19

SODIUM ZIRCONIUM CYCLOSILICATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM ZIRCONIUM CYCLOSILICATE	LOKELMA	44935		

GUIDELINES FOR USE

1. Is the patient being treated for hyperkalemia and meet the following criteria?

) The patient is 18 years of age or older

 If yes, continue to #2.

 If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the requested drug being used as an emergency treatment for life-threatening hyperkalemia?

 If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

 If no, continue to #3.

3. Is the patient currently receiving dialysis?

 If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

 If no, continue to #4.

4. Is the requested drug being prescribed by or in consultation with a nephrologist or cardiologist?

 If yes, continue to #5.

 If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Has the patient attempted any **ONE** of the following approaches in an effort to reduce the modifiable risks for hyperkalemia?

) Limit to taking no more than one of the following drugs at any given time:

 ○ Angiotensin converting enzyme inhibitor (ACE-I)

 ○ Angiotensin receptor blocker (ARB)

) Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)

 If yes, continue to #6.

 If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

SODIUM ZIRCONIUM CYCLOSILICATE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73 m²?

If yes, continue to #7.

If no, continue to #8.

7. Has the patient tried loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide) for the treatment of hyperkalemia?

If yes, **approve for 12 months by HICL with a quantity limit of #90 packets per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

8. Has the patient tried at least **ONE** of the following therapies for the treatment of hyperkalemia?

- ☐ loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide)
- ☐ thiazide diuretics (e.g., chlorthalidone, hydrochlorothiazide, metolazone)

If yes, **approve for 12 months by HICL with a quantity limit of #90 packets per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma)** requires a diagnosis of hyperkalemia. In addition, the following criteria must also be met:

- ☐ The patient is 18 years of age or older
- ☐ The requested drug is not being used as an emergency treatment for life-threatening hyperkalemia
- ☐ The requested drug will not be used in a patient currently receiving dialysis
- ☐ The requested drug is being prescribed by or in consultation with a nephrologist or cardiologist
- ☐ The patient has attempted any **ONE** of the following approaches in an effort to reduce the modifiable risks for hyperkalemia:
 - Limit to taking no more than one of the following drugs at any given time:
 - Angiotensin converting enzyme inhibitor (ACE-I)
 - Angiotensin receptor blocker (ARB)
- ☐ Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)
- ☐ The patient has tried to treat hyperkalemia with loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide) if estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2), or with loop diuretics or thiazide diuretics (e.g., chlorthalidone, hydrochlorothiazide, metolazone) if eGFR is 30 mL/min/1.73 m(2) or above

SODIUM ZIRCONIUM CYCLOSILICATE

RATIONALE

Promote appropriate utilization of SODIUM ZIRCONIUM CYCLOSILICATE based on FDA approved indication.

FDA APPROVED INDICATION

Lokelma is a potassium binder indicated for the treatment of hyperkalemia in adults.

Limitation of Use

Lokelma should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action.

DOSAGE AND ADMINISTRATION

For initial treatment of hyperkalemia, the recommended dose of Lokelma is 10 g administered three times a day for up to 48 hours.

For continued treatment, the recommended dose is 10 g once daily. Monitor serum potassium and adjust the dose of Lokelma based on the serum potassium level and desired target range. During maintenance treatment, the dose may be up-titrated based on the serum potassium level at intervals of 1-week or longer and in increments of 5 g. The dose of Lokelma should be decreased or discontinued if the serum potassium is below the desired target range. The recommended maintenance dose range is from 5 g every other day to 15 g daily.

AVAILABLE STRENGTHS

-) 5 gram powder for oral suspension packet
-) 10 gram powder for oral suspension packet

REFERENCES

-) Lokelma [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2018.

Created	FS Committee Approval	Effective
4/2019	4/2019	7/1/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

OMALIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
OMALIZUMAB	XOLAIR	25399		

THIS DRUG REQUIRES A WRITTEN REQUEST FOR PRIOR AUTHORIZATION.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of chronic idiopathic urticaria (CIU) and still experiences hives on most days of the week for at least 6 weeks **AND** meets all of the following criteria?

- ☐ The patient is 12 years of age or older
- ☐ Member remains symptomatic despite second generation H1 antihistamine therapy with maximized dosing used continuously for at least 2 weeks.
- ☐ Patient remains symptomatic despite a two week continuous trial of at least one of the following:
 - ☐ Higher dose (up to four times the recommended dose) of second generation H1 antihistamine therapy
 - ☐ Addition of another second generation antihistamine to existing therapy
 - ☐ Addition of a leukotriene receptor antagonist (LTRA) to existing therapy
 - ☐ Addition of a H2-antagonist to existing therapy
 - ☐ Addition of a first generation antihistamine taken at bedtime
- ☐ Patient remains symptomatic despite the addition of a potent antihistamine (e.g., hydroxyzine or doxepin) used continuously for at least two weeks
- ☐ Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

If yes, **approve for 24 weeks by GPID for the requested product as follows:**

- ☐ **Xolair 150mg vial (GPID 19966) with a quantity limit of #2 vials per 28 days.**
- ☐ **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #2mL per 28 days.**
- ☐ **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #2mL per 28 days.**

APPROVAL TEXT: Renewal requires a diagnosis of chronic idiopathic urticaria (CIU).

If no, continue to #2.

- Does the patient have moderate to severe persistent asthma and meet **ALL** the following criteria?
 - ☐ The patient is 6 years of age or older
 - ☐ The patient has a positive skin prick or RAST test to a perennial aeroallergen
 - ☐ The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL

-) The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
-) The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
-) The patient has **ONE** of the following:
 - o Asthma Control Test (ACT) score of less than 20
 - o Asthma Control Questionnaire (ACQ) score of at least 1.5
 - o Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
-) Xolair will be used as add-on maintenance treatment
-) The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
-) Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

If yes, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

APPROVAL TEXT: Renewal for the diagnosis of moderate to severe persistent asthma requires all of the following:

-) The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
-) The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
-) The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **OMALIZUMAB (Xolair)** requires a diagnosis of chronic idiopathic urticaria or moderate to severe persistent asthma. In addition, the following criteria must also be met:

For patients with chronic idiopathic urticaria (CIU), approval requires:

-] The patient is 12 years of age or older
-] The patient still experiences hives on most days of the week for at least 6 weeks
-] Member remains symptomatic despite second generation H1 antihistamine therapy with maximized dosing used continuously for at least 2 weeks (see Appendix)
-] Patient remains symptomatic despite a two week continuous trial of at least one of the following:
 - o Higher dose (up to four times the recommended dose) of second generation H1 antihistamine therapy
 - o Addition of another second generation antihistamine to existing therapy
 - o Addition of a leukotriene receptor antagonist (LTRA) to existing therapy
 - o Addition of a H2-antagonist to existing therapy
 - o Addition of a first generation antihistamine taken at bedtime
-] Patient remains symptomatic despite the addition of a potent antihistamine (e.g., hydroxyzine or doxepin) used continuously for at least two weeks
-] Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

For patients with moderate to severe persistent asthma, approval requires:

-] The patient is 6 years of age or older
-] The patient has a positive skin prick or RAST test to a perennial aeroallergen
-] The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
-] The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
-] The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
-] The patient has **ONE** of the following:
 - o Asthma Control Test (ACT) score of less than 20
 - o Asthma Control Questionnaire (ACQ) score of at least 1.5
 - o Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
-] Xolair will be used as add-on maintenance treatment
-] The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
-] Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

OMALIZUMAB (NSA)**RENEWAL CRITERIA**

1. Does the patient have a diagnosis of chronic idiopathic urticaria (CIU)?

If yes, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #2 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #2mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #2mL per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?

-) The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
-) The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), **OR** Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

1. Was the patient treated with a maintenance therapy regimen of oral corticosteroids prior to initiation of Xolair?

If yes, continue to #4.

If no, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

2. Has the patient decreased their total daily dose of oral corticosteroids from baseline?

If yes, **approve for 12 months by GPID for the requested product as follows:**

-) **Xolair 150mg vial (GPID 19966) with a quantity limit of #6 vials per 28 days.**
-) **Xolair 75mg/0.5mL syringe (GPID 30555) with a quantity limit of #5mL per 28 days.**
-) **Xolair 150mg/mL syringe (GPID 30556) with a quantity limit of #5mL per 28 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

OMALIZUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **OMALIZUMAB (Xolair)** renewal requires a diagnosis of moderate to severe persistent asthma or chronic idiopathic urticaria. In addition, the following criteria must also be met:

For patients with moderate to severe persistent asthma, approval requires:

-)] The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
-)] The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
-)] The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES

-)] Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc. September 2018.
-)] Khan DA. Chronic spontaneous urticaria: standard management and patient education. Saini S and Callen J, ed. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on April 09, 2019).

Created	FS Committee Approval	Effective
4/2019	4/23/2019	7/1/2019

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

TASIMELTEON

Generic	Brand	HICL	GCN	Exception/Other
TASIMELTEON	HETLIOZ	40927		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of non-24 hour sleep-wake disorder (N24HSD)?

If yes, continue to #2

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

- Is the patient totally blind with no perception of light?

If yes, continue to question #3.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

- Is the medication prescribed by or in consultation with a physician specializing in the treatment of sleep disorders?

If yes, continue to question #4.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

- Has the diagnosis of Non-24 been confirmed by ONE of the following?
 - Actigraphy performed for at least 14 days along with evaluation of sleep logs for at least 14 days which demonstrate a gradual daily drift in rest-activity patterns.
 - Assessment of at least one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature).

If yes, continue to question #5.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

- Has the patient had a trial and failure of melatonin?

If yes, continue to question #6.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

6. Is the patient receiving concomitant therapy with a sedative hypnotic (e.g., zolpidem, zaleplon) or other medications for insomnia or other sleep disorders?

If no, **approve for 6 months by HICL.**

APPROVAL TEXT: Renewal of therapy requires the patient has achieved adequate results with HetlioZ therapy as documented by entrainment, clinically meaningful or significant increases in nighttime sleep, or clinically meaningful or significant decreases in daytime sleep.

If yes, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

DENIAL TEXT: The guideline named **TASIMELTION (HETLIOZ)** requires a diagnosis of Non-24 Hour Sleep Wake Disorder (N24HSWD). In addition, ALL the following criteria must be met:

-) The patient is totally blind with no perception of light.
-) The medication is prescribed by or in consultation with a physician who specializes in the treatment of sleep disorders.
-) The patient is not receiving concomitant therapy with a sedative hypnotic (e.g., zolpidem, zaleplon) or other medications for insomnia or other sleep disorders.
-) The diagnosis of Non-24 has been confirmed by ONE of the following:
 - o Actigraphy performed for at least 14 days along with evaluation of sleep logs for at least 14 days which demonstrate a gradual daily drift in rest-activity patterns.
 - o Assessment of at least one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature).
-) The patient has had a trial of melatonin with inadequate results.

RENEWAL CRITERIA

1. Has the patient achieved adequate results with HetlioZ therapy as documented by entrainment, clinically meaningful or significant increases in nighttime sleep, or clinically meaningful or significant decreases in daytime sleep?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: Renewal of HetlioZ requires the patient has achieved adequate results with HetlioZ therapy as documented by entrainment, clinically meaningful or significant increases in nighttime sleep, or clinically meaningful or significant decreases in daytime sleep.

RATIONALE

Promote appropriate utilization of HetlioZ based on FDA approved indication and dosage.



Hetlioz is the first FDA approved treatment for non-24 hour sleep-wake disorder (N24HSWD), a chronic circadian rhythm disorder in which a person's day length is not synchronized with the 24-hour day-night cycle. Hetlioz is a melatonin receptor agonist that has high affinity for MT1 and MT2 receptors in the suprachiasmatic nucleus of the brain, which are thought to synchronize the body's melatonin and cortisol circadian rhythms with the day-night cycle.

The majority of people with N24HSWD are completely blind due to the lack of light information received from the eyes, which normally regulates the 24-hour day-night cycle. Currently there are 1.3 million legally blind people in the United States (US); 130,000 are completely blind and approximately 70% of those people suffer from N24HSWD.

Treatments for N24HSWD are aimed at resynchronizing the patient's internal body clock to the 24-hour day-night cycle. Phototherapy and dietary melatonin are commonly used to help manage symptoms, as there is no permanent cure for the disorder. In sighted patients, exposure to bright light may counteract the tendency for circadian rhythms to delay. It involves 30-120 minutes of exposure to 3,000 to 10,000 lux light intensity upon awakening daily. Use of melatonin may also be successful in advancing a patient's circadian rhythm; however the dosage and time of administration need to be adjusted on an individual basis.

Aside from Hetlioz, branded Rozerem (ramelteon) is the only other melatonin receptor agonist approved in the US. However, Rozerem is not indicated for N24HSWD, but rather for the treatment of insomnia characterized by difficulty with sleep onset. Hetlioz offers another option for the treatment of N24HSWD in which there is FDA oversight and regulation, unlike over-the-counter dietary melatonin.

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TASIMELTEON

RATIONALE (CONTINUED)

The most frequently reported adverse reactions in patients receiving Hetlioz include headache (17%), alanine aminotransferase increase (10%), nightmare/abnormal dreams (10%), upper respiratory tract infection (7%), and urinary tract infection (7%). In placebo-controlled studies, 6% of patients exposed to Hetlioz discontinued treatment due to an adverse event, compared with 4% of patients who received placebo.

There were no signs or symptoms indicative of abuse potential or physical dependence in clinical studies with Hetlioz. Discontinuation of Hetlioz following chronic administration did not produce withdrawal signs.

DOSAGE

The recommended dosage of Hetlioz is 20 mg per day taken before bedtime, at the same time every night. Because of individual differences in circadian rhythms, drug effect may not occur for weeks or months. Hetlioz should be taken without food.

FDA APPROVED INDICATIONS

Hetlioz is a melatonin receptor agonist indicated for the treatment of non-24-hour sleep-wake disorder.

REFERENCES

-) Hetlioz [Prescribing Information]. Washington, D.C., Vanda Pharmaceuticals, Inc., Jan 2014.
-) FDA News Release on Jan 31, 2014: FDA approves Hetlioz: first treatment for non-24 hour sleep-wake disorder in blind individuals. Available online at:
<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm384092.html>
-) Circadian Sleep Disorders Network. <http://www.circadiansleepdisorders.org/index.php>

Created	FS Committee Approval	Effective
4/2019	4/2019	7/2019

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

CANNABIDIOL

Generic	Brand	HICL	GCN	Exception/Other
CANNABIDIOL	EPIDIOLEX	45006		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - Therapy is prescribed by or in consultation with a neurologist
 - The patient had a trial of or contraindication to clobazam **AND** valproic acid derivative

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

- Does the patient have a diagnosis of seizures associated with Lennox-Gastaut syndrome and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - Therapy is prescribed by or in consultation with a neurologist
 - The patient had a trial of or contraindication to **TWO** of the following: clobazam, valproic acid derivative, topiramate, lamotrigine

If yes, **approve for 12 months by HICL.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **CANNABIDIOL (Epidiolex)** requires a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. In addition, the following criteria must be met:

For the diagnosis of seizures associated with Dravet syndrome, approval requires:

- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a neurologist
- The patient had a trial of or contraindication to clobazam **AND** valproic acid derivative

For the diagnosis of seizures associated with Lennox-Gastaut syndrome, approval requires:

- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a neurologist
- The patient had a trial of or contraindication to **TWO** of the following: clobazam, valproic acid derivative, topiramate, lamotrigine

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CANNABIDIOL**GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **CANNABIDIOL (Epidiolex)** requires a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome.

RATIONALE

For further information please refer to the Prescribing Information and/or Drug Monograph for Epidiolex.

REFERENCES

- Epidiolex [Prescribing Information]. Carlsbad, CA: Greenwich Biosciences, Inc.; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 10/18

Client Approval: 05/19

P&T Approval: 04/19

CAPLACIZUMAB-YHDP

Generic	Brand	HICL	GCN	Exception/Other
CAPLACIZUMAB-YHDP	CABLIVI	45591		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

3. Is the request for continuation of Cablivi therapy from inpatient (hospital) setting **AND** the patient meets the following criterion?

- Cablivi was previously initiated as part of the FDA approved treatment regimen in combination with plasma exchange and immunosuppressive therapy within the inpatient setting

If yes, **approve for 30 days by HICL with a quantity limit of #1 vial per day.**

If no, continue to #4.

4. Is the request for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and the patient meets **ALL** of the following criteria?

- The patient is receiving immunosuppressive therapy
- Physician attestation that the patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

If yes, **approve for 28 days by HICL with a quantity limit of #1 vial per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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CAPLACIZUMAB-YHDP

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **CAPLACIZUMAB-YHDP (Cablivi)** requires a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Therapy is prescribed by or in consultation with a hematologist
- The patient has NOT experienced more than two recurrences of aTTP, while on Cablivi therapy (i.e., new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy [PEX] and up to 28 days of extended therapy)
- The patient also meets ONE of the following:
 - Request is for continuation of Cablivi therapy from inpatient (hospital) setting and the patient previously received plasma exchange and immunosuppressive therapy within the inpatient setting
 - Requests is for continuation of Cablivi therapy from the initial 30 days treatment course (e.g., no break in therapy) and meets the following:
 - The patient is receiving immunosuppressive therapy
 - Physician attestation that the patient is experiencing signs of persistent underlying disease (e.g., suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13] activity level remain present)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cablivi.

REFERENCES

- Cablivi [Prescribing Information]. Cambridge, MA: Genzyme Corporation; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19

DENOSUMAB-PROLIA (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DENOSUMAB	PROLIA		28656	

GUIDELINES FOR USE

- Does the patient have a diagnosis of postmenopausal osteoporosis and meet **ONE** of the following criteria?
 - The patient is at high risk for fractures defined as **ONE** of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score \geq 20% for any major fracture OR \geq 3% for hip fracture
 - The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)
 - The patient is unable to use oral therapy (upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)

If yes, **approve for 12 months by GPID for 2 fills with a quantity limit of #1mL (#1 pre-filled syringe) per fill.**
 If no, continue to #2.
- Does the patient have **ONE** of the following diagnoses?
 - Osteoporosis in a male patient
 - Glucocorticoid-induced osteoporosis

If yes, continue to #3.
 If no, continue to #4.

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DENOSUMAB-PROLIA (NSA)**GUIDELINES FOR USE (CONTINUED)****3. Does the patient meet ALL of the following criteria?**

- The patient is at high risk for fractures defined as **ONE** of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

If yes, **approve for 12 months by GPID for 2 fills with a quantity limit of #1mL (#1 pre-filled syringe) per fill.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have ONE of the following diagnoses?

- Bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer
- Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient meet ALL of the following criteria?

- The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

If yes, **approve for 12 months by GPID for 2 fills with a quantity limit of #1mL (#1 pre-filled syringe) per fill.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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DENOSUMAB-PROLIA (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **DENOSUMAB (Prolia)** requires that the patient have a diagnosis of postmenopausal osteoporosis, osteoporosis in a male patient, glucocorticoid-induced osteoporosis, bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, or bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer. In addition, the following criteria must be met:

For the diagnosis of postmenopausal osteoporosis, approval requires ONE of the following:

- The patient is at high risk for fractures defined as ONE of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis AND FRAX score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)
- The patient is unable to use oral therapy (upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)

For the diagnosis of osteoporosis in a male patient or glucocorticoid-induced osteoporosis, approval requires all of the following:

- The patient is at high risk for fractures defined as ONE of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, bone marrow density [BMD] T-score less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

For diagnosis of bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer, or bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer, approval requires all of the following:

- The patient is at high risk for fracture (e.g., history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
- The patient had a previous trial of or contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva, Reclast)

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DENOSUMAB-PROLIA (NSA)**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Prolia.

REFERENCES

- Prolia [Prescribing Information]. Thousand Oaks, CA: Amgen; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 07/10

Client Approval: 05/19

P&T Approval: 04/19

IBRUTINIB

Generic	Brand	HICL	GCN	Exception/Other
IBRUTINIB	IMBRUVICA	40745		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of mantle cell lymphoma (MCL) **AND** meet the following criterion?

- Patient has received at least one prior therapy for mantle cell lymphoma (MCL)

If yes, continue to #6.

If no, continue to #3.

3. Does the patient have a diagnosis of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), or Waldenström's macroglobulinemia (WM)?

If yes, continue to #8.

If no, continue to #4.

4. Does the patient have a diagnosis of marginal zone lymphoma (MZL) and meet **ALL** of the following criteria?

- Patient requires systemic therapy
- Patient has received at least one prior anti-CD20-based therapy (e.g., Rituxan)

If yes, continue to #6.

If no, continue to #5.

5. Does the patient have a diagnosis of chronic graft versus host disease (cGVHD) **AND** meet the following criteria?

- The patient has failed one or more lines of systemic therapy (e.g., corticosteroids)

If yes, continue to #8.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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IBRUTINIB**GUIDELINES FOR USE (CONTINUED)**

6. Is the request for Ibrutinib 140mg or 280mg tablets?

If yes, continue to #7.

If no, **approve for 12 months by GPID for all of the following strengths:**

- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**
- **560mg tablet (GPID 44468) with a quantity limit of #1 tablet per day.**

7. Has the patient tried or have a contraindication to Ibrutinib 140mg capsules?

If yes, **approve for 12 months by GPID (44465, 44466) (140mg, 280mg tablet) with a quantity limit of #1 per day. Please also enter approvals for all of the following:**

- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**
- **560mg tablet (GPID 44468) with a quantity limit of #1 tablet per day.**

If no, do not approve. **Please enter proactive approvals for 12 months by GPID for all of the following:**

- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**
- **560mg tablet (GPID 44468) with a quantity limit of #1 tablet per day.**

DENIAL TEXT: See the denial text at the end of the guideline.

8. Is the request for Ibrutinib 140mg or 280mg tablets?

If yes, continue to #9.

If no, **approve for 12 months by GPID for all of the following strengths:**

- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**

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IBRUTINIB

GUIDELINES FOR USE (CONTINUED)

9. Has the patient tried or have a contraindication to Ibrutinib 140mg capsules?

If yes, **approve for 12 months by GPID (44465, 44466) (140mg, 280mg tablet) with a quantity limit of #1 per day. Please also enter approvals for all of the following:**

- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**

If no, do not approve. **Please enter proactive approvals for 12 months by GPID for all of the following:**

- **70mg capsule (GPID 44475) with a quantity limit of #1 capsule per day.**
- **140mg capsule (GPID 35599) with a quantity limit of #2 capsules per day.**
- **420mg tablet (GPID 44467) with a quantity limit of #1 tablet per day.**

DENIAL TEXT: The guideline named **IBRUTINIB (Imbruvica)** requires a diagnosis of mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), Waldenström's macroglobulinemia (WM), marginal zone lymphoma (MZL), or chronic graft versus host disease (cGVHD). Request for Ibrutinib 140mg or 280mg tablets requires a trial of or contraindication to Ibrutinib 140mg capsules. The following criteria must also be met:

- The patient is 18 years of age or older

For patients with mantle cell lymphoma (MCL), approval requires:

- Patient has received at least one prior therapy for mantle cell lymphoma (MCL)

For patients with marginal zone lymphoma (MZL), approval requires:

- Patient requires systemic therapy
- Patient has received at least one prior anti-CD20-based therapy (e.g., Rituxan)

For patients with chronic graft versus host disease (cGVHD), approval requires:

- The patient has failed one or more lines of systemic therapy (e.g., corticosteroids)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Imbruvica.

REFERENCES

- Imbruvica [Prescribing Information]. Janssen Biotech, Inc.: Horsham, PA; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/25/19

Created: 01/14

Client Approval: 02/19

P&T Approval: 07/18

LEVODOPA

Generic	Brand	HICL	GCN	Exception/Other
LEVODOPA	INBRIJA	01897		ROUTE = INHALATION

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?
 - Inbrija is being used for intermittent treatment of OFF episodes associated with Parkinson's disease
 - The patient is currently being treated with carbidopa/levodopa
 - Therapy is prescribed by or in consultation with a neurologist
 - The patient is **NOT** currently taking more than 1600mg of levodopa per day
 - The physician has optimized drug therapy as evidenced by **BOTH** of the following:
 - Change in levodopa/carbidopa dosing strategy or formulation
 - Trial of or contraindication to at least **TWO** Parkinson's disease agents from two different classes of the following: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

If yes, **approve for 6 months by GPID with a quantity limit of #10 capsules per day.**

APPROVAL TEXT: Renewal requires physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **LEVODOPA (Inbrija)** requires a diagnosis of Parkinson's disease. In addition, the following criteria must be met:

- Inbrija is being used for intermittent treatment of OFF episodes associated with Parkinson's disease
- The patient is currently being treated with carbidopa/levodopa
- Treatment is prescribed by or in consultation with a neurologist
- The patient is **NOT** currently taking more than 1600mg of levodopa per day
- The physician has optimized drug therapy as evidenced by **BOTH** of the following:
 - Change in levodopa/carbidopa dosing strategy or formulation
 - Trial of or contraindication to at least **TWO** Parkinson's disease agents from two different classes of the following: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

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LEVODOPA**GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of Parkinson's disease **AND** meet the following criterion?
 - Physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

If yes, **approve for 12 months by GPID with a quantity limit of #10 capsules per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **LEVODOPA (Inbrija)** requires a diagnosis of Parkinson's disease. In addition, the following must be met:

- Physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Inbrija (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inbrija.

REFERENCES

- Inbrija [Prescribing Information]. Ardsley, NY: Acorda Therapeutics, Inc., December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19

PEMETREXED (NSA)

Generic	Brand	HICL	GCN	Exception/Other
PEMETREXED DISODIUM	ALIMTA	25905		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ONE** of the following criteria?
 - The requested medication is being used in combination with cisplatin for initial treatment
 - The requested medication is being used as a single agent, maintenance therapy and meet the following:
 - The patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

- Does the patient have a diagnosis of metastatic, non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The requested medication is being used for initial treatment
 - The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
 - The patient does not have EGFR or ALK genomic tumor aberrations

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

- Does the patient have a diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The requested medication is being used as a single agent
 - The patient has received prior chemotherapy

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

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PEMETREXED (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of malignant pleural mesothelioma and meet **ALL** of the following criteria?
- The requested medication is being used in combination with cisplatin for initial treatment
 - The patient's disease is unresectable **OR** the patient is not a candidate for curative surgery

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **PEMETREXED (Alimta)** requires ONE of the following diagnoses and related criteria to be met:

For diagnosis of locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) approval requires ONE of the following:

- The requested medication is being used in combination with cisplatin for initial treatment
- The requested medication is being used as a single agent, maintenance therapy and meet the following:
 - The patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy

For diagnosis of metastatic, non-squamous, non-small cell lung cancer (NSCLC) approval requires:

- The requested medication is being used for initial treatment
- The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
- The patient does not have EGFR or ALK genomic tumor aberrations

For diagnosis of recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC), approval requires:

- The requested medication is being used as a single agent
- The patient has received prior chemotherapy

For diagnosis of malignant pleural mesothelioma, approval requires:

- The requested medication is being used in combination with cisplatin for initial treatment
- The patient's disease is unresectable **OR** the patient is not a candidate for curative surgery

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Alimta.

REFERENCES

- Alimta [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/25/19

Created: 11/13

Client Approval: 02/19

P&T Approval: 07/18

STIRIPENTOL

Generic	Brand	HICL	GCN	Exception/Other
STIRIPENTOL	DIACOMIT	35461		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - The patient is currently being treated with clobazam
 - Therapy is prescribed by or in consultation with a neurologist
 - The patient had a trial of or contraindication to valproic acid derivatives

If yes, **approve for 12 months by GPID for the requested drug with the following quantity limits:**

- Diacomit 250mg capsule (99500): #12 capsules per day.**
- Diacomit 500mg capsule (99501): #6 capsules per day.**
- Diacomit 250mg powder packet (99502): #12 powder packets per day.**
- Diacomit 500mg powder packet (99503): #6 packets per day.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **STIRIPENTOL (Diacomit)** requires a diagnosis of seizures associated with Dravet syndrome. In addition, the following criteria must be met:

- The patient is 2 years of age or older
- The patient is currently being treated with clobazam
- Therapy is prescribed by or in consultation with a neurologist
- The patient had a trial of or contraindication to valproic acid derivatives

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STIRIPENTOL**GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
 - The patient is currently being treated with clobazam

If yes, **approve for 12 months by GPID for the requested drug with the following quantity limits:**

- **Diacomit 250mg capsule (99500): #12 capsules per day.**
- **Diacomit 500mg capsule (99501): #6 capsules per day.**
- **Diacomit 250mg powder packet (99502): #12 powder packets per day.**
- **Diacomit 500mg powder packet (99503): #6 packets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **CANNABIDIOL (Epidiolex)** requires a diagnosis of seizures associated with Dravet syndrome AND the patient is currently being treated with clobazam.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Diacomit.

REFERENCES

- Diacomit [Prescribing Information]. Beauvais, France: Biocodex, August 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19

TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Exception/Other
TRIFLURIDINE/TIPIRACIL	LONSURF	42544		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic colorectal cancer and meets the following criterion?
 - Previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)]

If yes, continue to #2.

If no, continue to #4.

- Does the patient also have RAS mutation negative (i.e., RAS wild-type)?

If yes, continue to #3.

If no, **approve for 12 months by GPID for the requested strength with the following quantity limits (PAC NOTE: Enter prior authorizations for all strengths):**

- Trifluridine/tipiracil 15/6.14mg tablet (GPID 39596): **#100 tablets per 28 days.**
- Trifluridine/tipiracil 20/8.19mg tablet (GPID 39597): **#80 tablets per 28 days.**

- Has the patient had previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits (PAC Note: Enter prior authorizations for all strengths):**

- Trifluridine/tipiracil 15/6.14mg tablet (GPID 39596): **#100 tablets per 28 days.**
- Trifluridine/tipiracil 20/8.19mg tablet (GPID 39597): **#80 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet the following criterion?
 - Previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits (PAC NOTE: Enter prior authorizations for all strengths):**

- Trifluridine/tipiracil 15/6.14mg tablet (GPID 39596): **#100 tablets per 28 days.**
- Trifluridine/tipiracil 20/8.19mg tablet (GPID 39597): **# 80 tablets per 28 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires a diagnosis of metastatic colorectal cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. The following criteria must also be met:

For patients with a diagnosis of metastatic colorectal cancer, approval requires:

- The patient must have had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)]
- For patients who are negative for the RAS mutation (e.g., patient is RAS wild-type), approval requires that the patient had a previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]

For patients with a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:

- Previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

- Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/08/19

Created: 10/15

Client Approval: 03/19

P&T Approval: 11/15



PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

Generic	Brand	HICL	GCN	Exception/Other
SOLRIAMFETOL	SUNOSI	45666		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** physician attestation that narcolepsy is confirmed by **ONE** of the following criteria?
 - J The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
 - J The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
 - J The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay

If yes, continue to #2.

If no, continue to #3.

2. Does the patient meet **ALL** of the following criteria?
 - J Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
 - J Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
 - J The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

If yes, **approve for 6 months by HICL with a quantity limit of #1 tablet per day.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA) **AND** physician attestation that OSA is confirmed by **ONE** of the following criteria?
-) Polysomnography
 -) Home sleep apnea testing devices
 -) Hospital-based bedside monitoring

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?
-) Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
 -) The patient had a trial of or contraindication to modafinil or armodafinil
 -) Physician attestation that the patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weight-loss intervention (if BMI > 30)

If yes, **approve for 6 months by HICL with a quantity limit of #1 tablet per day.**

APPROVAL TEXT: Renewal requires physician attestation that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **SOLRIAMFETOL (Sunosi)** requires a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA). In addition, the following criteria must be met:

For the diagnosis of excessive daytime sleepiness (EDS) with narcolepsy, approval requires:

-) Physician attestation that narcolepsy is confirmed by **ONE** of the following:
 - o The patient has a Multiple Sleep Latency Test (MSLT) showing a both mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
 - o The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
 - o The patient has low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay
-) Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10

Initial denial text continued on the next page

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PRIOR AUTHORIZATION GUIDELINES

SOLRIAMFETOL

INITIAL CRITERIA (CONTINUED)

-) Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
-) The patient had a trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil

For the diagnosis of excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval requires:

-) Physician attestation that OSA is confirmed by polysomnography, home sleep apnea testing devices, or hospital-based bedside monitoring
-) Physician attestation of Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
-) The patient had a trial of or contraindication to modafinil or armodafinil
-) Physician attestation that the patient is on ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and have been counseled on weight-loss intervention (if BMI > 30)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA) **AND** meet the following criterion?
 -) Physician attestation that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline

If yes, **approve for 12 months by HICL with a quantity limit of #30 per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **SOLRIAMFETOL (Sunosi)** requires a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy or obstructive sleep apnea (OSA). In addition, the following must be met:

-) Physician attestation of sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sunosi.

REFERENCES

-) Sunosi [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/01/19

Created: 07/19

Client Approval: 07/19

P&T Approval: 10/19



APOMORPHINE

Generic	Brand	HICL	GCN	Exception/Other
APOMORPHINE	APOKYN		42078	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of advanced Parkinson's disease and meet **ALL** of the following criteria?

-) Apokyn is being used for the acute, intermittent treatment of hypomobility, OFF episodes associated with advanced Parkinson's disease
-) Therapy is prescribed by or in consultation with a neurologist
-) The physician has optimized drug therapy as evidenced by **BOTH** of the following:
 - o Change in levodopa/carbidopa dosing strategy or formulation
 - o Trial of or contraindication to at least **TWO** Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

If yes, **approve for 6 months by GPID (42078) with a quantity limit of #60mL (20 cartridges) per month.**

APPROVAL TEXT: Renewal requires physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **APOMORPHINE (Apokyn)** requires a diagnosis of advanced Parkinson's disease. In addition, the following criteria must be met:

-) Apokyn is being used for the acute, intermittent treatment of hypomobility, OFF episodes associated with advanced Parkinson's disease
-) Therapy is prescribed by or in consultation with a neurologist
-) The physician has optimized drug therapy as evidenced by **BOTH** of the following:
 - o Change in levodopa/carbidopa dosing strategy or formulation
 - o Trial of or contraindication to at least **TWO** Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

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APOMORPHINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of advanced Parkinson's disease **AND** meet the following criterion?
-) Physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

If yes, **approve for 12 months by GPID (42078) with a quantity limit of #60mL (20 cartridges) per month.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **APOMORPHINE (Apokyn)** requires a diagnosis of advanced Parkinson's disease. In addition, the following must be met:

-) Physician attestation of patient improvement with motor fluctuations during OFF episodes with the use of Apokyn (e.g., improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Apokyn.

REFERENCES

-) Apokyn [Prescribing Information]. Louisville, KY: US WorldMeds, LLC, March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/01/19

Created: 11/04

Client Approval: 07/19

P&T Approval: 04/19

PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

Generic	Brand	HICL	GCN	Exception/Other
DEFLAZACORT	EMFLAZA	11668		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and meet **ALL** of the following criteria?

- ☐ Patient is 2 years of age or older
- ☐ Documented genetic testing confirming Duchenne muscular dystrophy (DMD) diagnosis
- ☐ Prescribed by or given in consultation with a neurologist specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient tried prednisone or prednisolone for at least 6 months?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Is the request for Emflaza due to lack of efficacy with prednisone or prednisolone and **ALL** of the following criteria are met?

- ☐ Patient is not in Stage 1: pre-symptomatic phase
- ☐ Steroid myopathy has been ruled out
- ☐ Documented deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone, using standard measures over time, consistent with advancing disease (stage 2 or higher); Acceptable standard measures: [such as 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA), pulmonary function (FVC, PFTs), upper limb strength (propelling a wheelchair 30 feet)]

If yes, **approve for 6 months by GPID for all the following strengths with the following quantity limits:**

(Initial approval directions continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

If yes, **approve for 6 months by GPID for all the following strengths with the following quantity limits:**

-] 6mg tablet (GPID 23761): #60 per 30 days
-] 18mg tablet (GPID 43012): #30 per 30 days
-] 30mg tablet (GPID 23762): #60 per 30 days
-] 36mg tablet (GPID 43015): #60 per 30 days
-] 22.75mg/mL oral suspension (GPID 43016): #39mL (3 bottles) per 30 days

If no, continue to #4.

4. Is the patient experiencing an adverse consequence of prednisone or prednisolone and is the adverse consequence named or listed in the prescribing information adverse event profile of Emflaza?

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #5.

5. Has documentation of literature-based evidence been provided supporting the mitigating effect of Emflaza for the named adverse consequence?

If yes, **approve for 6 months by GPID for all the following strengths with the following quantity limits:**

-] 6mg tablet (GPID 23761): #60 per 30 days
-] 18mg tablet (GPID 43012): #30 per 30 days
-] 30mg tablet (GPID 23762): #60 per 30 days
-] 36mg tablet (GPID 43015): #60 per 30 days
-] 22.75mg/mL oral suspension (GPID 43016): #39mL (3 bottles) per 30 days

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **DEFLAZACORT (Emflaza)** requires a diagnosis of Duchenne muscular dystrophy (DMD) and that all of the following criteria are met:

-) Patient is 2 years of age or older
-) Documented genetic testing confirming Duchenne muscular dystrophy (DMD) diagnosis
-) Prescribed by or given in consultation with a neurologist specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
-) Trial of prednisone or prednisolone for at least 6 months and one of the following:
 - o Request due to lack of efficacy with prednisone or prednisolone and all of the following criteria are met:
 - Patient is not in Stage 1: pre-symptomatic phase
 - Steroid myopathy has been ruled out
 - Documented deterioration in ambulation, functional status, or pulmonary function while on prednisone or prednisolone, using standard measures over time, consistent with advancing disease (stage 2 or higher); Acceptable standard measures: [such as 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA), pulmonary function (FVC, PFTs), upper limb strength (propelling a wheelchair 30 feet)]
 - o Request due to adverse consequence while on prednisone or prednisolone and documentation of literature-based evidence has been provided citing and supporting the mitigating effect of Emflaza for the named adverse consequence
 - Requests due to adverse consequences while on prednisone or prednisolone that is named or listed in the prescribing information of Emflaza will not be approved

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) and is currently ambulatory?

If yes, continue to #2.

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES**DEFLAZACORT****RENEWAL CRITERIA (CONTINUED)**

2. Has the patient shown function, stabilization or improvement in a standard set of ambulatory or functional status measures since being on Emflaza that are being monitored, tracked, and documented consistently; Acceptable standard measures: [such as 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA)]?

If yes, **approve for 12 months by GPID for all the following strengths with the following quantity limits:**

-] 6mg tablet (GPID 23761): #60 per 30 days
-] 18mg tablet (GPID 43012): #30 per 30 days
-] 30mg tablet (GPID 23762): #60 per 30 days
-] 36mg tablet (GPID 43015): #60 per 30 days
-] 22.75mg/mL oral suspension (GPID 43016): #39mL (3 bottles) per 30 days

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient non-ambulatory and has the patient maintained or demonstrated a less than expected decline in pulmonary function and/or upper limb strength assessed by standard measures since being on Emflaza, that are being monitored, tracked and documented consistently; Acceptable standard measures: pulmonary function (FVC, PFTs), upper limb strength measures (propelling a wheelchair 30 feet), Physician Global assessments (PGA)?

If yes, **approve for 12 months by GPID for all the following strengths with the following quantity limits:**

-] 6mg tablet (GPID 23761): #60 per 30 days
-] 18mg tablet (GPID 43012): #30 per 30 days
-] 30mg tablet (GPID 23762): #60 per 30 days
-] 36mg tablet (GPID 43015): #60 per 30 days
-] 22.75mg/mL oral suspension (GPID 43016): #39mL (3 bottles) per 30 days

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

DEFLAZACORT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **DEFLAZACORT (Emflaza)** requires a diagnosis of Duchenne muscular dystrophy (DMD) and one of the following criteria are met:

) **For patient who are currently ambulatory, approval requires:**

- Patient has shown function, stabilization or improvement in a standard set of ambulatory or functional status measures since being on Emflaza, that are being monitored, tracked, and documented consistently; Acceptable standard measures: [such as 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA)]

) **For patient who are currently non-ambulatory, approval requires:**

- Patient has maintained or demonstrated a less than expected decline in pulmonary function and/or upper limb strength assessed by standard measures since being on Emflaza that are being monitored, tracked, and documented consistently; Acceptable standard measures: pulmonary function (FVC, PFTs), upper limb strength measures (propelling a wheelchair 30 feet), Physician Global assessments (PGA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Emflaza.

REFERENCES

) Emflaza [Prescribing Information]. Northbrook, IL: Marathon Pharmaceuticals. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/22/19

Created: 02/17

Client Approval: 07/19

P&T Approval: 07/19

**PRIOR AUTHORIZATION GUIDELINES
SAXENDA**

Generic	Brand	HICL	GCN	Exception/Other
LIRAGLUTIDE	SAXENDA		37637	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Is the request for weight loss or weight management and does the patient meet **ALL** of the following criteria?
 - The patient has **ONE** of the following:
 - Body mass index (BMI) of 30 kg/m² or greater **OR**
 - BMI of 27 kg/m² or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
 - Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient meet **ALL** of the following criteria?
 - The patient is **NOT** currently taking a GLP-1 receptor agonist (e.g., Victoza, Byetta, Bydureon, Tanzeum)
 - The patient is 18 years of age or older

If yes, **approve for 4 months by GPID (37637) with a quantity limit of #15mL per 30 days.**

APPROVAL TEXT: Renewal for Saxenda requires the patient has lost at least 4% of baseline body weight after 4 months of treatment.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

INITIAL DENIAL TEXT: The guideline named **Saxenda (liraglutide)** requires an indication of weight loss or weight management. In addition, the following criteria must be met:

- The patient has **ONE** of the following:
 - Body mass index (BMI) of 30 kg/m² or greater **OR**
 - BMI of 27 kg/m² or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
- Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
- The patient is **NOT** currently taking a GLP-1 receptor agonist (e.g., Victoza, Byetta, Bydureon, Tanzeum)
- The patient is 18 years of age or older

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**PRIOR AUTHORIZATION GUIDELINES
SAXENDA****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Is the request for weight loss or weight management?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet the following criterion?

- The patient lost at least 4% of baseline body weight after 4 months of treatment

If yes, **approve for 12 months by GPID (37637) with a quantity limit of #15mL per 30 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline named **Saxenda (liraglutide)** requires an indication of weight loss or weight management. In addition, the following criteria must be met:

- The patient lost at least 4% of baseline body weight after 4 months of treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the requested Anti-Obesity agent.

Created	FS Committee Approval	Effective
7/5/2019		

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

Created: 07/19

Effective: 08/01/19

Client Approval: 07/08/19

P&T Approval: N/A



TRASTUZUMAB-ANNS (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB-ANNS	KANJINTI	45796		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
 -) The request is for adjuvant therapy
 -) The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
 -) The patient meets **ONE** of the following:
 - o Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - o Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - o Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 -) The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
 -) The patient meets **ONE** of the following:
 - o Requested medication is being used in combination with paclitaxel for first-line treatment
 - o The requested medication is being used as a single agent in a patient who has previously received **ONE** or more chemotherapy regimens for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
 -) The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
 -) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 -) The patient has not received prior treatment for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, do not approve.

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TRASTUZUMAB-ANNS (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **TRASTUZUMAB-ANNS (Kanjinti)** requires one of the following diagnoses and associated criteria:

For the diagnosis of breast cancer, approval requires:

-) The request is for adjuvant therapy
-) The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
-) The patient meets **ONE** of the following:
 - o Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - o Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - o Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

For the diagnosis of metastatic breast cancer, approval requires:

-) The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
-) The patient meets ONE of the following:
 - o Requested medication is being used in combination with paclitaxel for first-line treatment
 - o The requested medication is being used as a single agent in a patient who has previously received ONE or more chemotherapy regimens for metastatic disease

For the diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:

-) The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
-) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
-) The patient has not received prior treatment for metastatic disease

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kanjinti.

REFERENCES

-) Kanjinti [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; July 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/12/19

Created: 07/19

Client Approval: 07/19

P&T Approval: 07/19

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ASPIRIN-OMEPRAZOLE

Generic	Brand	HICL	GCN	Exception/Other
ASPIRIN-OMEPRAZOLE	YOSPRALA, ASPIRIN-OMEPRAZOLE	43771		

GUIDELINES FOR USE

1. Does the patient require aspirin for secondary prevention of cardiovascular or cerebrovascular events and have **ONE** of the following diagnoses?

- ☐ Ischemic stroke
- ☐ Transient ischemia of the brain due to fibrin platelet emboli
- ☐ Previous myocardial infarction
- ☐ Unstable angina pectoris
- ☐ Chronic stable angina pectoris
- ☐ Previously undergone revascularization procedures (i.e., coronary artery bypass graft, percutaneous transluminal coronary angioplasty)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a risk of developing aspirin associated gastrointestinal (GI) ulcers and meet **ALL** of the following criteria?

- ☐ The patient is 55 years of age or older
- ☐ Documented history of gastrointestinal (GI) ulcers

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient tried **ALL** of the following medications?

- ☐ Aspirin over-the-counter (OTC)
- ☐ Generic proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, or rabeprazole)

If yes, **approve for 12 months by HICL (43771) with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**ASPIRIN-OMEPRAZOLE****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: The guideline named **ASPIRIN-OMEPRAZOLE (Yosprala)** requires that Aspirin request is for secondary prevention of cardiovascular or cerebrovascular events in a patient with a diagnosis of Ischemic stroke, transient ischemia of the brain due to fibrin platelet emboli, previous myocardial infarction, unstable angina pectoris, chronic stable angina pectoris, or previously undergone revascularization procedures (i.e., coronary artery bypass graft, percutaneous transluminal coronary angioplasty). In addition, the following criteria must be met:

-) The patient has a risk of developing aspirin associated gastrointestinal (GI) ulcers due to age (55 years or older) **AND** documented history of gastrointestinal (GI) ulcers
-) The patient has tried both aspirin over-the-counter (OTC) **AND** generic proton pump inhibitors (e.g., omeprazole, lansoprazole, pantoprazole, or rabeprazole)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yosprala.

REFERENCES

-) Yosprala [Prescribing Information]. Princeton, NJ: Aralez Pharmaceuticals US Inc. June 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/12/19

Created: 05/19

Client Approval: 07/19

P&T Approval: 11/16

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
BEVACIZUMAB-AWWB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BEVACIZUMAB-AWWB	MVASI	44500		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) **AND** meet the following criterion?
 - The requested medication is being used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment

If yes, **approve for 12 months by HICL.**
 If no, continue to #2.
- Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
 - The requested medication is being used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment
 - The patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL.**
 If no, continue to #3.
- Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
 - The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment

If yes, **approve for 12 months by HICL.**
 If no, continue to #4.
- Does the patient have a diagnosis of recurrent glioblastoma (GBM) **AND** is 18 years or older?

If yes, **approve for 12 months by HICL.**
 If no, continue to #5.

CONTINUED ON NEXT PAGE

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
BEVACIZUMAB-AWWB (NSA)
GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) **AND** meet the following criterion?

) The requested medication is being used in combination with interferon-alfa

 If yes, **approve for 12 months by HICL.**

 If no, continue to #6.

6. Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer **AND** meet the following criterion?

) The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

 If yes, **approve for 12 months by HICL.**

 If no, do not approve.

DENIAL TEXT: The guideline named **BEVACIZUMAB-AWWB (Mvasi)** requires a diagnosis of **ONE** of the following:

) **Metastatic colorectal cancer (mCRC)** and meet **ONE** of the following:

- The requested medication is being used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
- The requested medication is being used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CAPeOX) based chemotherapy as a second-line treatment **AND** the patient has progressed on a first-line bevacizumab product-containing regimen

) **Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC)** in combination with carboplatin and paclitaxel for first-line treatment

) **Recurrent glioblastoma (GBM)** **AND** patient is 18 years or older

) **Metastatic renal cell carcinoma (mRCC)** in combination with interferon-alfa

) **Persistent, recurrent, or metastatic cervical cancer**, in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mvasi.

REFERENCES

) Mvasi [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; July 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/12/19

Created: 07/19

Client Approval: 07/19

P&T Approval: 10/17

PRIOR AUTHORIZATION GUIDELINES

BREMELANOTIDE

Generic	Brand	HICL	GCN	Exception/Other
BREMELANOTIDE	VYLEESI	45878		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Vyleesi (bremelanotide) a covered benefit?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?

- ☐ Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- ☐ HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- ☐ HSDD symptom causes marked distress or interpersonal difficulty

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?

- ☐ The patient is a premenopausal female
- ☐ The patient is 18 years of age or older
- ☐ The patient had a previous trial of or contraindication to bupropion
- ☐ The patient is **NOT** currently using Addyi (flibanserin)

If yes, **approve for 8 weeks by HICL with a quantity limit of #2.4mL per month.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES**BREMELANOTIDE****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: The guideline named **BREMELANOTIDE (Vyleesi)** requires a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria:

- ✓ Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- ✓ HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- ✓ HSDD symptom causes marked distress or interpersonal difficulty

The following criteria must also be met for approval:

- ✓ The patient is a premenopausal female
- ✓ The patient is 18 years of age or older
- ✓ The patient had a previous trial of or contraindication to bupropion
- ✓ The patient is **NOT** currently using Addyi (flibanserin)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?

- ✓ Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- ✓ HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- ✓ HSDD symptom causes marked distress or interpersonal difficulty

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?

- ✓ The patient is a premenopausal female
- ✓ The patient is **NOT** currently using Addyi (flibanserin)
- ✓ Physician attestation that the patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

If yes, **approve for 6 months by HICL with a quantity limit of #2.4mL per month.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES**BREMELANOTIDE****RENEWAL CRITERIA (CONTINUED)**

RENEWAL DENIAL TEXT: The guideline named **BREMELANOTIDE (Vyleesi)** requires a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria:

-) Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
-) HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
-) HSDD symptom causes marked distress or interpersonal difficulty

The following criteria must also be met for approval:

-) The patient is a premenopausal female
-) The patient is **NOT** currently using Addyi (flibanserin)
-) Physician attestation that the patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyleesi.

REFERENCES

-) Vyleesi [Prescribing Information]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/26/19

Created: 08/19

Client Approval: 08/19

P&T Approval: 07/19

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE

Generic	Brand	HICL	GCN	Exception/Other
CLADRIBINE	MAVENCLAD		44338	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) **AND** meet the following criterion?

☐ The patient is 18 years of age or older

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?

☐ The patient had a previous trial of **ONE** agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** other MS agents may also require prior authorization)

☐ Physician attestation that the patient shows signs of severe disease requiring high-efficacy disease modifying therapy (DMT) (e.g., high lesion volume and/or count, walking disability, or rapid decline)

If yes, **approve for 48 weeks by GPID for the requested quantity up to a maximum quantity limit of #20 tablets for 1 fill (NOTE: If the requested quantity is less than or equal to 10 tablets, please enter a proactive PA for 48 weeks by GPID with a maximum quantity limit of #10 tablets for 1 fill to cover the second cycle).**

APPROVAL TEXT: Renewal requires 1) physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline, 2) the patient does not have lymphopenia, and 3) the patient has not received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **CLADRIBINE (Mavenclad)** requires a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.). In addition, the following criteria must be met:

☐ The patient is 18 years of age or older

☐ The patient meets ONE of the following:

- The patient had a previous trial of **ONE** agent indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Tecfidera)
- Physician attestation that the patient shows signs of severe disease requiring high-efficacy disease modifying therapy (DMT) (e.g., high lesion volume and/or count, walking disability, or rapid decline)

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**CLADRIBINE****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Has the patient received a total of two years of Mavenclad treatment (i.e., two treatment cycles divided into 2 yearly treatment courses)?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

If no, continue to #3.

3. Does the patient meet **ALL** of the following criteria?

-) Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
-) The patient does not have lymphopenia

If yes, **approve for 48 weeks by GPID for the requested quantity up to a maximum quantity limit of #20 tablets for 1 fill (NOTE: If the requested quantity is less than or equal to 10 tablets, please enter a proactive PA for 48 weeks by GPID with a maximum quantity limit of #10 tablets for 1 fill to cover the second cycle).**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **CLADRIBINE (Mavenclad)** requires a diagnosis of relapsing forms of multiple sclerosis (MS) (e.g. relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.) AND the patient has not received a total of two years of Mavenclad treatment. In addition, the following criteria must be met:

-) Physician attestation that the patient has demonstrated a clinical benefit compared to pre-treatment baseline
-) The patient does not have lymphopenia

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

CLADRIBINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mavenclad.

REFERENCES

) Mavenclad [Prescribing Information]. Rockland, MA: EMD Serono, Inc., March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/12/19

Created: 04/19

Client Approval: 05/19

P&T Approval: 04/19



PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
DARATUMUMAB	DARZALEX	42814		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient at least 18 years old?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See denial text at the end of guideline.

2. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?

-) The patient has received at least three prior therapies, including agents from **BOTH** of the following drug classes:
 - o Proteasome inhibitors (PI): bortezomib (Velcade), carfilzomib (Kymprolis), ixazomib (Ninlaro)
 - o Immunomodulatory agents: lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)
-) The requested medication will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?

-) The patient is refractory to both a proteasome inhibitor (PI) (bortezomib (Velcade), carfilzomib (Kymprolis), or ixazomib (Ninlaro)) **AND** an immunomodulatory agent (lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid))
-) The requested medication will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?

-) The patient has received at least one prior therapy
-) The requested medication will be used in combination with lenalidomide and dexamethasone

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

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PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a new diagnosis of multiple myeloma and meet **ALL** of the following criteria?
-) The patient is ineligible for autologous stem cell transplant
 -) The requested medication will be used in combination with lenalidomide and dexamethasone

If yes, **approve for 12 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
-) The patient has received at least one prior therapy
 -) The requested medication will be used in combination with bortezomib and dexamethasone

If yes, **approve for 12 months by HICL.**

If no, continue to #7.

7. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
-) The patient has received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI) (bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro))
 -) The requested medication will be used in combination with pomalidomide and dexamethasone

If yes, **approve for 12 months by HICL.**

If no, continue to #8.

8. Does the patient have a new diagnosis of multiple myeloma and meet **ALL** of the following criteria?
-) The patient is ineligible for autologous stem cell transplant
 -) The requested medication will be used in combination with bortezomib (Velcade), melphalan and prednisone [VMP]

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See denial text at the end of guideline.

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PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **DARATUMUMAB (Darzalex)** requires a diagnosis of multiple myeloma and that the patient is at least 18 years old. In addition, at least **ONE** of the following criteria must also be met:

-) The patient has received at least three prior therapies, including a proteasome inhibitor (PI) and an immunomodulatory agent **AND** will receive daratumumab as monotherapy
-) The patient is refractory to both a proteasome inhibitor (PI) and an immunomodulatory agent **AND** will receive daratumumab as monotherapy
-) The patient has relapsed or refractory multiple myeloma and received at least one prior therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
-) The patient has received at least one prior therapy **AND** will receive daratumumab in combination with bortezomib and dexamethasone
-) The patient has newly diagnosed multiple myeloma and is ineligible for autologous stem cell transplant **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
-) The patient has received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone
-) The patient is newly diagnosed with multiple myeloma, ineligible for autologous stem cell transplant, **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone

Proteasome inhibitors include: bortezomib, carfilzomib, or ixazomib; immunomodulatory agents include: lenalidomide, pomalidomide, or thalidomide.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Darzalex.

REFERENCES

-) Darzalex [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; June 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/12/19

Created: 12/15

Client Approval: 07/19

P&T Approval: 07/19



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC)?

If yes, **approve for 12 months by HICL with a quantity limit of 4 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **DAROLUTAMIDE (Nubeqa)** requires a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC).

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/9/19

Created: 08/19

Client Approval: 10/19

P&T Approval: 10/19



PRIOR AUTHORIZATION GUIDELINES

HYALURONATE

Generic	Brand	HICL	GCN	Exception/Other
HYALURONATE SODIUM	EUFLEXXA, ORTHOVISC		21448, 32121,	ROUTE = INTRAARTIC BRAND GENVISC 850, SUPARTZ FX
HYALURONATE SODIUM, STABILIZED	MONOVISC	39477		BRAND DUROLANE

GUIDELINES FOR USE

1. Has the patient received previous treatment on the same knee with Synvisc, Synvisc-One, Hyalgan, Euflexxa, Supartz, Gel-One, Monovisc, Orthovisc, Hymovis, OR Gelsyn-3?

If yes, continue to #3.

If no, continue to #2.

2. For Euflexxa, Monovisc or Orthovisc, does the patient have a diagnosis of osteoarthritis of the knee and meets **ALL** of the following criteria?

-) The patient is at least 21 years of age
-) The patient has failed a minimum of a 6-week trial of non-pharmacologic therapy such as education, exercise, use of insoles or braces, weight reduction and physical therapy
-) The patient had a previous trial of intra-articular steroids

If yes, **approve for 6 months by GPID with the following quantity limits per affected knee:**

-) **Euflexxa - 6 mL (3 syringes)**
-) **Monovisc - 4 mL (1 syringe)**
-) **Orthovisc - 8 mL (4 syringes)**

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES

HYALURONATE

GUIDELINES FOR USE (CONTINUED)

3. Has it been at least 6 months since the last treatment with this agent?

If yes, **approve for 6 months by GPID with the following quantity limits per affected knee:**

-) **Euflexxa - 6 mL (3 syringes)**
-) **Monovisc - 4 mL (1 syringe)**
-) **Orthovisc - 8 mL (4 syringes)**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**HYALURONATE****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: The guideline named **HYALURONATE** requires a diagnosis of osteoarthritis of the knee. In addition, the following criteria must also be met for Euflexxa, Monovisc or Othovisc:

-) The patient is at least 21 years of age
-) The patient has failed a minimum of a 6-week trial of non-pharmacologic therapy such as education, exercise, use of insoles or braces, weight reduction and physical therapy
-) The patient had a previous trial of intra-articular steroids

For Gel-One, Gelsyn-3, Hyalgan, Hymovis, Supartz, Synvisc or Synvisc-One:

-) The patient is at least 21 years of age
-) The patient has failed a minimum of a 6-week trial of non-pharmacologic therapy such as education, exercise, use of insoles or braces, weight reduction and physical therapy
-) The patient had a previous trial of intra-articular steroids
-) Previous trial or contraindication to one of the following preferred formulary agents: Euflexxa, Monovisc or Orthovisc.

For patients who have been previously treated on the same knee with Synvisc, Synvisc-One, Hyalgan, Euflexxa, Supartz, Gel-One, Monovisc, Orthovisc, Hymovis, or Gelsyn-3 approval requires:

-) At least 6 months since the last treatment has been received

RATIONALE

Ensure appropriate use of hyaluronic acids in the treatment of osteoarthritis.

FDA APPROVED INDICATIONS

Euflexxa, Orthovisc, and Monovisc are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen.

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PRIOR AUTHORIZATION GUIDELINES

HYALURONATE

REFERENCES

-) Anika Therapeutics Inc. Orthovisc Product information. Woburn, MA. June 2006.
-) FDA Approves Monovisc, A New Single Injection Treatment for Treatment of Pain Due to Osteoarthritis of the Knee. Accessed on 4/15/2014 at <http://www.businesswire.com/news/home/20140225007021/en/FDA-Approves-MONOVISC%C2%AE-Single-Injection-Treatment-Treatment>
-) Micromedex® Healthcare Series [database online]. Greenwood Village, CO: Thomson Healthcare. Available at: <http://www.thomsonhc.com/hcs/librarian/>. [Accessed: June 22, 2010].
-) Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2009. Available at: <http://www.clinicalpharmacology.com>. [Accessed: June 22, 2010].
-) Pagnano M, Westrich G. Successful non-operative management of chronic osteoarthritis pain of the knee: safety and efficacy of retreatment with intra-articular hyaluronans. Osteoarthritis Cartilage. 2005; 13(9):751-61.
-) Ferring Pharmaceuticals. Euflexxa product information. Parsippany, NJ. (Revision 9, no date available).
-) Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee. Arthritis and Rheumatism 2000; 43:905-1915.

Created: 10/17; revised 8/2/19

Effective: 08/16/19

Client Approval: 10/06/17

P&T Approval: N/A

PRIOR AUTHORIZATION GUIDELINES

PEXIDARTINIB

Generic	Brand	HICL	GCN	Exception/Other
PEXIDARTINIB	TURALIO	45912		

GUIDELINES FOR USE

- Does the patient have a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) and meet **ALL** of the following criteria?

- ☐ TGCT is associated with severe morbidity or functional limitations
- ☐ TGCT is **NOT** amenable to improvement with surgery
- ☐ The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **PEXIDARTINIB (Turalio)** requires a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT). In addition, the following criteria must be met:

- ☐ TGCT is associated with severe morbidity or functional limitations
- ☐ TGCT is **NOT** amenable to improvement with surgery
- ☐ The patient is 18 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Turalio.

REFERENCES

- ☐ Turalio [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/26/19

Created: 08/19

Client Approval: 08/19

P&T Approval: 07/19



ENTRECTINIB (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
ENTRECTINIB	ROZLYTREK	45952		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient has *ROS1*-positive tumors

If yes, **approve for 12 months by GPID for all strengths as follows:**

- ☐ **Rozlytrek 100mg (GPID 46815): #5 per day.**
- ☐ **Rozlytrek 200mg (GPID 46816): #3 per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of solid tumor and meet **ALL** of the following criteria?

- ☐ The patient is 12 years of age or older
- ☐ The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
- ☐ The tumor is metastatic or surgical resection is likely to result in severe morbidity
- ☐ There are no satisfactory alternative treatments, or the patient has progressed following treatment

If yes, **approve for 12 months by GPID for all strengths as follows:**

- ☐ **Rozlytrek 100mg (GPID 46815): #5 per day.**
- ☐ **Rozlytrek 200mg (GPID 46816): #3 per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENTRECTINIB (Rozlytrek)** requires a diagnosis of metastatic non-small cell lung cancer (NSCLC) or solid tumor. In addition, the following criteria must be met:

For a diagnosis of metastatic non-small cell lung cancer (NSCLC), approval requires:

- ☐ The patient is 18 years of age or older
- ☐ The patient has *ROS1*-positive tumors

For a diagnosis of solid tumor, approval requires:

- ☐ The patient is 12 years of age or older
- ☐ The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
- ☐ The tumor is metastatic or surgical resection is likely to result in severe morbidity
- ☐ There are no satisfactory alternative treatments, or the patient has progressed following treatment

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WELLFLEET

RX PLAN

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ENTRECTINIB (INTERIM)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rozlytrek.

REFERENCES

Rozlytrek [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 8/30/19

Created: 8/19

Client Approval: 10/19

P&T Approval: 10/19

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
FEDRATINIB (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
FEDRATINIB	INREBIC	45953		

GUIDELINES FOR USE

- Does the patient have a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytemia) myelofibrosis (MF) **AND** meet the following criterion?

) The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **FEDRATINIB (Inrebic)** requires a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocytemia) myelofibrosis (MF). In addition, the following must be met:

) The patient is 18 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inrebic.

REFERENCES

Inrebic [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 8/30/19

Created: 8/19

Client Approval: 10/19

P&T Approval: 10/19

PRIOR AUTHORIZATION GUIDELINES
GLATIRAMER ACETATE

Generic	Brand	HICL	GCN	Exception/Other
GLATIRAMER ACETATE	COPAXONE, GLATOPA	12810		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion?

) The patient is 18 years of age or older

 If yes, **approve for 12 months by GPID with the following quantity limits:**

) **Glatiramer acetate 20mg/mL: #1mL per day.**

) **Glatiramer acetate 40mg/mL: #12 syringes per 28 days.**

 If no, do not approve.

DENIAL TEXT: The guideline named **GLATIRAMER ACETATE (Copaxone/Glatopa)** requires a diagnosis of a relapsing form of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. The following must also be met:

) The patient is 18 years of age or older

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Copaxone/Glatopa.

REFERENCES

-) Copaxone [Prescribing Information]. Overland Park, KS: Teva; July 2019.
-) Glatopa [Prescribing Information], Princeton, NJ: Sandoz Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/09/19

Created: 02/14

Client Approval: 08/19

P&T Approval: 02/14

PRIOR AUTHORIZATION GUIDELINES

LEFAMULIN

Generic	Brand	HICL	GCN	Exception/Other
LEFAMULIN	XENLETA		46826	

GUIDELINES FOR USE

- Does the patient have a diagnosis of community-acquired bacterial pneumonia (CABP) and meet **ALL** of the following criteria?
 -) The patient is 18 years of age or older
 -) Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydia pneumoniae*

If yes, continue to #2.
 If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
- Is therapy prescribed by or given in consultation with an Infectious Disease (ID) specialist?

If yes, **approve Xenleta 600mg tablet for one fill by GPID (46826) with a quantity limit of #10 tablets per 5 days.**
 If no, continue to #3.
- Have antimicrobial susceptibility tests been performed that meet **ALL** of the following criteria?
 -) The results from the infection site culture indicate pathogenic organism(s) with **resistance** to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)
 -) The results from the infection site culture indicate pathogenic organism(s) with susceptibility to Xenleta

If yes, **approve Xenleta 600mg tablet for one fill by GPID (46826) with a quantity limit of #10 tablets per 5 days.**
 If no, continue to #4.
- Does the patient meet **ALL** of the following criteria?
 -) Antimicrobial susceptibility results are unavailable
 -) The patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

If yes, **approve Xenleta 600mg tablet for one fill by GPID (46826) with a quantity limit of #10 tablets per 5 days.**
 If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**LEFAMULIN****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: The guideline named **LEFAMULIN (Xenleta)** requires a diagnosis of community-acquired bacterial pneumonia (CABP). In addition, the following criteria must be met:

-) The patient is 18 years of age or older
-) Infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *Chlamydia pneumoniae*
-) The patient meets **ONE** of the following criteria:
 - o Therapy is prescribed by or given in consultation with an Infectious Disease (ID) specialist
 - o Antimicrobial susceptibility test is available, and the infection site culture results indicate pathogenic organism(s) with 1) resistance to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid), **AND** 2) the culture is susceptible to Xenleta
 - o Antimicrobial susceptibility test is unavailable, and the patient has had a trial of or contraindication to at least **TWO** standard of care agents for CABP (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xenleta.

REFERENCES

-) Xenleta [Prescribing Information]. Ireland DAC: Nabriva Therapeutics US, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/09/19

Created: 08/19

Client Approval: 08/19

P&T Approval: 07/19



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

Yes	Yes	No
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Part D Effective: N/A

Commercial Effective: 09/06/19

Created: 05/19

Client Approval: 05/19

P&T Approval: 04/19

USTEKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB	STELARA	36187		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient has had a previous trial of at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
-) The patient is 12 years of age or older
-) Documentation of the patient's current weight

If yes, **approve for a total of 6 months by GPID as follows:**

Patients weighing 100kg (220 lbs) or less:

Enter both of the following approvals:

-) **Loading dose:** Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.
-) **Maintenance dose:** Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.

Patients weighing over 100kg (220 lbs):

Enter both of the following approvals:

-) **Loading dose:** Approve for 1 month with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 28 days for 1 fill.
-) **Maintenance dose:** Approve for 5 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days for 2 fills with a start date after the end date of the previous fill.

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis **OR** moderate to severe PsO with co-existent psoriatic arthritis requires that the patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more **AND** documentation of the patient's current weight.

If no, continue to #2.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- ☐ Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - ☐ The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - ☐ The patient is 18 years of age or older

If yes, **approve for a total of 6 months by GPID as follows:**

- ☐ **Loading dose: Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.**
- ☐ **Maintenance dose: Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

3. Does the patient have a diagnosis of moderately to severely active Crohn's disease (CD) and meet **ALL** of the following criteria?
- ☐ Therapy is prescribed by or given in consultation with a gastroenterologist
 - ☐ The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - ☐ The patient is 18 years of age or older
 - ☐ Documentation of the patient's current weight

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #5.

If no, **approve maintenance dose for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

APPROVAL TEXT: Stelara subcutaneous has been approved for 6 months for maintenance treatment. Stelara intravenous loading dose is excluded from your pharmacy benefit coverage.

5. Has the patient **already received** the intravenous loading dose of Stelara for the treatment of moderately to severely active Crohn's disease (CD)?

If yes, **approve for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

If no, **enter two approvals for a total of 6 months by GPID as follows:**

First approval - Please enter one of the following loading doses based on the patient's weight (NOTE: Do not enter a loading dose if the member does not have coverage for non-self-administered drug benefit. Please deny for benefit exclusion.):

Patients weighing 55kg (121 lbs.) or less:

) **Loading dose: Approve for 2 months by GPID with a quantity limit of 52mL (two 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 55kg up to 85kg (122 lbs. up to 187 lbs.):

) **Loading dose: Approve for 2 months by GPID with a quantity limit of 78mL (three 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 85kg (187 lbs.):

) **Loading dose: Approve for 2 months by GPID with a quantity limit of 104mL (four 130mg/26mL vials) per 56 days for 1 fill.**

Second approval:

) **Maintenance dose: Approve for 4 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 2 fills with a start date after the end date of the previous fill.**

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of moderate to severe plaque psoriasis, **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, psoriatic arthritis without co-existent plaque psoriasis, or moderately to severely active Crohn's disease. In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval requires all of the following criteria:

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient has had a previous trial of at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
-) The patient is 12 years of age or older
-) Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval requires all of the following criteria:

-) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 18 years of age or older

For patients with moderately to severely active Crohn's disease (CD), approval requires all of the following criteria:

-) Therapy is prescribed by or given in consultation with a gastroenterologist
-) The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
-) The patient is 18 years of age or older
-) Documentation of the patient's current weight

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

If yes, **approve for 12 months by GPID with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

If no, continue to #2.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
-) The patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
 -) Documentation of the patient's current weight

If yes, **approve for 12 months by GPID as follows:**

Patients weighing 100kg (220 lbs.) or less:

-) **Approve for 12 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

Patients weighing over 100kg (220 lbs.):

-) **Approve for 12 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of moderately to severely active Crohn's disease (CD)?

If yes, **approve for 12 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of psoriatic arthritis without co-existent plaque psoriasis, moderate to severe plaque psoriasis **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, or moderately to severely active Crohn's disease. The following criteria must also be met:

-) **Renewal for the diagnosis of psoriatic arthritis without co-existent plaque psoriasis** requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
-) **Renewal for the diagnosis of moderate to severe plaque psoriasis OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis** requires that the patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more **AND** documentation of the patient's current weight.

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USTEKINUMAB

RATIONALE

Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of Stelara.

FDA APPROVED INDICATIONS

Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of:

-) Adult patients with:
 - Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
 - Psoriatic arthritis (PsA), alone or in combination with methotrexate
 - Moderately to severely active Crohn's disease (CD) who have
 - Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or
 - Failed or were intolerant to treatment with one or more TNF blockers
-) Adolescent patients (12 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.

DOSAGE AND ADMINISTRATION**Psoriasis Adult Subcutaneous Recommended Dosage:**

-) For patients weighing 100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
-) For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

For adolescent patients (12 years and older) Subcutaneous Recommended Dosage:

Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

-) Less than 60 kg: 0.75 mg/kg
-) 60 kg to 100 kg: 45 mg
-) Greater than 100 kg: 90 mg

Psoriatic Arthritis

-) The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
-) For patients with co-existent moderate-to-severe plaque psoriasis weighing >100kg (220 lbs), the recommended dose is 90mg initially and 4 weeks later, followed by 90mg every 12 weeks.

Crohn's Disease

-) Intravenous Induction Adult Dosage Regimen: A single intravenous infusion dose using the weight-based dosage regimen specified in Table 1.

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USTEKINUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Table 1. Initial Intravenous Dosage of Stelara

Body weight of patient at the time of dosing	Dose	Number of 130 mg/26 mL (5 mg/mL) vials
55 kg	260 mg	2
>55 – 85 kg	390 mg	3
> 85 kg	520 mg	4

-) Subcutaneous Maintenance Adult Dosage Regimen: The recommended maintenance dosage is a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

REFERENCES

-) Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. February 2018.

Created	FS Committee Approval	Effective
5/2019; revised 8/2019	8/19	9/15/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ACLIDINIUM – FORMOTEROL (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
ACLIDINIUM BROMIDE/ FORMOTEROL FUMARATE	DUAKLIR PRESSAIR	41692		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic obstructive pulmonary disease (COPD) **AND** meet the following criterion?

) Duaklir will be used as a maintenance treatment

If yes, **approve for 12 months by HICL with a quantity limit of #1 inhaler per 30 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ACLIDINIUM – FORMOTEROL (Duaklir Pressair)** requires a diagnosis of chronic obstructive pulmonary disease (COPD). In addition, the following must be met:

) Duaklir will be used as maintenance treatment

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duaklir Pressair.

REFERENCES

Duaklir Pressair [Prescribing Information]. Morrisville, NC: Circassia Pharmaceuticals, Inc.; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/4/19

Created: 9/19

Client Approval: 10/19

P&T Approval: 10/19

BRODALUMAB

Generic	Brand	HICL	GCN	Exception/Other
BRODALUMAB	SILIQ	44102		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a dermatologist
- ☐ The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- ☐ The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- ☐ The patient is 18 years of age or older
- ☐ The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
- ☐ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara SC, or Tremfya [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by entering TWO approvals by HICL as follows:**

- ☐ **FIRST APPROVAL:** approve for 1 month with a quantity limit of #4.5mL (#3 210mg/1.5mL syringes)
- ☐ **SECOND APPROVAL:** approve for 5 months with a quantity limit of #3mL (#2 210mg/1.5mL syringes) per 28 days (Please enter a start date of 1 WEEK AFTER the END date of the first approval)

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more, and that the patient has not developed or reported worsening depressive symptoms or suicidal ideation and behaviors while on treatment with Siliq.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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BRODALUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **BRODALUMAB (Siliq)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient had a previous trial of or contraindication to at least **ONE** or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
-) The patient is 18 years of age or older
-) The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
-) The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara SC, or Tremfya.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criteria?
 -) The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
 -) The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors

If yes, **approve for 12 months by HICL with a quantity limit of #3mL (#2 210mg/1.5mL syringes) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **BRODALUMAB (Siliq)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) for renewal. The following criteria must also be met:

-) The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
-) The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors while on treatment with Siliq

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BRODALUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Siliq.

REFERENCES

) Siliq [Prescribing Information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2017.

Created	FS Committee Approval	Effective
8/1/19	08/19	9/15/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

Generic	Brand	HICL	GCN	Exception/Other
ETANERCEPT	ENBREL	18830		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - ☐ Therapy is prescribed by or given in consultation with a rheumatologist
 - ☐ The patient is 18 years of age or older
 - ☐ The patient meets one of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

If yes, **approve for 6 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

- Does the patient have moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
 - ☐ Therapy is prescribed by or given in consultation with a rheumatologist
 - ☐ The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - ☐ The patient is 2 years of age or older

If yes, **approve for 6 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- ☐ Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - ☐ The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - ☐ The patient is 18 years of age or older

If yes, **approve for 6 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
 - ☐ The patient is 18 years of age or older

If yes, **approve for 6 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- ☐ Therapy is prescribed by or given in consultation with a dermatologist
 - ☐ The patient has plaque psoriasis involving at least 10% of body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
 - ☐ The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

INITIAL CRITERIA (CONTINUED)

6. Is the patient 18 years of age or older?

If yes, continue to #7.

If no, continue to #8.

7. Has the patient had a trial of the preferred formulary tumor necrosis factor inhibitor (TNF), Humira?

If yes, **approve for a total of 6 months and enter two approvals as follows:**

-) **FIRST APPROVAL:** approve for the first 3 months for #16 of the 25mg syringes/vials (4 kits) per 28 days or #8 of the 50mg syringes/vials/cartridges (2 kits) per 28 days.
-) **SECOND APPROVAL:** approve for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days for the next 3 months.

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, continue to #8.

8. Is the patient aged 4 to 17 years?

If yes, **approve initially for 6 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

INITIAL DENIAL TEXT: The guideline named **ETANERCEPT (Enbrel)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis. In addition, the following criteria must be met.

For patients with moderate to severe rheumatoid arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient is 18 years of age or older
-) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).



WELLFLEET
RX PLAN

PRIOR AUTHORIZATION GUIDELINES

- Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
(Initial denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 2 years of age or older

For patients with psoriatic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 18 years of age or older

For patients with ankylosing spondylitis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient is 18 years of age or older

For patients with moderate to severe plaque psoriasis, approval requires:

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient has plaque psoriasis involving at least 10% of body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
-) The patient is 4 years of age or older.
-) If the patient is 18 years of age or older, the patient has had a trial of the preferred tumor necrosis factor inhibitor (TNF), Humira.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

If no, continue to #2.

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PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
-) The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?

-) The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, **approve for 12 months for #8 of the 25mg syringes/vials (2 kits) per 28 days or #4 of the 50mg syringes /pen injectors/cartridges (1 kit) per 28 days.**

If no, do not approve.

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PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ETANERCEPT (Enbrel)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe juvenile polyarticular idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis, approval requires:

- ✓ The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

- ✓ The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of psoriatic arthritis, approval requires:

- ✓ The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of ankylosing spondylitis, approval requires:

- ✓ The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

Renewal for the diagnosis of moderate to severe plaque psoriasis, approval requires:

- ✓ The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

RATIONALE

Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of requests for Enbrel.

FDA APPROVED INDICATIONS

Enbrel is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- ✓ Rheumatoid Arthritis (RA)
- ✓ Polyarticular Juvenile Idiopathic Arthritis (JIA) in patients aged 2 years or older
- ✓ Psoriatic Arthritis (PsA)
- ✓ Ankylosing Spondylitis (AS)
- ✓ Plaque Psoriasis (PsO) in patients aged 4 years or older

DOSING AND ADMINISTRATION

Enbrel is administered by subcutaneous injection.

- ✓ **Adult RA and PsA:** 50 mg once weekly with or without methotrexate (MTX)
- ✓ **AS:** 50 mg once weekly
- ✓ **Adult PsO:** 50 mg twice weekly for 3 months, followed by 50 mg once weekly
- ✓ **Pediatric PsO or PJIA:** 0.8 mg/kg weekly, with a maximum of 50 mg per week

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PRIOR AUTHORIZATION GUIDELINES

ETANERCEPT

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE FORMS AND STRENGTHS

-) Injection: 25 mg/0.5 mL and 50 mg/mL solution in a single-dose prefilled syringe
-) Injection: 50 mg/mL solution in single-dose prefilled SureClick autoinjector
-) For injection: 25 mg lyophilized powder in a multiple-dose vial for reconstitution
-) Injection: 50 mg/mL solution in Enbrel Mini single-dose pre-filled cartridge for use with the AutoTouch reusable autoinjector only.

REFERENCES

-) Enbrel [Prescribing Information]. Thousand Oaks, CA: Immunex Corporation; November 2017.
-) Cohen S, Mikuls TR. Initial treatment of rheumatoid arthritis in adults. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019)
-) Cohen S, Cannella A. Treatment of rheumatoid arthritis in adults resistant to initial nonbiologic DMARD therapy. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019).

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 08/01/19	08/19	09/15/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ISTRADEFYLLINE (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
ISTRADEFYLLINE	NOURIANZ	45994		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease (PD) and meet **ALL** of the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ The patient is experiencing "off" episodes
- ☐ Nourianz will be used as adjunctive treatment to levodopa/carbidopa

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ISTRADEFYLLINE (Nourianz)** requires a diagnosis of Parkinson's disease (PD). In addition, the following criteria must be met:

- ☐ The patient is 18 years of age or older
- ☐ The patient is experiencing "off" episodes
- ☐ Nourianz will be used as adjunctive treatment to levodopa/carbidopa in patients experiencing "off" episodes

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nourianz.

REFERENCES

Nourianz [Prescribing Information]. Bedminster, NJ: Kyowa Kirin, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/4/19

Created: 9/19

Client Approval: 10/19

P&T Approval: 10/19

PRIOR AUTHORIZATION GUIDELINES

ADO-TRASTUZUMAB EMTANSINE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ADO-TRASTUZUMAB EMTANSINE	KADCYLA	40046		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 - The patient's breast cancer is HER2- positive
 - The patient has previously received trastuzumab and a taxane, separately or in combination
 - The patient has received prior therapy for metastatic disease **OR** developed disease recurrence during or within six months of completing adjuvant therapy

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

- Does the patient have a diagnosis of early breast cancer and meet **ALL** of the following criteria?
 - The patient's breast cancer is HER2- positive
 - The patient has residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

If yes, **approve for 12 months by HICL for #1 fill every 21 days for 14 fills.**

If no, do not approve.

DENIAL TEXT: The guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires a diagnosis of metastatic breast cancer or early breast cancer. In addition, the following criteria must be met:

For the diagnosis of metastatic breast cancer, approval requires:

- The patient's breast cancer is HER2- positive
- The patient has previously received trastuzumab and a taxane, separately or in combination
- The patient has received prior therapy for metastatic disease **OR** developed disease recurrence during or within six months of completing adjuvant therapy

For the diagnosis of early breast cancer, approval requires:

- The patient's breast cancer is HER2- positive
- The patient has residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment

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PRIOR AUTHORIZATION GUIDELINES

ADO-TRASTUZUMAB EMTANSINE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kadcyla.

REFERENCES

- Kadcyla [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 03/13

Client Approval: 08/19

P&T Approval: 07/19

PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE EXTENDED-RELEASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BUPRENORPHINE EXTENDED- RELEASE	SUBLOCADE		44186 44187	

GUIDELINES FOR USE

- Does the patient have a diagnosis of moderate to severe opioid use disorder and meet the following criterion?

- The patient previously initiated treatment with a transmucosal buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: The guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires a diagnosis of moderate to severe opioid use disorder. In addition, the following must be met:

- The patient previously initiated treatment with a transmucosal buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

- Is the patient new to Sublocade treatment?

If yes, please enter **TWO** approvals by GPID as follows:

- FIRST APPROVAL:** approve GPID 44186 for 2 months with a quantity limit of #1.5mL (#1 300mg/1.5mL syringe) per 30 days.
- SECOND APPROVAL:** approve for 10 months, please enter a start date **2 MONTHS AFTER** the **START** date of the first approval for the requested strength with a quantity limit as follows:
 - GPID 44187: #0.5mL (#1 100mg/0.5mL syringe) per 30 days.
 - GPID 44186: #1.5mL (#1 300mg/1.5mL syringe) per 30 days.

(NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

If no, approve by GPID for 12 months for the requested strength with the associated quantity limit as follows:

- GPID 44187: 0.5mL (#1 100mg/0.5mL syringe) per 30 days.
- GPID 44186: 1.5mL (#1 300mg/1.5mL syringe) per 30 days.

(NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

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PRIOR AUTHORIZATION GUIDELINES

BUPRENORPHINE EXTENDED-RELEASE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sublocade.

REFERENCES

- Sublocade [Prescribing Information]. North Chesterfield, VA: Invidor, Inc. March 2018.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 05/18

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

POLATUZUMAB VEDOTIN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
POLATUZUMAB VEDOTIN-PIIQ	POLIVY	45781		

GUIDELINES FOR USE

- Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication will be used in combination with bendamustine and a rituximab product
 - The patient has had at least two prior therapies
 - The patient is not a candidate for autologous hematopoietic stem cell transplant

If yes, **approve for 6 months by HICL for #1 fill per 21 days with a maximum of #6 fills.**
If no, do not approve.

DENIAL TEXT: The guideline named **POLATUZUMAB VEDOTIN (Polivy)** requires a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication will be used in combination with bendamustine and a rituximab product
- The patient has had at least two prior therapies
- The patient is not a candidate for autologous hematopoietic stem cell transplant

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Polivy.

REFERENCES

- Polivy [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; June 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 08/19

Client Approval: 08/19

P&T Approval: 07/19

PRIOR AUTHORIZATION GUIDELINES
CETUXIMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CETUXIMAB	ERBITUX	25947		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
 - Patient's cancer is KRAS wild-type (without mutation) as determined by an FDA-approved test
 - Patient's cancer is epidermal growth factor receptor (EGFR)-expressing as determined by an FDA-approved test

If yes, continue to #2.
 If no, continue to #3.
- Does the patient meet **ONE** of the following criteria?
 - The requested medication is being used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment
 - The requested medication is being used in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
 - The requested medication is being used as a single agent **AND** the patient has failed oxaliplatin-based and irinotecan-based chemotherapy unless patient is intolerant to irinotecan

If yes, **approve for 12 months by HICL.**
 If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
- Does the patient have a diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck **AND** meet the following criterion?
 - The requested medication will be used in combination with radiation therapy

If yes, **approve for 12 months by HICL.**
 If no, continue to #4.
- Does the patient have a diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck **AND** meet the following criterion?
 - The requested medication is being used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

If yes, **approve for 12 months by HICL.**
 If no, continue to #5.

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PRIOR AUTHORIZATION GUIDELINES

CETUXIMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

5. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck and meet **ALL** of the following criteria?
- The requested medication will be used as a single agent
 - The patient has failed prior platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **CETUXIMAB (Erbix)** requires a diagnosis of metastatic colorectal cancer (mCRC), locally or regionally advanced squamous cell carcinoma of the head and neck, recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, OR recurrent or metastatic squamous cell carcinoma of the head and neck. In addition, the following criteria must be met:

For the diagnosis of metastatic colorectal cancer (mCRC), approval requires:

- Patient's cancer is KRAS wild-type (without mutation) as determined by an FDA-approved test
- Patient's cancer is epidermal growth factor receptor (EGFR)-expressing as determined by an FDA-approved test
- In addition, **ONE** of the following must be met:
 - The requested medication is being used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment
 - The requested medication is being used in combination with irinotecan in patients who are refractory to irinotecan-based chemotherapy
 - The requested medication is being used as a single agent AND the patient has failed oxaliplatin-based and irinotecan-based chemotherapy unless patient is intolerant to irinotecan

For the diagnosis of locally or regionally advanced squamous cell carcinoma of the head and neck, approval requires:

- The requested medication will be used in combination with radiation therapy

For the diagnosis of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval requires:

- The requested medication is being used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

For the diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck, approval requires:

- The requested medication will be used as a single agent
- The patient has failed prior platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

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PRIOR AUTHORIZATION GUIDELINES

CETUXIMAB (NSA)

RATIONALE

For further information, please refer to the prescribing information and/or Drug Monograph for Erbitux.

REFERENCES

- Erbitux [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 02/13

Client Approval: 08/19

P&T Approval: 02/13

PRIOR AUTHORIZATION GUIDELINES
ALPELISIB

Generic	Brand	HICL	GCN	Exception/Other
ALPELISIB	PIQRAY	45761		

GUIDELINES FOR USE

- Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative and meet **ALL** of the following criteria?

- The patient is a postmenopausal female or male
- Piqray will be used in combination with Faslodex (fulvestrant)
- The patient has presence of PIK3CA-mutation as detected by an FDA-approved test
- The patient has experienced disease progression on or after an endocrine-based regimen

If yes, **approve for 12 months by GPID for all strengths as follows:**

- Piqray 300mg daily dose (GPID 46358): #56 per 28 days.**
- Piqray 250mg daily dose (GPID 46359): #56 per 28 days.**
- Piqray 200mg daily dose (GPID 46362): #28 per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ALPELISIB (Piqray)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative. In addition, the following criteria must be met:

- The patient is a postmenopausal female or male
- Piqray will be used in combination with Faslodex (fulvestrant)
- The patient has presence of PIK3CA-mutation as detected by an FDA-approved test
- The patient has experienced disease progression on or after an endocrine-based regimen

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Piqray.

REFERENCES

- Piqray [Prescribing Information]. East Hanover, NJ. Novartis Pharmaceuticals Corp., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 08/19

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

Generic	Brand	HICL	GCN	Exception/Other
AMIFAMPRIDINE	FIRDAPSE	36930		
AMIFAMPRIDINE	RUZURGI		46265	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
 - Diagnosis is confirmed by **ALL** of the following:
 - Electrodiagnostic studies (e.g., reduced compound muscle action potential (CMAP)) and/or voltage-gated calcium channel (VGCC) antibody testing
 - Clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for **Firdapse** and the patient meets the following criterion?
 - The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #8 tablets per day.**

APPROVAL TEXT: Renewal requires physician attestation of improvement or stabilization in muscle weakness compared to baseline.

If no, continue to #3.

3. Is the request for **Ruzurgi** and the patient meets the following criterion?
 - Documentation of patient's weight

If yes, **approve for 12 months by GPID (46265) as follows:**

- **Weight < 45kg: #150 tablets per 30 days.**

- **Weight ≥ 45kg: #300 tablets per 30 days.**

APPROVAL TEXT: Renewal requires physician attestation of improvement or stabilization in muscle weakness compared to baseline.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). In addition, the following criteria must be met:

- Therapy is prescribed by or in consultation with a neurologist or hematologist-oncologist
- Diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (VGCC) antibody testing **AND** clinical triad of muscle weakness, autonomic dysfunction, and decreased tendon reflexes

Request for Firdapse also requires the following:

- The patient is 18 years of age or older

Request for Ruzurgi also requires the following:

- Documentation of patient's weight

RENEWAL CRITERIA

1. Does the patient have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) **AND** meet the following criterion?
 - Physician attestation of improvement or stabilization in muscle weakness compared to baseline

If yes, **approve for 12 months as follows:**

- **Firdapse: Approve by HICL with a quantity limit of #8 tablets per day.**
- **Ruzurgi: Approve by GPID (46265) as follows:**
 - **Weight < 45kg: #150 tablets per 30 days.**
 - **Weight ≥ 45kg: #300 tablets per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). In addition, the following criterion must be met:

- Physician attestation of improvement or stabilization in muscle weakness compared to baseline

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PRIOR AUTHORIZATION GUIDELINES

AMIFAMPRIDINE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Firdapse and Ruzurgi.

REFERENCES

- Firdapse [Prescribing Information]. Coral Gables, FL: Catalyst Pharmaceuticals, Inc: November 2018.
- Ruzurgi [Prescribing Information]. Princeton, NJ: Jacobus Pharmaceutical Company, Inc., May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 02/19

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

AMPHETAMINE SULFATE

Generic	Brand	HICL	GCN	Exception/Other
AMPHETAMINE SULFATE	EVEKEO		19821 19822	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of narcolepsy **AND** meet the following criterion?

- The patient is 6 years of age or older

If yes, **approve the requested strength for 12 months by GPID (19821 or 19822) with a quantity limit of #6 tablets per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of attention deficit disorder with hyperactivity and meet **ALL** of the following criteria?

- The patient is 3 years of age or older
- The patient had a previous trial of at least **ONE** of the following stimulant medications: mixed amphetamine salts (Adderall IR), methylphenidate (Ritalin IR), or dextroamphetamine (Dexedrine)

If yes, **approve the requested strength for 12 months by GPID (19821 or 19822) with a quantity limit of #4 tablets per day.**

If no, continue to #3.

3. Is the requested medication being used for weight loss or exogenous obesity?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Are weight loss products (anti-obesity medications) a covered benefit?

If yes, continue to #5.

If no, guideline does not apply for plans that exclude treatment of obesity.

5. Is this an initial request (per MRF and claims history)?

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

AMPHETAMINE SULFATE

GUIDELINES FOR USE (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?

- The patient is 12 years of age or older
- The patient had a previous trial of other weight loss medications (e.g., Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion)

If yes, **approve the requested strength for 12 weeks by GPID (19821 or 19822) with a quantity limit of #3 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **AMPHETAMINE SULFATE (Evekeo)** requires a diagnosis of narcolepsy, attention deficit disorder with hyperactivity, or use for weight loss or exogenous obesity. In addition, the following criteria must be met:

For the diagnosis of narcolepsy, approval requires:

- The patient is 6 years of age or older

For the diagnosis of attention deficit disorder with hyperactivity, approval requires:

- The patient is 3 years of age or older
- The patient had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall IR), methylphenidate (Ritalin IR), dextroamphetamine (Dexedrine)

For weight loss or exogenous obesity, approval requires:

- The patient is 12 years of age or older
- The patient had a previous trial of other weight loss medications (e.g., Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion)
- **Note:** The approval of Evekeo for use as a short-term adjunct in a regimen of weight reduction is for a maximum duration of 12 weeks

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evekeo.

REFERENCES

- Evekeo [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals LLC; October 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 05/15

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG

Generic	Brand	HICL	GCN	Exception/Other
AVATROMBOPAG	DOPTELET	44942		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of thrombocytopenia and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has chronic liver disease
 - The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy
 - The patient has a platelet count of $<50 \times 10^9/L$ measured within the last 30 days
 - The medication is prescribed by or given in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
 - The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., Promacta)

If yes, **approve for 1 fill with a quantity limit of #15 tablets by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient had a trial of or contraindication to corticosteroids or immunoglobulins **OR** had an insufficient response to splenectomy
 - The medication is prescribed by or given in consultation with a hematologist or immunologist

If yes, **approve for 2 months by HICL with a quantity limit of #2 tablets per day.**

APPROVAL TEXT: Renewal requires a clinical response to therapy as defined by an increase in platelet count to at least $50 \times 10(9)/L$ (at least 50,000 per microliter), compared to baseline.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **AVATROMBOPAG (Doptelet)** requires a diagnosis of thrombocytopenia or chronic immune thrombocytopenia (cITP). In addition, the following criteria must be met:

For diagnosis of thrombocytopenia, approval requires:

- The patient is 18 years of age or older
- The patient has chronic liver disease
- The patient is scheduled to undergo a procedure 10 to 13 days following the initiation of Doptelet therapy
- The patient has a platelet count of less than $50 \times 10^9/L$ measured within the last 30 days
- The medication is prescribed by or given in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
- The patient is not receiving other thrombopoietin receptor agonist therapy (e.g., Promacta)

For diagnosis of chronic immune thrombocytopenia (cITP), approval requires:

- The patient is 18 years of age or older
- The patient had a trial of or contraindication to corticosteroids or immunoglobulins **OR** had an insufficient response to splenectomy
- The medication is prescribed by or given in consultation with a hematologist or immunologist

RENEWAL CRITERIA

NOTE: For the diagnoses of thrombocytopenia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet the following criterion?
 - Patient had a clinical response to therapy as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter), compared to baseline.

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **AVATROMBOPAG (Doptelet)** requires a diagnosis of chronic immune thrombocytopenia (cITP). In addition, the following criterion must be met:

- Patient had a clinical response to therapy as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter), compared to baseline

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PRIOR AUTHORIZATION GUIDELINES

AVATROMBOPAG

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Doptelet.

REFERENCES

- Doptelet [prescribing information]. Durham, NC. Dova Pharmaceuticals, Inc. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 08/18

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

Generic	Brand	HICL	GCN	Strength	Exception/Other
FENTANYL	DURAGESIC		24635 19200 37952 19201 37947 19202 37948 19203	12MCG/HR 25MCG/HR 37.5MCG/HR 50MCG/HR 62.5MCG/HR 75MCG/HR 87.5MCG/HR 100MCG/HR	GPID ≠ 25879 ROUTE = TRANSDERM.

GUIDELINES FOR USE

- Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
- Does the request form indicate that this medication will be used on an "as needed" or "PRN" basis?

If yes, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
If no, continue to #3.
- Is the request for more than one strength of transdermal fentanyl patch OR does the patient have an active prior authorization(s) for a different strength of fentanyl patch?

If yes, send to Clinical Pharmacist for review.
If no, continue to #4.
- Is the request for every 72 hours dosing?

If yes, **approve for 12 months with the following quantity limits:**
 - FOR EVERY 72 HOUR DOSING:** (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr) approve by GPID for #10 patches per 30 days.
 - FOR 100mcg/hr:** approve by GPID (100mcg/hr) for up to #20 patches per 30 days. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).
If no, continue to #5.

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PRIOR AUTHORIZATION GUIDELINES

FENTANYL TRANSDERMAL PATCH

GUIDELINES FOR USE (CONTINUED)

5. Is the request for dosing every 48 hours?

If yes, continue to #6.

If no, send to Clinical Pharmacist for review.

6. Has the patient tried every 72 hours dosing?

If yes, **approve for 12 months with the following quantity limits:**

- **FOR EVERY 48 HOUR DOSING:** (12, 25, 37.5, 50, 62.5, 75, 87.5mcg/hr) approve by GPID for #15 patches per 30 days.
 - **FOR 100mcg/hr:** approve by GPID (100mcg/hr) for up to #30 patches per 30 days.
- (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).

If no, do not approve.

DENIAL TEXT: The guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires that the patient meets the following criteria:

- The patient meets the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid)
- The requested medication is not prescribed on an 'as needed' basis
- Requests for dosing every 48 hours requires a trial of transdermal fentanyl dosed every 72 hours

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Duragesic.

REFERENCES

- Fentanyl Patch [Prescribing Information]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; March 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 02/03

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

FLIBANSERIN

Generic	Brand	HICL	GCN	Exception/Other
FLIBANSERIN	ADDYI	42447		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Is Addyi (flibanserin) a covered benefit?

If yes, continue to #2.

If no, guideline does not apply.

2. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- HSDD symptom cause marked distress or interpersonal difficulty

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Have **ALL** of the following criteria been met?

- The patient is a premenopausal female
- The patient is at least 18 years old
- The patient had a previous trial of or contraindication to bupropion
- The patient is not currently using Vyleesi (bremelanotide)

If yes, **approve for 8 weeks by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

FLIBANSERIN

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **FLIBANSERIN (Addyi)** requires a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria:

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- HSDD symptom cause marked distress or interpersonal difficulty

The following criteria must also be met for approval:

- The patient is a premenopausal female
- The patient is at least 18 years old
- The patient had a previous trial of or contraindication to bupropion
- The patient is not currently using Vyleesi (bremelanotide)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria?
 - Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
 - HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
 - HSDD symptom cause marked distress or interpersonal difficulty

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
 - The patient is a premenopausal female
 - The patient is not currently using Vyleesi (bremelanotide)
 - Physician attestation that the patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

If yes, **approve for 6 months by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

FLIBANSERIN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **FLIBANSERIN (Addyi)** requires a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) (also referred to as female sexual interest/arousal disorder [FSIAD] per DSM-5), as defined by **ALL** of the following criteria:

- Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
- HSDD is not a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
- HSDD symptom cause marked distress or interpersonal difficulty

The following criteria must also be met for approval:

- The patient is a premenopausal female
- The patient is not currently using Vyleesi (bremelanotide)
- Physician attestation that the patient has demonstrated continued improvement in symptoms of HSDD/FSIAD (e.g., increased sexual desire, lessened distress)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Addyi.

REFERENCES

- Addyi [Prescribing Information]. Raleigh, NC: Sprout Pharmaceuticals, Inc. August 2015.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 09/15

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

Generic	Brand	HICL	GCN	Exception/Other
FOSTAMATINIB DISODIUM	TAVALISSE	44895		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a hematologist or immunologist

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Has the patient received splenectomy?

If yes, **approve for 3 months by HICL with a quantity limit of #2 tablets per day.**

APPROVAL TEXT: Renewal requires physician attestation of clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10(9)/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

If no, continue to #3.

3. Has the patient had a previous trial of or contraindication to at least **TWO** of the following treatments?

- Corticosteroids
- IVIG (intravenous immunoglobulin)
- Rhogam
- Rituxan (rituximab)
- Thrombopoietin receptor agonist (i.e., Promacta (eltrombopag), Nplate (romiplostim))

If yes, **approve for 3 months by HICL with a quantity limit of #2 tablets per day.**

APPROVAL TEXT: Renewal requires physician attestation of clinically significant prevention of bleeds while on therapy, attainment of platelet levels of 50-450 x 10(9)/L, and proof of normal LFTs (liver function tests), total bilirubin, and ANC (absolute neutrophil count).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **FOSTAMATINIB (Tavalisse)** requires a diagnosis of chronic immune thrombocytopenia (cITP). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- The requested medication is prescribed by or in consultation with a hematologist or immunologist
- The patient has had a splenectomy **OR** a previous trial of or contraindication to at least **TWO** of the following treatments:
 - Corticosteroids
 - IVIG (intravenous immunoglobulin)
 - Rhogam
 - Rituxan (rituximab)
 - Thrombopoietin receptor agonist (i.e., Promacta (eltrombopag), Nplate (romiplostim))

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (cITP) and meet **ALL** of the following criteria?
 - Physician attestation of clinically significant prevention of bleeds while on therapy
 - The patient's AST and ALT levels have remained under 3 times the upper limits of normal per reference range
 - The patient's total bilirubin level has remained under 2 times the upper limits of normal per reference range
 - The patient's ANC has remained within normal limits per reference range
 - The patient's platelets have attained a level between 50 and $450 \times 10^9/L$

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **FOSTAMATINIB (Tavalisse)** requires a diagnosis of chronic immune thrombocytopenia (cITP). In addition, the following criteria must be met:

- The patient has prevented clinically significant bleeds, per physician attestation
- The patient's AST (aspartate aminotransferase) and ALT (alanine aminotransferase) levels have remained under 3 times the upper limits of normal per reference range
- The patient's total bilirubin level has remained under 2 times the upper limits of normal per reference range
- The patient's ANC (absolute neutrophil count) has remained within normal limits per reference range
- The patient's platelets have attained a level between 50 and $450 \times 10^9/L$

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PRIOR AUTHORIZATION GUIDELINES

FOSTAMATINIB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tavalisse.

REFERENCES

- Tavalisse [Prescribing Information]. South San Francisco, CA. Rigel Pharmaceuticals, Inc. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 08/18

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Exception/Other
GLYCEROL PHENYLBUTYRATE	RAVICTI	39990		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
 - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
 - The patient is 2 months of age or older
 - Physician attestation of **ALL** the following:
 - Ravicti will be used as adjunctive therapy along with dietary protein restriction
 - The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
 - The patient does **NOT** have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
 - The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

If yes, **approve for 12 months by HICL with a quantity limit of #17.5mL per day.**

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires a diagnosis of a urea cycle disorder (UCD). In addition, the following criteria must be met:

- Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
- The patient is 2 months of age or older
- Physician attestation of **ALL** the following:
 - Ravicti will be used as adjunctive therapy along with dietary protein restriction
 - The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
- The patient does **NOT** have a deficiency of N-acetylglutamate synthetase deficiency (NAGS) or acute hyperammonemia
- The patient has tried or has a contraindication to Buphenyl (sodium phenylbutyrate)

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PRIOR AUTHORIZATION GUIDELINES

GLYCEROL PHENYLBUTYRATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet the following criterion?
 - Physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

If yes, **approve for 12 months by HICL with a quantity limit of #17.5mL per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires a diagnosis of a urea cycle disorder (UCD) and physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ravicti.

REFERENCES

- Ravicti [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 02/13

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

HYDROMORPHONE ER

Generic	Brand	HICL	GCN	Exception/Other
HYDROMORPHONE ER	EXALGO		22056 28427 22098 33088	EXTENDED RELEASE ONLY

GUIDELINES FOR USE

1. Does the patient meet the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day, or an equianalgesic dose of another opioid)?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the request form indicate that this medication will be used on an "as needed" or "PRN" basis?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

3. Does the patient require a dosage of 16mg or less?

If yes, **approve for 12 months by GPID (8mg, 12mg, 16mg) for #1 tablets per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

If no, continue to #4.

4. Was this dosage recommended by a pain specialist?

If yes, **approve for 12 months by GPID (32mg) for #2 tablets per day. (NOTE: Please override both PA and step therapy [if applicable] restrictions by entering 'Y' for OVR_RES).**

If no, do not approve.

DENIAL TEXT: The guideline named **HYDROMORPHONE ER** requires that the patient meets the following criteria:

- The patient meets the definition of opioid tolerance (defined as those who are taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl/hour, 30 mg oral oxycodone/day, 25 mg oral oxymorphone/day, 8 mg oral hydromorphone/day), or an equianalgesic dose of another opioid)
- The requested medication is not prescribed on an 'as needed' basis
- Dosages above 16mg require recommendation by a pain specialist

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PRIOR AUTHORIZATION GUIDELINES

HYDROMORPHONE ER

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Exalgo.

REFERENCES

- Exalgo [Prescribing Information]. Hazelwood, MO: Mallinckrodt; April 2014.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 04/10

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

Generic	Brand	HICL	GCN	Exception/Other
LENALIDOMIDE	REVLIMID	33412		

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have a diagnosis of multiple myeloma (MM)?

If yes, continue to #3.

If no, continue to #5.

3. Will Revlimid (lenalidomide) be used as induction treatment for multiple myeloma (MM)?

If yes, **approve for 12 months by HICL for #21 capsules every 28 days.**

If no, continue to #4.

4. Will Revlimid (lenalidomide) be used as maintenance treatment for multiple myeloma (MM)?

If yes, **approve for 12 months by HICL for #1 capsule per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Does the patient have a diagnosis of anemia due to a myelodysplastic syndrome (MDS) **AND** meet the following criterion?

- The patient's myelodysplastic syndrome (MDS) is associated with a deletion 5q abnormality

If yes, **approve for 12 months by HICL for #1 capsule per day.**

If no, continue to #6.

6. Does the patient have a diagnosis of mantle cell lymphoma (MCL) **AND** meet the following criterion?

- Patient has relapsed or progressed after at least two prior therapies, one of which included Velcade (bortezomib)

If yes, **approve for 12 months by HICL for #21 capsules per 28 days.**

If no, continue to #7.

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PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

GUIDELINES FOR USE (CONTINUED)

7. Does the patient have a diagnosis of follicular lymphoma (FL) and meet **ALL** of the following criteria?

- The patient has previously been treated for follicular lymphoma (FL)
- The requested drug is being taken in combination with a rituximab product

If yes, **approve for 12 months by HICL for #21 capsules per 28 days for 12 fills.**

If no, continue to #8.

8. Does the patient have a diagnosis of marginal zone lymphoma (MZL) and meet **ALL** the following criterion?

- The patient has previously been treated for marginal zone lymphoma (MZL)
- The requested drug is being taken in combination with a rituximab product

If yes, **approve for 12 months by HICL for #21 capsules per 28 days for 12 fills.**

If no, do not approve.

DENIAL TEXT: The guideline named **LENALIDOMIDE (Revlimid)** requires a diagnosis of multiple myeloma (MM), anemia due to a myelodysplastic syndrome (MDS), mantle cell lymphoma (MCL), follicular lymphoma (FL), or marginal zone lymphoma (MZL). The patient also must be 18 years of age or older. In addition, the following criteria must be met:

For patients with myelodysplastic syndrome (MDS), approval requires:

- The patient's MDS is associated with a deletion 5q abnormality

For patients with mantle cell lymphoma (MCL), approval requires:

- The patient has relapsed or progressed after at least two prior therapies, one of which included Velcade (bortezomib). Velcade may be covered under the medical benefit and/or require prior authorization.

For patients with follicular lymphoma (FL), approval requires:

- The patient has previously been treated for follicular lymphoma (FL)
- The requested drug is being taken in combination with a rituximab product

For patients with marginal zone lymphoma (MZL), approval requires:

- The patient has previously been treated for marginal zone lymphoma (MZL)
- The requested drug is being taken in combination with a rituximab product

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Revlimid.

REFERENCES

- Revlimid [Prescribing Information]. Summit, NJ: Celgene Corporation; May 2019.

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PRIOR AUTHORIZATION GUIDELINES

LENALIDOMIDE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 08/12

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

PREDNISONE DELAYED-RELEASE TABS

Generic	Brand	HICL	GCN	Exception/Other
PREDNISONE	RAYOS		33097 33098 33099	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for an FDA approved indication and the patient meets **ALL** of the following criteria?

- The patient had a previous trial of or contraindication to **ONE** of the following: generic prednisone, prednisolone, or methylprednisolone
- Physician attestation of subclinical response or treatment failure of generic prednisone, prednisolone, or methylprednisolone

If yes, **approve for 6 months by GPID for the requested strength.**

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit from using Rayos (e.g., improvement in inflammatory condition from baseline) and physician attestation that the patient cannot be tapered off corticosteroid (i.e., Rayos).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires that the request is for an FDA approved indication. In addition, the following criteria must be met:

- The patient had a previous trial of or contraindication to **ONE** of the following: generic prednisone, prednisolone, or methylprednisolone
- Physician attestation of subclinical response or treatment failure of generic prednisone, prednisolone, or methylprednisolone

RENEWAL CRITERIA

1. Is the request for an FDA approved indication and the patient meets **ALL** of the following criteria?

- Physician attestation of clinical benefit from using Rayos (e.g., improvement in inflammatory condition from baseline)
- Physician attestation that the patient cannot be tapered off corticosteroid (i.e., Rayos)

If yes, **approve for 6 months by GPID for the requested strength.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires that the request is for an FDA approved indication. In addition, the following criteria must be met:

- Physician attestation of clinical benefit from using Rayos (e.g., improvement in inflammatory condition from baseline)
- Physician attestation that the patient cannot be tapered off corticosteroid (i.e., Rayos)

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PRIOR AUTHORIZATION GUIDELINES

PREDNISONE DELAYED-RELEASE TABS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rayos.

REFERENCES

- Rayos [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc., September 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Created: 08/19

Commercial Effective: 10/01/19

Client Approval: 08/19

P&T Approval: 07/19

PRIOR AUTHORIZATION GUIDELINES
SODIUM PHENYLBUTYRATE

Generic	Brand	HICL	GCN	Exception/Other
SODIUM PHENYLBUTYRATE	BUPHENYL		43370 43371	

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet **ALL** of the following criteria?
 - Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
 - Physician attestation of **ALL** the following:
 - Buphenyl will be used as adjunctive therapy along with dietary protein restriction
 - The patient cannot be managed by dietary protein restriction and/or amino acid supplementation alone

If yes, **approve the requested agent for 12 months by GPID with a quantity limit:**

- Oral tablet: #40 tablets per day.**
- Oral powder: #750 grams per 30 days.**

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires a diagnosis of a urea cycle disorder (UCD). In addition, the following criteria must be met:

- Documentation of confirmation of UCD via enzymatic, biochemical or genetic testing
- Physician attestation of **ALL** the following:
 - Buphenyl will be used as adjunctive therapy along with dietary protein restriction
 - The patient cannot be managed by dietary protein restriction and/or amino acid supplementation alone

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PRIOR AUTHORIZATION GUIDELINES

SODIUM PHENYLBUTYRATE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of a urea cycle disorder (UCD) and meet the following criterion?
 - Physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity)

If yes, **approve the requested agent for 12 months by GPID with a quantity limit:**

- **Oral tablet: #40 tablets per day.**
- **Oral powder: #750 grams per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires a diagnosis of urea cycle disorder (UCD) and physician attestation of clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Buphenyl.

REFERENCES

- Buphenyl [Prescribing Information]. Lake Forest, IL: Horizon Pharma USA, Inc.; November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 08/19

Client Approval: 08/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS

Generic	Brand	HICL	GCN	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		
TAFAMIDIS	VYNDAMAX	45729		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) as confirmed by **ONE** of the following?
 - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD
(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
 - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
 - The patient has New York Heart Association (NYHA) class I, II, or III heart failure

If yes, **approve for 12 months for both of the following drugs:**

- **Vyndaqel (tafamidis meglumine): Approve by HICL (41631) with a quantity limit of #4 per day.**
- **Vyndamax (tafamidis): Approve by HICL (45729) with a quantity limit of #1 per day.**

APPROVAL TEXT: Renewal requires the physician attestation that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires a documented diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). In addition, the following criteria must be met.

- Diagnosis confirmed by ONE of the following:
 - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD (**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)
 - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
- The patient has New York Heart Association (NYHA) class I, II or III heart failure

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) **AND** meet the following criterion?
 - Physician attestation that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

If yes, **approve for 12 months for both of the following drugs:**

- **Vyndaqel (tafamidis meglumine): Approve by HICL (41631) with a quantity limit of #4 per day.**
- **Vyndamax (tafamidis): Approve by HICL (45729) with a quantity limit of #1 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). In addition, the following must be met.

- Physician attestation that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

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PRIOR AUTHORIZATION GUIDELINES

TAFAMIDIS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES

- Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; May 2019.
- Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 05/19

Client Approval: 09/19

P&T Approval: 04/19

PRIOR AUTHORIZATION GUIDELINES
CABOZANTINIB S-MALATE

Generic	Brand	HICL	GCN	Exception/Other
CABOZANTINIB S-MALATE	COMETRIQ, CABOMETYX	39815		

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE
COMETRIQ

1. Does the patient have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC)?

If yes, **approve for 12 months by GPID with a quantity limit of #112 capsules per 28 days for the requested daily dose pack. (NOTE: Cometriq is available in three dosage packs each containing 7 days' supply)**

- **Cometriq 140mg daily dose pack (GPID 33903): Seven 80mg capsules and twenty one 20mg capsules.**
- **Cometriq 100mg daily dose pack (GPID 33904): Seven 80mg capsules and seven 20mg capsules.**
- **Cometriq 60mg daily dose pack (GPID 33905): Twenty one 20mg capsules.**

If no, do not approve.

DENIAL TEXT: The guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires a diagnosis of progressive, metastatic medullary thyroid cancer (MTC).

CABOMETYX

1. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC)?

If yes, **approve for 12 months by GPID for the requested strength with the applicable quantity limit:**

- **Cabometyx 60mg tablet (GPID 41148): #1 tablet per day.**
- **Cabometyx 40mg tablet (GPID 41147): #2 tablets per day.**
- **Cabometyx 20mg tablet (GPID 41146): #1 tablet per day.**

If no, continue to #2.

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PRIOR AUTHORIZATION GUIDELINES

CABOZANTINIB S-MALATE

GUIDELINES FOR USE - CABOMETYX (CONTINUED)

2. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) AND meet the following criterion?

- Patient has previously been treated with Nexavar (sorafenib)

If yes, **approve for 12 months by GPID for the requested strength with the applicable quantity limit:**

- Cabometyx 60mg tablet (GPID 41148): #1 tablet per day.
- Cabometyx 40mg tablet (GPID 41147): #2 tablets per day.
- Cabometyx 20mg tablet (GPID 41146): #1 tablet per day.

If no, do not approve.

DENIAL TEXT: The guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires a diagnosis of advanced renal cell carcinoma (RCC) or hepatocellular carcinoma (HCC). In addition, the following criteria must be met:

For patients with hepatocellular carcinoma (HCC), approval requires:

- The patient has previously been treated with Nexavar (sorafenib)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cometriq or Cabometyx.

REFERENCES

- Cometriq [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; January 2018.
- Cabometyx [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; January 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/01/19

Created: 01/13

Client Approval: 09/19

P&T Approval: 01/19

TILDRAKIZUMAB-ASMN (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TILDRAKIZUMAB-ASMN	ILUMYA	44823		

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a dermatologist
 -) The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
 -) The patient had a previous trial of or contraindication to at least **ONE** or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 -) The patient is 18 years of age or older
 -) The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara SC, or Tremfya [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, approve for 6 months by entering **TWO** approvals by HICL as follows:

-) **FIRST APPROVAL:** approve for 1 month with a quantity limit of #2mL (#2 100mg/mL syringes) per 28 days.
-) **SECOND APPROVAL:** approve for 5 months with a quantity limit of #1mL (#1 100mg/mL syringe) per 84 days (Please enter a start date of 1 WEEK AFTER the END date of the first approval).

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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TILDRAKIZUMAB-ASMN (NSA)**INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

-) Therapy is prescribed by or given in consultation with a dermatologist
-) The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
-) The patient had a previous trial of or contraindication to at least ONE or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
-) The patient is 18 years of age or older
-) The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara SC, or Tremfya.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
 -) The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL with a quantity limit of #1mL (#1 100mg/mL syringe) per 84 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) for renewal. The following criterion must also be met:

-) The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

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TILDRAKIZUMAB-ASMN (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilumya.

REFERENCES

) Ilumya [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2018.

Created	FS Committee Approval	Effective
5/2019; revised 8/2019	8/2019	9/15/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV

Generic	Brand	HICL	GCN	Exception/Other
TOCILIZUMAB - IV	ACTEMRA - IV		27366 27367 27368	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient meets **ONE** of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 -) The patient is 18 years of age or older

If yes, **approve for 6 months by GPID for a maximum quantity limit of 40mL per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
-) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 -) The patient is 2 years of age or older
 -) The patient has had a previous trial of the formulary preferred immunomodulator: Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID.**

APPROVAL TEXT: Renewal for polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

3. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
-) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 -) The patient is 2 years of age or older

If yes, **approve for 6 months by GPID.**

APPROVAL TEXT: Renewal for systemic juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #4.

4. Does the patient meet **ALL** of the following criteria?
-) Request is for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS)
 -) The patient is 2 years of age or older

If yes, **approve for 1 fill by GPID with a quantity limit of 160mL.**

CLINICAL PHARMACISTS: Patient must also meet all criteria in Kymriah guideline to be approvable for both agents.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB – IV

INITIAL CRITERIA (CONTINUED)

PRIOR AUTHORIZATION GUIDELINES

INITIAL DENIAL TEXT: The guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA), systemic juvenile idiopathic arthritis (SJIA), or chimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (CRS). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
-) The patient is 18 years of age or older

For patients with polyarticular juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 2 years of age or older
-) The patient has had a previous trial of the formulary preferred immunomodulator: Humira

For patients with systemic juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 2 years of age or older

For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), approval requires all:

-) The patient is 2 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID for a maximum quantity limit of 40mL per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) **OR** systemic juvenile idiopathic arthritis (SJIA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy for renewal.

RATIONALE

Ensure appropriate use of Actemra IV consistent with its FDA approved indications.

FDA APPROVED INDICATIONS

Actemra - IV (tocilizumab - IV) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of:

-) Adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).
-) Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.
-) Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.
-) Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB – IV

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Rheumatoid Arthritis	
Recommended Adult Intravenous (IV) Dosage	
When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response. Doses exceeding 800 mg per infusion are not recommended in RA patients.	
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	
Recommended Intravenous PJIA Dosage Every 4 Weeks	
Patients less than 30 kg weight	10 mg per kg
Patients at or above 30 kg weight	8 mg per kg
Systemic Juvenile Idiopathic Arthritis (SJIA)	
Recommended Intravenous SJIA Dosage Every 2 Weeks	
Patients less than 30 kg weight	12 mg per kg
Patients at or above 30 kg weight	8 mg per kg
Cytokine Release Syndrome (CRS)	
Recommended Intravenous CRS Dosage	
Patients less than 30 kg weight	12 mg per kg
Patients at or above 30 kg weight	8 mg per kg
Alone or in combination with corticosteroids.	
If no clinical improvement in the signs and symptoms of CRS occurs after the first dose, up to 3 additional doses of ACTEMRA may be administered. The interval between consecutive doses should be at least 8 hours. Doses exceeding 800 mg per infusion are not recommended in CRS patients.	

DOSAGE FORMS AND STRENGTHS

Single-use vials of ACTEMRA (20 mg per mL) are available for intravenous administration:

- ⌋ 80 mg per 4 mL
- ⌋ 200 mg per 10 mL
- ⌋ 400 mg per 20 mL

REFERENCE

- ⌋ Actemra [Prescribing Information]. South San Francisco, CA: Genentech. August 2017.

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 08/19	08/19	9/15/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	Yes

PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Exception/Other
TOCILIZUMAB - SQ	ACTEMRA - SQ		35486 45082	

PAC NOTE: For requests for the IV dosage form of Actemra, please see the Actemra IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient meets **ONE** of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 -) The patient is 18 years of age or older

If yes, **approve for 6 months by GPID (35486 and 45082) with a quantity limit of 3.6mL per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis (RA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) and meet the following criterion?
 -) The patient is 18 years of age or older

If yes, **approve for 6 months by GPID (35486 and 45082) with a quantity limit of 3.6mL per 28 days.**

APPROVAL TEXT: Renewal requires a diagnosis of giant cell arteritis (GCA).

If no, continue to #3

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?

- ✓ Therapy is prescribed by or given in consultation with a rheumatologist
- ✓ The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- ✓ The patient is 2 years of age or older
- ✓ The patient has had a previous trial of the formulary preferred immunomodulator: Humira
(**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID (35486 and 45082) with a quantity limit of 1.8mL per 28 days.**

APPROVAL TEXT: Renewal for polyarticular juvenile idiopathic arthritis (PJIA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet the following criteria?

- ✓ Therapy is prescribed by or given in consultation with a rheumatologist
- ✓ The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- ✓ The patient is 2 years of age or older

If yes, **approve for 6 months by GPID (35486 and 45082) with a quantity limit of 3.6mL per 28 days.**

APPROVAL TEXT: Renewal for systemic juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA), or systemic juvenile idiopathic arthritis (SJIA) for approval. In addition, the following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient meets **ONE** of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

-) The patient is 18 years of age or older

For patients with giant cell arteritis, approval requires:

-) The patient is 18 years of age or older

For patients with polyarticular juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 2 years of age or older
-) The patient has had a previous trial of the formulary preferred immunomodulator: Humira

For patients with systemic juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 2 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID (35486 and 45082) with a quantity limit of 3.6mL per 28 days.**
If no, continue to #2.
2. Does the patient have a diagnosis of giant cell arteritis (GCA)?

If yes, **approve for 12 months by GPID (35486 and 45082) with a quantity limit of 3.6mL per 28 days.**
If no, continue to #3.
3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID (35486 and 45082) with a quantity limit of 1.8mL per 28 days.**
If no, continue to #4.
4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID (35486 and 45082) with a quantity limit of 3.6mL per 28 days.**
If no, do not approve.
DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), giant cell arteritis (GCA), systemic juvenile idiopathic arthritis (SJIA), or polyarticular juvenile idiopathic arthritis (PJIA) for renewal. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis, approval requires:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE

-) Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2018.

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 8/1/19	08/19	09/15/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



Generic	Brand	HICL	GCN	Exception/Other
UPADACITINIB	RINVOQ	45955		

1014 Vine St. Cincinnati, OH 45202
Phone: (800) 917-4926
www.kpp-rx.com



-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **UPADACITINIB (Rinvoq)** requires a diagnosis of moderate to severe rheumatoid arthritis. In addition, the following must be met:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rinvoq.

REFERENCES

Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc., August 2019.

Created	FS Committee Approval	Effective
9/2019		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



ABATACEPT - SQ

Generic	Brand	HICL	GCN	Exception/Other
ABATACEPT - SQ	ORENCIA - SQ ORENCIA CLICKJECT - SQ		30289 41656 43389 43397	

NOTE: For requests for the IV dosage form of Orencia, please see the Orencia IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
-) The patient is 18 years of age or older
-) The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID with the following quantity limits:**

-) **Orencia 125mg/mL SQ syringes (GPID 30289): 4mL (#4 - 125mg/mL syringes) per 28 days.**
-) **Orencia 125mg/mL ClickJect - SQ (GPID 41656): 4mL (#4 - 125mg/mL auto-injectors) per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

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ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
-) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 -) The patient is 2 years of age or older
 -) The patient has had a previous trial of TWO of the formulary preferred immunomodulators: Enbrel, Humira, or Actemra SC. (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID with the following quantity limits:**

-) **Orencia 125mg/mL SQ syringes (GPID 30289): 4mL (#4 - 125mg/mL syringes) per 28 days.**
-) **Orencia 87.5mg/0.7mL SQ syringes (GPID 43397): 2.8mL (#4 - 87.5mg/0.7mL syringes) per 28 days.**
-) **Orencia 50mg/0.4mL SQ syringes (GPID 43389): 1.6mL (#4 - 50mg/0.4mL syringes) per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe polyarticular juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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ABATACEPT - SQ**INITIAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- ☐ The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- ☐ The patient is 18 years of age or older
- ☐ The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara SC, or Xeljanz
(**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID with the following quantity limits:**

- ☐ **Orencia 125mg/mL SQ syringes (GPID 30289): 4mL (#4 - 125mg/mL syringes) per 28 days.**
- ☐ **Orencia 125mg/mL ClickJect - SQ (GPID 41656): 4mL (#4 - 125mg/mL auto-injectors) per 28 days.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

DENIAL TEXT: The guideline named **ABATACEPT - SQ (Orencia - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), or psoriatic arthritis (PsA). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient meets **ONE** of the following:
 - ☐ Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - ☐ For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - ☐ Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
- ☐ The patient is 18 years of age or older
- ☐ The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz.

(Initial denial text continued on next page)



ABATACEPT - SQ

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 2 years of age or older
-) The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, or Actemra SC.

For patients with psoriatic arthritis (PsA), approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 18 years of age or older
-) The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara SC, or Xeljanz.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID with the following quantity limits:**

-) **Orencia 125mg/mL SQ syringes (GPID 30289): 4mL (#4 - 125mg/mL syringes) per 28 days.**
-) **Orencia 125mg/mL ClickJect - SQ (GPID 41656): 4mL (#4 - 125mg/mL auto-injectors) per 28 days.**

If no, continue to #2.

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ABATACEPT - SQ

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID with the following quantity limits:**

-) **Orencia 125mg/mL SQ syringes (GPID 30289): 4mL (#4 - 125mg/mL syringes) per 28 days.**
-) **Orencia 87.5mg/0.7mL SQ syringes (GPID 43397): 2.8mL (#4 - 87.5mg/0.7mL syringes) per 28 days.**
-) **Orencia 50mg/0.4mL SQ syringes (GPID 43389): 1.6mL (#4 - 50mg/0.4mL syringes) per 28 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **ABATACEPT - SQ (Orencia - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criteria must be met:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are met for the management of requests for abatacept.

FDA APPROVED INDICATIONS

Abatacept (Orencia) is a selective T cell costimulation modulator indicated for:

Adult Rheumatoid Arthritis (RA)

Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate. The safety and efficacy of Orencia ClickJect auto-injector for subcutaneous injection has not been studied in patients under 18 years of age.

Adult Psoriatic Arthritis (PsA)

Orencia is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

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ABATACEPT - SQ

FDA APPROVED INDICATIONS (CONTINUED)

Important Limitations of Use

Abatacept (Orencia) should not be given concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic rheumatoid arthritis therapy, such as anakinra.

DOSAGE AND ADMINISTRATION

Adult Rheumatoid Arthritis (RA)

ORENCIA 125 mg in prefilled syringes or in ORENCIA ClickJect™ autoinjector should be administered by subcutaneous injection once weekly and may be initiated with or without an intravenous loading dose. For patients initiating therapy with an intravenous loading dose, ORENCIA should be initiated with a single intravenous infusion (as per body weight categories listed in Table 1), followed by the first 125 mg subcutaneous injection administered within a day of the intravenous infusion.

Patients transitioning from ORENCIA intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

Adult Psoriatic Arthritis (PsA)

ORENCIA SC 125 mg should be administered by subcutaneous injection once weekly without the need for an intravenous loading dose.

Patients switching from ORENCIA intravenous therapy to subcutaneous administration should administer the first subcutaneous dose instead of the next scheduled intravenous dose.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

ORENCIA for subcutaneous injection should be initiated without an intravenous loading dose and be administered utilizing the weight range-based dosing as specified in the Table below.

The safety and efficacy of ORENCIA ClickJect autoinjector for subcutaneous injection has not been studied in patients under 18 years of age.

Dose of Orencia for subcutaneous administration in patients 2 years of age or older

BODY WEIGHT OF PATIENT	DOSE (ONCE WEEKLY)
10 to less than 25 kg	50 mg
25 to less than 50 kg	87.5 mg
50 kg or more	125 mg

REFERENCES

- 1) Orencia [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2017.

Created	FS Committee Approval	Effective
8/2019; revised 9/2019	8/2019	10/21/19
Library	Commercial	Non Self-Administered Product
Yes	Yes	No



Generic	Brand	HICL	GCN	Exception/Other
ABATACEPT/MALTOSE	ORENCIA - IV		26306	

1014 Vine St. Cincinnati, OH 45202
Phone: (800) 917-4926
www.kpp-rx.com

ABATACEPT - IV (NSA)**INITIAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
-) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 -) The patient is 6 years of age or older
 -) The patient has had a previous trial of TWO of the formulary immunomodulators: Enbrel, Humira, or Actemra SC (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID as follows:**

-) **Approve for 1 month by GPID with a maximum quantity limit of #4 vials (four 250mg vials) for 3 fills AND**
 -) **Approve for 5 months by GPID with a maximum quantity limit of #4 vials (four 250mg vials) per month (start date is 1 month after the start of the 1st PA).**
- APPROVAL TEXT:** Renewal for moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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ABATACEPT - IV (NSA)**INITIAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

-)] Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-)] The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-)] The patient is 18 years of age or older
-)] The patient has had a previous trial of any two of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID as follows:**

-)] **Approve for 1 month by GPID with a maximum quantity limit of #4 vials (four 250mg vials) for 3 fills AND**
-)] **Approve for 5 months by GPID with a maximum quantity limit of #4 vials (four 250mg vials) per month (start date is 1 month after the start of the 1st PA).**

APPROVAL TEXT: Renewal for psoriatic arthritis (PsA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

DENIAL TEXT: The guideline named **ABATACEPT - IV (Orencia - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, or psoriatic arthritis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

-)] Therapy is prescribed by or given in consultation with a rheumatologist
-)] The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

-)] The patient is 18 years of age or older

-)] The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, and Xeljanz
(Initial denial text continued on next page)

ABATACEPT - IV (NSA)

INITIAL CRITERIA (CONTINUED)

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 6 years of age or older
-) The patient has had a previous trial of TWO of the formulary immunomodulators: Enbrel, Humira, and Actemra SC

For patients with psoriatic arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
-) The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
-) The patient is 18 years of age or older
-) The patient has had a previous trial of any two of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID with a quantity limit of #4 vials (four 250mg vials) per month.**

If no, do not approve.

DENIAL TEXT: The guideline named **ABATACEPT - IV (ORENCIA - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criterion must be met:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

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ABATACEPT - IV (NSA)

RATIONALE

Ensure appropriate use of abatacept-IV consistent with its FDA approved indications.

FDA APPROVED INDICATIONS

ABATACEPT (Orencia) is a selective T cell costimulation modulator indicated for:

Adult Rheumatoid Arthritis (RA)

Moderately to severely active RA in adults. Orencia may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Moderately to severely active polyarticular juvenile idiopathic arthritis in pediatric patients 2 years of age and older. Orencia may be used as monotherapy or concomitantly with methotrexate.

Adult Psoriatic Arthritis (PsA)

ORENCIA is indicated for the treatment of adult patients with active psoriatic arthritis (PsA).

Important Limitations of Use

ABATACEPT (Orencia) should not be given concomitantly with TNF antagonists. Orencia is not recommended for use concomitantly with other biologic rheumatoid arthritis (RA) therapy, such as anakinra.

DOSAGE AND ADMINISTRATION**Adult Rheumatoid Arthritis (RA) and Adult Psoriatic Arthritis (PsA)**

ORENCIA IV lyophilized powder should be reconstituted and administered after as a 30-minute intravenous infusion utilizing the weight range-based dosing specified in the Table below. Following the initial intravenous administration, an intravenous infusion should be given at 2 and 4 weeks after the first infusion and every 4 weeks thereafter.

TABLE 1

BODY WEIGHT OF PATIENT	DOSE	NUMBER OF VIALS
Less than 60 kg	500 MG	2
60 to 100 kg	750 MG	3
More than 100 kg	1000 MG	4

Each vial provides 250mg of abatacept for administration

CONTINUED ON NEXT PAGE



ABATACEPT - IV (NSA)

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

ORENCIA should be administered as a 30-minute intravenous infusion based on body weight. Pediatric patients with body weight less than 75 kg should be administered a dose of 10 mg/kg. Pediatric patients with body weight of 75 kg or more should be administered ORENCIA following the adult intravenous dosing regimen (see Table 1 above), not to exceed a maximum dose of 1000 mg.

Following the initial administration, ORENCIA should be given at 2 and 4 weeks after the first infusion and every 4 weeks thereafter. Any unused portions in the vials must be immediately discarded.

REFERENCES

) Orenzia [Prescribing Information]. Princeton, NJ: E.R. Squibb & Sons, L.L.C. June 2017.

Created	FS Committee Approval	Effective
8/2019	8/2019	9/15/19
Revised 9/2019		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	Yes



ANAKINRA

Generic	Brand	HICL	GCN	Exception/Other
ANAKINRA	KINERET	22953		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
-) The patient is 18 years of age or older
-) The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz (**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL with a quantity limit of #28 syringes per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

If yes, **approve for 6 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis or Neonatal-Onset Multisystem Inflammatory



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Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient meets ONE of the following:
 - a. Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - b. For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - c. Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
-) The patient is 18 years of age or older
-) The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq or Xeljanz.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.



ANAKINRA

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 -) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of #28 syringes per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis or Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS) for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

RATIONALE

Promote appropriate utilization of **KINERET** based on FDA approved indications.

FDA APPROVED INDICATIONS

Kineret is an interleukin-1 receptor antagonist indicated for:

Rheumatoid Arthritis (RA)

-) Reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs).
-) Kineret can be used alone or in combination with DMARDs other than Tumor Necrosis Factor (TNF) blocking agents.



ANAKINRA

FDA APPROVED INDICATIONS (CONTINUED)

Cryopyrin-Associated Periodic Syndromes (CAPS)

) Treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).

DOAGE AND ADMINISTRATION

Rheumatoid Arthritis (RA): The recommended dose of Kineret is 100mg/day administered daily by subcutaneous injection. Higher doses did not result in a higher response. The dose should be administered at approximately the same time every day.

Cryopyrin-Associated Periodic Syndromes (CAPS): The recommended starting dose is 1 to 2 mg/kg daily for NOMID patients. The dose can be individually adjusted to a maximum of 8mg/kg daily to control active inflammation. Adjust doses in 0.5 to 1.0 mg/kg increments. Once daily administration is generally recommended, but the dose may be split into twice daily administrations. Each syringe is intended for a single use. A new syringe must be used for each dose. Any unused portion after each dose should be discarded.

Physicians may consider administration of the prescribed dose of Kineret every other day for patients who have severe renal insufficiency or end stage renal disease (defined as creatinine clearance less than 30 ml/min).

DOSAGE FORMS AND STRENGTHS

Single-use prefilled syringes are available for subcutaneous administration:

) 100 mg per 0.67 mL

REFERENCES

) Kineret [Prescribing Information]. SE-112 76 Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ). May 2016.

Created	FS Committee Approval	Effective
8/2019	8/2019	9/15/19
Revised 9/2019		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

APALUTAMIDE

Generic	Brand	HICL	GCN	Exception/Other
APALUTAMIDE	ERLEADA	44773		

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**
If no, continue to #2.
- Does the patient have a diagnosis of non-metastatic castration-resistant prostate cancer (nmCRPC) **AND** meet the following criteria?
) The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
- Has the patient previously received a bilateral orchiectomy?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**
If no, continue to #4.
- Is the requested medication being used concurrently with a gonadotropin releasing hormone (GnRH) agonist or antagonist (i.e., leuprolide, goserelin, histrelin, degarelix)?

If yes, **approve for 12 months by HICL with a quantity limit of #4 tablets per day.**
If no, do not approve.
DENIAL TEXT: The guideline named **APALUTAMIDE (Erleada)** requires a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC) or non-metastatic castration-resistant prostate cancer (nmCRPC). In addition, the following must be met:
For a diagnosis of non-metastatic castration-resistant prostate cancer, approval requires:
) The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)
) The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) agonist or antagonist (i.e., leuprolide, goserelin, histrelin, degarelix) **OR** the patient has previously received a bilateral orchiectomy

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APALUTAMIDE

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Erleada.

REFERENCES

) Erleada [Prescribing Information]. Horsham, PA: Janssen. September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/21/19

Created: 05/18

Client Approval: 10/19

P&T Approval: 04/18



PRIOR AUTHORIZATION GUIDELINES

ASPARAGINASE (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ASPARAGINASE (ERWINIA CHRYSAN)	ERWINAZE		30918	
PEGASPARGASE	ONCASPAR		24231	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) **AND** meet the following criterion?

) The requested medication will be used as a component of a multi-agent chemotherapeutic regimen

 If yes, continue to #2.

 If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for **Oncaspar** and the patient meets **ONE** of the following criteria?

) Oncaspar will be used as a first-line therapy

) The patient has hypersensitivity to native forms of L-asparaginase

 If yes, **approve Oncaspar (GPID 24231) for 12 months for 1 fill per 14 days.**

 If no, continue to #3.

3. Is the request for **Erwinaze** and the patient meets the following criterion?

) The patient has developed a hypersensitivity to *E. Coli*-derived asparaginase?

 If yes, **approve Erwinaze (GPID 30918) for 12 months with no quantity limit.**

 If no, do not approve.

DENIAL TEXT: The guideline named **ASPARAGINASE (Erwinaze, Oncaspar)** requires a diagnosis of acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met:

) The requested medication will be used as a component of a multi-agent chemotherapeutic regimen

Request for Oncaspar also requires ONE of the following:

) Oncaspar will be used as a first-line therapy

) The patient has hypersensitivity to native forms of L-asparaginase

Request for Erwinaze also requires:

) The patient has developed a hypersensitivity to *E. Coli*-derived asparaginase

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ASPARAGINASE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Asparaginase.

REFERENCES

-) Erwinaze [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; March 2016.
-) Oncaspar [Prescribing Information]. Lexington, MA: Baxalta US Inc.; January 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/21/19

Created: 12/11

Client Approval: 10/19

P&T Approval: 04/19



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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

BACLOFEN (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
BACLOFEN	OZOBAX		64209	

GUIDELINES FOR USE

1. Is the request for the treatment of spasticity resulting from multiple sclerosis (MS) **AND** the patient meets the following criterion?

-) The requested medication is for the relief of flexor spasms and concomitant pain, clonus, and muscle rigidity

If yes, **approve for 12 months by GPID with a quantity limit of 80mL per day.**

If no, continue to #2.

2. Does the patient have spinal cord injuries or other spinal cord diseases?

If yes, **approve for 12 months by GPID with a quantity limit of 80mL per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **BACLOFEN (Ozobax)** requires that ONE of the following is met:

-) The request is for the treatment of spasticity resulting from multiple sclerosis (MS) for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity
-) The patient has spinal cord injuries or other spinal cord diseases

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ozobax.

REFERENCES

Ozobax [Prescribing Information]. Athens, GA: Metacel Pharmaceuticals, LLC; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/11/19

Created: 10/19

Client Approval: 10/19

P&T Approval: 10/19



WELLFLEET

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PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

Generic	Brand	HICL	GCN	Exception/Other
BARICITINIB	OLUMIANT	44296		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 -) Therapy is prescribed by or given in consultation with a rheumatologist
 -) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 -) The patient is 18 years of age or older
 -) The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz (**Note:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL with a quantity limit of #1 tablet per day.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **BARICITINIB (Olumiant)** requires a diagnosis of moderate to severe rheumatoid arthritis. In addition, the following criteria must also be met:

-) Therapy is prescribed by or given in consultation with a rheumatologist
-) The patient meets ONE of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

(Initial denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

INITIAL CRITERIA (CONTINUED)

- The patient is 18 years of age or older
- The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **BARICITINIB (Olumiant)** requires a diagnosis of moderate to severe rheumatoid arthritis or psoriatic arthritis and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

RATIONALE

To ensure appropriate use of Olumiant consistent with its FDA approved indication and dosing.

FDA APPROVED INDICATION

Olumiant is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Limitation of Use: Use of Olumiant in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

DOSAGE FORMS AND STRENGTHS

Olumiant is available as 2 mg oral tablets.

DOSAGE AND ADMINISTRATION

The recommended dose of Olumiant is 2 mg orally once daily. Olumiant may be used as monotherapy or in combination with methotrexate or other DMARDs.

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PRIOR AUTHORIZATION GUIDELINES

BARICITINIB

REFERENCES

-) Olumiant [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. May 2018.
-) Cohen S, Mikuls TR. Initial treatment of rheumatoid arthritis in adults. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019)
-) Cohen S, Cannella A. Treatment of rheumatoid arthritis in adults resistant to initial nonbiologic DMARD therapy. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019).

Created	FS Committee Approval	Effective
1/2019	2/2019	04/26/19
Revised 8/2019	8/2019	09/15/19
Revised 9/2019		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



PRIOR AUTHORIZATION GUIDELINES

CALASPARGASE PEGOL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
CALASPARGASE PEGOL-MKNL	ASPARLAS	45566		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?

- ☐ The patient is 1 month to 21 years of age
- ☐ Asparlas will be used as a component of a multi-agent chemotherapeutic regimen

If yes, **approve for 12 months by HICL for 1 fill per 21 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **CALASPARGASE PEGOL (Asparlas)** requires a diagnosis of acute lymphoblastic leukemia. In addition, the following must be met:

- ☐ The patient is 1 month to 21 years of age
- ☐ Asparlas will be used as a component of a multi-agent chemotherapeutic regimen

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Asparlas.

REFERENCES

- ☐ Asparlas [Prescribing Information]. Boston, MA: Servier Pharmaceuticals LLC; September 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/21/19

Created: 10/19

Client Approval: 10/19

P&T Approval: 04/19

GALCANEZUMAB-GNLM

Generic	Brand	HICL	GCN	Exception/Other
GALCANEZUMAB-GNLM	EMGALITY	45281	40418 40419 46397	

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of episodic migraines and meet **ALL** the following criteria?
 -) The patient is 18 years of age or older
 -) Emgality is prescribed for the preventive treatment of migraines
 -) The patient has had a previous trial of any TWO of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

If yes, **approve for a total of 6 months by entering TWO approvals as follows:**

-) **FIRST APPROVAL:** approve for 1 month by GPID (40418 or 40419) with a quantity limit of #2mL per 30 days for one fill.
-) **SECOND APPROVAL:** approve for 5 months by GPID (40418 or 40419) with a quantity limit of #1mL per 30 days for 5 fills (Please enter a start date of 23 days AFTER the start date of the first approval).

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month OR the patient has experienced a reduction in migraine severity OR migraine duration with Emgality therapy.

If no, continue to #2.

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GALCANEZUMAB-GNLM**INITIAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of chronic migraines and meet **ALL** the following criteria?

- ☐ The patient is 18 years of age or older
- ☐ Emgality is prescribed for the preventive treatment of migraines
- ☐ The patient has had a previous trial of any **TWO** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox **[Note: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]**

If yes, **approve for a total of 6 months by entering TWO approvals as follows:**

- ☐ **FIRST APPROVAL:** approve for 1 month by GPID (40418 or 40419) with a quantity limit of #2mL per 30 days for one fill.
- ☐ **SECOND APPROVAL:** approve for 5 months by GPID (40418 or 40419) with a quantity limit of #1mL per 30 days for 5 fills (Please enter a start date of 23 days AFTER the start date of the first approval).

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month OR the patient has experienced a reduction in migraine severity OR migraine duration with Emgality therapy.

If no, continue to #3.

3. Is the request for the treatment of episodic cluster headache **AND** the patient meets the following criterion?

- ☐ The patient is 18 years of age or older.

If yes, **approve for 12 months by GPID (46397) with a quantity limit of #3mL per 30 days.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **GALCANEZUMAB-GNLM (Emgality)** requires a diagnosis of episodic or chronic migraines, or treatment of episodic cluster headache. The following criteria must also be met:

For episodic migraines, approval requires:

- ☐ The patient is 18 years of age or older
- ☐ Emgality is prescribed for the preventive treatment of migraines
- ☐ The patient has had a previous trial of any TWO of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

For chronic migraines, approval requires:

- ☐ The patient is 18 years of age or older



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-) Emgality is prescribed for the preventive treatment of migraines
-) The patient has had a previous trial of any TWO of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox

For treatment of episodic cluster headache, approval requires:

-) The patient is 18 years of age or older.

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GALCANEZUMAB-GNLM

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is Emgality prescribed for the preventive treatment of migraines AND does the patient meets at least ONE of the following criteria?

- ☐ The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
- ☐ The patient has experienced a reduction in migraine severity with Emgality therapy
- ☐ The patient has experienced a reduction in migraine duration with Emgality therapy

If yes, **approve for 12 months by GPID (40418 or 40419) with a quantity limit of #1mL per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named GALCANEZUMAB-GNLM (Emgality) requires that Emgality is prescribed for preventive treatment of migraines. In addition, at least ONE of the following criteria must be met:

- ☐ The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
- ☐ The patient has experienced a reduction in migraine severity with Emgality therapy
- ☐ The patient has experienced a reduction in migraine duration with Emgality therapy

Rationale

For further information, please refer to the Prescribing information for Emgality.

References

- ☐ Emgality [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company. June 2019.

Created	FS Committee Approval	Effective
4/2019; revised 6/2019; revised 10/2019	4/2019	10/16/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

GOLIMUMAB - IV (NSA)

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB - IV	SIMPONI ARIA - IV		34983	

GUIDELINES FOR USE
INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient meets **ONE** of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
- ☐ The patient is concurrently using or has a contraindication to methotrexate
- ☐ The patient is 18 years of age or older
- ☐ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID for Simponi Aria 50mg/4mL vials (GPID 34983).**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis (RA) requires concurrent use of methotrexate (unless contraindicated) and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- ☐ The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- ☐ The patient is 18 years of age or older
- ☐ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara, or Xeljanz



[**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID for Simponi Aria 50mg/4mL vials (GPID 34983).**

APPROVAL TEXT: Renewal for psoriatic arthritis (PsA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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GOLIMUMAB - IV (NSA)

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient is 18 years of age or older
- ☐ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by GPID for Simponi Aria 50mg/4mL vials (GPID 34983).**

Approval Text: Renewal for ankylosing spondylitis (AS) requires that the patient has experienced or maintained an improvement of at least 50% or 2 units in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient meets ONE of the following:
 - a. Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - b. For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - c. Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
- ☐ The patient is concurrently using or has a contraindication to methotrexate
- ☐ The patient is 18 years of age or older
- ☐ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Actemra, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz

For the diagnosis of psoriatic arthritis (PsA), approval requires:

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- ☐ The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- ☐ The patient is 18 years of age or older



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-) The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx, Stelara, or Xeljanz

(Initial denial text continued on next page)

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GOLIMUMAB - IV (NSA)

INITIAL CRITERIA (CONTINUED)

For the diagnosis of ankylosing spondylitis (AS), approval requires:

- ☐ Therapy is prescribed by or given in consultation with a rheumatologist
- ☐ The patient is 18 years of age or older
- ☐ The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Cosentyx

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?

- ☐ The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- ☐ The patient is concurrently using or has a contraindication to methotrexate

If yes, **approve for 12 months by GPID with a duration of 2 months per fill.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?

- ☐ The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID with a duration of 2 months per fill.**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?

- ☐ The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months by GPID with a duration of 2 months per fill.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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GOLIMUMAB - IV (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
-) The patient is concurrently using or has a contraindication to methotrexate

For the diagnosis of psoriatic arthritis (PsA), approval requires:

-) The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis (AS), approval requires:

-) The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Simponi

REFERENCES

-) Simponi Aria [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. February 2018.

Created	FS Committee Approval	Effective
8/1/19	8/2019	9/15/19
Revised 9/2019		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	Yes



PRIOR AUTHORIZATION GUIDELINES

LENVATINIB

Generic	Brand	HICL	GCN	Exception/Other
LENVATINIB MESYLATE	LENVIMA	41756		ROUTE = ORAL

GUIDELINES FOR USE

1. Does the patient have a diagnosis of differentiated thyroid cancer (DTC) and meet **ALL** of the following criteria; (**NOTE:** Differentiated thyroid cancer (DTC) can be classified as papillary (PTC), follicular (FTC), or Hurthle cell)?
 -) The thyroid cancer is locally recurrent or metastatic
 -) The thyroid cancer is progressive
 -) Patient has tried or has a contraindication to radioactive iodine therapy

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

-) For a daily dose of 10mg, approve for 30 blisters per 30 days.
-) For a daily dose of 14mg, approve for 60 blisters per 30 days.
-) For a daily dose of 20mg, approve for 60 blisters per 30 days.
-) For a daily dose of 24mg, approve for 90 blisters per 30 days.

If no, continue to #2.

2. Does the patient have a diagnosis of advanced renal cell cancer (RCC) and meet **ALL** of the following criteria?
 -) Lenvima will be used in combination with everolimus
 -) Patient has previously tried one anti-angiogenic therapy (e.g., Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib))

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

-) For a daily dose of 8mg, approve for 60 blisters per 30 days.
-) For a daily dose of 10mg, approve for 30 blisters per 30 days.
-) For a daily dose of 14mg, approve for 60 blisters per 30 days.
-) For a daily dose of 18mg, approve for 90 blisters per 30 days.

If no, continue to #3.

3. Does the patient have a diagnosis of unresectable hepatocellular carcinoma (HCC)?

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

-) For a dose of 4mg every other day, approve for 15 blisters per 30 days.
-) For a daily dose of 4mg, approve for 30 blisters per 30 days.
-) For a daily dose of 8mg, approve for 60 blisters per 30 days.
-) For a daily dose of 12mg, approve for 90 blisters per 30 days.

If no, continue to #4.

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LENVATINIB

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced endometrial carcinoma and meet **ALL** of the following criteria?

- ☐ The medication is used in combination with pembrolizumab (Keytruda)
- ☐ The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
- ☐ The patient has experienced disease progression following prior systemic therapy
- ☐ The patient is not a candidate for curative surgery or radiation

If yes, **approve for 12 months by GPID based on the following daily dose requirements:**

- ☐ For a daily dose of 8mg, approve for 60 blisters per 30 days.
- ☐ For a daily dose of 10mg, approve for 30 blisters per 30 days.
- ☐ For a daily dose of 14mg, approve for 60 blisters per 30 days.
- ☐ For a daily dose of 20mg, approve for 60 blisters per 30 days.

If no, do not approve.

DENIAL TEXT: The guideline named **LENVATINIB (Lenvima)** requires a diagnosis of differentiated thyroid cancer, advanced renal cell cancer, unresectable hepatocellular carcinoma, or advanced endometrial carcinoma. In addition, the following criteria must be met:

For the diagnosis of differentiated thyroid cancer, approval requires:

- ☐ Thyroid cancer is progressive and is locally recurrent **or** metastatic
- ☐ Patient has tried or has contraindication to radioactive iodine therapy

For the diagnosis of advanced renal cell cancer, approval requires:

- ☐ Lenvima will be used in combination with everolimus
- ☐ Patient has previously tried one anti-angiogenic therapy

For the diagnosis of advanced endometrial carcinoma, approval requires:

- ☐ The medication is used in combination with pembrolizumab (Keytruda)
- ☐ The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
- ☐ The patient has experienced disease progression following prior systemic therapy
- ☐ The patient is not a candidate for curative surgery or radiation

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lenvima.

REFERENCES

- ☐ Lenvima [Prescribing Information]. Woodcliff Lake, NJ: Eisai, Inc. September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/21/19

Created: 2/15

Client Approval: 10/19

P&T Approval: 10/18



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RX PLAN PRIOR AUTHORIZATION GUIDELINES

PITOLISANT

Generic	Brand	HICL	GCN	Exception/Other
PITOLISANT	WAKIX	45575		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of narcolepsy as demonstrated by cataplexy **AND** meet the following criterion?
 -) Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine

If yes, **approve for 6 months by HICL with a quantity limit of #2 per day.**

APPROVAL TEXT: Renewal requires that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR the patient has shown improvement in cataplexy compared to baseline.

If no, continue to #2.

2. Does the patient have a diagnosis of excessive daytime sleepiness (EDS) with narcolepsy **AND** narcolepsy is confirmed by **ONE** of the following criteria?
 -) The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
 -) The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
 -) The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PITOLISANT

INITIAL CRITERIA (CONTINUED)

3. Does the patient meet **ALL** of the following criteria?

-) The patient has Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
-) Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
-) The patient had a trial of or contraindication to one generic typical stimulant (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil

If yes, **approve for 6 months by HICL with a quantity limit of #2 per day.**

APPROVAL TEXT: Renewal requires that the patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR the patient has shown improvement in cataplexy compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **PITOLISANT (Wakix)** requires a diagnosis of narcolepsy as demonstrated by cataplexy OR excessive daytime sleepiness (EDS) with narcolepsy. In addition, the following criteria must be met:

For the diagnosis of narcolepsy as demonstrated by cataplexy, approval requires:

-) Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine

For the diagnosis of excessive daytime sleepiness (EDS) with narcolepsy, approval requires:

-) The patient has narcolepsy that is confirmed by **ONE** of the following:
 - o The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
 - o The patient has a Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
 - o The patient has low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay
-) The patient has Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
-) Therapy is prescribed by or given in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
-) The patient had a trial of or contraindication to one generic typical stimulant (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** solriamfetol, armodafinil, or modafinil

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PITOLISANT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of narcolepsy and meet **ONE** of the following criteria?
 -) The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR
 -) The patient has shown improvement in cataplexy compared to baseline

If yes, **approve for 12 months by HICL with a quantity limit of #2 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **PITOLISANT (Wakix)** requires a diagnosis of narcolepsy. In addition, **ONE** of the following must be met:

-) The patient has demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline, OR
-) The patient has shown improvement in cataplexy compared to baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Wakix.

REFERENCES

-) Wakix [Prescribing Information]. Plymouth Meeting, PA: Harmony Biosciences, LLC; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/21/19

Created: 10/19

Client Approval: 10/19

P&T Approval: 07/19



PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

Generic	Brand	HICL	GCN	Exception/Other
SARILUMAB	KEVZARA	44183		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 -) Therapy initiated by or given in consultation with a rheumatologist
 -) The patient meets **ONE** of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 -) Patient is 18 years of age or older
 -) Previous trial of **two** formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz. (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by HICL with a quantity limit of #2.28 mL (#2 prefilled syringes) per 28 days.**

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, do not approve.

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PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

GUIDELINES FOR USE (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SARILUMAB (Kevzara)** requires a diagnosis of moderate to severe rheumatoid arthritis. The following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

-) Therapy initiated by or given in consultation with a rheumatologist
-) The patient meets **ONE** of the following:
 - o Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - o For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - o Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
-) Patient is 18 years of age or older
-) Previous trial of **two** formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet the following criteria?
 -) Documentation that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of #2.28 mL (#2 prefilled syringes) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **SARILUMAB (Kevzara)** requires a diagnosis of moderate to severe rheumatoid arthritis for renewal. The following criteria must also be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:

-) Documentation that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

RATIONALE

Ensure appropriate utilization criteria for Kevzara (sarilumab) per FDA-approved indication, dosing and to promote use of preferred formulary agents.

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PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

FDA APPROVED INDICATIONS

Indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

DOSAGE AND ADMINISTRATION

Kevzara may be used as monotherapy or in combination with methotrexate (MTX) or other conventional DMARDs. The recommended dosage of Kevzara is 200 mg once every two weeks given as a subcutaneous injection. Reduce dose to 150 mg once every two weeks for management of neutropenia, thrombocytopenia and elevated liver enzymes.

REFERENCE

Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; 2017

Created	FS Committee Approval	Effective
01/2019	02/2019	04/26/19
Revised 08/2019	08/2019	09/15/19
Revised 9/19		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

BROLUCIZUMAB-DBLL (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BROLUCIZUMAB-DBLL	BEOVU	46051		

GUIDELINES FOR USE

- Does the patient have a diagnosis of neovascular (wet) age-related macular degeneration (AMD) **AND** meet the following criterion?

- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist

If yes, **approve for a total of 12 months by HICL as follows:**

- INITIAL DOSE:** Approve for 3 fills with a quantity limit of 0.1mL every 4 weeks.
- MAINTENANCE DOSE:** Approve for 6 fills with a quantity limit of 0.1mL every 8 weeks.

(NOTE: Please enter both approvals for initial request. For continuation of therapy requests, approve only the maintenance dose)

If no, do not approve.

DENIAL TEXT: The guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires a diagnosis of neovascular (wet) age-related macular degeneration (AMD). In addition, the following must be met:

- Therapy is prescribed by or in consultation with an ophthalmologist or retina specialist

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Beovu.

REFERENCES

- Beovu [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 10/28/19

Created: 10/19

Client Approval: 10/19

P&T Approval: 10/19

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
COLCHICINE (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
COLCHICINE	GLOPERBA		45974	

GUIDELINES FOR USE

- Is the requested medication being used for the prophylaxis of gout flares **AND** the patient meets the following criterion?

) The patient is 18 years of age or older

 If yes, **approve for 12 months by GPID with a quantity limit of 10mL per day.**

 If no, do not approve.

DENIAL TEXT: The guideline named **COLCHICINE (Gloperba)** requires the requested medication is being used for the prophylaxis of gout flares. In addition, the patient must meet the following:

) The patient is 18 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gloperba.

REFERENCES

Gloperba. [Prescribing Information]. Alpharetta, GA: Avion Pharmaceuticals, LLC; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/9/19

Created: 11/19

Client Approval: 1/20

P&T Approval: 1/20

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
TRASTUZUMAB-DKST (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB-DKST	OGIVRI	44673		

GUIDELINES FOR USE

- Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
 -) The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
 -) The request is for adjuvant therapy
 -) The patient meets **ONE** of the following:
 - o Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - o Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - o Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

- Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 -) The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
 -) The patient meets **ONE** of the following:
 - o Requested medication is being used in combination with paclitaxel for first-line treatment
 - o Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

- Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
 -) The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
 -) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 -) The patient has not received prior treatment for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, do not approve.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-DKST (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **TRASTUZUMAB-DKST (Ogivri)** requires a diagnosis of breast cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. In addition, the following criteria must be met:

For the diagnosis of breast cancer, approval requires:

-) The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
-) The request is for adjuvant therapy
-) The patient meets **ONE** of the following:
 - o Requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - o Requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - o Requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

For the diagnosis of metastatic breast cancer, approval requires:

-) The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
-) The patient meets **ONE** of the following:
 - o Requested medication is being used in combination with paclitaxel for first-line treatment
 - o Requested medication is being used as a single agent in patients who have previously tried chemotherapy for metastatic disease

For the diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:

-) The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
-) Requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
-) The patient has not received prior treatment for metastatic disease

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ogivri.

REFERENCES

Ogivri [Prescribing Information]. Steinhausen, Switzerland: Mylan GmbH; April 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 11/16/19

Created: 11/19

Client Approval: 1/18

P&T Approval: 1/18

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

DIROXIMEL FUMARATE

Generic	Brand	HICL	GCN	Exception/Other
DIROXIMEL FUMARATE	VUMERITY	46164		

GUIDELINES FOR USE

- Does the patient have a diagnosis of relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?

- ✓ The patient is 18 years of age or older
- ✓ The patient had a trial or failure of or contraindication to Tecfidera **AND** one of the following: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Rebif, Plegridy

If yes, **approve for 12 months by HICL with a quantity limit of 4 capsules per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **DIROXIMEL FUMARATE (Vumerity)** requires a diagnosis of relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. In addition, the following criteria must be met:

- ✓ The patient is 18 years of age or older
- ✓ The patient had a trial or failure of or contraindication to Tecfidera **AND** one of the following: Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Rebif, Plegridy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vumerity.

REFERENCES

- ✓ Vumerity [Prescribing Information]. Waltham, MA: Alkermes, Inc.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/16/19

Created: 11/19

Client Approval: 10/19

P&T Approval: 10/19

ELUXADOLINE

Generic	Brand	HICL	GCN	Exception/Other
ELUXADOLINE	VIBERZI	42445		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets the following criteria?
 -) The patient is at least 18 years old
 -) The medication is prescribed by or in consultation with a gastroenterologist
 -) The patient has had a trial of or contraindication to either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** gastrointestinal anti-spasmodics (e.g., dicyclomine or hyoscyamine)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Our guideline for **ELUXADOLINE (Viberzi)** requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply. The following criteria must also be met:

-) The patient is at least 18 years old
-) The medication is being prescribed by or in consultation with a gastroenterologist
-) The patient has had a trial of or contraindication to either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** gastrointestinal anti-spasmodics (e.g., dicyclomine or hyoscyamine)

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ELUXADOLINE

INITIAL CRITERIA (CONTINUED)

2. Does the patient meet **ANY** of the following criteria?

- ☐ Patient does not have a gallbladder
- ☐ Patient is receiving concomitant OATP1B1 inhibitors (e.g., atazanavir, cyclosporine, eltrombopag, gemfibrozil, lopinavir, rifampin, ritonavir, saquinavir, tipranavir)
- ☐ Patient has mild or moderate hepatic impairment
- ☐ Patient is intolerant to Viberzi 100mg

If yes, **approve ELUXADOLINE 75MG for 12 weeks by GPID with a quantity limit of #2 tablets per day.**

APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

If no, **approve ELUXADOLINE 100MG for 12 weeks by GPID with a quantity limit of #2 tablets per day.**

APPROVAL TEXT: Renewal requires that the patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale) and the patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

RENEWAL CRITERIA

1. Is the patient being treated for irritable bowel syndrome with diarrhea (IBS-D) and meets **ALL** of the following criteria?

- ☐ Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
- ☐ Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7)

If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**

If no, do not approve.

DENIAL TEXT: Our guideline for **ELUXADOLINE (Viberzi)** renewal requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply. The following criteria must also be met:

- ☐ Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale).
- ☐ Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7).

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ELUXADOLINE

RATIONALE

To ensure appropriate utilization of Viberzi for irritable bowel syndrome with diarrhea (IBS-D).

Per the American College of Gastroenterology, there is high quality evidence that tricyclic anti-depressants are effective in providing symptom relief in IBS-D. However, tolerance to these agents could be an issue for some patients.

Renewal criteria for IBS-D is based on the definition of a responder used in Study 1 and 2 of the Viberzi pivotal trials. Efficacy of Viberzi was assessed in both trials using an overall composite responder primary endpoint. The primary endpoint was defined by the simultaneous improvement in the daily worst abdominal pain score by 30% as compared to the baseline weekly average AND a reduction in the BSS to <5 on at least 50% of the days within a 12-week time interval. Improvement in daily worst abdominal pain in the absence of a concurrent bowel movement was also considered a response day.

FDA APPROVED INDICATIONS

Viberzi is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

DOSING

The recommended dosage in adults is 100 mg twice daily taken with food.

The recommended dosage is 75 mg twice daily taken with food in patients who:

-) do not have a gallbladder
-) are unable to tolerate the 100 mg dose
-) are receiving concomitant OATP1B1 inhibitors

REFERENCES

-) Patheon Pharmaceuticals, Inc. Viberzi package insert. Cincinnati, OH 45209. May 2015.
-) Task Force on the Management of Functional Bowel Disorders. American College of Gastroenterology Monograph on the Management of Irritable Bowel syndrome and Chronic Idiopathic Constipation. Am J Gastroenterol 2014; 109:S2-S26.

Created	FS Committee Approval	Effective
7/2019	8/6/2019	11/15/2019

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

Generic	Brand	HICL	GCN	Exception/Other
GLECAPREVIR/ PIBRENTASVIR	MAVYRET	44453		

GUIDELINES FOR USE

- Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** the following criteria?
 -) The patient is at least 12 years old OR weighs at least 45 kg (99 lbs).
 -) The medication prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
 -) Documentation of chronic HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Does the patient meet at least **ONE** of the following criteria?
 -) The patient has moderate or severe liver impairment (Child-Pugh B or C)
 -) The patient is concurrently taking any of the following medications: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
 -) The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have hepatitis C, post-liver transplant?

If yes, continue to question #4.

If no, continue to #5.

4. Does the patient have cirrhosis?

If yes, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

If no, **approve for 12 weeks by HICL for #3 tablets per day.**

5. Does the patient have a kidney transplant?

If yes, **approve for 12 weeks by HICL for #3 tablets per day.**

If no, continue to #6.

6. Is the patient treatment experienced with an NS5A inhibitor?

If yes, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

If no, continue to #7.

7. Is the patient **ONE** of the following?

-) The patient has genotype 1 or 2 with no cirrhosis and is treatment experienced with sofosbuvir or an NS3 inhibitor.
-) The patient has genotype 1, 2, 4, 5 or 6 infection with compensated cirrhosis and is treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)

If yes, **approve for 12 weeks by HICL for #3 tablets per day.**

If no, continue to #8.

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PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

GUIDELINES FOR USE (CONTINUED)

8. Is the patient **ONE** of the following?

-) The patient is treatment naïve without cirrhosis or with compensated (Child Pugh A) cirrhosis
-) The patient has genotype 1, 2, 4, 5, or 6 infection with no cirrhosis and is treatment experienced with peginterferon and ribavirin.

If yes, **approve for 8 weeks by HICL for #3 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires a diagnosis of genotype 1, 2, 3, 4, 5, or 6 hepatitis C. The following criteria must also be met:

-) The patient is at least 12 years old OR weighs at least 45 kg (99 lbs).
-) The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
-) Documentation of chronic HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)
-) The patient meets one of the following:
 - o The patient is post liver transplant with no cirrhosis and is treatment naïve or treatment experienced.
 - o The patient is post kidney transplant with no cirrhosis or compensated cirrhosis and is treatment naïve or treatment experienced.
 - o The patient is treatment naïve with no cirrhosis or with compensated cirrhosis.
 - o The patient has genotype 1 or 2 with no cirrhosis and is treatment experienced with sofosbuvir or an NS3 inhibitor.
 - o The patient has genotype 1, 2, 4, 5 or 6 infection with compensated cirrhosis and is treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir).
 - o The patient has genotype 1, 2, 4, 5, or 6 infection with no cirrhosis and is treatment experienced with peginterferon and ribavirin.

The medication will not be approved for the following:

-) The patient is concurrently taking: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
-) The patient has moderate or severe liver impairment (Child-Pugh B or C)
-) The patient is treatment experienced with an NS5A containing regimen and is not a liver or kidney transplant recipient.
-) The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

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PRIOR AUTHORIZATION GUIDELINES

GLECAPREVIR/PIBRENTASVIR

RATIONALE

Ensure appropriate utilization of Mavyret (glecaprevir/pibrentasvir).

FDA APPROVED INDICATIONS

For the treatment of patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult patients with genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

FDA APPROVED DOSAGE

) Three tablets taken once daily with food.

Duration of therapy is as follows:

Patient type	Treatment duration	
	No cirrhosis	Compensated Cirrhosis
Treatment naïve; genotypes 1-6	8 weeks	8 weeks
Treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir; genotypes 1, 2,4,5 or 6	8 weeks	12 weeks
Treatment experienced with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir; genotype 3	16 weeks (alt regimen)	16 weeks (alt regimen)
Treatment experienced with NS3/4A protease inhibitor; genotype 1	12 weeks	12 weeks

FDA APPROVED DOSAGE

Mavyret is recommended for 12 weeks in liver or kidney transplant recipients. A 16-week treatment duration is recommended in genotype 1-infected patients who are NS5A inhibitor-experienced without prior treatment with an NS3/4A protease inhibitor or in genotype 3-infected patients who are PRS treatment-experienced.

Mavyret is not recommended in patients with moderate hepatic impairment (Child-Pugh B) and is contraindicated in patients with severe hepatic impairment (Child-Pugh C).

REFERENCES

-) Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed January 2, 2019.
-) Mavyret [Prescribing Information]. North Chicago, IL: Abbvie; August 2018.

Created	FS Committee Approval	Effective
01/19; revised 6/26/19	02/19	7/12/19
Revised 8/1/19	08/19	9/15/19
Revised 11/1/19	11/19	11/20/19
Library	Commercial	Non Self-Administered Product
Yes	Yes	No

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
PEGFILGRASTIM-BMEZ (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
PEGFILGRASTIM-BMEZ	ZIEXTENZO	46183		

GUIDELINES FOR USE

1. Is Ziextenzo being prescribed for patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of severe neutropenia with fever?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: The guideline named **PEGFILGRASTIM-BMEZ (Ziextenzo)** requires that Ziextenzo is being prescribed for patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of severe neutropenia with fever.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ziextenzo.

REFERENCES

Ziextenzo [Prescribing Information]. Princeton, NJ: Sandoz Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 11/22/19

Created: 11/19

Client Approval: 01/20

P&T Approval: 01/20

SOMATROPIN

Generic	Brand	HICL	GCN	Exception/Other
SOMATROPIN	GENOTROPIN		10554 21450 21451 21452 21453 21454 50177 50187 50197 50207 50217 63408	
SOMATROPIN	NORDITROPIN FLEXPRO		24145 24146 24147 25816	
SOMATROPIN	SEROSTIM		25955 25960 63405	BRAND ZOMACTON, SAIZEN, TEV-TROPIN
SOMATROPIN	ZORBTIVE		12767	BRAND SAIZEN

GUIDELINES FOR USE

NOTE: Please use the criteria for the specific drug requested.

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
SEROSTIM

- Is the request for Serostim for a patient with a diagnosis of HIV wasting/cachexia and meets **ALL** of the following criteria?
 -) The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
 -) The medication is prescribed by or given in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist, or Infectious Disease Specialist
 -) Patient is on HIV anti-retroviral therapy
 -) Patient has inadequate response to previous therapy (e.g., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
 -) Patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
 -) Alternative causes of wasting has been ruled out; alternative causes include:
 - o Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
 - o Diarrhea
 - o Inadequate energy (caloric) intake
 - o Malignancies
 - o Opportunistic infections

(Initial criteria continued on next page)

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

-) The patient meets **ONE** of the following criteria for weight loss:
- 10% unintentional weight loss over 12 months
 - 7.5% unintentional weight loss over 6 months
 - 5% body cell mass (BCM) loss within 6 months
 - BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
 - BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
 - BMI less than 18.5 kg per meter squared

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the **SEROSTIM** guideline.

2. Is the patient hypogonadal as defined by **ONE** of the following?
-) Total serum testosterone level of less than 300 ng/dL (10.4 nmol/L)
-) A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
-) A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

If yes, continue to #3.

If no, **approve Serostim for 12 weeks by GPID.**

3. For patients who are hypogonadal, does the patient meet the following criteria?
-) Patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)

If yes, **approve Serostim for 12 weeks by GPID.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the **SEROSTIM** guideline.

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Serostim)** requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.

-) The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
-) The medication is prescribed by or given in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist, or Infectious Disease Specialist
-) The patient is on HIV anti-retroviral therapy
-) The patient has inadequate response to previous therapy (e.g., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)

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SOMATROPIN

INITIAL CRITERIA - SEROSTIM (CONTINUED)

-) The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
-) Alternative causes of wasting has been ruled out; alternative causes include:
 - o Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
 - o Diarrhea
 - o Inadequate energy (caloric) intake
 - o Malignancies
 - o Opportunistic infections
-) The patient meets **ONE** of the following criteria for weight loss:
 - o 10% unintentional weight loss over 12 months
 - o 7.5% unintentional weight loss over 6 months
 - o 5% body cell mass (BCM) loss within 6 months
 - o BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
 - o BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27 kg per meter squared
 - o BMI less than 18.5 kg per meter squared

For patients who are hypogonadal (patients with low testosterone levels), approval requires the following:

-) The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)
-) The patient meets one of the following criteria for low testosterone:
 - o Total serum testosterone level of less than 300 ng/dL (10.4 nmol/L)
 - o A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
 - o A free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

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SOMATROPIN

INITIAL CRITERIA (CONTINUED)

ZORBTIVE

1. Is the request for Zorbtive for a patient with a diagnosis of short bowel syndrome and meets **ALL** of the following criteria?
 -) The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
 -) The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
 -) The medication is prescribed by or given in consultation with a gastroenterologist

If yes, **approve Zorbtive for 4 weeks by GPID for #1 vial per day (max dose not to exceed 8mg per day).**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the **ZORBTIVE** guideline.

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** requires a diagnosis of short bowel syndrome. The following criteria must also be met.

-) The requested agent is **NOT** prescribed for athletic enhancement or anti-aging purposes
-) The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
-) The medication is prescribed by or given in consultation with a gastroenterologist

GENOTROPIN/NORDITROPIN

1. Is the request for Genotropin or Norditropin for the treatment of **ANY** of the following?
 -) Athletic enhancement
 -) Anti-aging purposes
 -) Idiopathic Short Stature

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the **GENOTROPIN/NORDITROPIN** guideline.

If no, continue to #2.

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SOMATROPIN

INITIAL CRITERIA – GENOTROPIN/NORDITROPIN (CONTINUED)

2. Does the patient have **ONE** of the following diagnoses and meets **ALL** of the following criteria?

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Patient meets at least **ONE** of the following criteria for short stature:
 - o Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
 - o Height velocity less than the 25th percentile for age
 - o Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age

For the diagnosis of growth failure associated with Turner Syndrome, approval requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:

-] Confirmed diagnosis of PWS
-] The medication is prescribed by or given in consultation with an endocrinologist

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Patient with no catch-up growth by age 2 years
-] Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For the diagnosis of adult growth hormone deficiency, approval requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] Adults with growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

If yes, **approve the requested product (Genotropin or Norditropin) for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the **GENOTROPIN/NORDITROPIN** guideline.

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SOMATROPIN

INITIAL CRITERIA – GENOTROPIN/NORDITROPIN (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **SOMATROPIN (Genotropin/Norditropin)** requires **ONE** of the following diagnoses:

-] Pediatric growth hormone deficiency
-] Growth failure associated with Turner Syndrome
-] Growth failure due to Prader-Willi Syndrome (PWS)
-] Growth failure in children born small for gestational age (SGA)
-] Adult growth hormone deficiency

This medication will not be approved for treatment of **ANY** of the following conditions:

-] Athletic enhancement
-] Anti-aging purposes
-] Idiopathic Short Stature

The following criteria must also be met:

For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Patient meets at least **ONE** of the following criteria for short stature:
 - o Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
 - o Height velocity less than the 25th percentile for age
 - o Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age

For the diagnosis of growth failure associated with Turner Syndrome, approval requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), approval requires:

-] Confirmed diagnosis of PWS
-] The medication is prescribed by or given in consultation with an endocrinologist

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

-] The medication is Prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Patient with no catch-up growth by age 2 years
-] Patient's height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender

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SOMATROPIN

INITIAL CRITERIA – GENOTROPIN/NORDITROPIN (CONTINUED)

For the diagnosis of adult growth hormone deficiency, approval requires:

-) The medication is prescribed by or in consultation with an endocrinologist
-) Adults with growth hormone deficiency alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary diseases, hypothalamic disease, surgery, radiation therapy, trauma, or continuation of therapy from childhood onset growth hormone deficiency

RENEWAL CRITERIA

SEROSTIM

1. Has the patient received more than 24 weeks of therapy within plan year?

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.

If no, continue to #2.

2. Is the request for Serostim for a patient with HIV wasting/cachexia and meets the following criteria?

-) **NOT** prescribed for athletic enhancement or anti-aging purposes
-) The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
 - o 10% increase in weight or BCM from baseline (**NOTE:** Current and baseline weight must be documented including dates of measurement)

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.

3. Is the patient on HIV anti-retroviral therapy?

If yes, **approve Serostim for 12 weeks by GPID.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the **SEROSTIM** guideline.

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Serostim)** renewal requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.

-) **NOT** prescribed for athletic enhancement or anti-aging purposes
-) The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
 - o 10% increase in weight or BCM from baseline (**NOTE:** current and baseline weight must be documented including dates of measurement)
-) Patient must be on HIV anti-retroviral therapy

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SOMATROPIN**RENEWAL CRITERIA (CONTINUED)****ZORBTIVE**

1. Does the patient have a diagnosis of short bowel syndrome?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the **ZORBTIVE** guideline.

2. Has the patient been on the medication for 4 weeks?

If yes, do not approve. [**Note:** The patient should only be approved for one 4 week fill in a lifetime.]

DENIAL TEXT: See the renewal denial text at the end of the **ZORBTIVE** guideline.

If no, **approve Zorbtive by GPID for the remainder of therapy with a maximum of 4 weeks of therapy. (Please subtract any previous fills; maximum cumulative approval is for 4 weeks.)**

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Zorbtive)** renewal requires a diagnosis of short bowel syndrome. Therapy is limited to 4 weeks of treatment.

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SOMATROPIN

RENEWAL CRITERIA – GENOTROPIN/NORDITROPIN (CONTINUED)

GENOTROPIN/NORDITROPIN

1. Is the request for the treatment of **ANY** of the following?

- ☐ Athletic enhancement
- ☐ Anti-aging purposes
- ☐ Idiopathic Short Stature

If yes, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the **GENOTROPIN/NORDITROPIN** guideline.

If no, continue to #2.

2. Does the patient have one of the following diagnoses and meets the following criteria?

For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:

- ☐ The medication is prescribed by or in consultation with an endocrinologist
- ☐ The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- ☐ Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For the diagnosis of short stature associated with Turner Syndrome, renewal requires:

- ☐ The medication is prescribed by or in consultation with an endocrinologist
- ☐ The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- ☐ Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:

- ☐ The medication is prescribed by or given in consultation with an endocrinologist
- ☐ Improvement in body composition

For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:

- ☐ The medication is prescribed by or in consultation with an endocrinologist
- ☐ The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
- ☐ Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For the diagnosis of adult growth hormone deficiency, renewal requires:

- ☐ The medication is prescribed by or given in consultation with an endocrinologist

If yes, **approve the requested product (Genotropin or Norditropin) for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the **GENOTROPIN/NORDITROPIN** guideline.

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SOMATROPIN

RENEWAL CRITERIA – GENOTROPIN/NORDITROPIN (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **SOMATROPIN (Genotropin/Norditropin)** renewal requires a diagnosis of Pediatric Growth Hormone Deficiency, Short Stature Associated with Turner Syndrome, Growth Failure Due to Prader-Willi Syndrome (PWS), Growth Failure in Child Born Small for Gestation Age, or Adult Growth Hormone Deficiency.

This medication will not be approved for treatment of **ANY** of the following conditions:

-] Athletic enhancement
-] Anti-aging purposes
-] Idiopathic Short Stature

The following criteria must also be met.

For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For the diagnosis of short stature associated with Turner Syndrome, renewal requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:

-] The medication is prescribed by or given in consultation with an endocrinologist
-] Improvement in body composition

For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:

-] The medication is prescribed by or in consultation with an endocrinologist
-] The patient's epiphyses are **NOT** closed (as confirmed by radiograph of the wrist and hand)
-] Growth velocity of 2 cm or more compared with what was observed from the previous year or patient has not reached 50th percentile for patient's predicted adult height

For the diagnosis of adult growth hormone deficiency, renewal requires:

-] The medication is prescribed by or given in consultation with an endocrinologist

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SOMATROPIN

RATIONALE

Ensure appropriate use of growth hormone with respect to evidence based guidelines.

Growth hormone (GH) is secreted from the anterior pituitary, and is considered a trophic hormone – that is, its release stimulates other body glands and tissues to release additional hormonally active substances. Release of GH from the pituitary is controlled by the hypothalamic release of growth hormone-releasing hormone (GHRH). The secretion and circulating levels of GH vary with age.

Many safety concerns have been raised with recombinant growth hormone (rhGH) treatment. In 2016, the Growth Hormone Research Society, in conjunction with other endocrinology societies, released a position paper stating that there was insufficient evidence to attribute rhGH treatment with increased risk of all-cause mortality, new or recurrent cancers, or stroke. Treatment with rhGH appears to be safe when used within recommended doses.

Currently, there are nine rhGH products being marketed. With the exception of Serostim and Zorbtive, all of the products are indicated for the treatment of pediatric GH deficiency, and additional indications are product specific. Recombinant GH products are used off-label for anti-aging effects and enhancing athletic performance. Use of rhGH in patients with Idiopathic Short Stature (ISS) is controversial as these patients are not growth hormone deficient.

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SOMATROPIN
RATIONALE (CONTINUED)

	PED GROWTH HORMONE DEFICIENCY	ADULT GROWTH HORMONE	SMALL FOR GESTATIONAL AGE	IDIOPATHIC SHORT STATURE	TURNER SYNDROME	PRADER WILLI SYNDROME	HIV-ASSOCIATED WASTING	SHORT BOWEL SYNDROME	NOONAN	SHORT STATURE HOMEBOX- CONTAINING GENE	CHRONIC KIDNEY DISEASE (CHRONIC RENAL INSUFFICIENCY)
ZORBTIVE											
SEROSTIM											
GENOTROPIN											
NORDITROPIN											
HUMATROPE											
NUTROPIN											
OMNITROPE											
SAIZEN											
ZOMACTON											

Dosing of rhGH products varies amongst the products and their indications. Treatment guidelines recommend that treatment be individualized. For pediatric patients, weight based-dosing is utilized, whereas in adult patients, either weight-base dosing or fixed-doses may be used.

CONTINUED ON NEXT PAGE

SOMATROPIN

REFERENCES

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Created	FS Committee Approval	Effective
10/2017; revised 11/2019	11/19	11/20/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

AFLIBERCEPT (NSA)

Generic	Brand	HICL	GCN	Exception/Other
AFLIBERCEPT	EYLEA		30919 34816	

GUIDELINES FOR USE

1. Is this medication being prescribed by or given in consultation with an ophthalmologist and/or retina specialist?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have **ONE** of the following diagnoses?

- ☐ Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- ☐ Macular Edema Following Retinal Vein Occlusion (RVO)
- ☐ Diabetic Macular Edema (DME)
- ☐ Diabetic Retinopathy (DR)

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient receiving treatment in both eyes at this time?

If yes, **approve for 12 months by GPID with a quantity not to exceed 0.10mL (#2 vials/syringes) every 4 weeks.**

If no and one eye is being treated at this time, **approve for 12 months by GPID with a quantity not to exceed 0.05mL (#1 vial/syringe) every 4 weeks.**

DENIAL TEXT: The guideline named **AFLIBERCEPT (Eylea)** requires that the medication is prescribed by or given in consultation with an ophthalmologist and/or retina specialist and the patient has a diagnosis of neovascular (wet) age-related macular degeneration (AMD); macular edema following retinal vein occlusion (RVO); diabetic macular edema (DME); or diabetic retinopathy (DR).

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eylea.

REFERENCES

- ☐ Eylea [Prescribing Information]. Tarrytown, NY: Regeneron; August 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/13/19

Created: 04/14

Client Approval: 11/19

P&T Approval: 10/19

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

TESTOSTERONE UNDECANOATE (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
TESTOSTERONE UNDECANOATE	JATENZO		46152 46153 46144	

GUIDELINES FOR USE

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) **AND** meet the following criterion?

) The patient is 18 years of age or older

If yes, **approve for 12 months by GPID for all strengths with the following quantity limits:**

) **Jatenzo 158mg: #4 per day.**

) **Jatenzo 198mg: #4 per day.**

) **Jatenzo 237mg: #2 per day.**

If no, do not approve.

DENIAL TEXT: Our guideline named **TESTOSTERONE UNDECANOATE (Jatenzo)** requires the following rule(s) be met for approval:

A. You are a male with primary or secondary hypogonadism (hypotestosteronism or low testosterone)

B. You are 18 years of age or older

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Jatenzo.

REFERENCES

Jatenzo [Prescribing Information]. Northbrook, IL: Clarus Therapeutics, Inc.; March 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 12/27/19

Created: 12/19

Client Approval: 01/20

P&T Approval: 01/20

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

ASENAPINE (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
ASENAPINE	SECUADO	46175		

GUIDELINES FOR USE

- Does the patient have a diagnosis of schizophrenia **AND** meet the following criterion?

) The patient is 18 years of age or older

If yes, **approve for 12 months by HICL with a quantity limit of #1 per day**

If no, do not approve.

DENIAL TEXT: Our guideline named **ASENAPINE (Secuado)** requires the following rule(s) be met for approval:

- You have a diagnosis of schizophrenia (an illness that affects your ability to think, feel, and behave clearly)
- You are 18 years of age or older

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Secuado.

REFERENCES

Secuado [Prescribing Information]. Miami, FL: Noven Therapeutics, LLC.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 12/27/19

Created: 12/19

Client Approval: 01/20

P&T Approval: 01/20

PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ROMIPLOSTIM	NPLATE	35798		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of chronic immune thrombocytopenia (ITP) **AND** meet the following criteria?
 -) The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy
 -) The requested medication is prescribed by or given in consultation with a hematologist or immunologist

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Is the patient between age 1 and 17 years old **AND** meet the following criterion?
 -) The patient has had ITP for at least 6 months

If yes, **approve for 4 months by GPID for all strengths as follows:**

-) **Nplate 125mcg: no quantity limit.**
-) **Nplate 250mcg: #8 vials per 28 days.**
-) **Nplate 500mcg: #8 vials per 28 days.**

APPROVAL TEXT: Renewal requires the patient to have a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter).

If no continue to #3.

- Is the patient 18 years of age or older?

If yes, **approve for 4 months by GPID for all strengths as follows:**

-) **Nplate 125mcg: no quantity limit.**
-) **Nplate 250mcg: #8 vials per 28 days.**
-) **Nplate 500mcg: #8 vials per 28 days.**

APPROVAL TEXT: Renewal requires the patient to have a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

ROMIPLOSTIM (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **ROMIPLOSTIM (Nplate)** requires a diagnosis of chronic immune thrombocytopenia (ITP) and the patient is 1 years of age or older. In addition, **ALL** of the following criteria must be met:

-) The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy
-) The requested medication is prescribed by or given in consultation with a hematologist or immunologist

For patients between 1 and 17 years old, approval requires:

-) The patient has had ITP for at least 6 months

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic immune thrombocytopenia (ITP) **AND** meet the following criterion?

-) The patient had a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter)

If yes, **approve for 12 months by GPID for all strengths as follows:**

-) **Nplate 125mcg: no quantity limit.**
-) **Nplate 250mcg: #8 vials per 28 days.**
-) **Nplate 500mcg: #8 vials per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **ROMIPLOSTIM (Nplate)** requires a diagnosis of chronic immune thrombocytopenia (ITP). In addition, the following criterion must also be met:

-) The patient had a clinical response, as defined by an increase in platelet count to at least $50 \times 10(9)/L$ (at least 50,000 per microliter)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nplate.

REFERENCES

-) Nplate [Prescribing Information] Thousand Oaks, CA: Amgen Inc.; October 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 12/16/19

Created: 10/08

Client Approval: 11/19

P&T Approval: 07/19

TESTOSTERONE

Generic	Brand	HICL	GCN	Exception/Other
TESTOSTERONE	ANDRODERM, ANDROGEL, AXIRON, STRIANT, TESTIM, VOGELXO	01403		ROUTE ≠ MISCELL.
TESTOSTERONE CYPIONATE	DEPO- TESTOSTERONE	01400		ROUTE ≠ MISCELL. GCN ≠ 38586
TESTOSTERONE ENANTHATE	DELATESTRYL, TESTOSTERONE ENANTHATE,	01401		ROUTE ≠ MISCELL.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ONE** of the following criteria?
 - The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history **OR**
 - The patient has **AT LEAST ONE** of the following laboratory values confirming low testosterone levels:
 - At least two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state
 - Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

If yes, continue to #2.

If no, continue to #4.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

2. Is the request for AndroGel 1%, AndroGel 1.62%, Axiron, Depo-Testosterone (testosterone cypionate), or Delatestryl (intramuscular testosterone enanthate)?

If yes, **approve the requested agent for 12 months by GPID with the following quantity limits:**

- **AndroGel 1% (testosterone): (2.5 gram packet): #5 grams per day per 30 days; (5 gram packet): #10 grams per day per 30 days; (75 gram pump): #300 grams (4 pumps) per 30 days.**
- **AndroGel 1.62% (testosterone): (1.25 gram packet): #1.25 grams per day per 30 days; (2.5 gram packet): #5 grams per day per 30 days; (75 gram pump): #150 grams (2 pumps) per 30 days.**
- **Axiron (testosterone): (90 mL pump): #180 mL per 30 days.**
- **Testosterone Cypionate (50mg/mL [5 mL vial]): #1 vial per 30 days.**
- **Depo-Testosterone (testosterone cypionate): (100mg/mL, 200mg/mL [10mL vial]): #1 vial per 30 days.**
- **Depo-Testosterone (testosterone cypionate): (200mg/mL [1mL vial]): #4 vials per 30 days.**
- **Intramuscular testosterone enanthate (Delatestryl): (200mg/mL [5mL vial]): #1 vial per 30 days.**

If no, continue to #3.

3. Is the request for Androderm patches, Striant, Testim, or Vogelxo **AND** has the following criterion been met?

- Trial of or contraindication to a generic lower cost agent (i.e., AndroGel 1%, AndroGel 1.62%, Axiron, Depo-Testosterone, intramuscular testosterone enanthate [Delatestryl])

If yes, **approve the requested agent for 12 months by GPID with the following quantity limits:**

- **Androderm (testosterone): (2mg, 2.5mg, 4mg, 5mg patches): #30 patches per 30 days.**
- **Striant (testosterone): #60 buccal systems per 30 days.**
- **Testim (testosterone): (5 gram gel tube): #10 grams per day per 30 days.**
- **Vogelxo (testosterone): (5 gram gel tube): #10 grams per day per 30 days; (5 gram gel packet): #10 grams per day per 30 days; (75 gram pump): #300 grams (4 pumps) per 30 days.**

If no, continue to #4.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder and the request is for intramuscular testosterone enanthate (Delatestryl)?

If yes, **approve the requested agent for lifetime by GPID with the following quantity limits:**

- **Intramuscular Delatestryl (testosterone enanthate): (200mg/mL, 5mL vial): #1 vial per 30 days.**

If no, continue to #5.

5. Is the requested agent for gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)?

If yes, **approve the requested agent for lifetime by GPID and override quantity limits.**

If no, continue to #6.

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TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

6. Is the request for a female patient with a diagnosis of metastatic breast cancer and the request is for intramuscular testosterone enanthate (Delatestryl)?

If yes, **approve the requested agent for lifetime by GPID with the following quantity limits:**

- **Intramuscular Delatestryl (testosterone enanthate): (200mg/mL, 5mL vial): #1 vial per 30 days.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **TESTOSTERONE** requires a diagnosis of primary or secondary male hypogonadism (hypotestosteronism or low testosterone), delayed puberty in males not secondary to a pathological disorder, gender dysphoria, or metastatic female breast cancer. For a diagnosis of metastatic female breast cancer or delayed puberty in males not secondary to a pathological disorder, only intramuscular testosterone enanthate (Delatestryl) may be approved. For patients with gender dysphoria, only agents supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) may be approved. In addition, the following criteria must be met.

For male patients with a diagnosis of primary or secondary hypogonadism, approval requires:

- The patient has a previously approved prior authorization for testosterone or has been receiving any form of testosterone replacement therapy as indicated per physician attestation or claims history **OR**
- The patient has **AT LEAST ONE** of the following laboratory values confirming low testosterone levels:
 - At least two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state
 - Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

For requests of Androderm patch, Striant, Testim, or Vogelxo approval requires:

- Trial of or contraindication to a generic lower cost agent (i.e., AndroGel 1%, AndroGel 1.62%, Axiron, Depo-Testosterone, intramuscular testosterone enanthate [Delatestryl])

TESTOSTERONE

INITIAL CRITERIA (CONTINUED)

RENEWAL CRITERIA

1. Is the request for a male patient with a diagnosis of primary or secondary hypogonadism (hypotestosteronism or low testosterone) who meets **ALL** of the following criteria?
 - Physician attestation of improved symptoms compared to baseline and tolerance to treatment
 - Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline

If yes, **approve requested agent for 12 months by GPID with the following quantity limits:**

- **AndroGel 1% (testosterone): (2.5 gram packet): #5 grams per day per 30 days; (5 gram packet): #10 grams per day per 30 days; (75 gram pump): #300 grams (4 pumps) per 30 days.**
- **Axiron (testosterone): (90 mL pump): #180 mL per 30 days.**
- **Testim (testosterone): (5 gram gel tube): #10 grams per day per 30 days.**
- **Vogelxo (testosterone): (5 gram gel tube): #10 grams per day per 30 days; (5 gram gel packet): #10 grams per day per 30 days; (75 gram pump): #300 grams (4 pumps) per 30 days.**
- **Testosterone Cypionate (50mg/mL [5 mL vial]): #1 vial per 30 days.**
- **Depo-Testosterone (testosterone cypionate): (100mg/mL, 200mg/mL [10mL vial]): #1 vial per 30 days.**
- **Depo-Testosterone (testosterone cypionate): (200mg/mL [1mL vial]): #4 vials per 30 days.**

(Approval directions continued on next page)

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

- Intramuscular testosterone enanthate (Delatestryl): (200mg/mL [5mL vial]): #1 vial per 30 days.
- Androderm (testosterone): (2mg, 2.5mg, 4mg, 5mg patches): #30 patches per 30 days.
- AndroGel 1.62% (testosterone): (1.25 gram packet): #1.25 grams per day per 30 days; (2.5 gram packet): #5 grams per day per 30 days; (75 gram pump): #150 grams (2 pumps) per 30 days.
- Striant (testosterone): #60 buccal systems per 30 days.

If no, continue to #2.

2. Is the request for a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder?

If yes, **approve the requested agent for lifetime by GPID with the following quantity limits:**

- Intramuscular Delatestryl (testosterone enanthate): (200mg/mL, 5mL vial): #1 vial per 30 days.

If no, continue to #3.

3. Is the requested agent for gender dysphoria as supported by the compendia (e.g. DrugDex strength of recommendation Class I, IIa, or IIb)?

If yes, **approve the requested agent for lifetime by GPID and override quantity limits.**

If no, continue to #4.

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TESTOSTERONE

RENEWAL CRITERIA (CONTINUED)

4. Is the request for a female patient with a diagnosis of metastatic breast cancer?

If yes, **approve the requested agent for lifetime by GPID with the following quantity limits:**

- **Intramuscular Delatestryl (testosterone enanthate): (200mg/mL, 5mL vial): #1 vial per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TESTOSTERONE** requires a diagnosis of primary or secondary male hypogonadism (hypotestosteronism or low testosterone), delayed puberty in males not secondary to a pathological disorder, gender dysphoria, or metastatic female breast cancer for renewal. For patients with gender dysphoria, only agents sufficiently supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb) may be approved. In addition, the following criteria must be met:

For male patients with a diagnosis of primary or secondary hypogonadism, approval requires:

- Physician attestation of improved symptoms compared to baseline and tolerance to treatment
- Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline

For a male patient with a diagnosis of delayed puberty not secondary to a pathological disorder, only the following will be approved:

- Intramuscular Delatestryl (testosterone enanthate)

For a female patient with a diagnosis of metastatic breast cancer, only the following will be approved:

- Intramuscular Delatestryl (testosterone enanthate)

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TESTOSTERONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the related testosterone formulation.

REFERENCES

- Androderm [Prescribing Information]. Parsippany, NJ: Allergan. October 2016.
- Androgel 1% [Prescribing Information]. North Chicago, IL: AbbVie Inc. June 2014.
- Androgel 1.62% [Prescribing Information]. North Chicago, IL: Abbvie Inc. October 2016.
- Axiron [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC. July 2017.
- Delatestryl [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals Solutions Inc. October 2016.
- Depo-Testosterone [Prescribing Information]. New York, NY: Pharmacia & Upjohn Company. July 2018.
- Striant [Prescribing Information]. Malvern, PA: Actient Pharmaceuticals LLC. October 2016.
- Testim [Prescribing Information]. Malvern, PA: Auxilium Pharmaceuticals, Inc. October 2016.
- Vogelxo [Prescribing Information]. Maple Grove, MN: Upsher-Smith Lab., Inc. October 2016.

Created	FS Committee Approval	Effective
04/19; revised 12/2019	04/19	12/16/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT

Generic	Brand	HICL	GCN	Exception/Other
UBROGEPANT	UBRELVY	46273		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has a trial of or contraindication to TWO triptans (e.g., sumatriptan, rizatriptan)

If yes, **approve for 6 months by HICL with a quantity limit of #16 per 30 days.**

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **UBROGEPANT (Ubrelyvy)** requires the following rule(s) be met for approval:

- You are being treated for acute (quick onset) migraine
- You are 18 years of age or older
- You had a trial of TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

- Is the request for the acute treatment of migraine and the patient meets **ONE** of the following criteria?
 - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
 - The patient has experienced clinical improvement as defined by **ONE** of the following:
 - Ability to function normally within 2 hours of dose
 - Headache pain disappears within 2 hours of dose
 - Therapy works consistently in majority of migraine attacks

If yes, **approve for 12 months by HICL with a quantity limit of #16 per 30 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

UBROGEPANT

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **UBROGEPANT (Ubrovelvy)** requires the following rule(s) be met for approval:

- A. You are being treated for acute (quick onset) migraine
- B. You meet ONE of the following:
 - 1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
 - 2. You have experienced clinical improvement as defined by ONE of the following:
 - a. Ability to function normally within 2 hours of dose
 - b. Headache pain disappears within 2 hours of dose
 - c. Treatment works consistently in majority of migraine attacks

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ubrovelvy.

REFERENCES

- Ubrovelvy [Prescribing Information]. Madison, NJ: Allergan; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/01/20

Created: 01/20

Client Approval: 01/20

P&T Approval: 10/19

USTEKINUMAB

Generic	Brand	HICL	GCN	Exception/Other
USTEKINUMAB	STELARA	36187		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a dermatologist
 - The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
 - The patient has had a previous trial of at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 - The patient is 12 years of age or older
 - Documentation of the patient's current weight

If yes, **approve for a total of 6 months by GPID as follows:**

Patients weighing 100kg (220 lbs) or less:

Enter both of the following approvals:

- Loading dose:** Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.
- Maintenance dose:** Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.

Patients weighing over 100kg (220 lbs):

Enter both of the following approvals:

- Loading dose:** Approve for 1 month with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 28 days for 1 fill.
- Maintenance dose:** Approve for 5 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days for 2 fills with a start date after the end date of the previous fill.

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis **OR** moderate to severe PsO with co-existent psoriatic arthritis requires that the patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more **AND** documentation of the patient's current weight.

If no, continue to #2.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older

If yes, **approve for a total of 6 months by GPID as follows:**

- **Loading dose:** Approve for 1 month with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 28 days for 1 fill.
- **Maintenance dose:** Approve for 5 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days for 2 fills with a start date after the end date of the previous fill.

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

3. Does the patient have a diagnosis of moderately to severely active Crohn's disease (CD) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - Documentation of the patient's current weight

If yes, continue to #4.

If no, continue to #6.

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #5.

If no, **approve maintenance dose for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

APPROVAL TEXT: Stelara subcutaneous has been approved for 6 months for maintenance treatment. Stelara intravenous loading dose is excluded from your pharmacy benefit coverage.

5. Has the patient **already received** the intravenous loading dose of Stelara for the treatment of moderately to severely active Crohn's disease (CD)?

If yes, **approve for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

If no, **enter two approvals for a total of 6 months by GPID as follows:**

First approval - Please enter one of the following loading doses based on the patient's weight (NOTE: Do not enter a loading dose if the member does not have coverage for non-self-administered drug benefit. Please deny for benefit exclusion.):

Patients weighing 55kg (121 lbs.) or less:

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 52mL (two 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 55kg up to 85kg (122 lbs. up to 187 lbs.):

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 78mL (three 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 85kg (187 lbs.):

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 104mL (four 130mg/26mL vials) per 56 days for 1 fill.**

Second approval:

- **Maintenance dose: Approve for 4 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 2 fills with a start date after the end date of the previous fill.**

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USTEKINUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - The patient has had a previous trial of **ONE** formulary preferred immunomodulator: Humira or Renflexis (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)
 - Documentation of the patient's weight

If yes, continue to #7.

If no, do not approve.

DENIAL TEXT: See denial text at end of guideline

7. Does the patient have non-self-administered (NSA) drug benefit coverage?

If yes, continue to #8.

If no, **approve maintenance dose for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

APPROVAL TEXT: Stelara subcutaneous has been approved for 6 months for maintenance treatment. Stelara intravenous loading dose is excluded from your pharmacy benefit coverage.

8. Has the patient **already received** the intravenous loading dose of Stelara for the treatment of moderately to severely active ulcerative colitis (UC)?

If yes, **approve for 6 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 3 fills.**

If no, **enter two approvals for a total of 6 months by GPID as follows:**

First approval - Please enter one of the following loading doses based on the patient's weight (NOTE: Do not enter a loading dose if the member does not have coverage for non-self-administered drug benefit. Please deny for benefit exclusion.):

Patients weighing 55kg (121 lbs.) or less:

- **Loading dose: Approve for 2 months by GPID with a quantity limit of 52mL (two 130mg/26mL vials) per 56 days for 1 fill.**

Patients weighing over 55kg up to 85kg (122 lbs. up to 187 lbs.):



- **Loading dose: Approve for 2 months by GPID with a quantity limit of 78mL (three 130mg/26mL vials) per 56 days for 1 fill.**
Patients weighing over 85kg (187 lbs.):
- **Loading dose: Approve for 2 months by GPID with a quantity limit of 104mL (four 130mg/26mL vials) per 56 days for 1 fill.**

Second approval:

- **Maintenance dose: Approve for 4 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days for 2 fills with a start date after the end date of the previous fill.**

INITIAL DENIAL TEXT: The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of moderate to severe plaque psoriasis, **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, psoriatic arthritis without co-existent plaque psoriasis, **OR** moderately to severely active Crohn's disease **OR** moderately to severely active ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval requires all of the following criteria:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
- The patient has had a previous trial of at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 12 years of age or older
- Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval requires all of the following criteria:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with moderately to severely active Crohn's disease (CD), approval requires all of the following criteria:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- Documentation of the patient's current weight



For patients with moderately to severely active ulcerative colitis (UC), approval requires all the following criteria:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient has had a previous trial of **ONE** formulary preferred immunomodulator: Humira or Renflexis (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)
- Documentation of the patient's weight

RENEWAL CRITERIA

1. Does the patient have a diagnosis of psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO) and experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

If yes, **approve for 12 months by GPID with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

If no, continue to #2.

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USTEKINUMAB

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **OR** moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- The patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
 - Documentation of the patient's current weight

If yes, **approve for 12 months by GPID as follows:**

Patients weighing 100kg (220 lbs.) or less:

- **Approve for 12 months with a quantity limit of 0.5mL (one 45mg/0.5mL prefilled syringe or one 45mg/0.5mL vial) per 84 days.**

Patients weighing over 100kg (220 lbs.):

- **Approve for 12 months with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 84 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of moderately to severely active Crohn's disease (CD) or moderately to severely active ulcerative colitis (UC)?

If yes, **approve for 12 months by GPID with a quantity limit of 1mL (two 45mg/0.5mL prefilled syringes, two 45mg/0.5mL vials, or one 90mg/mL prefilled syringe) per 56 days.**

If no, do not approve.

DENIAL TEXT: The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of psoriatic arthritis without co-existent plaque psoriasis, moderate to severe plaque psoriasis **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, **OR** moderately to severely active Crohn's disease, **OR** moderately to severely active ulcerative colitis (UC). The following criteria must also be met:

- **Renewal for the diagnosis of psoriatic arthritis without co-existent plaque psoriasis** requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
- **Renewal for the diagnosis of moderate to severe plaque psoriasis OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis** requires that the patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more **AND** documentation of the patient's current weight.

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USTEKINUMAB

RATIONALE

Ensure that appropriate diagnostic, utilization, and safety criteria are utilized for the management of Stelara.

FDA APPROVED INDICATIONS

Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of:

- Adult patients with:
 - Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
 - Psoriatic arthritis (PsA), alone or in combination with methotrexate
 - Moderately to severely active Crohn's disease (CD) who have
 - Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or
 - Failed or were intolerant to treatment with one or more TNF blockers
- Adolescent patients (12 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.
- Moderately to severely active ulcerative colitis (UC)

DOSAGE AND ADMINISTRATION

Psoriasis Adult Subcutaneous Recommended Dosage:

- For patients weighing ≤ 100 kg (220 lbs), the recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients weighing >100 kg (220 lbs), the recommended dose is 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.

For adolescent patients (12 years and older) Subcutaneous Recommended Dosage:

Weight based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

- Less than 60 kg: 0.75 mg/kg
- 60 kg to 100 kg: 45 mg
- Greater than 100 kg: 90 mg

Psoriatic Arthritis

- The recommended dose is 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
- For patients with co-existent moderate-to-severe plaque psoriasis weighing >100 kg (220 lbs), the recommended dose is 90mg initially and 4 weeks later, followed by 90mg every 12 weeks.

Crohn's Disease or Ulcerative Colitis

- Intravenous Induction Adult Dosage Regimen: A single intravenous infusion dose using the weight-based dosage regimen specified in Table 1.

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USTEKINUMAB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Table 1. Initial Intravenous Dosage of Stelara

Body weight of patient at the time of dosing	Dose	Number of 130 mg/26 mL (5 mg/mL) vials
≤55 kg	260 mg	2
>55 – 85 kg	390 mg	3
> 85 kg	520 mg	4

- Subcutaneous Maintenance Adult Dosage Regimen: The recommended maintenance dosage is a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

REFERENCES

- Stelara [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. November 2019.

Created	FS Committee Approval	Effective
5/2019; revised 8/2019; revised 12/2019	8/19	1/17/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB-BVZR (NSA)

Generic	Brand	HICL	GCN	Exception/Other
BEVACIZUMAB-BVZR	ZIRABEV	45849		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) **AND** meet the following criterion?

- The requested medication is being used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?

- The requested medication is being used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment
- The patient has progressed on a first-line bevacizumab product-containing regimen

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?

- The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment

If yes, **approve for 12 months by HICL.**

If no, continue to #4.

4. Does the patient have a diagnosis of recurrent glioblastoma (GBM) and meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL.**

If no, continue to #5.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**BEVACIZUMAB-BVZR (NSA)****GUIDELINES FOR USE (CONTINUED)**

5. Does the patient have a diagnosis of metastatic renal cell carcinoma (mRCC) **AND** meet the following criterion?

- The requested medication is being used in combination with interferon-alfa

If yes, **approve for 12 months by HICL.**

If no, continue to #6.

6. Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer **AND** meet the following criterion?

- The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB-BVZR (Zirabev)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses: metastatic colorectal cancer (mCRC: colon cancer that has spread in the body); unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/ returned); recurrent glioblastoma (GBM: type of brain tumor); metastatic renal cell carcinoma (mRCC: type of kidney cancer); persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
- B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
1. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
 2. The requested medication is being used in combination with fluoropyrimidine- irinotecan- (for example FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example FOLFOX, CApeOX) based chemotherapy as a second-line treatment **AND** your disease has progressed (gotten worse) on a first-line bevacizumab product-containing regimen
- C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
1. The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment
- D. **If you have recurrent glioblastoma, approval also requires**
1. You are 18 years of age or older
- (Denial text continued on the next page)**

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**BEVACIZUMAB-BVZR (NSA)****GUIDELINES FOR USE (CONTINUED)**

- E. **If you have metastatic renal cell carcinoma, approval also requires:**
1. The requested medication is being used in combination with interferon-alfa
- F. **If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:**
1. The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zirabev.

REFERENCES

Zirabev [Prescribing Information]. New York, New York: Pfizer Inc., June 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 01/10/20

Created: 01/20

Client Approval: 03/19

P&T Approval: 03/19

PRIOR AUTHORIZATION GUIDELINES

DIMETHYL FUMARATE

Generic	Brand	HICL	GCN	Exception/Other
DIMETHYL FUMARATE	TECFIDERA	40168		

GUIDELINES FOR USE

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL for #2 capsules per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DIMETHYL FUMARATE (Tecfidera)** requires the following rules be met for approval:

- You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
- You are 18 years of age or older

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tecfidera.

REFERENCES

- Tecfidera [Prescribing Information]. Cambridge, MA: Biogen Inc.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/01/20

Created: 05/13

Client Approval: 01/20

P&T Approval: 01/20

PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
ECULIZUMAB	SOLIRIS	34618		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)?

If yes, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

If no, continue to #2.

- Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS)?

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

- Does the patient have a diagnosis of generalized myasthenia gravis (gMG) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Diagnosis is confirmed by a positive serologic test for anti-acetylcholine receptor (AChR) antibody
- The patient is Myasthenia Gravis Foundation of America class II, III, or IV
- The patient has had a trial of or contraindication to corticosteroids
- Patient meets **ONE** of the following:
 - Failure of treatment with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclophosphamide, methotrexate)
 - Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange
- The requested medication is prescribed by or in consultation with a neurologist

If yes, **approve for a total of 6 months by HICL by entering two approvals as follows:**

- FIRST APPROVAL:** Approve for 1 month with a quantity limit of #360 mL per 28 days for 1 fill.
- SECOND APPROVAL:** Approve for 5 months with a quantity limit of #240 mL per 28 days for 5 fills. (Please enter a start date of 1 day after the end date of the first approval)

APPROVAL TEXT: See the approval text on the next page.

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PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool).

If no, continue to #4.

4. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - The patient has confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
 - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
 - PNH granulocyte clone size $\geq 10\%$
 - The requested medication is prescribed by or in consultation with a hematologist

If yes, continue to #5.

If no continue to #6.

5. Does the patient meet **ONE** of the following criteria?
- The patient is transitioning from an alternative complement inhibitor therapy (i.e., Ultomiris)
 - Documentation of evidence of intravascular hemolysis (e.g., lactate dehydrogenase [LDH] level $\geq 1.5 \times \text{ULN}$, hemoglobinuria) **OR** history of major adverse vascular event from thromboembolism

If yes, **approve for 6 months by HICL as follows:**

Enter both of the following approvals:

- **FIRST APPROVAL:** Approve for 1 month with a quantity limit of #240 mL per 28 days for 1 fill.
- **SECOND APPROVAL:** Approve for 5 months with a quantity limit of #180 mL per 28 days for 5 fills. (Please enter a start date of 1 day after the end date of the first approval)

APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4) receptor antibody
 - Physician attestation of presence of at least ONE core clinical characteristic:
 - Optic neuritis
 - Acute myelitis
 - Area postrema syndrome
 - Acute brainstem syndrome
 - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
 - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
 - Patient will **NOT** use rituximab concurrently and has not received rituximab for at least 90 days
 - The requested medication is prescribed by or in consultation with a neurologist

If yes, **approve for 12 months by HICL as follows by entering two approvals as follows:**

- **FIRST APPROVAL:** Approve for 1 month with a quantity limit of #360 mL per 28 days for 1 fill.
- **SECOND APPROVAL:** Approve for 11 months with a quantity limit of #240 mL per 28 days for 11 fills. (Please enter a start date of 1 day after the end date of the first approval)

APPROVAL TEXT: Renewal requires physician attestation of reduction in relapse frequency compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:

- A. You have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH-life-threatening condition with red blood cells being destroyed), atypical hemolytic uremic syndrome (aHUS-condition where blood clots form in small blood vessels of kidneys), generalized Myasthenia gravis (gMG-a disease that causes skeletal muscle weakness) OR or neuromyelitis optica spectrum disorder (NMOSD-inflammatory disorder affecting the optic nerve in eye and spinal cord)

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PRIOR AUTHORIZATION GUIDELINES**ECULIZUMAB (NSA)****INITIAL CRITERIA (CONTINUED)**

- B. Eculizumab (Soliris) is NOT being used for hemolytic uremic syndrome related to Shiga toxin E. coli (small blood vessels in your kidneys become damaged and inflamed caused by a type of bacteria)
- C. **If you have generalized Myasthenia gravis (gMG), approval also requires:**
1. You are 18 years of age or older
 2. Your diagnosis is confirmed by a positive Anti-acetylcholine receptor (AchR) antibody test
 3. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
 4. You had a trial of corticosteroids, unless there is a medical reason why you cannot (contraindication)
 5. You meet ONE of the following:
 - a. Failure of treatment with at least 2 immunosuppressive therapies (drugs that weaken your immune system such as azathioprine, cyclophosphamide, methotrexate)
 - b. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (types of blood therapy)
 6. The requested medication is prescribed by or in consultation with a neurologist (nerve doctor)
- D. **If you have paroxysmal nocturnal hemoglobinuria (PNH-life-threatening condition with red blood cells being destroyed), approval requires:**
1. You are 18 years of age or older
 2. You have confirmed PNH as demonstrated by **ALL** of the following via flow cytometry (test to measure characteristics of cells):
 - a. At least 2 different GPI-protein deficiencies (such as CD55, CD59) on at least 2 cell lineages (such as erythrocytes, granulocytes)
 - b. PNH granulocyte clone size greater than or equal to 10%
 3. The requested medication is prescribed by or in consultation with a hematologist (blood specialist)
 4. You meet **ONE** of the following:
 - a. Transitioning from alternative complement inhibitor therapy such as Ultomiris
 - b. Documentation of evidence of intravascular hemolysis (blood cells get destroyed) such as lactate dehydrogenase [LDH] level greater than or equal to 1.5 X upper limit of normal, hemoglobinuria (type of blood protein is in urine) OR you have history of major adverse vascular event from thromboembolism (blood clot)

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PRIOR AUTHORIZATION GUIDELINES

ECULIZUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

E. If you have neuromyelitis optica spectrum disorder (NMOSD), approval requires:

1. You are 18 years of age or older
2. Diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4) receptor antibody
3. Physician attestation of presence of at least ONE core clinical characteristic:
 - a. Optic neuritis (inflammation that damages eye nerve)
 - b. Acute myelitis (sudden and severe spinal cord inflammation)
 - c. Area postrema syndrome (hiccups, nausea, and/or uncontrollable vomiting for several days)
 - d. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
 - e. Symptomatic narcolepsy (sudden sleepiness) or acute diencephalic clinical syndrome (tumor in a part of brain) with NMOSD-typical diencephalic MRI lesions (affected areas)
 - f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
4. You will NOT use rituximab concurrently and you have not received rituximab for at least 90 days
5. The requested medication is prescribed by or in consultation with a neurologist (nerve doctor)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of atypical hemolytic uremic syndrome (aHUS)?

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **AND** meet the following criterion?

- Physician attestation of clinical benefit compared to baseline (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) and hemoglobin levels)

If yes, **approve for 12 months by HICL with a quantity limit of #180 mL per 28 days.**

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES**ECULIZUMAB (NSA)****RENEWAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG) and meet the following criterion?

- Physician attestation of clinical benefit compared to baseline according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

If yes, **approve for 12 months by HICL with a quantity limit of #240mL per 28 days.**

If no, continue to #4.

4. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet the following criterion?

- Physician attestation of reduction in relapse frequency compared to baseline

If yes, **approve for 12 months by HICL with a quantity limit of #240mL per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal approval:

- A. You have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH-life-threatening condition with red blood cells being destroyed), atypical hemolytic uremic syndrome (aHUS-condition where blood clots form in small blood vessels of kidneys), generalized Myasthenia gravis (gMG-a disease that causes skeletal muscle weakness) OR neuromyelitis optica spectrum disorder (NMOSD-inflammatory disorder affecting the optic nerve in eye and spinal cord)
- B. **If you have paroxysmal nocturnal hemoglobinuria (PNH-life-threatening condition with red blood cells being destroyed), approval requires:**
1. Physician attestation of clinical benefit compared to baseline. This includes a reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (type of enzyme) and hemoglobin levels
- C. **If you have generalized myasthenia gravis (gMG), approval requires:**
1. Physician attestation of clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)
- D. **If you have neuromyelitis optica spectrum disorder (NMOSD), approval requires:**
1. Physician attestation of reduction in relapse frequency compared to baseline

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

PRIOR AUTHORIZATION GUIDELINES**ECULIZUMAB (NSA)****RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Soliris.

REFERENCES

- Soliris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; July 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/01/20

Created: 08/13

Client Approval: 01/20

P&T Approval: 07/19

**LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
GOLIMUMAB - SQ**

Generic	Brand	HICL	GCN	Exception/Other
GOLIMUMAB - SQ	SIMPONI - SQ		22533 22536 34697 35001	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient meets ONE of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - Concurrent use of methotrexate (unless contraindicated)
 - The patient is 18 years of age or older
 - The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID for 0.5 mL of the 50 mg prefilled SmartJect autoinjector or syringe per 28 days.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

- Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older
 - The patient has had a previous trial of any **TWO** of the following preferred formulary immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months for by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.



WELLFLEET
RX PLAN

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

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**LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
GOLIMUMAB - SQ**

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, or Renflexis (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**

APPROVAL TEXT: Renewal requires documentation that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient has had a previous trial of **ONE** formulary preferred immunomodulator: Humira or Renflexis (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for 6 months and enter two authorizations by GPID as follows:**

- **2mL of the 100mg prefilled SmartJect autoinjectors or syringes for 1 fill, then 2 weeks after initial authorization,**
- **1mL of the 100mg prefilled SmartJect autoinjectors or syringes every 28 days.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
GOLIMUMAB - SQ**

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **GOLIMUMAB - SQ (Simponi - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient meets ONE of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
- Concurrent use of methotrexate (unless contraindicated)
- The patient is 18 years of age or older
- The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz.

For patients with psoriatic arthritis (PsA), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following preferred formulary immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz.

For patients with moderate to severe ankylosing spondylitis (AS), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, or Renflexis.

For patients with moderate to severe ulcerative colitis (UC), approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient has had a previous trial of **ONE** formulary preferred immunomodulator: Humira or Renflexis

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES GOLIMUMAB - SQ

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- Concurrent use of methotrexate (unless contraindicated)

If yes, **approve for 12 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ankylosing spondylitis (AS) and meet the following criteria?

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months by GPID for 0.5mL of the 50mg prefilled SmartJect autoinjector or syringe per 28 days.**

If no, continue to #4.

4. Does the patient have moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by GPID for 1mL of the 100mg prefilled SmartJect autoinjector or syringe per 28 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES GOLIMUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **GOLIMUMAB - SQ (Simponi - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must also be met.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- Concurrent use of methotrexate (unless contraindicated)

Renewal for the diagnosis of psoriatic arthritis (PsA), approval requires all of the following:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of moderate to severe ankylosing spondylitis (AS), approval requires the following:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for golimumab.

DOSAGE

RA, PsA, and AS: 50 mg administered by subcutaneous injection once a month

UC: 200 mg initially administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then 100 mg every 4 weeks

FDA APPROVED INDICATIONS

Simponi is a tumor necrosis factor (TNF) blocker indicated for the treatment of adult patients with:

- Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- Active psoriatic arthritis (PsA) alone, or in combination with methotrexate
- Active ankylosing spondylitis (AS)

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**LIBRARY OF PRIOR AUTHORIZATION GUIDELINES
 GOLIMUMAB - SQ**

FDA APPROVED INDICATIONS (CONTINUED)

- Moderate to severe Ulcerative colitis (UC) with an inadequate response or intolerant to prior treatment or requiring continuous steroid therapy
 - Inducing and maintaining clinical response
 - Improving endoscopic appearance of the mucosa during induction
 - Inducing clinical remission
 - Achieving and sustaining clinical remission in induction responders

REFERENCES

- Simponi [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. June 2016. Inman RD, Davis JC, Heijde D, et al. Efficacy and safety of golimumab in patients with ankylosing spondylitis. *Arthritis & Rheumatism*. 2008; 58(11): 3402-3412.
- Kavanaugh A, McInnes I, Mease P, et al. Golimumab, a new human tumor necrosis factor α antibody administered every four weeks as a subcutaneous injection in psoriatic arthritis. *Arthritis & Rheumatism*. 2009; 60(4): 976-986.
- Keystone EC, Genovese MC, Klareskog L, et al. Golimumab, a human antibody to tumor necrosis factor α antibody given by monthly subcutaneous injections, in active rheumatoid arthritis despite methotrexate therapy: the GO-FORWARD study. *Ann Rheum*. 2009;68: 789-796.

Created	FS Committee Approval	Effective
8/2019	8/2019	9/15/19
Revised 9/2019		10/21/19
Revised 1/2020		1/17/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
NATALIZUMAB	TYSABRI	26750		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient had a previous trial of or contraindication to one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira **OR** Stelara (**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance programs do not qualify)

If yes, **approve for 6 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

APPROVAL TEXT: Renewal requires one of the following: 1) The patient has received at least 12 months of Tysabri therapy and has not received more than 3 months of corticosteroids for control of Crohn's disease while on Tysabri, or 2) The patient has received only 6 months of Tysabri therapy and is not currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy).

If no, continue to #2.

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication is being used as monotherapy
 - The patient had a previous trial of **TWO** agents indicated for the treatment of multiple sclerosis (MS) (**Please note** that other MS agents may also require prior authorization)

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**NATALIZUMAB (NSA)****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: ****Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for approval:

A. You have ONE of the following:

1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract) OR
2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, approval also requires:**

1. You are 18 years of age or older
2. The requested medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
3. You also tried or have a contraindication to (a medical reason why you cannot take a medication) at least one of the following conventional agents such as corticosteroids (for example, budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
4. You also tried or have a contraindication to (a medical reason why you cannot take a medication) one of the following formulary preferred immunomodulators: Humira **OR** Stelara (**NOTE:** Pharmaceutical samples from the prescriber or manufacturer assistance programs do not qualify.)

C. **If you have a relapsing form of multiple sclerosis (MS), approval also requires:**

1. You are 18 years of age or older
2. The requested medication is being used as monotherapy (used by itself)
3. You also tried at least TWO agents indicated for the treatment of multiple sclerosis (MS) (**NOTE:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, Tecfidera, Mavenclad, Mayzent)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PRIOR AUTHORIZATION GUIDELINES

NATALIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease and meet ALL of the following criteria?

- The patient has received at least 12 months of Tysabri therapy
- The patient has **NOT** received more than 3 months of corticosteroids for control of Crohn's disease

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe Crohn's disease and meet **ALL** of the following criteria?

- The patient has received only 6 months of Tysabri therapy
- The patient is **NOT** currently on corticosteroids (i.e., the patient has tapered off corticosteroids during the first 6 months of Tysabri therapy)

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease?

If yes, **approve for 12 months by HICL with a quantity limit of 15mL (#1 of 300mg/15mL) per 28 days.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**NATALIZUMAB (NSA)****RENEWAL CRITERIA (CONTINUED)**

RENEWAL DENIAL TEXT: ****Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for renewal:

- A. You have ONE of the following:
1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract) OR
 2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms goes away and returns), and active secondary progressive disease (advanced disease)
- B. **If you have moderate to severe Crohn's disease, approval also requires ONE of the following:**
1. **If you have received at least 12 months of Tysabri therapy, renewal also requires** that you have NOT received more than 3 months of corticosteroid within the past 12 months to control your Crohn's disease while on Tysabri
 2. **If you have only received 6 months of Tysabri therapy, renewal also requires** that you are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Review for Tysabri.

REFERENCES

- Tysabri [Prescribing Information]. Cambridge, MA: Biogen Inc.; August 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/01/20

Created: 08/06

Client Approval: 01/20

P&T Approval: 01/20

PRIOR AUTHORIZATION GUIDELINES

METFORMIN ER SUSPENSION (INTERIM)

Generic	Brand	HICL	GCN	Exception/Other
METFORMIN EXTENDED-RELEASE	RIOMET ER		46873	

GUIDELINES FOR USE

- Does the patient have a diagnosis of type 2 diabetes mellitus and meet **ALL** of the following criteria?

- The patient is 10 years of age or older
- The requested medication will be used as an adjunct to diet and exercise

If yes, **approve for 12 months by GPID with a quantity limit of #20 ml per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **METFORMIN ER SUSPENSION (Riomet ER)** requires the following rule(s) be met for approval:

- You have type 2 diabetes mellitus (a disease that results in too much sugar in the blood)
- You are 10 years of age or older
- The medication will be used as an adjunct (addition) to diet and exercise

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Riomet ER.

REFERENCES

- Riomet ER [Prescribing Information]. Cranbury, NJ: Sun Pharmaceutical Industries Limited, August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/07/20

Created: 02/20

Client Approval: 04/20

P&T Approval: 04/20

PRIOR AUTHORIZATION GUIDELINES

RITUXIMAB-PVVR (NSA)

Generic	Brand	HICL	GCN	Exception/Other
RITUXIMAB-PVVR	RUXIENCE	45899		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Non-Hodgkin's Lymphoma (NHL) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with an oncologist

If yes, **approve for 6 months by HICL for up to #8 fills.**

If no, continue to #2.

2. Does the patient have a diagnosis of Chronic Lymphocytic Leukemia (CLL) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with an oncologist
- The patient is on concurrent chemotherapy

If yes, **approve for 6 months by HICL for up to #6 fills.**

If no, continue to #3.

3. Does the patient have a diagnosis of Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient is on concurrent glucocorticoids (such as methylprednisolone or prednisone)

If yes, **approve for 1 month by HICL for #4 fills.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **RITUXIMAB-PVVR (Ruxience)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
2. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
3. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
4. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)

(Denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES**RITUXIMAB-PVVR (NSA)****GUIDELINES FOR USE (CONTINUED)**

- B. If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
- C. If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
 3. You are currently using chemotherapy at the same time with requested medication
- D. If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
1. You are 18 years of age or older
 2. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) with the requested medication

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ruxience.

REFERENCES

- Ruxience [Prescribing Information]. New York, NY: Pfizer Ireland Pharmaceuticals; July 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/17/20

Created: 02/20

Client Approval: 02/20

P&T Approval: 04/19

PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

Generic	Brand	HICL	GCN	Exception/Other
TOFACITINIB CITRATE	XELJANZ, XELJANZ XR	39768		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient meets **ONE** of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

If yes, approve for 6 months for the requested strength by GPID as follows:

- Xeljanz 5mg (GPID 33617): #2 tablets per day.**
- Xeljanz XR 11mg (GPID 38086): #1 tablet per day.**

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

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PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
 - The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient is 18 years of age or older

If yes, **approve for 6 months for the requested strength by GPID as follows:**

- **Xeljanz 5mg (GPID 33617): #2 tablets per day.**
- **Xeljanz XR 11mg (GPID 38086): #1 tablet per day.**

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

3. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet the following criteria?
- The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of at least one of the following conventional agents, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient has tried ONE preferred formulary alternative: Humira or Renflexis.

If yes, **approve for 6 months by GPID for the requested strength by GPID as follows:**

- **Xeljanz 5mg (GPID 33617): #2 tablets per day.**
- **Xeljanz 10 mg (GPID 44882): #2 tablets per day.**
- **Xeljanz XR 11mg (GPID 38086): #1 tablet per day.**
- **Xeljanz XR 22mg (GPID 47546): #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**TOFACITINIB****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient meets **ONE** of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older

For patients with moderate to severe ulcerative colitis (UC), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of at least one of the following conventional agents, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient has tried ONE preferred formulary alternative: Humira or Renflexis

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PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA) and has the patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy?

If yes, **approve for 12 months for the requested strength by GPID as follows:**

- **Xeljanz 5mg (GPID 33617): #2 tablets per day**
- **Xeljanz XR 11mg (GPID 38086): #1 tablet per day**

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months for the requested strength by GPID as follows:**

- **Xeljanz 5mg (GPID 33617): #2 tablets per day.**
- **Xeljanz 10mg (GPID 44882): #2 tablets per day.**
- **Xeljanz XR 11mg (GPID 38086): #1 tablet per day.**
- **Xeljanz XR 22mg (GPID 47546): #1 tablet per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe ulcerative colitis, or psoriatic arthritis. In addition, the following criteria must also be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis or psoriatic arthritis, approval requires that:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy for renewal.

RATIONALE

To ensure appropriate use of Xeljanz/Xeljanz XR consistent with its FDA approved indications.

FDA APPROVED INDICATIONS

Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

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PRIOR AUTHORIZATION GUIDELINES

TOFACITINIB

FDA APPROVED INDICATIONS (CONTINUED)

Xeljanz/Xeljanz XR is indicated for the treatment of adult patients with psoriatic arthritis who have had an inadequate response or intolerance to methotrexate or other disease-modifying antirheumatic drugs (DMARDs).

XELJANZ is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

DOSAGE AND ADMINISTRATION

Rheumatoid Arthritis:

Xeljanz/Xeljanz XR may be used as a monotherapy or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs). The recommended dose of Xeljanz is 5mg twice daily, and the recommended dose of Xeljanz XR is 11mg once daily.

Psoriatic Arthritis:

The recommended dose of Xeljanz is 5mg twice daily, and the recommended dose of Xeljanz XR is 11mg once daily used in combination with nonbiologic DMARDs. The efficacy of XELJANZ/XELJANZ XR as a monotherapy has not been studied in psoriatic arthritis.

Ulcerative Colitis:

The recommended dose of Xeljanz for ulcerative colitis is 10mg twice daily for at least 8 weeks; then 5 or 10 mg twice daily. Discontinue after 16 weeks of 10mg twice daily, if inadequate therapeutic benefit is not achieved. Use the lowest effective dose to maintain response.

REFERENCES

- Xeljanz, Xeljanz XR [Prescribing Information]. New York, NY: Pfizer Laboratories Div Pfizer Inc. May 2018.
- Cohen S, Mikuls TR. Initial treatment of rheumatoid arthritis in adults. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019)
- Cohen S, Cannella A. Treatment of rheumatoid arthritis in adults resistant to initial nonbiologic DMARD therapy. O'Dell JR, ed. UpToDate. Waltham, MA: UpToDate, Inc. <https://www.uptodate.com>. (Accessed January 25, 2019).

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 08/1/19	08/19	09/15/19
Revised 1/2020		1/17/2020
Revised 2/2020		02/14/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

DPP4 INHIBITOR-GLP1 AGONIST CONCURRENT USE EDIT OVERRIDE

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

- Is the request for concurrent use of a DPP-4 inhibitor with a GLP-1 Agonist **OR** is the claim rejecting with the following error code?
 - REJ- 433: CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY**

If yes, continue to #2.

If no, guideline does not apply.

- Is the patient discontinuing the GLP-1 Agonist due to contraindication allergy, or intolerance and switching to a DPP-4 inhibitor? Prescriber must provide documented reason for discontinuation.

If yes, **approve for 4 months by HICL and set DUR_CONCURRENT_OVR to 'Y' for Yes.**

If no, do not approve.

DENIAL TEXT: The guideline named **DPP4 INHIBITOR-GLP1 AGONIST CONCURRENT USE EDIT OVERRIDE** requires a patient to be discontinuing the GLP1 Agonist with a documented reason for discontinuation (e.g., contraindication, allergy or intolerance to a GLP-1.). According to the American Diabetes Association (ADA) 2020 guidelines, there is no added benefit for a patient to be taking both a GLP-1 Agonist and a DPP-4 inhibitor for diabetes management. The mechanisms of action of these two classes of medications overlap and concurrent use is not recommended. A DPP-4 inhibitor will not be approved if the patient is concurrently on a GLP-1 agonist.

RATIONALE

Ensure appropriate utilization of DPP-4 Inhibitors and GLP-1 Agonists.

REFERENCES

- American Diabetes Association Standards of Medical Care in Diabetes – 2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

Created: 06/19

Effective: 02/14/20

Client Approval: 02/10/20

P&T Approval: N/A

PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN

Generic	Brand	HICL	GCN	Exception/Other
LASMIDITAN SUCCINATE	REYVOW	46082		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Is the request for the acute treatment of migraine and the patient meets **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has a trial of or contraindication to **TWO** triptans (e.g., sumatriptan, rizatriptan)

If yes, **approve for 6 months for the requested strength by GPID as follows:**

- 50mg tablet: #4 per 30 days.**
- 100mg tablet: #8 per 30 days.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for approval:

- You are being treated for acute (quick onset) migraine
- You are 18 years of age or older
- You had a trial of TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PRIOR AUTHORIZATION GUIDELINES

LASMIDITAN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the request for the acute treatment of migraine and the patient meets **ONE** of the following criteria?
 - The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT])
 - The patient has experienced clinical improvement as defined by **ONE** of the following:
 - Ability to function normally within 2 hours of dose
 - Headache pain disappears within 2 hours of dose
 - Therapy works consistently in majority of migraine attacks

If yes, **approve for 12 months for the requested strength by GPID as follows:**

- **50mg tablet: #4 per 30 days.**
- **100mg tablet: #8 per 30 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LASMIDITAN (Reyvow)** requires the following rule(s) be met for renewal:

- A. You are being treated for acute (quick onset) migraine
- B. You meet ONE of the following:
 1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
 2. You have experienced clinical improvement as defined by ONE of the following:
 - a. Ability to function normally within 2 hours of dose
 - b. Headache pain disappears within 2 hours of dose
 - c. Treatment works consistently in majority of migraine attacks

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PRIOR AUTHORIZATION GUIDELINES**LASMIDITAN****RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reyvow.

REFERENCES

- Reyvow [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC, January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/24/20

Created: 02/20

Client Approval: 02/20

P&T Approval: 01/20

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

PEANUT ALLERGEN POWDER-DNFP

Generic	Brand	HICL	GCN	Exception/Other
PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-DNFP	PALFORZIA	46332		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of peanut allergy and meet **ALL** of the following criteria?
 - The patient is 4 to 17 years of age
 - Therapy is prescribed by or given in consultation with an allergist/immunologist
 - The patient has a clinical history of allergic reaction to peanuts
 - The requested medication will be used in conjunction with a peanut-avoidance diet
 - Documentation of a positive skin prick test (wheal diameter ≥ 3 mm) **OR** peanut-specific immunoglobulin E (≥ 0.35 kUA/L) within the past 24 months

If yes, continue to #2.

If no, do not approve.

INITIAL DENIAL TEXT: See denial text at the end of the guideline.

- Is the request for the 300 mg powder packet/sachet?

If yes, **approve for 12 months by GPID with a quantity limit of #1 per day.**

If no, **approve for 12 months by GPID for all requested strengths with no quantity limit.**

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:

- You have a peanut allergy
- You are 4 to 17 years of age
- The medication is prescribed by given in consultation with an allergist/immunologist (allergy/immune system doctor)
- You have a clinical history of allergic reaction to peanuts
- The medication is to be used in conjunction with a peanut-avoidance diet
- You have documentation of a positive skin prick test (wheal diameter ≥ 3 mm) (skin test to check for peanut allergy) **OR** peanut-specific immunoglobulin E (IgE ≥ 0.35 kUA/L) (blood test that indicates an allergy to peanuts) within the past 24 months

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**CONTINUED ON NEXT PAGE
PEANUT ALLERGEN POWDER-DNFP****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a peanut allergy and meet **ALL** of the following criteria?
 - Therapy is prescribed by given in consultation with an allergist/immunologist
 - The requested medication is to be used in conjunction with a peanut-avoidance diet

If yes, continue to #2.
If no, do not approve.
2. Does the patient meet **ONE** of the following criteria?
 - The patient has a *persistent* peanut allergy
 - Documentation of persistent peanut allergy by positive skin prick test (wheal diameter ≥ 3 mm) **OR** Peanut-specific immunoglobulin E (≥ 0.35 kUA/L) within the past 24 months

If yes, continue to #3.
If no, do not approve.
3. If the request for the 300mg powder packet/sachet?

If yes, **approve for 24 months by GPID with a quantity limit of #1 per day.**
If no, **approve for 24 months by GPID for all requested strengths with no quantity limit.**

RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for renewal:

- A. You have an allergy to peanuts
- B. The medication is prescribed by given in consultation with an allergist/immunologist (allergy/immune system doctor)
- C. The medication is to be used in conjunction with a peanut-avoidance diet
- D. You meet ONE of the following:
 1. You continue to have a persistent a peanut allergy (your peanut allergy has not gone away)
 2. You have documentation of a peanut allergy by a positive skin prick test (wheal diameter ≥ 3 mm) (skin test to check for peanut allergy) **OR** peanut-specific immunoglobulin E (IgE ≥ 0.35 kUA/L) (blood test that indicates an allergy to peanuts) within the past 24 months

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with



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your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON THE NEX PAGE PEANUT ALLERGEN POWDER-DNFP

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Palforzia.

REFERENCES

- Palforzia [Prescribing Information]. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/21/20

Created: 02/20

Client Approval: 02/20

P&T Approval: 04/19

CYCLOSPORINE OPHTHALMIC

Generic	Brand	HICL	GCN	Exception/Other
CYCLOSPORINE OPHTHALMIC	RESTASIS		42588 19216	
	CEQUA		45144	

GUIDELINES FOR USE

Please use the criteria for the requested medication

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
RESTASIS

1. Is the patient aged 16 years and older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the medication being prescribed by or in consultation with an optometrist or ophthalmologist?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient concurrently using punctal plugs?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #4.

4. Will the patient be using Restasis with topical ophthalmic anti-inflammatory drugs (e.g., corticosteroid, nonsteroidal anti-inflammatory drugs, etc.)?

If yes, continue to question #5.

If no, continue to question #6.

5. Will the topical ophthalmic anti-inflammatory drugs only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with Restasis?

If yes, continue to question #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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CYCLOSPORINE OPHTHALMIC**INITIAL CRITERIA (CONTINUED)**

6. Will the patient be using in combination with Xiidra?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #7.

7. Does the patient have a diagnosis of keratoconjunctivitis sicca (dry eye) or Sjogren syndrome with suppressed tear production due to ocular inflammation?

If yes, continue to #8.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

8. Has the diagnosis been confirmed by at least one of the following diagnostic tests?

- Schirmer test (aqueous tear production and clearance)
- Tear break up time (TBUT)
- Ocular surface dye staining
- Tear film osmolarity
- Fluorescein clearance test/tear function test

If yes, continue to #9.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

9. Did the patient have a trial and inadequate response or intolerance to at least one over-the-counter ocular lubricant product (e.g., artificial tears, lubricant gels/ointments, etc.) used at an optimal dose and frequency for at least 2 weeks?

If yes, **approve for 12 months by GPID for the requested product with the following quantity limits:**

- **Restasis Multidose (GPID 42588) approve 1 multi-dose vial (5.5mL) per 30 days.**
- **Restasis Dropperettes (GPID 19216) approve 60 single use vials per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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CYCLOSPORINE OPHTHALMIC**GUIDELINES FOR USE (CONTINUED)****CEQUA**

1. Is the patient aged 18 years and older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the medication being prescribed by or in consultation with an optometrist or ophthalmologist?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient currently using punctal plugs?

If yes, do not approve

DENIAL TEXT: See denial text at the end of the guideline.

If no, continue to #4.

4. Will the patient be using Cequa with topical ophthalmic anti-inflammatory drugs (e.g., corticosteroid, nonsteroidal anti-inflammatory drugs, etc.)?

If yes, continue to question #5.

If no, continue to question #6.

5. Will the topical ophthalmic anti-inflammatory drugs only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with Cequa?

If yes, continue to question #6.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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CYCLOSPORINE OPHTHALMIC**INITIAL CRITERIA (CONTINUED)**

6. Will the patient be using in combination with Xiidra?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #7.

7. Does the patient have a diagnosis of keratoconjunctivitis sicca (dry eye) or Sjogren syndrome with suppressed tear production due to ocular inflammation?

If yes, continue to #8.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

8. Has the diagnosis been confirmed by at least one of the following diagnostic tests?

- Schirmer test (aqueous tear production and clearance)
- Tear break up time (TBUT)
- Ocular surface dye staining
- Tear film osmolarity
- Fluorescein clearance test/tear function test

If yes, continue to #9.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

9. Did the patient have a trial and inadequate response or intolerance to at least one over-the-counter ocular lubricant product (e.g., artificial tears, lubricant gels/ointments, etc.) used at an optimal dose and frequency for at least 2 weeks?

If yes, continue to question #10

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

10. Has the patient had a trial and failure of Restasis?

If yes, **approve for 12 months by GPID with a quantity limit of 60 single use vials per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



RENEWAL CRITERIA

1. Does the patient have punctal plugs?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #2.

2. Will the patient be using the requested medication with topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, nonsteroidal anti-inflammatory drugs) or Xiidra?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

3. Has the patient experienced an objective response to therapy with the requested medication such as an increase in tear production or decrease in dry eye symptoms?

If yes, **approve for 12 months by GPID for the requested product with the following quantity limits:**

- **Restasis Multidose (GPID 42588) approve 1 multi-dose vial (5.5mL) per 30 days.**
- **Restasis Dropperettes (GPID 19216) approve 60 single use vials per 30 days.**
- **Cequa Dropperettes (GPID 45144) approve 60 single use vials per 30 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **CYCLOSPORINE OPHTHALMIC** requires that the patient has a diagnosis of keratoconjunctivitis sicca (dry eye) or Sjogren syndrome with suppressed tear production due to ocular inflammation. In addition, the patient must meet **ALL** the following criteria for approval:

For the approval of Restasis:

- Patient is aged 16 years or older.
- The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
- The patient does not have punctal plugs and will not be using concurrently with Xiidra.
- Topical ophthalmic anti-inflammatory medications, if used to transition the patient to Restasis monotherapy, will not be continued past 8 weeks.
- The diagnosis has been confirmed by one of the following diagnostic tests: Schirmer test, tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test.
- A previous trial and inadequate response or intolerance to at least one over-the-counter ocular lubricant product (e.g., artificial tears, lubricant gels/ointments, etc.) used at an optimal dose and frequency for at least 2 weeks.

(Denial text continued on next page)

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CYCLOSPORINE OPHTHALMIC

GUIDELINES FOR USE (CONTINUED)

For the approval of Cequa:

- Patient is aged 18 years or older.
- The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
- The patient does not have punctal plugs and will not be using concurrently with Xiidra.
- Topical ophthalmic anti-inflammatory medications, if used to transition the patient to Cequa monotherapy, will not be continued past 8 weeks.
- The diagnosis has been confirmed by one of the following diagnostic tests: Schirmer test, tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test.
- A previous trial and inadequate response or intolerance to at least one over-the-counter ocular lubricant product (e.g., artificial tears, lubricant gels/ointments, etc.) used at an optimal dose and frequency for at least 2 weeks.
- The patient has had a previous trial and failure of Restasis.

For renewal of therapy, the patient must meet ALL the following criteria for approval:

- The patient experienced an objective response to therapy with the requested medication such as an increase in tear production or a decrease in dry eye symptoms.
- The requested medication will not be used in combination with punctal plugs, topical ophthalmic anti-inflammatory drugs, or Xiidra.

RATIONALE

To ensure safe and appropriate use of Cyclosporine Ophthalmic (Restasis or Cequa) per approved indication and dosing.

FDA APPROVED INDICATIONS

Indicated for the treatment of xerophthalmia (dry eyes) by increasing tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

DOSAGE AND ADMINISTRATION

The recommended dosage of Restasis is one drop into the affected eye(s) twice daily approximately 12 hours apart. Artificial tears may be used concurrently, allowing a 15-minute interval between administration of products.

REFERENCES

- Restasis [Prescribing Information]. Irvine, CA: Allergan; 2017.
- Shtein RM. Dry eyes. Trobe J, ed. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on January 29, 2019.)

Created	FS Committee Approval	Effective
1/2019		
Revised 1/2020	02/2020	04/01/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

CYSTEAMINE BITARTRATE

Generic	Brand	HICL	GCN	Exception/Other
CYSTEAMINE BITARTRATE	PROCYSBI		34656 34657 47723 47724	

GUIDELINES FOR USE

- Does the patient have a diagnosis of nephropathic cystinosis and meet **ALL** of the following criteria?
 - The patient is 1 year of age or older
 - The patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

If yes, **approve for 12 months by GPID for all strengths of the requested drug.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:

- You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
- You are 1 year of age or older
- You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Procysbi.

REFERENCES

- Procysbi [Prescribing Information]. Novato, CA: Raptor Pharmaceuticals Inc.; February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/28/20

Created: 08/13

Client Approval: 11/15

P&T Approval: 11/15

PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

Generic	Brand	HICL	GCN	Exception/Other
FILGRASTIM-AAFI	NIVESTYM	45154		
FILGRASTIM-SNDZ	ZARXIO	41814		
PEGFILGRASTIM	NEULASTA	23255		
PEGFILGRASTIM-CBQV	UDENYCA	45445		
PEGFILGRASTIM-JMDB	FULPHILA	45010		

****Please use the criteria for the specific drug requested****

GUIDELINES FOR USE NIVESTYM OR ZARXIO

- Is the medication prescribed by or given in consultation with a hematologist or oncologist for **ONE** of the following indications?
 - Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
 - Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
 - Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
 - Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
 - Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

If yes, **approve the requested agent (Nivestym or Zarxio) for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

NEULASTA

Please note: The preferred product is Udenyca.

1. Is Neulasta prescribed by or given in consultation with a hematologist or oncologist for the following indication?

- Increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

If yes, **approve Neulasta for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

FULPHILA OR UDENYCA

1. Is the requested medication prescribed by or given in consultation with a hematologist or oncologist for the following indication?

- Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

If yes, **approve the requested medication (Fulphila or Udenyca) for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **GRANULOCYTE COLONY-STIMULATING FACTORS (GCSF)** requires that the requested medication is prescribed by or given in consultation with a hematologist or oncologist. In addition, the following criteria must be met:

Requests for Nivestym or Zarxio require ONE of the following indications:

- Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
- Patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
- Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
- Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Requests for Neulasta requires the following indication:

- Increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

Requests for Fulphila or Udenyca require the following indication:

- Patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

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PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Granulocyte Colony-Stimulating Factors.

FDA APPROVED INDICATIONS

Population	FDA labeling	Drug(s) Approved
Patients receiving radiation	Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)	Neulasta (pegfilgrastim)
Non-myeloid cancer patients receiving myelosuppressive chemo	<u>Decrease the incidence of infection</u> , as manifested by neutropenia with fever, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever	Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz) Neulasta (pegfilgrastim) Fulphila (pegfilgrastim-jmdb) Udenyca (pegfilgrastim-cbqv)
AML patients receiving induction or consolidation chemo	Reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)	Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz)
Cancer patients undergoing BMT	Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation	Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz)
Undergoing peripheral blood progenitor cell collection	For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis	Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz)
Severe chronic neutropenia	For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia	Nivestym (filgrastim-aafi) Zarxio (filgrastim-sndz)

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PRIOR AUTHORIZATION GUIDELINES

GRANULOCYTE COLONY-STIMULATING FACTORS

REFERENCES

- Nivestym [Prescribing Information]. Lake Forest, IL. Hospira, Inc. July 2018.
- Zarxio [Prescribing Information]. Princeton, NJ. Sandoz Inc. December 2017.
- Neulasta [Prescribing Information]. Thousand Oaks, CA. Amgen Inc. June 2018.
- Udenyca [Prescribing Information]. Redwood City, CA. Coherus Biosciences Inc. November 2018.
- Fulphila [Prescribing Information]. Zurich, Switzerland: Mylan GmbH. June 2018.

Created	FS Committee Approval	Effective
01/19; revised 7/23/19	02/19	08/01/19
Revised 01/2020	02/2020	04/01/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

INTERFERONS FOR MULTIPLE SCLEROSIS

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON BETA-1A	AVONEX, AVONEX PEN	11253		
INTERFERON BETA-1A/ALBUMIN	AVONEX ADMINISTRATION PACK, REBIF, REBIF REBIDOSE		23230 15914 15918 24286 34166 34167 34168	
INTERFERON BETA-1B	, BETASERON	08537		DRUG ≠ EXTAVIA
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN	41331		

GUIDELINES FOR USE
PLEGRIDY, AVONEX, REBIF, BETASERON

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in patients 18 years of age or older.

If yes, **approve the requested drug as follows:**

Approve Plegridy and enter two prior authorizations by HICL as follows:

- **PLEGRIDY INJECTION STARTER PACK:** approve for 1 month of 1mL (#2 prefilled pens or syringes) then
- **PLEGRIDY:** approve for 12 months for 1mL (#2 125mcg prefilled pens or syringes) per 28 days

Approve Rebif, Avonex, Betaseron, or Extavia for 12 months by GPID as follows:

- **REBIF:** 6mL (#12 syringes) per 28 days
- **REBIF REBIDOSE:** 6mL (#12 syringes) per 28 days
- **AVONEX ADMINISTRATION PACK:** #4 kits per 28 days
- **AVONEX:** #1 kit per 28 days or 2mL (#4 syringes) per 28 days
- **AVONEX PEN:** #1 pen injector kit per 28 days or 2mL (#4 syringes) per 28 days
- **BETASERON:** #14 vials or kits per 28 days.

(Approval directions continued on next page)

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INTERFERONS FOR MULTIPLE SCLEROSIS

GUIDELINES FOR USE (CONTINUED)

- **REBIF FOR NEW STARTS ONLY**, approve for a total of 12 months by GPID and enter two prior authorizations as follows:
 - **REBIF TITRATION PACK:** 1 month of 4.2mL (#12 syringes) per 28 days, then
 - **REBIF:** 6mL (#12 syringes) per 28 days (total approval duration is 12 months)
- OR**
- **REBIF REBIDOSE TITRATION PACK:** 1 month of 4.2mL (#12 syringes) per 28 days, then
- **REBIF REBIDOSE:** 6mL (#12 syringes) per 28 days (total approval duration is 12 months)

If no, do not approve.

DENIAL TEXT: The guideline named **INTERFERONS FOR MULTIPLE SCLEROSIS** requires a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease AND meet the following criterion.

RATIONALE

Ensure appropriate utilization criteria are met for the management of requests for interferons used in the treatment of multiple sclerosis.

- **Rebif, Plegridy, and Avonex** will approve if indication is met.
- **Betaseron** will approve if indication is met.

FDA APPROVED INDICATIONS

For the treatment of relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations.

REFERENCES

- Plegridy [Prescribing Information]. Cambridge, MA: Biogen Inc; July 2019
- Rebif [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; July 2019
- Avonex [Prescribing Information]. Cambridge, MA: Biogen Inc; July 2019
- .
- Betaseron [Prescribing Information]. Whippany, NJ: Bayer; August 2019.

Created	FS Committee Approval	Effective
Revised 10/2019		12/7/19
Revised 01/2020	02/2020	4/1/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES**SOFOSBUVIR/VELPATASVIR**

Generic	Brand	HICL	GCN	Exception/Other
SOFOSBUVIR/VELPATASVIR	EPCLUSA	43561		

GUIDELINES FOR USE

1. Does the patient have hepatitis C genotype 1, 2, 3, 4, 5, or 6?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient at least 18 years old?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the last 6 months?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?

If yes, continue to #5

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

5. Is the patient currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #6.

6. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #7.

7. Does the patient have hepatitis C post-liver transplant?

If yes, continue to #8

If no, continue to question #10.

8. Does the patient have cirrhosis?

If yes, continue to #9.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient meet ALL the following?

- The patient has decompensated cirrhosis
- The patient has genotype 2 or 3
- The patient will be taking sofosbuvir/velpatasvir (Epclusa) in combination with ribavirin.

If yes, **approve for 12 weeks by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

10. Does the patient have decompensated cirrhosis?

If yes, continue to #11

If no, do not approve

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

11. Is the patient treatment experienced with a sofosbuvir (Sovaldi) or NS5A-containing regimen?

If yes, continue to #12

If no, continue to #13

12. Will the patient be taking sofosbuvir/velpatasvir (Epclusa) in combination with ribavirin?

If yes, **approve for 24 weeks by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

13. Will the patient be taking in combination with ribavirin?

If yes, **approve for 12 weeks by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline for **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires a diagnosis of hepatitis C. The following criteria must also be met.

- Patient has genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient is at least 18 years old
- Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Documentation of HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)
- For patients with genotype 1, 2, 3, 4, 5, or 6 and decompensated cirrhosis, the patient must be using a ribavirin-containing regimen.
- Patient is post-liver transplant with genotype 2 or 3 and decompensated cirrhosis and will be taking a ribavirin-containing regimen.

Epclusa will not be approved for the following patients:

- Patient using any of the following medications concurrently while on Epclusa: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

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PRIOR AUTHORIZATION GUIDELINES**SOFOSBUVIR/VELPATASVIR****RATIONALE**

Ensure appropriate utilization of Epclusa (sofosbuvir/velpatasvir).

FDA APPROVED INDICATIONS

For the treatment of chronic hepatitis C genotype 1-6 infection in adults.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed January 2, 2019.
- Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; June 2016.

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 01/2020	02/2020	04/01/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



PRIOR AUTHORIZATION GUIDELINES

TRASTUZUMAB-QYYP (NSA)

Generic	Brand	HICL	GCN	Exception/Other
TRASTUZUMAB-QYYP	TRAZIMERA	45657		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of breast cancer and meet **ALL** of the following criteria?
 - The request is for adjuvant therapy
 - The patient has HER2-overexpressing (HER2-positive) tumor as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - The requested medication is being used as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - The requested medication is being used as part of a treatment regimen with docetaxel and carboplatin
 - The requested medication is being used as a single agent following multi-modality anthracycline based therapy (e.g., daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin)

If yes, **approve for 12 months by HICL.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 - The patient has HER2-overexpressing (HER2-positive) metastatic breast cancer as detected by an FDA-approved test
 - The patient meets **ONE** of the following:
 - The requested medication is being used in combination with paclitaxel for first-line treatment
 - The requested medication is being used as a single agent in a patient who has previously received ONE or more chemotherapy regimens for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, continue to #3.

3. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
 - The patient has HER2-overexpressing (HER2-positive) metastatic cancer as detected by an FDA-approved test
 - The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 - The patient has not received prior treatment for metastatic disease

If yes, **approve for 12 months by HICL.**

If no, do not approve.

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PRIOR AUTHORIZATION GUIDELINES**TRASTUZUMAB-QYYP (NSA)****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRASTUZUMAB- QYYP (Trazimera)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Breast cancer
2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

If you have breast cancer, approval also requires:

- A. The request is for adjuvant (add-on) therapy
- B. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
- C. You meet ONE of the following:
 1. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 2. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
 3. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

If you have metastatic breast cancer, approval also requires:

- A. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
- B. You meet ONE of the following:
 1. The requested medication is being used in combination with paclitaxel for first-line treatment
 2. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)

If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:

- A. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
- B. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
- C. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

(Denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES**TRASTUZUMAB-QYYP (NSA)****GUIDELINES FOR USE (CONTINUED)**

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trazimera.

REFERENCES

- Trazimera [Prescribing Information]. New York, NY: Pfizer Ireland Pharmaceuticals; March 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 02/28/20

Created: 02/20

Client Approval: 04/19

P&T Approval: 04/19



VEDOLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Exception/Other
VEDOLIZUMAB	ENTYVIO	41146		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe Crohn's (CD) disease and meet **ALL** the following criteria?
 - Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older

If yes, **approve for 6 months as follows:**

Please enter two authorizations by HICL as follows:

- **FIRST APPROVAL:** Approve for 1 month (total fill count of 1) with a quantity limit of #600mg (#2 vials) for the first 4 weeks, then
- **SECOND APPROVAL:** Approve for 5 months (total fill count of 3) with a quantity limit of #300mg (#1 vial) per 56 days (Please enter a start date of **ONE** week after the last date of the first approval).

If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient had a previous trial of or contraindication to at least **ONE** of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older

If yes, **approve for 6 months as follows:**

Please enter two authorizations by HICL as follows:

- **FIRST APPROVAL:** Approve for 1 month (total fill count of 1) with a quantity limit of #600mg (#2 vials) for the first 4 weeks, then
- **SECOND APPROVAL:** Approve for 5 months (total fill count of 3) with a quantity limit of #300mg (#1 vial) per 56 days (Please enter a start date of **ONE** week after the last date of the first approval).

If no, do not approve.

(see denial text on next page)

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INITIAL DENIAL TEXT: The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe Crohn's disease, approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older

For patients with moderate to severe ulcerative colitis, approval requires all of the following:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient had a previous trial of or contraindication to at least one of the following conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) or moderate to severe ulcerative colitis (UC)?

If yes, **approve for 12 months by HICL with a quantity limit of #1 vial (300mg) per 8 weeks (total 6 fills in 12 months).**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis for renewal.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Entyvio.

REFERENCES

- Entyvio [Prescribing Information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; February 2018.

Created	FS Committee Approval	Effective
01/2020	02/2020	04/01/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	Yes

ERYTHROPOIESIS STIMULATING AGENTS

Generic	Brand	HICL	GCN	Exception/Other
EPOETIN ALFA	PROCRIT	04553		BRAND ≠ EPOGEN NDC ≠ 54868-2523-01, 54868-5802-00
EPOETIN ALFA-EPBX	RETACRIT	44931		

GUIDELINES FOR USE

INITIAL CRITERIA FOR PROCRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) **AND** meet the following criterion?
 - The patient has a hemoglobin level of less than 10g/dL

If yes, **approve Procrit for 12 months by NDC with the following quantity limits:**

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
 - 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
 - 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
 - 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
 - 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
 - 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
 - 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.
- APPROVAL TEXT:** Please provide current hemoglobin levels for renewal requests.

If no, continue to #2.

- Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ONE** of the following criteria?
 - The patient has a hemoglobin level of less than 11g/dL **OR**
 - The patient's hemoglobin level has decreased at least 2g/dL below their baseline level

If yes, **approve Procrit for 12 months by NDC with the following quantity limits:**
(See initial Procrit approval directions on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR PROCRT (CONTINUED)

If yes, approve Procrit for 12 months by NDC with the following quantity limits:

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #3.

3. Does the patient have a diagnosis of anemia related to zidovudine therapy **AND** meet the following criterion?

- The patient has a hemoglobin level of less than 10g/dL

If yes, approve Procrit for 12 months by NDC with the following quantity limits:

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?

- The patient has a hemoglobin level of less than 10g/dL
- The patient has had a trial or contraindication to ribavirin dose reduction

If yes, approve Procrit for 6 months by NDC with the following quantity limits:
(See *initial Procrit approval directions on next page*)

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ERYTHROPOIESIS STIMULATING AGENTS**INITIAL CRITERIA FOR PROCRIT (CONTINUED)**

If yes, approve Procrit for 6 months by NDC with the following quantity limits:

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.
-

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #5.

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery **AND** meet the following criterion?

- The patient has a hemoglobin level of less than 13g/dL

If yes, approve Procrit for 1 month by NDC with the following quantity limits:

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT)** requires that the following criteria are met:

For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires:

- The patient has a hemoglobin level of less than 10g/dL

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires one of the following:

- The patient has a hemoglobin level of less than 11g/dL **OR**
- The patient's hemoglobin level has decreased at least 2g/dL below their baseline level.

(Initial Procrit denial text continued on next page)

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR PROCRIT (CONTINUED)

For a diagnosis of anemia related to zidovudine therapy, approval requires:

- The patient has a hemoglobin level of less than 10g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

- The patient has had a trial of or contraindication to ribavirin dose reduction
- The patient has a hemoglobin level of less than 10g/dL

For patients undergoing elective, noncardiac, or nonvascular surgery, approval requires:

- The patient has a hemoglobin level of less than 13g/dL

Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE (CONTINUED)

INITIAL CRITERIA FOR RETACRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ALL** of the following criteria?
 - The patient has a hemoglobin level of less than 10g/dL

If yes, **approve Retacrit for 12 months by GPID with the following quantity limits:**

- 2000U/mL GPID 44764: #12mL in 28 days.
- 3000U/mL GPID 44765: #12mL in 28 days.
- 4000U/mL GPID 44766: #12mL in 28 days.
- 10000U/mL GPID 44767: #12mL in 28 days.
- 40000U/mL GPID 44768: #6mL in 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet **ALL** of the following criteria?
 - The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin level has decreased at least 2g/dL below their baseline level

If yes, **approve Retacrit for 12 months by GPID with the following quantity limits:**

- 2000U/mL GPID 44764: #12mL in 28 days.
- 3000U/mL GPID 44765: #12mL in 28 days.
- 4000U/mL GPID 44766: #12mL in 28 days.
- 10000U/mL GPID 44767: #12mL in 28 days.
- 40000U/mL GPID 44768: #6mL in 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #3.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR RETACRIT (CONTINUED)

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet **ALL** of the following criteria?

- The patient has a hemoglobin level of less than 10g/dL

If yes, **approve Retacrit for 12 months by GPID with the following quantity limits:**

- 2000U/mL GPID 44764: #12mL in 28 days.
- 3000U/mL GPID 44765: #12mL in 28 days.
- 4000U/mL GPID 44766: #12mL in 28 days.
- 10000U/mL GPID 44767: #12mL in 28 days.
- 40000U/mL GPID 44768: #6mL in 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet **ALL** of the following criteria?

- The patient has a hemoglobin level of less than 10g/dL
- The patient has had a trial or contraindication to ribavirin dose reduction

If yes, **approve Retacrit for 6 months by GPID with the following quantity limits:**

- 2000U/mL GPID 44764: #12mL in 28 days.
- 3000U/mL GPID 44765: #12mL in 28 days.
- 4000U/mL GPID 44766: #12mL in 28 days.
- 10000U/mL GPID 44767: #12mL in 28 days.
- 40000U/mL GPID 44768: #6mL in 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, continue to #5.

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ERYTHROPOIESIS STIMULATING AGENTS

INITIAL CRITERIA FOR RETACRIT (CONTINUED)

5. Is the patient undergoing elective, noncardiac, or nonvascular surgery and meet **ALL** of the following criteria?

- The patient has a hemoglobin level of less than 13g/dL

If yes, approve Retacrit for 1 month by GPID with the following quantity limits:

- 2000U/mL GPID 44764: #12mL in 28 days.
- 3000U/mL GPID 44765: #12mL in 28 days.
- 4000U/mL GPID 44766: #12mL in 28 days.
- 10000U/mL GPID 44767: #12mL in 28 days.
- 40000U/mL GPID 44768: #6mL in 28 days.

APPROVAL TEXT: Please provide current hemoglobin levels for renewal requests.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (RETACRIT)** requires that the following criteria are met:

For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires:

- The patient's hemoglobin level of less than 10g/dL

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:

- The patient has a hemoglobin level of less than 11g/dL **OR** the patient's hemoglobin has decreased at least 2g/dL below their baseline level

For a diagnosis of anemia related to zidovudine therapy, approval requires:

- The patient has a hemoglobin level of less than 10g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

- The patient has had a trial of or contraindication to ribavirin dose reduction
- The patient has a hemoglobin level of less than 10g/dL

For patients undergoing elective, noncardiac, or nonvascular surgery, approval requires:

- The patient has a hemoglobin level of less than 13g/dL

Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS**GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA FOR PROCIT**

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
 - The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
 - The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
 - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions **OR**
 - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

If yes, **approve Procrit for 12 months by NDC with the following quantity limits:**

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
 - The patient has a hemoglobin level between 10g/dL and 12g/dL

If yes, **approve Procrit for 12 months by NDC with the following quantity limits:**

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

If no, continue to #3.

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ERYTHROPOIESIS STIMULATING AGENTS**RENEWAL CRITERIA FOR PROCRIT (CONTINUED)**

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?

- The patient has a hemoglobin level between 10g/dL and 12g/dL

If yes, approve Procrit for 12 months by NDC with the following quantity limits:

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?

- The patient has a hemoglobin level between 10g/dL and 12g/dL

If yes, approve Procrit for 6 months by NDC with the following limits:

- 2,000U/mL NDC 59676-0302-00, 59676-0302-01: #12mL per 28 days.
- 3,000U/mL NDC 59676-0303-00, 59676-0303-01: #12mL per 28 days.
- 4,000U/mL NDC 59676-0304-00, 59676-0304-01: #12mL per 28 days.
- 10,000U/mL NDC 59676-0310-00, 59676-0310-01, 59676-0310-02: #12mL per 28 days.
- 20,000U/mL NDC 59676-0320-00, 59676-0320-04: #12mL per 28 days.
- 40,000U/mL NDC 59676-0340-00, 59676-0340-01: #6mL per 28 days.
- 20,000U/2mL NDC 59676-0312-00, 59676-0312-04: #12mL per 28 days.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of Procrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR PROCRIT (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (PROCRIT)** renewal requires that the following criteria are met:

For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires ONE of the following:

- The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
- The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
- The patient has a hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is require to reduce the need for blood transfusions **OR**
- The patient has a hemoglobin level has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia related to zidovudine therapy, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

Please discuss the information needed to get the drug approved with your physician.

CONTINUED ON NEXT PAGE

ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR RETACRIT

1. Does the patient have a diagnosis of anemia associated with chronic kidney disease (CKD) and meet **ONE** of the following criteria?
 - The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
 - The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
 - The patient has a hemoglobin level that has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions **OR**
 - The patient has a hemoglobin level that has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

If yes, approve Retacrit for 12 months by GPID with the following quantity limits:

- 2000U/mL GPID 44764: #12mL in 28 days.
- 3000U/mL GPID 44765: #12mL in 28 days.
- 4000U/mL GPID 44766: #12mL in 28 days.
- 10000U/mL GPID 44767: #12mL in 28 days.
- 40000U/mL GPID 44768: #6mL in 28 days.

If no, continue to #2.

2. Does the patient have a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy and meet the following criterion?
 - The patient has a hemoglobin level between 10g/dL and 12g/dL

If yes, approve Retacrit for 12 months by GPID with the following quantity limits:

- 2000U/mL GPID 44764: #12mL in 28 days
- 3000U/mL GPID 44765: #12mL in 28 days
- 4000U/mL GPID 44766: #12mL in 28 days
- 10000U/mL GPID 44767: #12mL in 28 days
- 40000U/mL GPID 44768: #6mL in 28 days

If no, continue to #3.

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ERYTHROPOIESIS STIMULATING AGENTS

3. Does the patient have a diagnosis of anemia related to zidovudine therapy and meet the following criterion?

- The patient has a hemoglobin level between 10g/dL and 12g/dL

If yes, **approve Retacrit for 12 months by GPID with the following quantity limits:**

- **2000U/mL GPID 44764: #12mL in 28 days.**
- **3000U/mL GPID 44765: #12mL in 28 days.**
- **4000U/mL GPID 44766: #12mL in 28 days.**
- **10000U/mL GPID 44767: #12mL in 28 days.**
- **40000U/mL GPID 44768: #6mL in 28 days.**

If no, continue to #4.

4. Does the patient have a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa and meet the following criterion?

- The patient has a hemoglobin level between 10g/dL and 12g/dL

If yes, **approve Retacrit for 6 months by GPID with the following quantity limits:**

- **2000U/mL GPID 44764: #12mL in 28 days**
- **3000U/mL GPID 44765: #12mL in 28 days**
- **4000U/mL GPID 44766: #12mL in 28 days**
- **10000U/mL GPID 44767: #12mL in 28 days**
- **40000U/mL GPID 44768: #6mL in 28 days**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of Retacrit renewal guideline.

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ERYTHROPOIESIS STIMULATING AGENTS

RENEWAL CRITERIA FOR RETACRIT (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **ERYTHROPOIESIS STIMULATING AGENTS (RETACRIT)** renewal requires that the following criteria are met:

For a diagnosis of anemia associated with chronic kidney disease (CKD), approval requires ONE of the following:

- The patient has a hemoglobin level of less than 10g/dL if not on dialysis **OR**
- The patient has a hemoglobin level of less than 11g/dL if on dialysis **OR**
- The patient has a hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is require to reduce the need for blood transfusions **OR**
- The patient has a hemoglobin level has reached 11g/dL (on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

For a diagnosis of anemia due to the effect of concomitantly administered cancer chemotherapy, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia related to zidovudine therapy, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

For a diagnosis of anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval requires:

- The patient has a hemoglobin level between 10g/dL and 12g/dL

Please discuss the information needed to get the drug approved with your physician.

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ERYTHROPOIESIS STIMULATING AGENTS

RATIONALE

To ensure appropriate utilization and promote use of preferred ESA treatment.

Anemia due to hepatitis C therapy is not an FDA approved indication for any ESA. AASLD does not recommend the use of ESAs, NIH/DHHS/NIDDKD state that the proper role and dose of ESAs has yet to be defined, and the AGA consider either ribavirin dose reduction or ESA use as viable options for managing treatment-related anemia. None of these guidelines provide specific hemoglobin levels at which to initiate or maintain hemoglobin levels for this patient population, therefore the hemoglobin levels selected for this diagnosis are based off of the recommendations for zidovudine therapy.

FDA APPROVED INDICATIONS

- CHRONIC KIDNEY DISEASE: The prescribing information (PI) of the ESAs and an FDA safety update recommend initiation of therapy only for patients with Hgb of <10g/dL. They recommend reducing or interrupting the dose of ESA and using the lowest dose of an ESA sufficient to reduce the need for blood transfusions at Hgb of 11g/dL for patients on dialysis or Hgb of 10g/dL for patients not on dialysis.
- ANEMIA RELATED TO CANCER CHEMOTHERAPY: ASCO recommends initiating ESA therapy at Hgb levels at less than 10g/dL while NCCN recommends initiation at or below Hgb levels of 11g/dL. ASCO recommends maintaining Hgb levels between 10 and 12g/dL, while NCCN does not comment on a maintenance Hgb range.
- ANEMIA RELATED TO ZIDOVUDINE THERAPY: The clinical trials contained within the prescribing information (PI) of the ESAs recommend initiating therapy at an Hgb of < 10g/dL and maintaining between 10 and 12g/dL.
- PATIENTS SCHEDULED FOR ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: The prescribing information (PI) of the ESAs recommends therapy only for those patients with Hgb ≤13g/dL.

ERYTHROPOIESIS STIMULATING AGENTS

Procrit & Retacrit

- Treatment of anemia due to:
 - Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis
 - Zidovudine in HIV-infected patients
 - The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy
- Reduction of allogeneic RBC transfusions in patients undergoing elective, noncardiac, nonvascular surgery

Recommended starting dose:

- CKD on dialysis:
 - Adults: 50-100 units/kg 3 times weekly
 - Pediatrics: 50 units/kg 3 times weekly
- CKD not on dialysis:
 - Adult patients: 50-100 units/kg 3 times weekly
- Zidovudine-treated HIV-infected patients
 - Adults: 100 units/kg 3 times per week
- Cancer chemotherapy:
 - Adults: 150 units/kg SC 3 times per week until completion of a chemotherapy course, or 40,000 units SC weekly until completion of a chemotherapy course
 - Pediatrics: 600 units/kg IV until completion of a chemotherapy course
- Surgery:
 - 300 units/kg per day SC for 15 days total: administered daily for 10 days before surgery, on the day of surgery, and for 4 days after surgery
 - 600 units/kg SC in 4 doses administered 21, 14, and 7 days before surgery and on the day of surgery

REFERENCES

- Retacrit [Prescribing Information]. Lake Forest, IL: Pfizer Inc. May 2018.
- Procrit [Prescribing Information]. Thousand Oaks, CA: Amgen, September 2017.

Created	FS Committee Approval	Effective
2/2020		2/14/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

PRIOR AUTHORIZATION GUIDELINES

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR	VIEKIRA PAK		37614	GPI-10 (1235990460)	
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR	VIEKIRA XR		41932	GPI-10 (1235990460)	

GUIDELINES FOR USE

1. Does the patient meet **ONE** of the following criteria?

- Patient has a contraindication to therapy with Epclusa, Harvoni **AND** Mavyret
- Patient has previously failed a short trial with Epclusa, Harvoni or Mavyret (e.g., adverse effect early in therapy); [**NOTE:** An individual who has completed a full course of therapy with Epclusa, Harvoni or Mavyret that did not achieve SVR will not be approved]

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient have one or more of the following conditions?

- Decompensated liver disease
- Moderate liver impairment (Child-Pugh B) or severe liver impairment (Child-Pugh C)
- A limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)
- Patient is on hemodialysis
- Concurrent use with any of these (contraindicated or not recommended by the manufacturer) medications: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylethergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio (sildenafil dose of 20mg and/or dosed TID for PAH), triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, salmeterol
- Prior use (failure of a full course of therapy) or concurrent use of any HCV protease inhibitors including Olysio (simeprevir), Victrelis (boceprevir), or Incivek (telaprevir)
- Prior use (failure of a full course of therapy) or concurrent use of any NS5B polymerase inhibitor including Sovaldi (sofosbuvir)
- Prior use (failure of a full course of therapy) of concurrent use of any NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES**OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR****GUIDELINES FOR USE (CONTINUED)**

3. Does the patient have a recent HCV infection documented by one detectable HCV RNA level within the last 6 months?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient meet **ALL** of the following criteria?

- Patient at least 18 years of age
- Hepatitis C, genotype 1
- Patient is treatment naïve or treatment experienced (previous treatment with peginterferon/ribavirin)
- Patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the requested medication being used with ribavirin; (**NOTE:** Ribavirin combination therapy with Viekira is approved for genotype 1a without cirrhosis, genotype 1a with cirrhosis, and for use in liver transplant patients.)?

If yes, continue to #6.

If no, continue to #12.

6. Is the patient a liver transplant recipient?

If yes, **approve the requested strength for 24 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients who are liver transplant recipients to complete a total of 24 weeks of therapy):**

- Viekira XR: #84 tablets (1 pack) per 28 days OR
- Viekira Pak: #112 tablets (1 pack) per 28 days

If no, continue to #7.

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PRIOR AUTHORIZATION GUIDELINES**OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR****GUIDELINES FOR USE (CONTINUED)**

7. Does the patient have genotype 1a without cirrhosis?

If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a without cirrhosis to complete a total maximum of 12 weeks of therapy):**

- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, continue to #8.

8. Does the patient have genotype 1a with cirrhosis **AND** is treatment naïve?

If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows treatment naïve patients with genotype 1a with cirrhosis to complete a total maximum of 12 weeks of therapy):**

- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, continue to #9.

9. Does the patient have genotype 1a with cirrhosis and has received prior treatment (e.g., treatment-experienced patient) for hepatitis C with peginterferon and ribavirin; (**NOTE:** Approval not granted for patients with history of prior use of **OR** concurrent use of HCV protease inhibitors or HCV polymerase inhibitors: Olysio (simeprevir), Victrelis (boceprevir), Incivek (telaprevir), Sovaldi (sofosbuvir), or Harvoni (ledipasvir/sofosbuvir)?

If yes, continue to #10.

If no, continue to #12.

10. Is the patient a previous prior relapser or a prior partial responder?

If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a that are previous prior relapsers or prior partial responders to complete a total of 12 weeks of therapy):**

- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, continue to #11.

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PRIOR AUTHORIZATION GUIDELINES**OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR****GUIDELINES FOR USE (CONTINUED)**

11. Is the patient a treatment-experienced patient and is a previous null responder?

If yes, **approve the requested strength for 24 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1a that are previous null responders to complete a total of 24 weeks of therapy):**

- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

12. Does the patient have genotype 1b?

If yes, **approve the requested strength for 12 weeks by GPID or GPI-14 with the following quantity limits (NOTE: Approval allows patients with genotype 1b to complete a total of 12 weeks of therapy):**

- **Viekira XR: #84 tablets (1 pack) per 28 days OR**
- **Viekira Pak: #112 tablets (1 pack) per 28 days**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR/ DASABUVIR (Viekira Pak or Viekira XR)** requires the following rule(s) be met for approval:

- A. You have chronic hepatitis C, genotype 1
- B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
- C. You will be using ribavirin with the requested medication, unless you have genotype 1b
- D. You are 18 years of age or older
- E. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- F. You have previously failed a short trial with Epclusa, Harvoni or Mavyret. Reasons for failure include adverse effect early in therapy, intolerance to therapy, or if you have a medical reason why you cannot use (contraindication) all 3 drugs. (**NOTE:** If you completed a full course of therapy with Epclusa, Harvoni or Mavyret and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
- G. You have documentation of a recent hepatitis C virus infection shown by at least one HCV RNA level (amount of virus in the blood) within the past 6 months

(Denial text continued on the next page)

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PRIOR AUTHORIZATION GUIDELINES

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR

GUIDELINES FOR USE (CONTINUED)

The medication will not be approved for the following patients:

- A. You are using any of the following medications at the same time while on Viekira: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylegonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or salmeterol
- B. You have decompensated cirrhosis (symptoms related to liver damage)
- C. You have moderate liver impairment (Child Pugh B) or severe liver impairment (Child Pugh C)
- D. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
- E. You have a limited life expectancy (less than 12 months) due to other conditions not related to the liver
- F. You have previously used/failed a full course of therapy, or currently using any of the following regimens:
 - 1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
 - 2. A combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
 - 3. A hepatitis C virus protease inhibitor (type of hepatitis drug) including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

A total of 12 weeks of therapy will be approved except 24 weeks of therapy for 1) genotype 1a with cirrhosis if patient is treatment experienced, previous null responder or 2) a liver transplant recipient.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PRIOR AUTHORIZATION GUIDELINES**OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR****RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viekira Pak/XR.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed July 26, 2016.
- Viekira Pak [Prescribing Information]. North Chicago, IL: Abbvie Inc.; December 2019.
- Viekira XR [Prescribing Information]. North Chicago, IL: Abbvie Inc.; July 2016.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 03/16/20

Created: 01/15

Client Approval: 02/20

P&T Approval: 01/20

PRIOR AUTHORIZATION GUIDELINES

RISANKIZUMAB-RZAA

Generic	Brand	HICL	GCN	Exception/Other
RISANKIZUMAB-RZAA	SKYRIZI	45699		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

If yes, **approve for a total of 6 months by HICL with a fill limit of 3.**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

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PRIOR AUTHORIZATION GUIDELINES**RISANKIZUMAB-RZAA****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL with a quantity limit of #1 kit (2 syringes) per 12 weeks.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Skyrizi.

REFERENCES

- Skyrizi [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; April 2019.

Created	FS Committee Approval	Effective
5/2019; revised 8/2019	8/19	9/15/19
Revised 3/2020		3/13/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

CENOBAMATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CENOBAMATE	XCOPRI	46241		GPI-10 (7212001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of partial-onset seizures and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient had a trial of TWO generic anticonvulsant agents indicated for partial-onset seizures

If yes, **approve for 6 months by GPID or GPI-14 for all strengths with the following quantity limits:**

- Xcopri 12.5mg-25mg blister pack: #1 per day.
- Xcopri 50mg-100mg blister pack: #1 per day.
- Xcopri 150mg-200mg blister pack: #1 per day.
- Xcopri 250mg daily dose blister pack: #2 per day.
- Xcopri 350mg daily dose blister pack: #2 per day.
- Xcopri 50mg, 100mg, 150mg: #1 per day.
- Xcopri 200mg: #2 per day.

APPROVAL TEXT: Renewal requires the patient has experienced an improvement in seizure rate compared to baseline at treatment initiation.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **CENOBAMATE (Xcopri)** requires the following rule(s) be met for approval:

- A. You have partial-onset seizures
- B. You are 18 years of age or older
- C. You have previously tried TWO generic anticonvulsant agents (drugs used to treat seizures) indicated for partial-onset seizures

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****CENOBAMATE****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of partial-onset seizures **AND** meet the following criterion?
 - The patient has experienced an improvement in seizure rate compared to baseline at treatment initiation

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**

- Xcopri 250mg daily dose blister pack: #2 per day.
- Xcopri 350mg daily dose blister pack: #2 per day.
- Xcopri 50mg, 100mg, 150mg: #1 per day.
- Xcopri 200mg: #2 per day.

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CENOBAMATE (Xcopri)** requires the following rule(s) be met for renewal:

- A. You have partial-onset seizures
- B. You have experienced an improvement in seizure rate compared to baseline at treatment initiation

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xcopri.

REFERENCES

- Xcopri [Prescribing Information]. Paramus, NJ: SK Life Science, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/13/20

Created: 04/01

Client Approval: 04/20

P&T Approval: 01/20



EPTINEZUMAB-JJMR (NSA)

Generic	Brand	HICL	GCN	Exception/Other
EPTINEZUMAB-JJMR	VYEPTI	46372		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the prescription benefit include coverage for non-self-administered (NSA) drugs?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: Your prescription drug benefit does not cover non-self-administered (NSA) drugs. Coverage may be available on the medical benefit.

2. Does the patient have a diagnosis of episodic migraines and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Vyepti is prescribed for the preventive treatment of migraines
- The patient had a previous trial of **TWO** of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
- The patient had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, and Emgality

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3mL per 3 months.**

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month, **OR** that the patient has experienced a reduction in migraine severity **OR** migraine duration with Vyepti therapy

If no, continue to #2.

3. Does the patient have a diagnosis of chronic migraines and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Vyepti is prescribed for the preventive treatment of migraines
- The patient had a previous trial of **TWO** of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox **[Note: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]**
- The patient had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, and Emgality

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EPTINEZUMAB-JJMR (NSA)

GUIDELINES FOR USE (CONTINUED)

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3mL per 3 months.**

APPROVAL TEXT: Renewal requires that the patient has experienced a reduction in migraine or headache frequency of at least 2 days per month **OR** the patient has experienced a reduction in migraine severity **OR** migraine duration with Vyepti therapy.

If no, do not approve.

DENIAL TEXT: See initial denial text at the end of the guideline.

INITIAL DENIAL TEXT:

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:

A. You have migraines

B. **If you have episodic migraines, approval also requires:**

1. You are 18 years of age or older
2. Vyepti is prescribed for the preventive treatment of migraines
3. You have had a previous trial of TWO of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
4. You have had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, and Emgality

C. **If you have chronic migraines, approval also requires:**

1. You are 18 years of age or older
2. Vyepti is prescribed for the preventive treatment of migraines
3. You have had a previous trial of ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox [**Note:** For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
4. You have had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, and Emgality

RENEWAL CRITERIA

1. Is Vyepti prescribed for the preventive treatment of migraines and the patient meets **ONE** of the following criteria?
 - The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Vyepti therapy
 - The patient has experienced a reduction in migraine severity with Vyepti therapy
 - The patient has experienced a reduction in migraine duration with Vyepti therapy

EPTINEZUMAB-JJMR (NSA)

RENEWAL CRITERIA (CONTINUED)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 3 months.**

If no, do not approve.

DENIAL TEXT: See renewal denial text at the end of the guideline.

RENEWAL DENIAL TEXT:

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:

- A. Vyepti is being prescribed for preventive treatment of migraines
- B. You also meet **ONE** of the following:
 - 1. You have experienced a reduction in migraine or headache frequency by at least 2 days per month with Vyepti therapy
 - 2. You have experienced a reduction in migraine severity with Vyepti therapy
 - 3. You have experienced a reduction in migraine duration (length of time) with Vyepti therapy

RATIONALE

For further information, please refer to the Prescribing information and/or Drug Monograph for Vyepti.

REFERENCES

- Vyepti [Prescribing Information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.

Created	FS Committee Approval	Effective
03/16/2020		04/01/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	Yes



COMMERCIAL MINNESOTA PRIOR AUTHORIZATION GUIDELINE

STEP THERAPY OVERRIDE DETERMINATION (MINNESOTA EXCEPTION)

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

1. Is the request for a step therapy exception **OR** an exception for step therapy (**ST**) requirements that are included within a PA guideline?

If yes, continue to #2.

If no, guideline does not apply.

2. Have at least ONE of the following conditions been met?

2.11 The prescription drug required under ST protocol is contraindicated (will cause any of the following):

- (i) Cause adverse reaction
- (ii) Decrease the ability of the member to achieve or maintain reasonable functional ability in performing daily activities
- (iii) Cause physical or mental harm

3.11 Patient tried and failed or had adverse effects with the required ST drug alternatives or a drug with the same mechanism of action covered by current or previous health plan. (Note: member may be required to try ST drug even though same pharmacologic class or same mechanisms of action if therapy sequence is supported by evidence-based and peer-reviewed clinical practice guidelines, FDA label or prescribing information)

4.11

Patient has previously received coverage for a prescription drug for the medical condition under consideration from their current health plan (or health plan immediately before the current one)

*Pharmaceutical samples will not meet the step therapy override requirements.

AND

Patient is experiencing a positive therapeutic outcome

AND

Patient's prescriber indicates the change to the required ST protocol prescription drug is expected to be ineffective or cause harm to member based on known characteristics of both the ST drug and the member

If yes, continue to #3.

If no, guideline does not apply.

3. The ST override must be granted, and MedImpact must authorize the coverage for the prescription drug if the prescription drug is a covered prescription drug under the enrollee's health plan.



COMMERCIAL MINNESOTA PRIOR AUTHORIZATION GUIDELINE

RATIONALE

To align with M.S.A. § 62Q.184 regarding step therapy protocol and override for prescription drug coverage. The law sets forth certain circumstances under which a Step Therapy override must be granted.

REFERENCES

Commercial Effective: 1/1/19

P&T Approval: x/xx

PRIOR AUTHORIZATION GUIDELINES

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AMLODIPINE SUSPENSION

Generic	Brand				
AMLODIPINE BENZOATE	KATERZIA				

GUIDELINES FOR USE

Our guideline named AMLODIPINE SUSPENSION (Katerzia) requires the following rule(s) be met for approval:

- A. You are unable to swallow oral amlodipine tablets at prescribed dose

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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AMLODIPINE/CELECOXIB

Generic	Brand				
AMLODIPINE BESYLATE/CELECOXIB	CONSENSI				

GUIDELINES FOR USE

Our guideline named AMLODIPINE/CELECOXIB (Consensi) requires the following rule(s) be met for approval:

- A. You have both hypertension (abnormal high blood pressure) and osteoarthritis (a type of arthritis that occurs when tissue at the ends of your bones wears down)
- B. You are 18 years of age or older
- C. You have previously tried amlodipine AND celecoxib
- D. You have an adherence or other challenge requiring the use of the combination product over separate agents
- E. You will NOT use Consensi together with any other calcium channel blocker agents (such as diltiazem, felodipine, verapamil)

Commercial Effective: 04/01/20

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DEFERASIROX

Generic	Brand			
DEFERASIROX	EXJADE, JADENU			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE) requires the following rule(s) be met for approval:

- A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)
- B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)
- C. If you have chronic Iron overload due to blood transfusions, approval also requires:
 1. You are 2 years of age or older
 2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values in the previous 3 months)
- D. If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:
 1. You are 10 years of age or older
 2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we at least 2 lab values in the previous 3 months)
 3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater
- E. Requests for Jadenu sprinkle packets requires a trial of equivalent generic Exjade or Jadenu tablets

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PRIOR AUTHORIZATION GUIDELINES

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DEFERASIROX

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE) requires the following rule(s) be met for renewal:

- A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (A blood disorder involving less than normal amounts of an oxygen-carrying protein)
- B. If you have chronic Iron overload due to blood transfusions, renewal also requires:
 - 1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (We need at least 2 lab values in the previous 3 months)
- C. If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:
 - 1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (We at least 2 lab values in the previous 3 months)
 - 2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

Commercial Effective: 04/01/20



PRIOR AUTHORIZATION GUIDELINES

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DELAFLORACIN

Generic	Brand			
DELAFLORACIN	BAXDELA			

GUIDELINES FOR USE

Our guideline named DELAFLORACIN (Baxdela) requires the following rule(s) be met for approval:

A. You meet ONE of the following:

1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist or
2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI); OR community-acquired bacterial pneumonia (CABP: type of lung infection)

B. If you have an acute bacterial skin or skin structure infection, approval also requires:

1. You are at least 18 years of age
2. The infection is caused by any of the following bacteria: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa
3. You do not have a diagnosis of animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitus ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum
4. You meet ONE of the following criteria:
 - i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to ONE standard of care agent for acute bacterial skin or skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin), AND b) delafloxacin will work against the bacteria
 - ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial of or contraindication to (a medical reason why you cannot use) ONE of the following agents: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)

(Criteria continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

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DELAFOXACIN

GUIDELINES FOR USE (CONTINUED)

- C. If you have community-acquired bacterial pneumonia (CABP: type of lung infection), approval also requires:
1. You are 18 years of age or older
 2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila* or *Mycoplasma pneumoniae*
 3. You meet ONE of the following criteria:
 - i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) AND b) delafloxacin will work against the bacteria
 - ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (a medical reason why you cannot use) TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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DICLOFENAC ORAL PACKET

Generic	Brand				
DICLOFENAC POTASSIUM	CAMBIA				

GUIDELINES FOR USE

Our guideline named DICLOFENAC ORAL PACKET (Cambia) requires the following rule(s) be met for approval:

- A. The request is for acute treatment of migraine attacks
- B. You are unable to swallow pills
- C. You had a previous trial of generic diclofenac AND over the counter (OTC) or generic aspirin, ibuprofen, or naproxen

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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ELEXACAFITOR/TEZACAFITOR/IVACAFITOR

Generic	Brand				
ELEXACAFITOR/ TEZACAFITOR/ IVACAFITOR	TRIKAFTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named ELEXACAFITOR/TEZACAFITOR/IVACAFITOR (Trikafta) requires the following rule(s) be met for approval:

- A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
- B. You are 12 years of age or older
- C. Documentation that you have at least one F508del mutation (a permanent change in your DNA that make up your gene) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
- D. The medication is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert

RENEWAL CRITERIA

Our guideline named ELEXACAFITOR/TEZACAFITOR/IVACAFITOR (Trikafta) requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
- B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
 1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
 2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
 3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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ENZALUTAMIDE

Generic	Brand			
ENZALUTAMIDE	XTANDI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named ENZALUTAMIDE (Xtandi) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
 2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)
- B. You meet ONE of the following:
 1. The requested medication will be used at the same time with a gonadotropin releasing hormone agonist or antagonist (such as leuprolide, goserelin, histrelin, degarelix)
 2. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
- C. If you have non-metastatic castration-resistant prostate cancer, approval also requires:
 1. You have a high-risk prostate cancer (rapidly increasing prostate specific antigen levels)
- D. If you have metastatic castration-resistant prostate cancer, approval also requires ONE of the following:
 1. You have previously tried Zytiga (abiraterone acetate) unless there is a medical reason why you cannot take it (contraindication)
 2. You cannot tolerate prednisone or there is a medical reason why you cannot take it (contraindication)

RENEWAL CRITERIA

Our guideline named ENZALUTAMIDE (Xtandi) requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
 1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
 2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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INTERFERON GAMMA-1B, RECOMB

Generic	Brand				
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named INTERFERON GAMMA-1B, RECOMB (Actimmune) requires the following rules be met for approval:

- A. You have ONE of the following diagnoses:
 1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
 2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)
- B. If you have chronic granulomatous disease, approval also requires:
 1. The medication is prescribed by or given in consultation with a hematologist (blood doctor), infectious disease specialist (doctor that specializes in treating infections), or immunologist (doctor that specializes in treating and managing allergies, asthma and immunologic disorders)
- C. If you have severe malignant osteopetrosis, approval also requires:
 1. The medication is prescribed by or given in consultation with an endocrinologist (doctor that specializes in all things relating to our hormones)

RENEWAL CRITERIA

Our guideline named INTERFERON GAMMA-1B, RECOMB (Actimmune) requires the following rules be met for renewal:

- A. You have ONE of the following diagnoses:
 1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
 2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)
- B. You have shown clinical (medical) benefit compared to baseline (such as reduction in frequency and severity of serious infections)
- C. You have not received hematopoietic cell transplantation (transplant of stem cells from bone marrow, peripheral blood, or umbilical cord blood)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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IVACAFTOR

Generic	Brand			
IVACAFTOR	KALYDECO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named IVACAFTOR (Kalydeco) requires the following rule(s) be met for approval:

- A. You are 6 months of age or older
- B. You have a diagnosis of cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
- C. If you are between 6 months and less than 6 years of age, Ivacaftor packets will be approved. Documentation of your weight is required
- D. You have documentation of one of the following mutations in the CFTR (Cystic fibrosis transmembrane conductance regulator) gene:

2789+5G→A	D1152H	G1069R	P67L	S1251N
3272-26A→G	D1270N	G1244E	R1070Q	S1255P
3849+10kbC→T	D579G	G1349D	R1070W	S549N
711+3A→G	E193K	G178R	R117C	S549R
A1067T	E56K	G551D	R117H	S945L
A455E	E831X	G551S	R347H	S977F
D110E	F1052V	K1060T	R352Q	
D110H	F1074L	L206W	R74W	

- E. You are NOT homozygous (have 2 copies of the same gene) for the F508del mutation in the CFTR (Cystic fibrosis transmembrane conductance regulator) gene
- F. The medication is prescribed by or given in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert

RENEWAL CRITERIA

Our guideline named IVACAFTOR (Kalydeco) requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (CF: life-threatening disorder that damages lungs and digestive system)
- B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
 - 1. You have maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
 - 2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
 - 3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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L-GLUTAMINE

Generic	Brand			
GLUTAMINE (L-GLUTAMINE)	ENDARI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named L-GLUTAMINE (ENDARI) requires the following rule(s) be met for approval:

- A. You have sickle cell disease (type of red blood cell disorder)
- B. You are 5 years of age or older
- C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
- D. The patient had a trial of or contraindication to hydroxyurea
- E. If you are 18 years of age or older, approval also requires ONE of the following:
 1. You had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered given into the vein, narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
 2. You are having sickle-cell associated symptoms such as pain or anemia (your blood doesn't have enough healthy red blood cells and you're tired) which are interfering with activities of daily living
 3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

RENEWAL CRITERIA

Our guideline named L-GLUTAMINE (Endari) requires the following rule(s) be met for renewal:

- A. You have sickle cell disease (type of red blood cell disorder)
- B. You have maintained or experienced a reduction in acute complications of sickle-cell disease such as number of sickle cell crises, hospitalizations, acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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LUMACAFITOR/IVACAFITOR

Generic	Brand			
LUMACAFITOR/IVACAFITOR	ORKAMBI			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named LUMACAFITOR-IVACAFITOR (Orkambi) requires the following rule(s) be met for approval:

- A. You are 2 years of age or older
- B. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
- C. Documentation that you are homozygous (have 2 copies of the same gene) for the F508del-CFTR (type of gene: Cystic fibrosis transmembrane conductance regulator) mutation
- D. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert

RENEWAL CRITERIA

Our guideline named LUMACAFITOR-IVACAFITOR (Orkambi) requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
- B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
 1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
 2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
 3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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PENTOSAN POLYSULFATE

Generic	Brand				
PENTOSAN POLYSULFATE SODIUM	ELMIRON				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named PENTOSAN POLYSULFATE (Elmiron) requires the following rule(s) be met for approval:

- A. You have a diagnosis of interstitial cystitis/bladder (painful bladder condition) pain syndrome ongoing for at least six weeks

RENEWAL CRITERIA

Our guideline named PENTOSAN POLYSULFATE (Elmiron) requires the following rule(s) be met for renewal:

- A. You have experienced clinical improvement from baseline secondary to treatment

Commercial Effective: 04/01/20



PRIOR AUTHORIZATION GUIDELINES

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PYRIMETHAMINE

Generic	Brand			
PYRIMETHAMINE	DARAPRIM			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline for PYRIMETHAMINE (Daraprim) requires the following rule(s) be met for approval:

- A. The request is ONE of the following:
 - 1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
 - 2. Chronic maintenance therapy for toxoplasmosis
 - 3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
 - 4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)
- B. If you are being treated for acute toxoplasmosis, approval also requires:
 - 1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
- C. If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:
 - 1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
 - 2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
 - 3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
- D. If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:
 - 1. You are also infected with human immunodeficiency virus (HIV)
 - 2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
 - 3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
 - 4. You tested positive for Toxoplasma gondii (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with Toxoplasma gondii)
 - 5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm(3)
- E. If you have congenital toxoplasmosis, approval also requires:
 - 1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

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PRIOR AUTHORIZATION GUIDELINES

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PYRIMETHAMINE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section.

Our guideline for PYRIMETHAMINE (Daraprim) requires the following rule(s) be met for renewal:

- A. The request is ONE of the following:
 - 1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
 - 2. Chronic maintenance therapy for toxoplasmosis
 - 3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
- B. If you are being treated for acute toxoplasmosis, renewal also requires:
 - 1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)
- C. If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:
 - 1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
 - 2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm(3)
 - 3. You are currently taking ART (anti-retroviral therapy)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

Generic	Brand			
SOFOSBUVIR/VELPATASVIR/ VOXILAPREVIR	VOSEVI			

GUIDELINES FOR USE

Our guideline named SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR requires the following rule(s) be met for approval:

- A. You are 18 years of age or older
- B. You have a diagnosis of chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6 infection
- C. Documentation of hepatitis C virus infection with at least ONE detectable HCV RNA level (amount of virus in your blood) within the last 6 months
- D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (liver inflammation) such as a hepatologist, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- E. You have failed a full course of therapy with a DAA (direct-acting antiviral) regimen that includes NS5A inhibitor (class of hepatitis C drug such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) OR you have genotype 1a or genotype 3 and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (class of hepatitis C drug such as Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other hepatitis c virus protease inhibitor in combination with Sovaldi))

The medication will not be approved for the following:

- A. You are concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
- B. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
- C. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (other diseases)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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TEZACAFTOR/IVACAFTOR

Generic	Brand			
TEZACAFTOR/IVACAFTOR	SYMDEKO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named TEZACAFTOR/IVACAFTOR (Symdeko) requires the following rule(s) be met for approval:

- A. You are 6 years of age or older
- B. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
- C. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
- D. You have documentation that you are either homozygous (you have 2 copies of the same gene) for the F508del-CFTR (Cystic fibrosis transmembrane conductance regulator) gene mutation;
OR you have documentation that you have at least one of the following mutations in the CFTR gene:

2789+5G→A	D110E	E56K	P67L	S945L
3272-26A→G	D110H	E831X	R1070W	S977F
3849+10kbC→T	D1152H	F1052V	R117C	
711+3A→G	D1270N	F1074L	R347H	
A1067T	D579G	K1060T	R352Q	
A455E	E193K	L206W	R74W	

RENEWAL CRITERIA

Our guideline named TEZACAFTOR/IVACAFTOR (Symdeko) requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (CF: inherited life-threatening disorder that damages the lungs and digestive system)
- B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
 - 1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
 - 2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
 - 3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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VOXELOTOR

Generic	Brand				
VOXELOTOR	OXBRYTA				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named VOXELOTOR (Oxbryta) requires the following rule(s) be met for approval:

- A. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
- B. You are 12 years of age or older
- C. Your hemoglobin (a protein that carries oxygen in the blood) is less than 10.5 g/dL
- D. The medication is prescribed by or given in consultation with a hematologist (a doctor who specializes in the study of blood, blood-forming organs and blood diseases)
- E. You are having symptoms of anemia which are interfering with activities of daily living
- F. You had a previous trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named VOXELOTOR (Oxbryta) requires the following rule(s) be met for renewal:

- A. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
- B. You have maintained an improvement in symptoms associated with anemia (condition where the blood doesn't have enough healthy red blood cells)

Commercial Effective: 04/01/20

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ZANUBRUTINIB

Generic	Brand				
ZANUBRUTINIB	BRUKINSA				

GUIDELINES FOR USE

Our guideline named ZANUBRUTINIB (Brukinsa) requires the following rule(s) be met for approval:

- A. You have a diagnosis of mantle cell lymphoma (type of white blood cell cancer)
- B. You are 18 years of age or older
- C. You have previously received at least ONE prior therapy for mantle cell lymphoma

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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MECASERMIN

Generic	Brand			
MECASERMIN	INCRELEX			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named MECASERMIN (Increlex) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
 2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone
- B. You are 2 years to less than 18 years of age
- C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)
- D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]
- E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

RENEWAL CRITERIA

Our guideline named MECASERMIN (Increlex) requires the following rule(s) be met for renewal:

- A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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NERATINIB

Generic	Brand			
NERATINIB	NERLYNX			

GUIDELINES FOR USE

Our guideline named NERATINIB (Nerlynx) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 1. Early stage (stage I-III) breast cancer
 2. Advanced or metastatic breast cancer
- B. If you have early stage (stage I-III) breast cancer, approval also requires:
 1. You are 18 years of age or older
 2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
 3. The tumor is hormone-receptor positive
 4. The requested medication will be used as extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
 5. The medication is being requested within 2 years of completing the last trastuzumab dose
- C. If you have advanced or metastatic breast cancer, approval also requires:
 1. You are 18 years of age or older
 2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
 3. The requested medication will be used in combination with capecitabine
 4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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RIOCIGUAT

Generic	Brand			
RIOCIGUAT	ADEMPAS			

GUIDELINES FOR USE (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

INITIAL CRITERIA

Our guideline named RIOCIGUAT (Adempas) requires the following rule(s) be met for approval:

- A. You have a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension World Health Organization Group 4 (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) or a diagnosis of pulmonary arterial hypertension World Health Organization Group 1 (PAH: type of high blood pressure affecting lungs and arteries)
- B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)
- C. If you have pulmonary arterial hypertension, approval also requires:
 1. You have a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
 - a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
 - b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
 - c. Pulmonary vascular resistance (PVR) greater than 3 Wood units
 2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
 3. You had a previous trial of a phosphodiesterase-5 inhibitor such as Revatio or Adcirca, unless there is a medical reason why you cannot (contraindication)
 4. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)
- D. If you have chronic thromboembolic pulmonary hypertension, approval also requires:
 1. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
 2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
 3. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

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RIOCIGUAT

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named RIOCIGUAT (Adempas) requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:

- i. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO (World Health Organization) Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
- ii. Pulmonary arterial hypertension (PAH) (WHO Group 1)

B. You show improvement from baseline in the 6-minute walk distance OR have a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class.

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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PALBOCICLIB

Generic	Brand			
PALBOCICLIB	IBRANCE			

GUIDELINES FOR USE

Our guideline named PALBOCICLIB (Ibrance) requires the following rule(s) be met for approval:

- A. You have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer (cancer that is in the advanced stage or that has spread to other parts of the body)
- B. You are 18 years of age or older
- C. You meet ONE of the following:
 1. The requested medication will be used with an aromatase inhibitor (type of cancer drug such as anastrozole, letrozole, or exemestane) AND you meet ALL of the following:
 - a. You are a postmenopausal female or a male
 - b. You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
 - c. Your disease has NOT worsened after cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancer by preventing the cancer cells from multiplying)
 2. The requested medication will be used in combination with Faslodex (fulvestrant) AND you meet ALL of the following:
 - a. Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
 - b. Your disease has NOT worsened after cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancers by preventing the cancer cells from multiplying)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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RIMEGEPANT

Generic	Brand				
RIMEGEPANT	NURTEC ODT				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named RIMEGEPANT (Nurtec) requires the following rule(s) be met for approval:

- A. You are being treated for acute (quick onset) migraine
- B. You are 18 years of age or older
- C. You had a trial of TWO triptans (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named RIMEGEPANT (Nurtec) requires the following rule(s) be met for renewal:

- A. You are being treated for acute (quick onset) migraine
- B. You meet ONE of the following:
 1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINE-ACT])
 2. You have experienced clinical improvement as defined by ONE of the following:
 - i. Ability to function normally within 2 hours of dose
 - ii. Headache pain disappears within 2 hours of dose
 - iii. Treatment works consistently in majority of migraine attacks

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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ALEMTUZUMAB (NSA)

Generic	Brand			
ALEMTUZUMAB	LEMTRADA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named ALEMTUZUMAB (Lemtrada) requires the following rules be met for approval:

- A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
- B. You are 18 years of age or older
- C. You have also tried at least TWO drugs that have been FDA (Food and Drug Administration) approved for the treatment of relapsing forms of multiple sclerosis (MS) (Please note: The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, Tecfidera, Mavenclad, Mayzent, Vumerity, Aubagio)

RENEWAL CRITERIA

Our guideline named ALEMTUZUMAB (Lemtrada) requires the following rules be met for renewal:

- A. You have a relapsing form of multiple sclerosis (MS: an illness where immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
- B. At least 12 months have passed since you received the most recent course of Lemtrada

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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BOTULINUM NEUROTOXIN (NSA)

Generic	Brand			
ONABOTULINUM TOXIN A	BOTOX			
ABOBOTULINUM TOXIN A	DYSPORE			
RIMABOTULINUM TOXIN B	MYOBLOC			
INCOBOTULINUM TOXIN A	XEOMIN			

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

BOTOX

Our guideline named BOTULINUM NEUROTOXIN (Botox) requires the following rule(s) be met for approval:

- A. The requested medication is being used for ONE of the following non-cosmetic (not for appearance) conditions: treatment of overactive bladder (OAB); treatment of urinary incontinence (uncontrolled leakage of urine); prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer); treatment of upper or lower limb spasticity; treatment of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles); treatment of severe axillary hyperhidrosis (excessive underarm sweating); treatment of blepharospasm (involuntary forcible closure of the eyelid); or treatment of strabismus (cross-eyed).

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

- B. For the treatment of overactive bladder (OAB), approval also requires:

1. You are 18 years of age or older.
2. You previously tried an anticholinergic medication unless there is a medical reason why you cannot (contraindication), such as: oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura.

- C. For the treatment of urinary incontinence, approval also requires:

1. You are 18 years of age or older.
2. You have detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition such as: spinal cord injury (SCI) or multiple sclerosis (MS).
3. You previously tried an anticholinergic medication, unless there is a medical reason why you cannot, such as: oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura.

(Botox criteria continued on next page)

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BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE - BOTOX (CONTINUED)

- D. For the prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer), approval also requires:
 - 1. You are 18 years of age or older.
 - 2. You previously tried any TWO (2) of the following migraine prevention treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol.
- E. For the treatment of cervical dystonia and severe axillary hyperhidrosis, approval also requires:
 - 1. You are 18 years of age or older.
- F. For the treatment of upper limb spasticity, approval also requires:
 - 1. You are 2 years of age or older.
- G. For the treatment of lower limb spasticity, approval also requires ONE of the following:
 - 1. You are 18 years of age or older.
 - 2. You are 2 to 17 years of age AND do NOT have spasticity caused by cerebral palsy (an illness that affects movement, muscle tone or posture).
- H. For the treatment of blepharospasm and strabismus, approval also requires:
 - 1. You are 12 years of age or older.

DYSPORT

Our guideline named BOTULINUM NEUROTOXIN (Dysport) requires you have ONE of the following non-cosmetic (not for appearance) diagnoses and meet the associated rule(s) for approval:

- A. You have cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) AND you are 18 years of age or older
- B. You have spasticity (stiffness or tightness of your muscles) AND you are 18 years of age or older
- C. You have upper limb spasticity AND you are 2 years of age or older AND spasticity is not caused by cerebral palsy (inherited disorder that affects movement, muscle tone or posture)
- D. You have lower limb spasticity AND you are 2 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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PRIOR AUTHORIZATION GUIDELINES

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BOTULINUM NEUROTOXIN (NSA)

GUIDELINES FOR USE (CONTINUED)

MYOBLOC

Our guideline named BOTULINUM NEUROTOXIN (Myobloc) requires the following rule(s) be met for approval:

A. You have a non-cosmetic (not for appearance) diagnosis of cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles) or chronic sialorrhea (drooling or excessive salivation).

B. You are 18 years of age or older.

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

XEOMIN

Our guideline named BOTULINUM NEUROTOXIN (Xeomin) requires the following rules be met for approval:

A. You have one of the following a non-cosmetic (not for appearance) conditions: chronic sialorrhea (drooling or excessive salivation), cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles), blepharospasm (involuntary forcible closure of the eyelid), or upper limb spasticity.

B. You are 18 years of age or older.

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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CRIZANLIZUMAB-TMCA (NSA)

Generic	Brand			
CRIZANLIZUMAB-TMCA	ADAKVEO			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named CRIZANLIZUMAB-TMCA (Adakveo) requires the following rule(s) be met for approval:

- A. You have sickle cell disease (type of red blood cell disorder)
- B. You are at least 16 years old
- C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
- D. You have previously tried hydroxyurea, unless there is a medical reason why you cannot (contraindication)
- E. If you are 18 years of age or older, approval also requires ONE of the following:
 1. You had at least 2 sickle cell crises in the past year. (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
 2. You are having sickle cell associated symptoms (such as pain or anemia) which are interfering with activities of daily living
 3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever and low oxygen levels)

RENEWAL CRITERIA

Our guideline named CRIZANLIZUMAB-TMCA (Adakveo) requires the following rule(s) be met for renewal:

- A. You have sickle cell disease (type of red blood cell disorder)
- B. You have maintained or experienced a reduction in acute (sudden and severe) complications of sickle cell disease (SCD) (such as a reduction in number of sickle cell crises, hospitalizations, acute chest syndrome [ACS: chest pain, cough, fever and low oxygen levels]).

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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ENFORTUMAB (NSA)

Generic	Brand				
ENFORTUMAB VEDOTIN-EJFV	PADCEV				

GUIDELINES FOR USE

Our guideline named ENFORTUMAB (Padcev) requires the following rule(s) be met for approval:

- A. You have locally advanced or metastatic urothelial cancer (type of urinary system cancer that has spread to other parts of the body)
- B. You are 18 years of age or older
- C. You have previously received a medication that works against a type of protein called programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor
- D. You have previously received a platinum-containing chemotherapy (type of cancer medication) in the neoadjuvant/adjuvant (given before surgery or as an add-on), locally advanced or metastatic setting (cancer has spread to other parts of the body)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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FAM-TRASTUZUMAB (NSA)

Generic	Brand				
FAM-TRASTUZUMAB DERUXTECAN-NXKI	ENHERTU				

GUIDELINES FOR USE

Our guideline named FAM-TRASTUZUMAB (Enhertu) requires the following rule(s) be met for approval:

- A. You have unresectable (cannot be surgically removed) or metastatic (cancer has spread to other parts of the body) HER2-positive (type of protein that causes breast cancer cells to grow) breast cancer
- B. You are 18 years of age or older
- C. You have received two or more prior anti-HER2-based regimens (drug that works against a protein called human epidermal growth factor receptor 2) in the metastatic setting (cancer has spread to other parts of the body)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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GOLODIRSEN (NSA)

Generic	Brand				
GOLODIRSEN	VYONDYS-53				

GUIDELINES FOR USE

Our guideline named GOLODIRSEN (Vyondys 53) requires the following rule(s) be met for approval:

- A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
- B. You have a confirmed mutation (a permanent change in DNA that make up your gene) of the Duchenne muscular dystrophy gene that will respond to exon 53 skipping therapy (a process that allows a protein to still function with sections of faulty genetic code)

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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LUSPATERCEPT-AAMT (NSA)

Generic	Brand				
LUSPATERCEPT-AAMT	REBLOZYL				

GUIDELINES FOR USE

Our guideline named LUSPATERCEPT-AAMT (Reblozyl) requires the following rule(s) be met for approval:

- A. You have anemia (low amount of healthy red blood cells)
- B. You are 18 years of age or older
- C. You have beta thalassemia (blood disorder that reduces the production of hemoglobin) and you require regular red blood cell (RBC) transfusions

Commercial Effective: 04/01/20

PRIOR AUTHORIZATION GUIDELINES

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RITUXIMAB (NSA)

Generic	Brand			
RITUXIMAB	RITUXAN			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)

Our guideline named RITUXIMAB (Rituxan) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
2. Non Hodgkin's Lymphoma (NHL: type of blood cancer)
3. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
4. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
5. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)
6. Moderate to severe Pemphigus Vulgaris (PV: immune disease with blisters that break out on the skin and on the lining of the mouth)

B. If you have moderate to severe rheumatoid arthritis (RA), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
4. You have previously tried at least ONE DMARD (disease modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
5. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvog, Xeljanz (Immediate Release/Extended Release)

C. If you have Non Hodgkin's Lymphoma (NHL), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)

D. If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
3. You are currently using chemotherapy at the same time with the requested medication

(Initial criteria continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

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RITUXIMAB (NSA)

INITIAL CRITERIA (CONTINUED)

- E. If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:
 - 1. You are 2 years of age or older
 - 2. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) along with the requested medication
- F. If you have moderate to severe Pemphigus Vulgaris (PV), approval also requires:
 - 1. You are 18 years of age or older

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

Our guideline named RITUXIMAB (Rituxan) requires the following rule(s) be met for renewal:

- A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
- B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy for renewal

Commercial Effective: 04/01/20



PRIOR AUTHORIZATION GUIDELINES

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RITUXIMAB-ABBS (NSA)

Generic	Brand			
RITUXIMAB-ABBS	TRUXIMA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named RITUXIMAB-ABBS (Truxima) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
2. Chronic Lymphocytic Leukemia (CLL: type of blood and bone marrow cancer)
3. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
4. Wegener's Granulomatosis (WG: condition that causes inflammation of the blood vessels)
5. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)

B. If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with an oncologist (cancer doctor)

C. If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with an oncologist (cancer doctor)

D. If you have moderate to severe rheumatoid arthritis (RA), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
3. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
4. You had a previous trial of at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
5. You had a previous trial of any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvog, Xeljanz (Immediate release/extended release)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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PRIOR AUTHORIZATION GUIDELINES

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RITUXIMAB-ABBS (NSA)

INITIAL CRITERIA (CONTINUED)

- E. If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:
 - 1. You are 18 years of age or older
 - 2. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) with requested medication

RENEWAL CRITERIA

Our guideline named RITUXIMAB-ABBS (Truxima) requires the following rule(s) be met for renewal:

- A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
- B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Commercial Effective: 04/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

TERIPARATIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TERIPARATIDE	FORTEO, TERIPARATIDE	24700		GPI-10 (3004407000)	

GUIDELINES FOR USE

1. Is the medication being used for **ONE** of the following diagnoses?

- Postmenopausal osteoporosis
- Primary or hypogonadal osteoporosis in a male patient
- Glucocorticoid-induced osteoporosis

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?

- The patient is at high risk for fractures defined as **ONE** of the following:
 - History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
 - No prior treatment for osteoporosis **AND** FRAX score $\geq 20\%$ for any major fracture OR $\geq 3\%$ for hip fracture
- The patient is unable to use oral therapy (i.e., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
- The patient has an adequate trial of, intolerance to, or a contraindication to bisphosphonates (e.g., alendronate, risedronate, ibandronate)

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received a total of 24 months cumulative treatment with any parathyroid hormone therapy (e.g., Forteo, Tymlos, Teriparatide)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve the requested drug up to 24 months cumulative lifetime treatment duration by GPID or GPI-14 with the following quantity limits:**

- Forteo 600mcg/2.4mL: #2.4mL (#1 multi-dose pen) per 28 days.
- Teriparatide 620mcg/2.48mL: #2.48mL (#1 multi-dose pen) per 28 days.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****TERIPARATIDE****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TERIPARATIDE (Forteo, Teriparatide)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Postmenopausal osteoporosis (weak and brittle bones)
 - 2. Primary or hypogonadal (sex organs don't function properly) osteoporosis in a male patient
 - 3. Glucocorticoid (steroid)-induced osteoporosis
- B. You have not received a total of 24 months or more cumulative treatment with any parathyroid hormone therapy (Forteo, Tymlos, Teriparatide)
- C. You meet ONE of the following:
 - 1. You are at high risk for fractures defined as ONE of the following:
 - a. History of osteoporotic (i.e., fragility, low trauma) fracture(s)
 - b. 2 or more risk factors for fracture (such as history of multiple recent low trauma fractures, bone marrow density (BMD) T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
 - c. No prior treatment for osteoporosis AND FRAX (test for your risk of fractures) score at least 20% for any major fracture OR at least 3% for hip fracture
 - 2. You are unable to use oral therapy due to reasons such as upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
 - 3. You had an adequate trial of or intolerance to bisphosphonates (such as alendronate, risedronate, ibandronate), unless there is a medical reason why you cannot (contraindication)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TERIPARATIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Forteo and Teriparatide.

REFERENCE

- Forteo [Prescribing Information]. Indianapolis, IN.: Eli Lilly and Company; October 2019.
- Teriparatide [Prescribing Information]. Morristown, NJ.: Alvogen, Inc; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/13/20

Created: 05/03

Client Approval: 04/20

P&T Approval: 10/19



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

Generic	Brand	HICL	GCN	Exception/Other
EXCLUDED DRUGS				

*******Customer Service/PAC Alert*******
(For Internal Use Only)

DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST OR PHYSICIAN REVIEW.

GUIDELINES FOR USE

1. Is the request for an excluded drug and the claim is rejecting with the error code **REJ-922?**

If yes, continue to #2.

If no, guideline does not apply.

2. Is the request for a glucose test strip or meter?

If yes, please refer to the corresponding guideline for further clinical review.

If no, continue to #3.

3. Is the requested drug being used for the treatment of an FDA-approved indication?

If yes, continue to #5.

If no, continue to #4.

4. If the drug is requested for a non-FDA approved indication, does the patient have a diagnosis for which the drug is considered safe and effective based on sound medical evidence found in peer-reviewed medical literature, accepted standards of medical practice, or in one of the following compendia?

American Hospital Formulary Service-Drug Information (AHFS-DI): Contains narrative text supporting use

Clinical Pharmacology: Contains narrative text supporting use

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium: Category 1 or 2A

Non-Formulary & Excluded Drug Exceptions Process

Truven Health Analytics Micromedex DrugDex: Class I, Class IIa, or Class IIb

Wolters Kluwer Lexi-Drugs: Use: Off-label rated as 'Evidence Level A' with a 'Strong' recommendation

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

5. Is the requested drug under **ANY** of the following categories?

Protected class drugs (such as Anticonvulsants, Antidepressants, Antineoplastic, Antipsychotics, Antiretroviral, or Immunosuppressants) and the member is already stabilized, and discontinuation of therapy could lead to harm

The request is for a member who is stabilized on an Attention Deficit Hyperactivity Disorder or an Anti-mania (Bipolar Affective Disorder) drug prescribed by or given in consultation with a psychiatrist and discontinuation of therapy could lead to harm

The member is in the middle of completing an antibiotic or Hepatitis C treatment regimen

If yes, **approve the requested drug for 12 months by GPID. For requests for antibiotic or Hepatitis C drugs, please approve based on the duration of remaining therapy per AASLD (Hepatitis C) or the FDA approved duration.**

If no, continue to #6.

6. Does the requested drug have a corresponding clinical PA guideline on the standard commercial formulary (please refer to [G:\PA & UM Programs \(430\)\PA Guidelines\MI CorporateDocuments\NAT01\) Library of Prescribing Guidelines\Library Guidelines \(Individual Documents\)\EFEP MP -S.COMM GLS](#))?

If yes, please refer to the corresponding guideline for further clinical review.

If no, continue to #7.

7. Is the request for a combination product (e.g., Vimovo, Duexis) for which the individual components with the same route of administration are commercially available and covered by the plan?

If yes, continue to #8.

If no, continue to #9.

8. Have **ALL** of the following criteria been met?

a. The patient has tried and failed the individual components together, **AND**

b. The prescriber provided a medical rationale that the requested combination product would be safer and/or more efficacious than using the individual components together. Document the rationale in PA approval.

If yes, continue to #11.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

9. Does the requested medication have clinically appropriate covered alternatives with the same active ingredient and same route of administration?

Examples of possible alternatives:

Conzip: generic tramadol extended-release capsules or tablets

Zipsor: generic diclofenac DR tablets

Metformin ER gastric: trial of generic Glucophage XR

Onzetra Xsail: trial of sumatriptan nasal spray

If yes, continue to #10.

If no, continue to #11.

10. Has the patient had a previous trial of at least three covered alternatives with the same active ingredients and same route of administration (if available), OR does the patient have a documented intolerance or contraindication to those agents? Provide reason for therapeutic failure, intolerance or contraindication.

If yes, continue to #11.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

11. Has the patient tried and failed at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested medication? Provide reasons for therapeutic failure.

If yes, **approve the requested drug for 12 months by GPID.**

If no, continue to #12.

12. Does the patient have a documented intolerance or contraindication to the agents identified in question #11? Provide reason for therapeutic failure, intolerance or contraindication.

If yes, **approve the requested drug for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA** (reviewed for **<insert drug name>**) requires that ALL of the following criteria have been met:

- A. The requested agent is being used for the treatment of ONE of the following:
 - 1. A Food and Drug Administration (FDA)-approved indication
 - 2. A medically accepted indication and it is considered safe and effective by approved compendia (medical references), peer-reviewed medical literature, or accepted standards of medical practice.
- B. You must meet one of the following criteria (1, 2, or 3):
 - 1. If the request is for a combination product and the individual components with the same route of administration are commercially available and are covered by your plan, you must meet the following (a, b, and c):
 - a. You have previously tried **<insert individual components>** together
 - b. Your doctor provided a medical rationale that the requested combination product would be safer and/or more efficacious than using the individual components together
 - c. You have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents
 - 2. If the request is for a medication that has clinically appropriate covered alternative(s) with the same active ingredient and same route of administration, you must meet the following (a and b):
 - a. You have previously tried at least three clinically appropriate covered alternative with the same active ingredients and same route of administration (if available), including but not limited to **<insert formulary agents>**, OR there is a medical rationale why the covered alternatives cannot be tried.
 - b. You have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents
 - 3. If the requested medication does NOT have clinically appropriate covered alternatives with the same active ingredient and same route of administration, you must have previously tried at least three clinically appropriate covered agents with different active ingredients but the same route of administration for the specified indication (if available), one of which must be in the same class as the requested drug for the specific indication (if available) OR your physician has provided documentation that you have experienced a therapeutic failure, contraindication to (medical reason why you cannot use), or intolerance to those agents.

(Denial text continued on next page)

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

GUIDELINES FOR USE (CONTINUED)

A previous trial of <insert applicable drugs/therapies to this case> is noted but we do not have information showing that you have tried the above alternatives. Therefore, your request was not approved. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request. Note: The preferred alternatives may also require a prior authorization.

RATIONALE

To allow an exception for coverage of an excluded drug based on the following considerations:

The drug is being requested for treatment of an FDA or medically supported indication.

The patient cannot use covered products due to therapeutic failure, contraindication or intolerance as documented by their physician.

Any applicable prior authorization clinical criteria for the excluded drug have been met.

FDA APPROVED INDICATIONS

See package insert for requested drug.

Part D Effective: N/A
Effective: 11/04/19

Created: 01/18
Client Approval: 11/19

P&T Approval: 10/19



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

OSILODROSTAT (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OSILODROSTAT	ISTURISA	46396		GPI-10 (3002206060)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of Cushing's disease and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Pituitary surgery is not an option or has not been curative

If yes, **approve for 12 months for all strengths by GPID or GPI-14 with the following quantity limits:**

- Isturisa 1mg: #60 per day
- Isturisa 5mg: #12 per day
- Isturisa 10mg: #6 per day

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:

- You have Cushing's disease (a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
- You are 18 years of age or older
- Pituitary surgery is not an option or has not cured your condition

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Isturisa.

REFERENCES

Isturisa [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases, Inc.; March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/24/20

Created: 04/20

Client Approval: 07/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

SELUMETINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELUMETINIB	KOSELUGO	46451		GPI-10 (2153356550)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neurofibromatosis type 1 (NF1) and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - The patient has symptomatic, inoperable plexiform neurofibromas (PN)

If yes, **approve for the requested strength for 12 months by GPID or GPI-14 with the following quantity limits:**

- **Koselugo 10mg: #10 per day**
- **Koselugo 25mg: #4 per day**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELUMETINIB (Koselugo)** requires the following rule(s) be met for approval:

- A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
- B. You are 2 years of age or older
- C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Koselugo.

REFERENCES

Koselugo [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/24/20

Created: 04/20

Client Approval: 07/20

P&T Approval: 07/20

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELTROMBOPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELTROMBOPAG OLAMINE	PROMACTA	35989		GPI-10 (8240503010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (cITP) and meet **ALL** of the following criteria?
 - The patient is 1 year of age or older
 - Therapy is prescribed by or given in consultation with a hematologist or immunologist
 - The patient had a trial of or contraindication to corticosteroids or immunoglobulins, or had an insufficient response to splenectomy

If yes, continue to #2.

If no, continue to #5.

- Is the request for Promacta tablets?

If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**

- Promacta 12.5mg tablet: #1 per day.**
- Promacta 25mg tablet: #1 per day.**
- Promacta 50mg tablet: #1 per day.**
- Promacta 75mg tablet: #1 per day.**

APPROVAL TEXT: Renewal requires a clinical response, as defined by an increase in platelet count to at least 50X10⁹/L (at least 50,000 per microliter).

If no, continue to #3.

- Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**

- Promacta 12.5mg packets: #1 per day.**
- Promacta 25mg packets: #3 per day.**

APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10⁹/L (at least 50,000 per microliter).

If no, continue to #4.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

4. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient had a trial of Promacta tablets
- The patient has a medical need for powder packets

If yes, **approve for 2 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #3 per day.**

APPROVAL TEXT: Renewal requires a clinical response as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter).

If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 2 months by GPID or GPI-14 as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #1 per day.**
- **Promacta 75mg tablet: #1 per day.**

DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have a diagnosis of thrombocytopenia due to chronic hepatitis C **AND** meet the following criterion?
- The patient's thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy

If yes, continue to #6.

If no, continue to #9.

6. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #1 per day.**

If no, continue to #7.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

7. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Promacta 12.5mg packets: #1 per day.
- Promacta 25mg packets: #4 per day.

If no, continue to #8.

8. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient had a trial of Promacta tablets
- The patient has a medical need for powder packets

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Promacta 12.5mg packets: #1 per day.
- Promacta 25mg packets: #4 per day.

If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**

- Promacta 12.5mg tablet: #1 per day.
- Promacta 25mg tablet: #1 per day.
- Promacta 50mg tablet: #2 per day.
- Promacta 75mg tablet: #1 per day.

DENIAL TEXT: See the initial denial text at the end of the guideline.

9. Does the patient have a diagnosis of severe aplastic anemia and meet **ALL** of the following criteria?

- The patient is 2 years of age or older
- Promacta will be used in combination with standard immunosuppressive therapy as first-line treatment

If yes, continue to #10.

If no, continue to #13.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ELTROMBOPAG****INITIAL CRITERIA (CONTINUED)**

10. Is the request for Promacta tablets?

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Promacta 12.5mg tablet: #3 per day.
- Promacta 25mg tablet: #1 per day.
- Promacta 50mg tablet: #2 per day.
- Promacta 75mg tablet: #2 per day.

If no, continue to #11.

11. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Promacta 12.5mg packets: #3 per day.
- Promacta 25mg packets: #6 per day.

If no, continue to #12.

12. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient had a trial of Promacta tablets
- The patient has a medical need for powder packets

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Promacta 12.5mg packets: #3 per day.
- Promacta 25mg packets: #6 per day.

If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**

- Promacta 12.5mg tablet: #3 per day.
- Promacta 25mg tablet: #1 per day.
- Promacta 50mg tablet: #2 per day.
- Promacta 75mg tablet: #2 per day.

DENIAL TEXT: See the initial denial text at the end of the guideline.

13. Does the patient have a diagnosis of severe aplastic anemia **AND** meet the following criterion?

- The patient had an insufficient response to immunosuppressive therapy

If yes, continue to #14.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ELTROMBOPAG

INITIAL CRITERIA (CONTINUED)

14. Is the request for Promacta tablets?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #2 per day.**

If no, continue to #15.

15. Is the request for Promacta packets **AND** the patient is 12 years of age or less?

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #6 per day.**

If no, continue to #16.

16. Is the request for Promacta packets and the patient meets **ALL** of the following criteria?

- The patient is greater than 12 years of age
- The patient had a trial of Promacta tablets
- The patient has a medical need for powder packets

If yes, **approve for 12 months by GPID or GPI-14 for all strengths as follows:**

- **Promacta 12.5mg packets: #1 per day.**
- **Promacta 25mg packets: #6 per day.**

If no, do not approve for Promacta packets. **Please enter proactive approvals for all strengths of Promacta tablets for 12 months by GPID or GPI-14 as follows:**

- **Promacta 12.5mg tablet: #1 per day.**
- **Promacta 25mg tablet: #1 per day.**
- **Promacta 50mg tablet: #2 per day.**
- **Promacta 75mg tablet: #2 per day.**

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ELTROMBOPAG****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **ELTROMBOPAG (Promacta)** requires the following rule(s) be met for approval:

- A. You have one of the following diagnoses:
 - 1. Chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
 - 2. Thrombocytopenia (low blood platelet count) due to chronic hepatitis C
 - 3. Severe aplastic anemia (type of blood disorder)
- B. **If you are greater than 12 years of age and the request is for Promacta packets, approval also requires:**
 - 1. You previously had a trial of Promacta tablets
 - 2. You have a medical need for powder packets
- C. **If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:**
 - 1. You are 1 year of age or older
 - 2. You have tried corticosteroids or immunoglobulins, or did not have a good enough response to a splenectomy (removal of spleen) - unless there is a medical reason why you cannot (contraindication)
 - 3. The medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
- D. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
 - 1. Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy
- E. **If you have severe aplastic anemia, approval also requires ONE of the following:**
 - 1. You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
 - 2. You did not have a good enough response to immunosuppressive therapy

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ELTROMBOPAG****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of chronic immune (idiopathic) thrombocytopenia (ciTP), **AND** meet the following criterion?
 - The patient has a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter)

If yes, **approve for 12 months by GPID or GPI-14 for all strengths and formulations as follows:**

- Promacta 12.5mg tablet: #1 per day.
- Promacta 25mg tablet: #1 per day.
- Promacta 50mg tablet: #1 per day.
- Promacta 75mg tablet: #1 per day.
- Promacta 12.5mg packets: #1 per day.
- Promacta 25mg packets: #3 per day.

If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ELTROMBOPAG (Promacta)** requires the following rules be met for **renewal:**

- A. You have chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
- B. You have a clinical response, as defined by an increase in platelet count to at least $50 \times 10^9/L$ (at least 50,000 per microliter)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ELTROMBOPAG****RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Promacta.

REFERENCES

- Promacta [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/20/20

Created: 01/09

Client Approval: 04/20

P&T Approval: 07/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

GIVOSIRAN (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
GIVOSIRAN	GIVLAARI	46222		GPI-10 (8508002520)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of acute hepatic porphyria (AHP) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP]) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has genetic confirmation of AHP mutation OR elevated (beyond reference range) urinary or plasma PBG (porphobilinogen) or ALA (aminolevulinic acid)
 - The patient has experienced two or more AHP attacks in the past 12 months
 - The requested medication is prescribed by or given in consultation with a geneticist, hepatologist, hematologist, gastroenterologist, neurologist, dermatologist, or a healthcare provider experienced in managing AHP
 - Documentation of patient's current weight (to the nearest 0.1 kg)

If yes, **approve for 6 months by HICL or GPI-10 at a dose of 2.5 mg/kg actual body weight as follows:**

- **Weight ≤ 75.6 kg: #1mL (1 vial) per month.**
- **Weight 75.7 kg to 151.2 kg: #2mL (2 vials) per month.**
- **Weight 151.3 to 226.8 kg: #3mL (3 vials) per month (and so forth).**

APPROVAL TEXT: Renewal requires: 1) patient has achieved or maintained clinical benefit compared to baseline, 2) patient has not received a liver transplant, and 3) documentation of patient's current weight.

If no, do not approve.

INITIAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for approval:

- A. You have acute hepatic porphyria (enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP])
- B. You are 18 years of age or older
- C. You have genetic confirmation of AHP mutation (a change in your DNA that make up your gene), OR high (beyond reference range) urinary or plasma porphobilinogen (PBG), or aminolevulinic acid (ALA) (PBG and ALA: urine or blood tests that measure the level of porphyrins – a chemical that helps make hemoglobin in your body)

(Initial denial text continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****GIVOSIRAN (NSA)****INITIAL CRITERIA (CONTINUED)**

- D. You have experienced two or more acute (sudden and severe) hepatic porphyria attacks in the past 12 months
- E. The medication is prescribed by or given in consultation with a geneticist (doctor who specializes in conditions of gene disorders), hepatologist (doctor who specializes in treating the liver), hematologist (doctor who specializes in the study of blood, blood-forming organs and blood diseases), gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), neurologist (doctor who specializes in disorders of the nervous system), dermatologist (doctor who treats conditions of the skin, hair and nails), or a healthcare provider experienced in managing acute hepatic porphyria
- F. Your doctor provided documentation of your weight

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of acute hepatic porphyria (AHP) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP]) and meet **ALL** of the following criteria?
 - The patient has achieved or maintained clinical benefit compared to baseline (e.g., less hemin use, less AHP attacks, improvement of AHP symptoms, etc.)
 - The patient has not received a liver transplant
 - Documentation of patient's current weight (to the nearest 0.1 kg)

If yes, **approve for 12 months by HICL or GPI-10 at a dose of 2.5 mg/kg actual body weight as follows:**

- **Weight ≤ 75.6 kg: #1mL (1 vial) per month.**
- **Weight 75.7 kg to 151.2 kg: #2mL (2 vials) per month.**
- **Weight 151.3 to 226.8 kg: #3mL (3 vials) per month (and so forth).**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****GIVOSIRAN (NSA)****RENEWAL CRITERIA (CONTINUED)**

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **GIVOSIRAN (Givlaari)** requires the following rule(s) be met for renewal:

- A. You have acute hepatic porphyria (AHP: enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP])
- B. You have achieved or maintained clinical (medical) benefit compared to baseline (such as less hemin use, less AHP attacks, improvement of AHP symptoms, etc.)
- C. You have not received a liver transplant (replaced your bad liver with a healthy liver from another person)
- D. Your doctor provided documentation of your weight

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Givlaari.

REFERENCES

- Givlaari [Prescribing Information]. San Diego, CA: Ajinomoto Althea, Inc., November 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 04/20/20

Created: 02/20

Client Approval: 04/20

P&T Approval: 01/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	ELIGARD		17377 18155 19219 24301	GPI-14 (21405010106415) (21405010156432) (21405010206435) (21405010256445)	
LEUPROLIDE ACETATE (GENERIC)	LEUPROLIDE ACETATE		84597	GPI-14 (21405010106407)	
NAFARELIN ACETATE	SYNAREL	21103		GPI-10 (3008005510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months for the requested agent and strength by GPID or GPI-14 and override quantity limits.**

If no, continue to #2.

2. Is the request for Eligard or Leuprolide (generic) for a patient who has a diagnosis of advanced prostate cancer?

If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- **Eligard 7.5mg: #1 injection per 28 days (every month).**
- **Eligard 22.5mg: #1 injection per 84 days (every 3 months).**
- **Eligard 30mg: #1 injection per 112 days (every 4 months).**
- **Eligard 45mg: #1 injection per 168 days (every 6 months).**
- **Leuprolide (generic): #1 kit per 14 days (every 2 weeks).**

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

3. Is the request for Synarel for a patient who has a diagnosis of moderate to severe pain associated with endometriosis and meets **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with an obstetrician/gynecologist
 - The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

If yes, **approve for 6 months by HICL or GPI-10 with the following quantity limit:**

- **Synarel 2mg/mL: #96mL per 180 days (#12 bottles).**

If no, continue to #4.

4. Is the request for Synarel or Leuprolide (generic) for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- The patient is 2 years of age or older
 - Therapy is prescribed by or given in consultation with a pediatric endocrinologist
 - Patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
 - Patient is younger than 8 years of age at the onset of CPP
 - Documentation of pubertal staging using the Tanner scale for:
 - Breast development (stage 2 or above) **AND**
 - Pubic hair growth (stage 2 or above)

If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- **Synarel 2mg/mL: #32mL per 30 days (#4 bottles).**
- **Leuprolide (generic) 1mg/0.2 mL: approve with no quantity limit.**

APPROVAL TEXT: Renewal requires the Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

5. Is the request for Synarel or Leuprolide (generic) for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- The patient is at least 2 years of age
 - The requested medication is prescribed by or given in consultation with a pediatric endocrinologist
 - Patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
 - Patient is younger than 9 years of age at the onset of CPP
 - Documentation of pubertal staging using the Tanner scale for:
 - Genital development (stage 2 or above) **AND**
 - Pubic hair growth (stage 2 or above)

If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- **Synarel 2 mg/mL: #32mL per 30 days (#4 bottles).**
- **Leuprolide (generic) 1mg/0.2 mL: approve with no quantity limit.**

APPROVAL TEXT: Renewal requires the Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, leuprolide acetate, Synarel)** requires the following rule(s) be met for approval:

- A. You have advanced prostate cancer, moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus), central precocious puberty (CPP; early sexual development in girls and boys), or gender dysphoria (you're distressed because your assigned sex/gender do not match your gender identity)
- B. **If you have moderate to severe pain associated with endometriosis, approval also requires:**
1. The request is for Synarel
 2. You are 18 years of age or older
 3. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
 4. You have previously tried a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (such as combination hormonal contraceptive preparation, progestin-only contraceptive preparation), unless there is a medical reason why you cannot (contraindication)

(Initial denial text continued on next page)



WELLFLEET
RX PLAN

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

INITIAL CRITERIA (CONTINUED)

C. If you are female and have central precocious puberty, approval also requires:

1. The request is for Synarel or Leuprolide (generic)
2. You are 2 years of age or older
3. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
5. You are/were younger than 8 years of age when your condition started
6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

D. If you are male and have central precocious puberty, approval also requires:

1. The request is for Synarel or Leuprolide (generic)
2. You are 2 years of age or older
3. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
5. You are/were younger than 9 years of age when your condition started
6. Documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months for the requested agent and strength by GPID or GPI-14.**

If no, continue to #2.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

RENEWAL CRITERIA (CONTINUED)

2. Is the request for Eligard or Leuprolide (generic) for a patient who has a diagnosis of advanced prostate cancer?

If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- **Eligard 7.5mg: #1 injection per 28 days (every month).**
- **Eligard 22.5mg: #1 injection per 84 days (every 3 months).**
- **Eligard 30mg: #1 injection per 112 days (every 4 months).**
- **Eligard 45mg: #1 injection per 168 days (every 6 months).**
- **Leuprolide (generic): #1 kit per 14 days (every 2 weeks)**

If no, continue to #3.

3. Is the request for Synarel for a patient who has a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
- The patient has had improvement of pain related to endometriosis while on therapy
 - The patient is receiving concomitant add-back therapy (e.g., combination estrogen-progestin or progestin-only contraceptive preparation)
 - The patient has **NOT** received a total course of Synarel therapy exceeding 12 months

If yes, **approve for 6 months by HICL or GPI-10 with the following quantity limit:**

- **Synarel 2mg/mL: #96mL per 180 days (#12 bottles).**

If no, continue to #4.

4. Is the request for Synarel or Leuprolide (generic) for a patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
 - Patient has not reached actual age which corresponds to current pubertal age

If yes, **approve for 12 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- **Synarel 2mg/mL: #32mL per 30 days (#4 bottles).**
- **Leuprolide 1mg/0.2mL (generic): approve with no quantity limit.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST****RENEWAL CRITERIA (CONTINUED)**

RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, leuprolide acetate, Synarel)** requires the following rule(s) be met for renewal:

- A. You have advanced prostate cancer, moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus), central precocious puberty (CPP; early sexual development in girls and boys), or gender dysphoria (you're distressed because your assigned sex/gender do not match your gender identity)
- B. **If you have moderate to severe pain associated with endometriosis, renewal also requires:**
1. The request is for Synarel
 2. You had improvement of pain related to endometriosis while on therapy
 3. You are receiving add-back therapy at the same time (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
 4. You have NOT received a total course of Synarel therapy exceeding 12 months
- C. **If you have central precocious puberty, renewal also requires:**
1. The request is for Synarel or Leuprolide (generic)
 2. Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
 3. You have not reached actual age which corresponds to current pubertal age

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Eligard, Leuprolide acetate, and Synarel.

REFERENCES

- Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.
- Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; Aug 2017.
- Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; March 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Created: 09/18

Commercial Effective: 04/20/20

Client Approval: 04/20

P&T Approval: 07/18

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEMIGATINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMIGATINIB	PEMAZYRE	46462		GPI-10 (2153226000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has been previously treated
 - The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10 for #14 per 21 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEMIGATINIB (Pemazyre)** requires the following rule(s) be met for approval:

- A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
- B. You are 18 years of age or older
- C. You have previously been treated
- D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement as detected by an Food and Drug Administration (FDA)-approved test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PEMIGATINIB (INTERIM)



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Pemazyre.

REFERENCES

Pemazyre [Prescribing Information]. Wilmington, DE: Incyte Corporation; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/01/20

Created: 04/20

Client Approval: 07/20

P&T Approval: 07/20

**STANDARD NON SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SACITUZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SACITUZUMAB GOVITECAN-HZIY	TRODELVY	46478		GPI-10 (2135506540)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic triple-negative breast cancer (mTNBC) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has received at least two prior therapies for metastatic disease

If yes, **approve for 12 months by HICL or GPI-10 for #2 fills per 21 days.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **SACITUZUMAB (Trodelvy)** requires the following rule(s) be met for approval:

- A. You have metastatic triple negative breast cancer (mTNBC: breast cancer that has spread to other parts of the body and does not have estrogen receptors, progesterone receptors, and human epidermal growth factor receptor 2 [HER2: type of protein])
- B. You are 18 years of age or older
- C. You have tried at least two previous therapies for metastatic disease (disease that has spread to other parts of the body)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trodelvy.

REFERENCES

Trodelvy [Prescribing Information]. Morris Plains, NJ: Immunomedics, Inc., April 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/01/20

Created: 04/20

Client Approval: 01/19

P&T Approval: 01/19



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

TUCATINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TUCATINIB	TUKYSA	46459		GPI-10 (2153408000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced unresectable or metastatic HER2-positive breast cancer and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has received one or more prior anti-HER2-based regimens in the metastatic setting
 - The requested medication will be used in combination with trastuzumab and capecitabine

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- Tukysa 50mg: #10 per day.
- Tukysa 150mg: #4 per day.

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TUCATINIB (Tukysa)** requires the following rule(s) be met for approval:

- A. You have advanced unresectable (cannot be removed with surgery) or metastatic (disease that has spread to other parts of the body) human epidermal growth factor receptor 2 (HER2: type of protein)-positive breast cancer
- B. You are 18 years of age or older
- C. You have previously received one or more anti-HER2-based treatment for metastatic disease
- D. The requested medication will be used in combination with trastuzumab and capecitabine

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TUCATINIB (INTERIM)



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tukysa.

REFERENCES

Tukysa [Prescribing Information]. Bothell, WA: Seattle Genetics, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/01/20

Created: 04/20

Client Approval: 07/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELPERCATINIB	RETEVMO	46525		GPI-10 (2153407900)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC) and meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by GPID or GPI-14 as follows:**

- **Less than 50kg: Retevmo 40mg with a quantity limit of #6 per day**
- **50 kg or greater: Retevmo 80mg with a quantity limit of #4 per day**

If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC) and meet **ALL** of the following criteria?

- The patient is 12 years of age or older
- The patient requires systemic therapy

If yes, **approve for 12 months by GPID or GPI-14 as follows:**

- **Less than 50kg: Retevmo 40mg with a quantity limit of #6 per day**
- **50 kg or greater: Retevmo 80mg with a quantity limit of #4 per day**

If no, continue to #3.

3. Does the patient have a diagnosis of advanced or metastatic *RET* fusion-positive thyroid cancer and meet **ALL** of the following criteria?

- The patient is 12 years of age or older
- The patient requires systemic therapy
- The patient is radioactive iodine-refractory (if radioactive iodine is appropriate)

If yes, **approve for 12 months by GPID or GPI-14 as follows:**

- **Less than 50kg: Retevmo 40mg with a quantity limit of #6 per day**
- **50 kg or greater: Retevmo 80mg with a quantity limit of #4 per day**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

SELPERCATINIB (INTERIM)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELPERCATINIB (Retevmo)** requires the following rule(s) be met for approval:

- A. You have one of the following diagnoses:
 - 1. Metastatic (disease has spread to other parts of the body) *RET* (type of gene) fusion-positive non-small cell lung cancer (NSCLC: type of lung cancer)
 - 2. Advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC: type of thyroid cancer)
 - 3. Advanced or metastatic *RET* fusion-positive thyroid cancer
- B. **If you have metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), approval also requires:**
 - 1. You are 18 years of age or older
- C. **If you have advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC), approval also requires:**
 - 1. You are 12 years of age or older
 - 2. You require systemic therapy (treatment that travels through the bloodstream to all areas of the body)
- D. **If you have advanced or metastatic *RET* fusion-positive thyroid cancer, approval also requires:**
 - 1. You are 12 years of age or older
 - 2. You require systemic therapy
 - 3. You are radioactive iodine-refractory (your tumor is resistant to treatment with radioactive iodine), if radioactive iodine is appropriate

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

SELPERCATINIB (INTERIM)



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Retevmo.

REFERENCES

Retevmo [Prescribing Information]. Indianapolis, IN: Lilly USA, LLC; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/22/20

Created: 05/20

Client Approval: 07/20

P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

CAPMATINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPMATINIB	TABRECTA	46519		GPI-10 (2153401620)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient's tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **CAPMATINIB (Tabrecta)** requires the following rule(s) be met for approval:

- You have metastatic non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body)
- You are 18 years of age or older
- Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tabrecta.

REFERENCES

Tabrecta [Prescribing Information]. East Hanover, NJ: Novartis; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/22/20

Created: 05/20

Client Approval: 07/20

P&T Approval: 07/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB-HYALURONIDASE-FIHJ (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DARATUMUMAB-HYALURONIDASE-FIHJ	DARZALEX FASPRO	46509		GPI-10 (2199000215)	

GUIDELINES FOR USE

1. Is the patient 18 years of age or older?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See denial text at the end of guideline.

2. Does the patient have a new diagnosis of multiple myeloma and meet **ALL** of the following criteria?

- The patient is ineligible for autologous stem cell transplant
- The requested medication will be used in combination with bortezomib (Velcade), melphalan and prednisone

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #3.

3. Does the patient have a new diagnosis of multiple myeloma and meet **ALL** of the following criteria?

- The patient is ineligible for autologous stem cell transplant
- The requested medication will be used in combination with lenalidomide and dexamethasone

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #4.

4. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?

- The patient has received at least one prior therapy
- The requested medication will be used in combination with lenalidomide and dexamethasone

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #5.

5. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?

- The patient has received at least one prior therapy
- The requested medication will be used in combination with bortezomib and dexamethasone

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #6.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DARATUMUMAB-HYALURONIDASE-FIHJ (NSA) (INTERIM)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
- The patient has received at least three prior therapies, including agents from **BOTH** of the following drug classes:
 - Proteasome inhibitors (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), ixazomib (Ninlaro)]
 - Immunomodulatory agents [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), thalidomide (Thalomid)]
 - The requested medication will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #7.

7. Does the patient have a diagnosis of multiple myeloma and meet **ALL** of the following criteria?
- The patient is refractory to an agent from **BOTH** of the following classes:
 - Proteasome inhibitors (PI) [e.g., bortezomib (Velcade), carfilzomib (Kyprolis), or ixazomib (Ninlaro)] **AND**
 - Immunomodulatory agents [e.g., lenalidomide (Revlimid), pomalidomide (Pomalyst), or thalidomide (Thalomid)]
 - The requested medication will be used as monotherapy (not in combination with a proteasome inhibitor or immunomodulatory agent)

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DARATUMUMAB-HYALURONIDASE-FIHJ (Darzalex Faspro)** requires the following rule(s) be met for approval:

- A. You have multiple myeloma (plasma cell cancer)
- B. You are 18 years of age or older

(Denial text continued on next page)

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DARATUMUMAB-HYALURONIDASE-FIHJ (NSA) (INTERIM)

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****GUIDELINES FOR USE (CONTINUED)****C. You meet ONE of the following criteria:**

1. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive daratumumab in combination with bortezomib, melphalan and prednisone
2. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive daratumumab in combination with lenalidomide and dexamethasone
3. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment), received at least one prior therapy AND will receive daratumumab in combination with lenalidomide and dexamethasone
4. You have received at least one prior therapy AND will receive daratumumab in combination with bortezomib and dexamethasone
5. You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for myeloma) and an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) AND you will receive daratumumab as monotherapy (single drug to treat condition)
6. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent AND will receive daratumumab as monotherapy

Note: Proteasome inhibitors include: bortezomib, carfilzomib, or ixazomib;
immunomodulatory agents include: lenalidomide, pomalidomide, or thalidomide.

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Darzalex Faspro.

REFERENCES

- Darzalex Faspro [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; May 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/15/20

Created: 05/20

Client Approval: 07/20

P&T Approval: 07/20

PRIOR AUTHORIZATION GUIDELINES

FINGOLIMOD

Generic	Brand	HICL	GCN	Exception/Other
FINGOLIMOD	GILENYA	37180		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

- Does the patient have a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease **AND** meet the following criterion:

The patient is 10 years of age and older

The patient has tried a preferred formulary agent: Rebif, Extavia, Avonex, Plegridy, Glatiramer or Glatopa

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

- Does the patient have **ANY** of the following contraindications to Gilenya?

A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure

A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has pacemaker

A baseline QTC interval 500ms or above

Concurrent treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, **approve for 12 months by HICL with a quantity limit of #1 capsule per day.**

DENIAL TEXT: The guideline named **FINGOLIMOD (Gilenya)** requires a diagnosis of relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in patients 10 years of age and older **AND** requires a trial one of the following preferred agents (Rebif, Extavia, Avonex, Plegridy, Glatiramer, or Glatopa); In addition, approval requires the absence of medical history or cardiac events that are contraindicated with the use of Gilenya (those that may increase risk of cardiac events associated with Gilenya), which includes any of the following criteria.

A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure

A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker

A baseline QTC interval 500ms or above

Concurrent treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

FINGOLIMOD

RATIONALE

To ensure appropriate use of Gilenya consistent with FDA approved indication and dosing. To prevent inappropriate utilization of Gilenya in those patients for whom it is contraindicated.

Cardiovascular adverse effects, including bradycardia and heart block, have been associated with Gilenya, especially early in therapy. Bradycardia was observed in fingolimod clinical trials (4% in fingolimod group versus 1% in placebo group), although patients at high risk of bradycardia were excluded from the clinical trials. When Gilenya was approved, initial product labeling included information on first dose monitoring and instructed health care professionals to observe patients for at least 6 hours after the first dose. Patients exhibiting symptomatic bradycardia should obtain continuous ECG monitoring until symptoms resolve. The manufacturer has recently updated labeling information to include a list of cardiovascular contraindications for Gilenya, including recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has pacemaker; baseline QTC interval 500ms or above; or treatment with Class Ia or Class III anti-arrhythmic drugs.

Type of MS	Description	% MS population
Clinically Isolated Syndrome (CIS)	Single neurologic symptomatic attack compatible with MS. Clinically defined MS occurs in about 80% of patients who have demyelinating lesions on MRI.	MS Precursor
Relapsing Remitting MS (RRMS)	Clearly defined acute exacerbations, followed by partial or complete recovery of the deficits.	85%
Secondary Progressive MS (SPMS)	Initiates as RRMS before developing into a more steady disability progression, which may also include occasional relapses. The transition to SPMS generally occurs in people who have been living with RRMS for at least 10 years.	85% of RRMS patients
Primary Progressive MS (PPMS)	Progression of disability from onset without plateaus or remissions. Does not experience acute attacks.	10%
Progressive Relapsing MS (PRMS)	Continuous worsening neurologic function with occasional relapses.	5%

FDA APPROVED INDICATIONS

Fingolimod is indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

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FINGOLIMOD

DOSING

The recommended dose of Gilenya is one 0.5mg capsule orally daily. Fingolimod doses higher than 0.5 mg are associated with a greater incidence of adverse reactions without additional benefit. Patients who initiate Gilenya and those who re-initiate treatment after discontinuation for longer than 14 days require first dose monitoring.

REFERENCES

Novartis Pharmaceutical Corporation. Gilenya package insert. East Hanover, NJ. August 2019.

Created	FS Committee Approval	Effective
09/2017; revised 8/2/19; revised 10.9.19		10/21/19

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIPTORELIN PAMOATE	TRIPTODUR, TRELSTAR	23164		GPI-10 (3008007040) (2140505020)	
HISTRELIN ACETATE	SUPPRELIN LA, VANTAS	21104		GPI-10 (3008004510) (2140500710)	
LEUPROLIDE ACETATE	LUPRON DEPOT-PED, LUPRON DEPOT, LUPANETA, FENSOLVI		84352 84350 84353 30357 30356 80254 84602 84598 84593 30083 34009 34034 47996	GPI-10 (3008005010) (3008005015) (3008990250) GPI-14 (21405010106405) (21405010106410) (21405010206430) (21405010156430) (21405010256450) (21405010156420) (21405010256445)	
GOSERELIN ACETATE	ZOLADEX	21114		GPI-10 (2140500510)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months for the requested agent and strength by GPID or GPI-14 and override quantity limits.**

If no, continue to #2.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

2. Is the request for Lupron Depot, Zoladex, Vantas, or Trelstar for a patient who has a diagnosis of advanced prostate cancer?

If yes, approve for 12 months for the requested agent and strength with the following quantity limits:

- Lupron Depot 7.5mg (GPID or GPI-14): #1 syringe/kit per 28 days (every month).
- Lupron Depot 22.5mg (GPID or GPI-14): #1 syringe/kit per 84 days (every 3 months).
- Lupron Depot 30mg (GPID or GPI-14): #1 syringe/kit per 112 days (every 4 months).
- Lupron Depot 45mg (GPID or GPI-14): #1 syringe/kit per 168 days (every 6 months).
- Zoladex 3.6mg (GPID or GPI-14): #1 implant per 28 days (every month).
- Zoladex 10.8mg (GPID or GPI-14): #1 implant per 84 days (every 3 months).
- Vantas 50mg (NDC [FDB and Medi-Span]): #1 kit per 12 months.
- Trelstar 3.75mg (GPID or GPI-14): #1 injection per 28 days (every month).
- Trelstar 11.25mg (GPID or GPI-14): #1 injection per 84 days (every 3 months).
- Trelstar 22.5mg (GPID or GPI-14): #1 injection per 168 days (every 6 months).

If no, continue to #3.

3. Is the request for Lupron Depot, Lupaneta, or Zoladex for a patient who has a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with an obstetrician/gynecologist
- The patient had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) **AND** a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation)

If yes, approve for 6 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:

- Lupron Depot 3.75mg: #1 syringe/kit per 28 days (every month).
- Lupron Depot 11.25mg: #1 syringe/kit per 84 days (every 3 months).
- Lupaneta 3.75mg: #1 syringe/kit per 28 days (every month).
- Lupaneta 11.25mg: #1 syringe/kit per 84 days (every 3 months).
- Zoladex 3.6mg: #1 implant per 28 days (every month).

If no, continue to #4.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

4. Is the request for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- The patient is 2 years of age or older
 - Therapy is prescribed by or given in consultation with a pediatric endocrinologist
 - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
 - The patient is younger than 8 years of age at the onset of CPP
 - Documentation of pubertal staging using the Tanner scale for:
 - Breast development (stage 2 or above) **AND**
 - Pubic hair growth (stage 2 or above)

If yes, **approve for 12 months for the requested agent and strength with the following quantity limits:**

- **Triptodur 22.5mg (GPID or GPI-14): #1 vial/kit per 24 weeks.**
- **Supprelin LA 50mg (NDC [FDB and Medi-Span]): #1 implant/kit per 52 weeks.**
- **Lupron Depot-Ped 1-months kits:**
 - **Lupron Depot-Ped 7.5mg (GPID or GPI-14): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 11.25mg 1-month (GPID or GPI-14): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 15mg (GPID or GPI-14): #1 syringe/kit per 30 days.**
- **Lupron Depot-Ped 3-months kits:**
 - **Lupron Depot-Ped 11.25mg 3-month (GPID or GPI-14): #1 syringe/kit per 90 days.**
 - **Lupron Depot-Ped 30mg (GPID or GPI-14): #1 syringe/kit per 90 days.**
- **Fensolvi 45mg (GPID or GPI-14): #1 syringe/kit per 24 weeks.**

APPROVAL TEXT: Renewal requires the Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

If no, continue to #5.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

5. Is the request for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- The patient is 2 years of age or older
 - Therapy is prescribed by or given in consultation with a pediatric endocrinologist
 - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
 - The patient is younger than 9 years of age at the onset of CPP
 - Documentation of pubertal staging using the Tanner scale for:
 - Genital development (stage 2 or above) **AND**
 - Pubic hair growth (stage 2 or above)

If yes, **approve for 12 months for the requested agent and strength with the following quantity limits:**

- **Triptodur 22.5mg (GPID or GPI-14): #1 vial/kit per 24 weeks.**
- **Supprelin LA 50mg (NDC [FDB and Medi-Span]): #1 implant/kit per 52 weeks.**
- **Lupron Depot-Ped 1-months kits:**
 - **Lupron Depot-Ped 7.5mg (GPID or GPI-14): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 11.25mg 1-month (GPID or GPI-14): #1 syringe/kit per 30 days.**
 - **Lupron Depot-Ped 15mg (GPID or GPI-14): #1 syringe/kit per 30 days.**
- **Lupron Depot-Ped 3-months kits:**
 - **Lupron Depot-Ped 11.25mg 3-month (GPID or GPI-14): #1 syringe/kit per 90 days.**
 - **Lupron Depot-Ped 30mg (GPID or GPI-14): #1 syringe/kit per 90 days.**
- **Fensolvi 45mg (GPID or GPI-14): #1 syringe/kit per 24 weeks.**

APPROVAL TEXT: Renewal requires the Tanner scale staging at initial diagnosis of CPP has become stable or regresses at three separate medical visits in previous year and that patient has not reached actual age which corresponds to current pubertal age.

If no, continue to #6.

6. Is the request for Zoladex to be used as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding?

If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limit:**

- **Zoladex 3.6mg: #1 implant per 28 days (every month).**

If no, continue to #7.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

7. Is the request for Zoladex to be used in the palliative treatment of advanced breast cancer **AND** the patient meets the following criterion?

- The patient is a premenopausal or perimenopausal female

If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limit:**

- **Zoladex 3.6mg: #1 implant per 28 days (every month).**

If no, continue to #8.

8. Is the request for Zoladex **AND** the medication will be used in combination with flutamide for the management of locally confined carcinoma of the prostate?

If yes, **approve for 4 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- **Zoladex 3.6mg: #1 implant per 28 days (every month).**
- **Zoladex 10.8mg: #1 implant (one time fill).**

If no, continue to #9.

9. Is the request for Lupron Depot to be used concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (fibroids)?

If yes, **approve by GPID or GPI-14 for the requested strength with the following quantity limits and approval durations:**

- **Lupron Depot 3.75mg: #1 syringe/kit per 28 days (every month) for 3 months.**
- **Lupron Depot 11.25mg: one fill of #1 syringe/kit.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Lupron Depot, Lupaneta, Zoladex, Supprelin LA, Vantas, Triptodur, Trelstar, Fensolvi)** requires the following rule(s) be met for approval:

- A. You have or are using the requested drug for ONE of the following:
 - 1. Advanced prostate cancer
 - 2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
 - 3. Central precocious puberty (CPP; early sexual development in girls and boys)
 - 4. Gender dysphoria (you are distressed because your assigned sex/gender do not match your gender identity)
 - 5. As an endometrial-thinning agent prior to endometrial ablation (surgical removal of body tissue) for dysfunctional uterine bleeding
 - 6. Palliative treatment (treatment for pain or discomfort) of advanced breast cancer
 - 7. Management of locally confined carcinoma (cancer) of the prostate
 - 8. Anemia caused by uterine leiomyomata (fibroids; small muscle tumor)
- B. **If you have advanced prostate cancer, approval also requires:**
 - 1. The request is for Lupron Depot, Zoladex, Vantas, or Trelstar
- C. **If you have moderate to severe pain from endometriosis, approval also requires:**
 - 1. The request is for Lupron Depot, Lupaneta, or Zoladex
 - 2. You are 18 years of age or older
 - 3. Therapy is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
 - 4. You had a previous trial of a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation), unless there is a medical reason why you cannot (contraindication)
- D. **If you are female and have central precocious puberty, approval also requires:**
 - 1. The request is for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
 - 2. You are 2 years of age or older
 - 3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
 - 4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
 - 5. You are/were younger than 8 years of age when your condition started
 - 6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

(Initial denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

INITIAL CRITERIA (CONTINUED)

- E. If you are male and have central precocious puberty, approval also requires:**
 - 1. The request is for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
 - 2. You are 2 years of age or older
 - 3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
 - 4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
 - 5. You are/were younger than 9 years of age when your condition started
 - 6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)
- F. If you are using the requested medication as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, approval also requires:**
 - 1. The request is for Zoladex
- G. If you are using the requested medication for palliative treatment of advanced breast cancer, approval also requires:**
 - 1. The request is for Zoladex
 - 2. You are a premenopausal or perimenopausal female
- H. If you are using the requested medication for the management of locally confined carcinoma of the prostate, approval also requires:**
 - 1. The request is for Zoladex
 - 2. The requested medication will be used in combination with flutamide
- I. If you have anemia caused by uterine leiomyomata, approval also requires:**
 - 1. The request is for Lupron Depot
 - 2. You are using the requested medication for preoperative hematologic (blood) improvement
 - 3. The requested medication will be used with iron therapy

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For palliative treatment of advanced breast cancer, management of locally confined prostate carcinoma, preoperative hematologic improvement of anemia caused by uterine leiomyomata, or use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, please refer to the Initial Criteria section.

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months for the requested agent and strength by GPID or GPI-14.**
If no, continue to #2.

2. Is the request for Lupron Depot, Zoladex, Vantas, or Trelstar for a patient who has a diagnosis of advanced prostate cancer?

If yes, **approve for 12 months for the requested agent and strength with the following quantity limits:**

- **Lupron Depot 7.5mg (GPID or GPI-14): #1 syringe/kit per 28 days (every month).**
- **Lupron Depot 22.5mg (GPID or GPI-14): #1 syringe/kit per 84 days (every 3 months).**
- **Lupron Depot 30mg (GPID or GPI-14): #1 syringe/kit per 112 days (every 4 months).**
- **Lupron Depot 45mg (GPID or GPI-14): #1 syringe/kit per 168 days (every 6 months).**
- **Zoladex 3.6mg (GPID or GPI-14): #1 implant per 28 days (every month).**
- **Zoladex 10.8mg (GPID or GPI-14): #1 implant per 84 days (every 3 months).**
- **Vantas 50mg (NDC [FDB and Medi-Span]): #1 kit per 12 months.**
- **Trelstar 3.75mg (GPID or GPI-14): #1 injection per 28 days (every month).**
- **Trelstar 11.25mg (GPID or GPI-14): #1 injection per 84 days (every 3 months).**
- **Trelstar 22.5mg (GPID or GPI-14): #1 injection per 168 days (every 6 months).**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

RENEWAL CRITERIA (CONTINUED)

3. Is the request for Lupron Depot, Lupaneta, or Zoladex for a patient who has a diagnosis of moderate to severe pain associated with endometriosis and meet **ALL** of the following criteria?
- The patient has improvement of pain related to endometriosis while on therapy
 - The patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation)
 - The patient has **NOT** received a total course of therapy exceeding 12 months

If yes, **approve for 6 months by GPID or GPI-14 for the requested agent and strength with the following quantity limits:**

- Lupron Depot 3.75mg: #1 syringe/kit per 28 days (every month).
- Lupron Depot 11.25mg: #1 syringe/kit per 84 days (every 3 months).
- Lupaneta 3.75mg: #1 syringe/kit per 28 days (every month).
- Lupaneta 11.25mg: #1 syringe/kit per 84 days (every 3 months).
- Zoladex 3.6mg: #1 implant per 28 days (every month).

If no, continue to #4.

4. Is the request for Triptodur, Supprelin LA, Lupron-Depot Ped, or Fensolvi for a patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
 - Patient has not reached actual age which corresponds to current pubertal age

If yes, **approve for 12 months for the requested agent and strength with the following quantity limits:**

- Triptodur 22.5mg (GPID or GPI-14): #1 vial/kit per 24 weeks.
- Supprelin LA 50mg (NDC [FDB and Medi-Span]): #1 implant/kit per 52 weeks.
- Lupron Depot-Ped 1-months kits:
 - Lupron Depot-Ped 7.5mg (GPID or GPI-14): #1 syringe/kit per 30 days.
 - Lupron Depot-Ped 11.25mg 1-month (GPID or GPI-14): #1 syringe/kit per 30 days.
 - Lupron Depot-Ped 15mg (GPID or GPI-14): #1 syringe/kit per 30 days.
- Lupron Depot-Ped 3-months kits:
 - Lupron Depot-Ped 11.25mg 3-month (GPID or GPI-14): #1 syringe/kit per 90 days.
 - Lupron Depot-Ped 30mg (GPID or GPI-14): #1 syringe/kit per 90 days.
- Fensolvi 45mg (GPID or GPI-14): #1 syringe/kit per 24 weeks.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Lupron Depot, Lupaneta, Zoladex, Supprelin LA, Vantas, Triptodur, Trelstar)** requires the following rule(s) be met for renewal:

- A. You have or are using the requested drug for ONE of the following:
 - 1. Advanced prostate cancer
 - 2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
 - 3. Central precocious puberty (CPP; early sexual development in girls and boys)
 - 4. Gender dysphoria (you are distressed because your assigned sex/gender do not match your gender identity)
- B. **If you have moderate to severe pain associated with endometriosis, renewal also requires:**
 - 1. The request is for Lupron Depot, Lupaneta, or Zoladex
 - 2. You experienced improvement of pain related to endometriosis while on therapy
 - 3. You are receiving add-back therapy at the same time (combination estrogen-progestin or progestin-only contraceptive preparation)
 - 4. You have NOT received a total course of therapy exceeding 12 months
- C. **If you have central precocious puberty (CPP), renewal also requires:**
 - 1. The request is for Triptodur, Supprelin LA, Lupron Depot-Ped, or Fensolvi
 - 2. Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
 - 3. You have not reached actual age which corresponds to current pubertal age
- D. **If you have advanced prostate cancer, renewal also requires:**
 - 1. The request is for Lupron Depot, Zoladex, Vantas, or Trelstar

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Triptodur, Trelstar, Lupaneta, Lupron Depot, Supprelin LA, Lupron Depot-Ped, Zoladex, Vantas and Fensolvi.

REFERENCES

- Triptodur [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, LLC.; June 2017.
- Trelstar [Prescribing Information]. Madison, NJ: Allergan; December 2018.
- Supprelin LA [Prescribing Information]. Malvern, PA: Endo Pharmaceuticals; May 2017.
- Lupron Depot-Ped [Prescribing Information]. North Chicago, IL: AbbVie Inc.; May 2017.
- Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; Aug 2017.
- Synarel [Prescribing Information]. New York, NY: Pfizer Inc.; March 2018.
- Eligard [Prescribing Information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.
- Zoladex [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2016.
- Fensolvi [Prescribing Information]. Fort Collins, CO: Tolmar, Inc.; May 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 05/15/20

Created: 03/18

Client Approval: 04/20

P&T Approval: 07/18



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

NIMODIPINE SOLUTION

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIMODIPINE	NYMALIZE		34794 43848 47984 47985	GPI-14 (34000022002050) (34000022002054)	

GUIDELINES FOR USE

1. Does the patient have a history of subarachnoid hemorrhage (SAH) from a ruptured intracranial berry aneurysm within the past 21 days and meet the following criterion?
 - The patient is 18 years of age or older

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient unable to swallow nimodipine capsules?

If yes, **approve once for the requested strength by GPID or GPI-14 up to a maximum 21 day supply with the following quantity limits:**

- Nymalize 30mg/10mL: #120mL per day
- Nymalize 60mg/20mL: #120mL per day
- Nymalize 30mg/5mL: #60mL per day
- Nymalize 60mg/10mL: #60mL per day

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:

- A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
- B. You are 18 years of age or older
- C. You are unable to swallow nimodipine oral capsules

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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PRIOR AUTHORIZATION GUIDELINES

ENDOTHELIN RECEPTOR ANTAGONISTS

Generic	Brand	HICL	GCN	Exception/Other
BOSENTAN	TRACLEER	22990		
AMBRISENTAN	LETAIRIS	34849		
MACITENTAN	OPSUMIT	40677		

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

LETAIRIS

- Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meets **ALL** of the following criteria?
 - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
 - The patient has NYHA-WHO Functional Class II to IV symptoms
 - The patient does not have idiopathic pulmonary fibrosis (IPF)

If yes, **approve Letairis for 12 months by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis)** requires a diagnosis of pulmonary arterial hypertension. The following criteria must also be met:

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
- The patient has NYHA-WHO Functional Class II to IV symptoms
- The patient does not have idiopathic pulmonary fibrosis (IPF)

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PRIOR AUTHORIZATION GUIDELINES**ENDOTHELIN RECEPTOR ANTAGONISTS****INITIAL CRITERIA (CONTINUED)****TRACLEER**

1. Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meets **ALL** of the following criteria?
 - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 - The patient is 3 years of age or older
 - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
 - The patient has NYHA-WHO Functional Class II to IV symptoms
 - The patient does not have idiopathic pulmonary fibrosis (IPF)
 - The patient is not concurrently taking cyclosporine A or glyburide
 - If the patient is 18 years or older, the patient has tried and failed or has a contraindication to Ambrisentan (generic Letairis).

If yes, **approve Tracleer for 12 months by GPID for all the following strengths with the following quantity limits:**

- **62.5mg tablet (GPID 14979): #2 tablets per day.**
- **125mg tablet (GPID 14978): #2 tablets per day.**
- **32mg tablet for suspension (GPID 43819): #4 tablets per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Tracleer)** requires a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- The patient is 3 years of age or older
- Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
- The patient has NYHA-WHO Functional Class II to IV symptoms
- The patient does not have idiopathic pulmonary fibrosis (IPF)
- The patient is not concurrently taking cyclosporine A or glyburide
- If the patient is 18 years or older, the patient has tried and failed or has a contraindication to Ambrisentan (generic Letairis)

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PRIOR AUTHORIZATION GUIDELINES**ENDOTHELIN RECEPTOR ANTAGONISTS****INITIAL CRITERIA (CONTINUED)****OPSUMIT**

1. Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meets **ALL** of the following criteria?
 - The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
 - Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
 - The patient has NYHA-WHO Functional Class II to IV symptoms
 - The patient has tried and failed or has a contraindication to Ambrisentan (generic Letairis)

If yes, **approve Opsumit for 12 months by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: The guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Opsumit)** requires a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

- The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
- Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
 - Mean pulmonary artery pressure (PAP) of ≥ 25 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 3 Wood units
- The patient has NYHA-WHO Functional Class II to IV symptoms
- The patient has tried and failed or has a contraindication to Ambrisentan (generic Letairis)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)?

If yes, continue to #2

If no, do not approve.

DENIAL TEXT: See the renewal text at the end of the guideline.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

ENDOTHELIN RECEPTOR ANTAGONISTS

RENEWAL CRITERIA (CONTINUED)

2. Is the request for Tracleer and the patient is between the ages of 3 and 17 years old and meets one of the following criteria?
- The patient has demonstrated an improvement in pulmonary vascular resistance (PVR)
 - OR**
 - The patient has remained stable or shown improvement in exercise ability (e.g., 6-minute walk test, World Health Organization [WHO] functional class symptoms)

If yes, **approve Tracleer for 12 months by GPID for all the following strengths with the following quantity limits:**

- **62.5mg tablet (GPID 14979): #2 tablets per day.**
- **125mg tablet (GPID 14978): #2 tablets per day.**
- **32mg tablet for suspension (GPID 43819): #4 tablets per day.**

If no, continue to #3.

3. Has the patient shown improvement from baseline in the 6-minute walk distance test?

If yes, **approve the requested agent for 12 months with the following quantity limits:**

- **Letairis: approve by HICL for #1 per day.**
- **Tracleer: approve by GPID for all the following strengths with the following quantity limits:**
 - **62.5mg tablet (GPID 14979): #2 tablets per day.**
 - **125mg tablet (GPID 14978): #2 tablets per day.**
 - **32mg tablet for suspension (GPID 43819): #4 tablets per day.**
- **Opsumit: approve by HICL for #1 per day.**

If no, continue to #4.

4. Has the patient remained stable from baseline in the 6-minute walk distance test?

If yes continue to #5.

If no, do not approve.

DENIAL TEXT: See the renewal text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES**ENDOTHELIN RECEPTOR ANTAGONISTS****RENEWAL CRITERIA (CONTINUED)**

5. Has the patient's WHO functional class remained stable or has improved?

If yes, **approve the requested agent for 12 months with the following quantity limits:**

- **Letairis:** approve by HICL for #1 per day.
- **Tracleer:** approve by GPID for all the following strengths with the following quantity limits:
 - **62.5mg tablet (GPID 14979): #2 tablets per day.**
 - **125mg tablet (GPID 14978): #2 tablets per day.**
 - **32mg tablet for suspension (GPID 43819): #4 tablets per day.**
- **Opsumit:** approve by HICL for #1 per day.

If no, do not approve.

DENIAL TEXT: See the renewal text at the end of the guideline.

RENEWAL DENIAL TEXT: The guideline named **ENDOTHELIN RECEPTOR ANTAGONISTS (Letairis, Tracleer, Opsumit)** requires a diagnosis of pulmonary arterial hypertension (PAH) and the following criteria must also be met for renewal:

- **For Tracleer patients 18 years of age or older, Letairis and Opsumit:** Patient shows improvement from baseline in the 6-minute walk distance **OR** that the patient has a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class symptom.
- **For Tracleer patients age 3-17:** The patient has demonstrated an improvement in pulmonary vascular resistance (PVR) **OR** has remained stable or shown improvement in exercise ability (e.g. 6-minute walk test, World Health Organization [WHO] functional class symptoms).

RATIONALE

Ensure appropriate utilization of Tracleer, Letairis and Opsumit.

Diagnosis of PAH involves a logical sequence of steps utilizing different diagnostic tests to assist in confirmation of PAH (chest x-ray, echocardiogram, electrocardiogram, CT angiogram, pulmonary function tests, VQ scan); however, right heart catheterization (RHC) remains the gold standard and is an essential component in the definitive diagnosis, prognosis, and evaluation of PAH. RHC is critical in distinguishing PH due to other etiologies, for example PH due to left heart disease (eg. diastolic dysfunction) or severe lung disease, which may appear similar to PAH on an echocardiogram. In addition, RHC can be used to monitor the therapeutic and adverse effects of medical interventions, to assess the severity of hemodynamic impairment, and to test the vasoreactivity of the pulmonary circulation.

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PRIOR AUTHORIZATION GUIDELINES

ENDOTHELIN RECEPTOR ANTAGONISTS

FDA APPROVED INDICATIONS

LETAIRIS is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO Group 1):

- in patients with NYHA-WHO class II or III symptoms to improve exercise capacity and delay clinical worsening. In addition, Letairis is approved in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

TRACLEER is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO Group 1)

- in adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to-right shunts (18%)
- in pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability

OPSUMIT is an endothelin receptor antagonist indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to delay disease progression, including death, initiation of intravenous or subcutaneous prostanoids, or clinical worsening of PAH (decreased 6 minute walk distance, worsened PAH symptoms and need for additional PAH treatment. Opsumit also reduced hospitalization for PAH.

REFERENCES

- Actelion Pharmaceuticals US, Inc. Tracleer package insert. South San Francisco, CA. September 2017.
- Actelion Pharmaceuticals US, Inc. Opsumit package insert. South San Francisco, CA. October 2013.
- Gilead Sciences, Inc., Letairis package insert. Foster City, CA. October 2015.
- Taichman DB, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. CHEST 2014 Aug;146(2):449-75.
- Klinger, James R. et al. Therapy for Pulmonary Arterial Hypertension in Adults. CHEST, Volume 155, Issue 3, 565 - 586
- N Galiè et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS) endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). Eur Heart J 2015 Aug 29.
- Hoeper MM, et al. Definitions and diagnosis of pulmonary hypertension. J Am Coll Cardiol 2013;62(Suppl):D42-D50.



WELLFLEET

R X P L A N

PRIOR AUTHORIZATION GUIDELINES

Created	FS Committee Approval	Effective
5/5/2020	5/5/2020	5/22/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AMANTADINE EXTENDED RELEASE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AMANTADINE EXTENDED RELEASE	GOCOVRI		43787 43788	GPI-14 (73200010107020) (73200010107040)	
AMANTADINE HCL	OSMOLEX ER		44471 44472 44473 48017	GPI-14 (73200010107520) (73200010107530) (73200010107540) (7320001010C320)	

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

GOCOVRI

- Does the patient have a diagnosis of dyskinesia and meet **ALL** of the following criteria?
 - The patient has a diagnosis of Parkinson's disease
 - The patient is receiving levodopa-based therapy
 - The patient has had a trial of generic amantadine capsules, tablets or solution

If yes, **approve for 12 months by GPID or GPI-14 for all the following strengths with the following quantity limits:**

- 68.5mg capsule: #1 per day.**
- 137mg capsule: #2 per day.**

If no, do not approve.

GOCOVRI DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:

- You have dyskinesia (abnormal involuntary movements)
- You have Parkinson's disease (nervous system disorder that affects movement)
- You are receiving levodopa-based therapy
- You have previously tried generic amantadine capsules, tablets or solution

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE (CONTINUED)

OSMOLEX ER

1. Does the patient have a diagnosis of Parkinson's disease?

If yes, continue to #3.

If no, continue to #2.

2. Is the request for the treatment of drug-induced extrapyramidal symptoms (EPS) **AND** the patient meets the following criterion?

- The patient is 18 years of age or older

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a psychiatrist, neurologist, or geriatrician
- The patient has had a trial of generic amantadine IR capsules, tablets, or solution

If yes, **approve for 12 months by GPID or GPI-14 for all strengths with a quantity limit of #1 per day.**

If no, do not approve.

OSMOLEX ER DENIAL TEXT: **Some terms are already pre-defined in parenthesis.*

Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AMANTADINE EXTENDED RELEASE (Osmolex ER)** requires the following rule(s) be met for approval:

- A. You have Parkinson's disease (nervous system disorder that affects movement) OR you are being treated for drug-induced extrapyramidal symptoms (group of movement disorders)
- B. Therapy is prescribed by or given in consultation with a psychiatrist (mental disorder doctor), neurologist (nerve doctor), or geriatrician (doctor who treats elderly people)
- C. You have previously tried generic amantadine immediate-release capsules, tablets or solution
- D. **If you are being treated for drug-induced extrapyramidal symptoms, approval also requires:**

1. You are 18 years of age or older

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AMANTADINE EXTENDED RELEASE

GUIDELINES FOR USE - OSMOLEX ER (CONTINUED)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gocovri and Osmolex ER.

REFERENCES

- Gocovri [Prescribing Information]. Emeryville, CA: Adamas Pharma, LLC. December 2019.
- Osmolex ER [Prescribing Information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC. October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/08/20

Created: 09/17

Client Approval: 05/20

P&T Approval: 07/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TOLVAPTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOLVAPTAN	JYNARQUE	36348		GPI-10 (3045406000)	BRAND ≠ SAMSCA

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Therapy is prescribed by or given in consultation with a nephrologist
 - The patient has confirmed polycystic kidney status via CT or MRI imaging **AND** one of the following:
 - The patient has a genotype causative of ADPKD **OR**
 - The patient has a family history of confirmed polycystic kidney disease in one or both parents
 - The patient does not have End-Stage Renal Disease (ESRD; including no renal transplantation or dialysis)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****TOLVAPTAN****INITIAL CRITERIA (CONTINUED)****2. Is the patient at high risk of rapid progression of disease?**

Examples of risk factors which may predicate higher risk progression include:

- *PKD1* genotype
- Hypertension
- Early onset of symptoms including proteinuria and hematuria
- Male gender
- Increased kidney size
- Increased left ventricular mass index
- Dipstick detectable proteinuria
- Low birth weight
- Decreased renal blood flow
- Increased urinary sodium excretion
- Increased low-density lipoprotein (LDL) cholesterol
- Increased plasma copeptin
- Higher serum uric acid levels
- High concentration of fibroblast growth factor (FGF)

If yes, **approve for 6 months for all strengths as follows:**

- **Jynarque 90mg-30mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 45mg-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 60mg-30mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 30-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 15-15mg (GPID or GPI-14): #56 per 28 days.**
- **Jynarque 15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.**
- **Jynarque 30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.**

APPROVAL TEXT: Renewal requires that the patient has not progressed to ESRD.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****TOLVAPTAN****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for approval:

- A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
- B. You are 18 years of age or older
- C. The requested medication is prescribed by or given in consultation with a nephrologist (kidney specialist)
- D. You have confirmed polycystic kidney status via CT or MRI imaging (type of lab imaging tests) AND one of the following:
 - 1. You have a genotype that causes of autosomal dominant polycystic kidney disease (inherited disorder in which clusters of cysts develop in the kidneys) OR
 - 2. You have a family history of confirmed polycystic kidney disease in one or both parents
- E. You do not have End-Stage Renal Disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis
- F. You are at high risk of rapidly progressing autosomal dominant polycystic kidney disease

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

- 1. Does the patient have a diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD) AND meet the following criterion?
 - The patient has not progressed to End-Stage Renal Disease (ESRD)

If yes, approve for 12 months for all strengths as follows:

- Jynarque 90mg-30mg (GPID or GPI-14): #56 per 28 days.
- Jynarque 45mg-15mg (GPID or GPI-14): #56 per 28 days.
- Jynarque 60mg-30mg (GPID or GPI-14): #56 per 28 days.
- Jynarque 30-15mg (GPID or GPI-14): #56 per 28 days.
- Jynarque 15-15mg (GPID or GPI-14): #56 per 28 days.
- Jynarque 15mg (NDC 59148-0082-13) [FDB & Medi-Span]: #60 per 30 days.
- Jynarque 30 mg (NDC 59148-0083-13) [FDB & Medi-Span]: #30 per 30 days.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOLVAPTAN

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **TOLVAPTAN (Jynarque)** requires the following rule(s) be met for renewal:

- A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
- B. You have NOT progressed to end stage renal (kidney) disease (ESRD)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Jynarque.

REFERENCES

- Jynarque [Prescribing Information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/08/20

Created: 08/18

Client Approval: 05/20

P&T Approval: 07/18

PRIOR AUTHORIZATION GUIDELINES

ANTIMIGRAINE AGENTS

Generic	Brand	HICL	GCN	Exception/Other
ALMOTRIPTAN	AXERT	21894		
ELETRIPTAN HBR	RELPAX	23093		
FROVATRIPTAN SUCCINATE	FROVA	22988		
NARATRIPTAN HCL	AMERGE	13266		
RIZATRIPTAN BENZOATE	MAXALT, MAXALT MLT	18535		
SUMATRIPTAN	IMITREX NASAL SPRAY	12779		
SUMATRIPTAN SUCCINATE	ALSUMA, IMITREX, SUMAVEL DOSEPRO	06587		
SUMATRIPTAN SUCC/NAPROXEN SOD	TREXIMET	35534		
ZOLMITRIPTAN	ZOMIG, ZOMIG ZMT	12958		

These agents have quantity restrictions in place. If the following criteria are met, an increased quantity beyond the quantity restrictions can be given:

GUIDELINES FOR USE

1. Is the requested medication rejecting for nonformulary?

If yes, this guideline does not apply. **Note:** Follow nonformulary procedure.
 If no, continue to #2.

2. Is the requested medication rejecting for step therapy not met?

If yes, this guideline does not apply. **Note:** Follow step therapy procedure.
 If no, continue to #3.

3. Is the request for a quantity limit override?

If yes, continue to #4
 If no, this guideline does not apply. Forward to Clinical for Review.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

ANTIMIGRAINE AGENTS

GUIDELINES FOR USE (CONTINUED)

4. Has the member currently tried/failed or have a contraindication to one of the following medications used for prophylactic migraine treatment?
- Calcium Channel Blockers: (nifedipine and verapamil)
 - Beta-Blockers: (propranolol, metoprolol, atenolol, timolol and nadolol)
 - Tricyclic Antidepressants: (amitriptyline, trazodone and nortriptyline)
 - Anticonvulsants: (divalproex sodium, carbamazepine, gabapentin, topiramate, valproic acid etc.)

If yes, continue to #5.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. **Approve for 12 months with quantity limit below per month:**

- | | |
|--|---|
| • ALSUMA (SUMATRIPTAN): | #8 auto-injectors |
| • AMERGE (NARATRIPTAN): | #18 tablets |
| • AXERT (ALMOTRIPTAN): | #24 tablets |
| • FROVA (FROVATRIPTAN): | #18 tablets |
| • IMITREX (SUMATRIPTAN): | #18 tablets |
| | #24 for 5mg or 20mg nasal sprays |
| | #8 vial/cartridge/pen |
| • MAXALT OR MAXALT MLT (RIZATRIPTAN): | #18 tablets |
| • RELPAX (ELETRRIPTAN): | #24 tablets |
| • SUMAVEL DOSEPRO (SUMATRIPTAN): | #8 syringes |
| • TREXIMET (SUMATRIPTAN/NAPROXEN): | #18 tablets |
| • ZOMIG OR ZOMIG ZMT (ZOLMITRIPTAN): | #24 tablets |
| | #24 nasal sprays |

APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

DENIAL TEXT: Our guideline for **ANTIMIGRAINE AGENTS** requires a trial of a formulary prophylactic migraine agent such as calcium channel blockers, beta blockers, tricyclic antidepressants, or anticonvulsants.

RATIONALE

To ensure appropriate utilization of abortive migraine therapy and limit occurrence of rebound headache.

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PRIOR AUTHORIZATION GUIDELINES

ANTIMIGRAINE AGENTS

FDA APPROVED INDICATION

Treatment of migraine headache with or without aura (all triptans), treatment of cluster headache (Imitrex injection).

REFERENCES

- AstraZeneca Pharmaceuticals. Zomig tablets and Zomig ZMT orally disintegrating tablets package insert. Wilmington, DE, March 2012.
- AstraZeneca Pharmaceuticals. Zomig nasal spray package insert. Wilmington, DE. March 2012.
- GlaxoSmithKline. Imitrex tablets package insert. Research Triangle Park, NC. October 2012.
- GlaxoSmithKline. Imitrex nasal spray package insert. Research Triangle Park, NC. October 2012.
- GlaxoSmithKline. Imitrex injection package insert. Research Triangle Park, NC. October 2012.
- GlaxoSmithKline. Amerge tablets package insert. Research Triangle Park, NC. March 2012.
- GlaxoSmithKline. Treximet package insert. Research Triangle Park, NC. March 2012.
- Merck & Co. Maxalt tablets and Maxalt-MLT orally disintegrating tablets package insert. Whitehouse Station, NJ. December 2009.
- Ortho-McNeil. Axert tablets package insert. Titusville, NJ. April 2009.
- Endo Pharmaceuticals. Frova tablets package insert. Chadds Ford, PA. April 2007.
- Pfizer Roerig. Relpax tablets package insert. New York, NY. May 2008.
- US WorldMeds, LLC. Alsuma package insert. Louisville, KY. June 2010.
- Zogenix, Inc. Sumavel DosePro package insert. San Diego, CA. July 2009.

Created	FS Committee Approval	Effective
5/2020		5/22/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

Generic	Brand	HICL	GCN	Exception/Other
CERTOLIZUMAB PEGOL	CIMZIA	35554		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient meets **ONE** of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - The patient is 18 years of age or older
 - The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial TWO of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, approve for a total of 6 months. Please enter two authorizations as follows:

- **FIRST APPROVAL:** Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
- **SECOND APPROVAL:** Approve for 5 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

APPROVAL TEXT: Renewal for moderate to severe rheumatoid arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**

- **FIRST APPROVAL:** Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
- **SECOND APPROVAL:** Approve for 5 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #3.

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient is 18 years of age or older
 - The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Renflexis, or Cosentyx (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**

- **FIRST APPROVAL:** Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
- **SECOND APPROVAL:** Approve for 5 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, continue to #4.

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD) and meet **ALL** of the following criteria?
- Therapy is prescribed by or given in consultation with a gastroenterologist
 - The patient has had a previous trial of one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
 - The patient is 18 years of age or older
 - The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial of the formulary preferred immunomodulator: Humira (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, approve for a total of 6 months. Please enter two authorizations as follows:

- **FIRST APPROVAL:** Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a package of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
- **SECOND APPROVAL:** Approve for 5 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Documentation of the patient's current weight
 - Therapy is prescribed by or given in consultation with a dermatologist
 - The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
 - The patient has had a previous trial of one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
 - The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara, or Tremfya (**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

PRIOR AUTHORIZATION GUIDELINES

6. Does the patient weigh 90 kg or less?

If yes, **approve for a total of 6 months. Please enter two authorizations as follows:**

- **FIRST APPROVAL:** Approve for 1 fill for #1 Starter kit (enter quantity 3 for a starter kit of 6 prefilled syringes) OR for #3 kits (enter quantity 3 for a total of 6 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) for the first month then,
- **SECOND APPROVAL:** Approve for 5 months for #1 kit (enter quantity 1 for a package of 2 vials or prefilled syringes) per month.

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

If no, **approve for 6 months for #2 kits (enter quantity 2 for a package of 4 vials or prefilled syringes, each kit is 2 vials or prefilled syringes) per month.**

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

INITIAL DENIAL TEXT: The guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe Crohn's disease, or moderate to severe psoriasis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient meets **ONE** of the following:
 - Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
 - For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
 - Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide).
- The patient is 18 years of age or older
- The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz

For patients with psoriatic arthritis (PsA), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient is 18 years of age or older
- The patient meets **ONE** of the following:
 - The patient is pregnant or breastfeeding.



WELLFLEET

R X P L A N

PRIOR AUTHORIZATION GUIDELINES

- The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz.

(Initial denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

INITIAL CRITERIA (CONTINUED)

For patients with ankylosing spondylitis (AS), approval requires:

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient meets ONE of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Renflexis, or Cosentyx

For patients with moderate to severe Crohn's disease (CD), approval requires:

- Therapy is prescribed by or given in consultation with a gastroenterologist
- The patient has had a previous trial of one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- The patient is 18 years of age or older
- The patient meets ONE of the following:
 - The patient is pregnant or breastfeeding.
 - The patient has had a previous trial of the formulary preferred immunomodulator: Humira

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

- The patient is 18 years of age or older
- Documentation of the patient's current weight
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient has had a previous trial of one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient meets ONE of the following:
 - The patient is pregnant or breastfeeding
 - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara, or Tremfya.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
 - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months for #1 kit per 28 days (enter quantity 1 for a package of 2 vials or prefilled syringes).**

If no, continue to #4.

4. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

If yes, **approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).**

If no, continue to #5.

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criteria?

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

If yes, continue to #6.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

6. Does the patient weigh 90 kg or less?

If yes, **approve for 12 months for #1 kit per month (enter quantity 1 for a package of 2 vials or prefilled syringes).**

If no, **approve for 12 months for #2 kits per month (enter quantity 2 for a package of 4 vials or prefilled syringes).**

RENEWAL DENIAL TEXT: The guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe Crohn's disease, or moderate to severe plaque psoriasis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of psoriatic arthritis (PsA), approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of ankylosing spondylitis (AS), approval requires:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

Renewal for the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

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PRIOR AUTHORIZATION GUIDELINES

CERTOLIZUMAB PEGOL

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for Cimzia.

FDA APPROVED INDICATIONS

CIMZIA is a tumor necrosis Factor (TNF) blocker indicated for:

- Reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Treatment of adults with moderately to severely active rheumatoid arthritis.
- Treatment of adult patients with active psoriatic arthritis.
- Treatment of adults with active ankylosing spondylitis.
- Treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy of phototherapy.

DOSAGE AND ADMINISTRATION

Cimzia is administered by subcutaneous injection.

Crohn's Disease: 400 mg initially and at weeks 2 and 4. If response occurs, follow with 400 mg every four weeks.

Rheumatoid Arthritis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered.

Psoriatic Arthritis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week. For maintenance dosing, 400 mg every 4 weeks can be considered.

Ankylosing Spondylitis: 400 mg initially and at weeks 2 and 4, followed by 200 mg every other week or 400 mg every 4 weeks.

Plaque Psoriasis: 400mg every other week. For some patients (with body weight ≤ 90 kg, a dose of 400mg initially and at weeks 2 and 4, followed by 200mg every other week may be considered.

REFERENCES

- Cimzia [Prescribing Information]. Smyrna, GA: UCB, Inc. May 2018.

Created	FS Committee Approval	Effective
8/2019; revised 9/2019; revised 12/2019	8/2019	1/17/2020
Revised 5/2020	5/2020	5/22/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



WELLFLEET

RX PLAN

PRIOR AUTHORIZATION GUIDELINES

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CONTRACEPTIVE ZERO COST SHARE OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CONTRACEPTIVES, ORAL				GPI-2 (25)	STC = 0248
CONTRACEPTIVES, TRANSDERMAL					STC = 9495
CONTRACEPTIVES, INTRAUTERINE, SYSTEMIC					STC = 9654
INTRA-UTERINE DEVICES (IUD'S)					STC = 4730
CONTRACEPTIVES, INJECTABLE					STC = 4139
CONTRACEPTIVES, IMPLANTABLE					STC = 3669
CONTRACEPTIVE, INTRAUTERINE				GPI-10 (5530001000)	STC = 0249
DIAPHRAGMS/CERVICAL CAP				GPI-10 (9740208000) (9740181000) (9740201000)	STC = 3322

GUIDELINES FOR USE

1. Is the patient requesting a cost share exception for the requested contraceptive agent **AND** does the plan cover contraceptives at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

If yes, continue to #2.

If no, guideline does not apply.

2. Do **ANY** of the following criteria apply?
 - The patient's plan has specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)
 - The request is for an agent with an excluded route of administration, such that the agent will be covered on the medical benefit

If yes, guideline does not apply.

If no, continue to #3.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CONTRACEPTIVE ZERO COST SHARE OVERRIDE

GUIDELINE FOR USE (CONTINUED)

3. Is the request for a single-source brand contraceptive agent that has no preferred generic agents or therapeutically equivalent products available **AND** the physician has provided documentation confirming that the requested drug is considered as medically necessary (considerations may include severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service)?

If yes, **approve for 12 months by GPID or GPI-14 at zero cost share.**

If no, continue to #4.

4. Is the request for a single-source or multi-source brand contraceptive agent that is rejecting for step therapy required **AND** the physician has provided documentation that satisfies at least **ONE** of the following criteria?
- Two preferred products are medically inappropriate for the patient (alternatively, one if only one agent is available)
 - The patient has tried or has a documented medical contraindication to two preferred products (alternatively, a trial of one if only one agent is available)
 - The requested drug is considered as medically necessary (considerations may include severity of side effects, differences in permanence and reversibility of contraceptives, and ability to adhere to the appropriate use of the item or service)

If yes, **approve for 12 months by GPID or GPI-14 at zero cost share.**

APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **CONTRACEPTIVE ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

- A. **If the request is for a single-source brand (no generic available) contraceptive medication that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:**
1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to appropriate use)

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CONTRACEPTIVE ZERO COST SHARE OVERRIDE

GUIDELINE FOR USE (CONTINUED)

- B. Your doctor has provided documentation supporting ONE of the following criteria:
1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
 2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
 3. The requested medication is considered medically necessary for you (considerations may include severity of side effects, differences in durability and reversibility of contraceptive and ability to adhere to the appropriate use)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

This guideline applies to plans where the pharmacy benefit allows for coverage of contraceptives at zero copay. The override criteria allow patient access to all FDA-approved contraceptive methods at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded contraceptives.

The MedImpact standard Zero Copay list currently offers coverage of all methods at zero cost share. The zero cost share list offers a variety of contraceptives. Covered methods (zero cost share) include

1) specified barrier contraceptives (condoms, diaphragms, cervical caps, and nonoxynol-9) 2) generic oral hormonal contraceptives under STC 0248, including generic emergency contraceptives and Ella 3) generic transdermal patch contraceptive (currently marketed by Mylan as Xulane) 4) Nuvaring vaginal ring 5) Intrauterine devices – levonorgestrel IUDs and copper IUDs 6) Depo-Provera injections and 7) Nexplanon implant devices. The majority of the contraceptives on the EHB Zero cost share list are generic agents, which promotes a cost-effective formulary.

The healthcare.gov website (<https://www.healthcare.gov/coverage/birth-control-benefits/>) currently recommends: All approved contraceptive methods prescribed by a woman's doctor are covered, including:

- Barrier methods (used during intercourse), like diaphragms and sponges
- Hormonal methods, like birth control pills and vaginal rings
- Implanted devices, like intrauterine devices (IUDs)
- Emergency contraception, like Plan B® and Ella®
- Sterilization procedures
- Patient education and counseling

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CONTRACEPTIVE ZERO COST SHARE OVERRIDE

REFERENCES

- Birth control benefits; <https://www.healthcare.gov/coverage/birth-control-benefits/>
- FAQs about Affordable Care Act Implementation Part XII; <http://www.dol.gov/ebsa/faqs/faq-aca12.html>
- FAQ about Affordable Care Act Implementation (Part XXVI); <http://www.dol.gov/ebsa/faqs/faq-aca26.html>

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/08/20

Created: 04/15

Client Approval: 05/20

P&T Approval: 05/15

**STANDARD COMMERCIAL DRUG FORMULARY
 PRIOR AUTHORIZATION GUIDELINES**
RIPRETINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RIPRETINIB	QINLOCK	46544		GPI-10 (2153407700)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has received prior treatment with 3 or more kinase inhibitors, including imatinib

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**
 If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:

- You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
- You are 18 years of age or older
- You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qinlock.

REFERENCES

Qinlock [Prescribing Information]. Waltham, MA: Deciphera Pharmaceuticals, May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/29/20

Created: 05/20

Client Approval: 07/20

P&T Approval: 07/20

PRIOR AUTHORIZATION GUIDELINES

IXEKIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
IXEKIZUMAB	TALTZ	43193		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to any **THREE** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara SC, or Tremfya [NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, approve for a total of 6 months by entering **THREE** approvals by HICL as follows:

- **FIRST APPROVAL:** approve for 4 weeks with a quantity limit of 3mL (#3 80mg/mL syringes or autoinjectors) per 28 days.
- **SECOND APPROVAL:** approve for 8 weeks with a quantity limit of 2mL (#2 80mg/mL syringes or autoinjectors) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).
- **THIRD APPROVAL:** approve for 12 weeks with a quantity limit of 1mL (#1 80mg/mL syringe or autoinjector) per 28 days (Please enter a start date of 4 WEEKS AFTER the END date of the second approval).

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, continue to #2.

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES**IXEKIZUMAB****INITIAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meet **ALL** of the following criteria?

- The patient is 6 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of preferred conventional therapies such as topical corticosteroids, calcipotriene, PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), acitretin, methotrexate, or cyclosporine
- The patient had a previous trial of or contraindication to the following formulary preferred immunomodulators: Enbrel. NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for a total of 6 months by entering TWO approvals by HICL as follows based on patient weight:**

Weight up to 50 kg

- **FIRST APPROVAL:** approve for 4 weeks with a quantity limit of 1mL (#1 80mg/mL syringes or autoinjectors) per 28 days.
- **SECOND APPROVAL:** approve for 20 weeks with a quantity limit of 1mL (#1 80mg/mL syringes or autoinjectors) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).

Weight greater than 50 kg

- **FIRST APPROVAL:** approve for 4 weeks with a quantity limit of 2mL (#2 80mg/mL syringes or autoinjectors) per 28 days.
- **SECOND APPROVAL:** approve for 20 weeks with a quantity limit of 1mL (#1 80mg/mL syringes or autoinjectors) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).

APPROVAL TEXT: Renewal for moderate to severe plaque psoriasis requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, continue to #3.

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara, or Xeljanz [NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]



PRIOR AUTHORIZATION GUIDELINES

If yes, approve for a total of 6 months by entering TWO approvals by HICL as follows:

- **FIRST APPROVAL:** approve for 4 weeks with a quantity limit of 2mL (#2 80mg/mL syringes or autoinjectors) per 28 days.
- **SECOND APPROVAL:** approve for 20 weeks with a quantity limit of 1mL (#1 80mg/mL syringe or autoinjector) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).

APPROVAL TEXT: Renewal for psoriatic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meet ALL of the following criteria?

- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient is 18 years of age or older
- The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, or Renflexis (NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify)

If yes, approve for a total of 6 months by entering TWO approvals by HICL as follows:

- **FIRST APPROVAL:** approve for 4 weeks with a quantity limit of 2mL (#2 80mg/mL syringes or autoinjectors) per 28 days.
- **SECOND APPROVAL:** approve for 20 weeks with a quantity limit of 1mL (#1 80mg/mL syringe or autoinjector) per 28 days (Please enter a start date of 4 WEEKS AFTER the START date of the first approval).

APPROVAL TEXT: Renewal for ankylosing spondylitis requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA), or ankylosing spondylitis (AS). In addition, the following criteria must be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:

- The patient is 6 years of age or older
- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
- The patient had a previous trial of or contraindication to at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- If 18 years of age or older, the patient had a previous trial of or contraindication to any **THREE** of the following formulary preferred immunomodulators: Cosentyx, Humira, Otezla, Renflexis, Skyrizi, Stelara SC, or Tremfya.

IXEKIZUMAB



PRIOR AUTHORIZATION GUIDELINES

- If age 6 to 18, the patient has had a previous trial of or contraindication to the preferred formulary immunomodulator, Enbrel.

For the diagnosis of psoriatic arthritis (PsA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Renflexis, Stelara SC, or Xeljanz.

For the diagnosis of ankylosing spondylitis (AS), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist
- The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, or Renflexis

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) **AND** meet the following criterion?
 - The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If yes, **approve for 12 months by HICL with a quantity limit of 1mL (#1 80mg/mL syringe/autoinjector) per 28 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of psoriatic arthritis (PsA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of 1mL (#1 80mg/mL syringe/autoinjector) per 28 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of ankylosing spondylitis (AS) **AND** meet the following criterion?
 - The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

If yes, **approve for 12 months by HICL with a quantity limit of 1mL (#1 80mg/mL syringe/autoinjector) per 28 days.**

IXEKIZUMAB

If no, do not approve.

PRIOR AUTHORIZATION GUIDELINES

RENEWAL DENIAL TEXT: The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) or psoriatic arthritis (PsA) for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:

- The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

For the diagnosis of psoriatic arthritis (PsA), approval requires:

- The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis (AS), approval requires:

- The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Taltz.

REFERENCES

- Taltz [Prescribing Information]. Eli Lilly and Company: Indianapolis, IN: December 2017.

Created	FS Committee Approval	Effective
8/1/19; revised 12/2019	08/19	1/17/2020
Revised 4/2020	05/2020	5/22/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

Generic	Brand	HICL	GCN	Exception/Other
SOFOBUVIR/VELPATASVIR	EPCLUSA	43561		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

HEPATITIS C FORMULARY PREFERRED PRODUCT IS MAVYRET. PLEASE FOLLOW GUIDELINE LANGUAGE CLOSELY.

GUIDELINES FOR USE

1. Does the patient have hepatitis C genotype 1, 2, 3, 4, 5, or 6?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Is the patient at least 6 years old and weighs at least 17kg (37 pounds)?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
3. Does the patient have a chronic HCV infection documented by at least **ONE** detectable HCV RNA level within the last 6 months?

If yes, continue to #4.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
4. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?

If yes, continue to #5
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

5. Is the patient currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #6.

6. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #7.

7. Is the request for a pediatric patient age 6-18 and who weighs between 17kg (37 pounds) and 45 kg (99 pounds) who have no cirrhosis or compensated cirrhosis? (Please note: for pediatric patients weighing at least 45 kg (99 pounds) with no cirrhosis or compensated cirrhosis, the preferred product is Mavyret).

If yes, **approve for 12 weeks by HICL for #1 tablet per day.**

If no, continue to #8.

8. Does the patient have hepatitis C post-liver transplant?

If yes, continue to #9

If no, continue to question #11.

9. Does the patient have cirrhosis?

If yes, continue to #10.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

10. Does the patient meet ALL the following?

- The patient has decompensated cirrhosis
- The patient has genotype 2 or 3
- The patient will be taking sofosbuvir/velpatasvir (Epclusa) in combination with ribavirin.
- The patient is 18 years or older.

If yes, **approve for 12 weeks by HICL for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

11. Does the patient have decompensated cirrhosis?

If yes, continue to #12

If no, do not approve



WELLFLEET

RX PLAN

PRIOR AUTHORIZATION GUIDELINES

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

SOFOSBUVIR/VELPATASVIR

GUIDELINES FOR USE (CONTINUED)

12. Is the patient treatment experienced with a sofosbuvir (Sovaldi) or NS5A-containing regimen?

If yes, continue to #13

If no, continue to #14

13. Will the patient be taking sofosbuvir/velpatasvir (Epclusa) in combination with ribavirin?

If yes, **approve for 24 weeks by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

14. Will the patient be taking in combination with ribavirin?

If yes, **approve for 12 weeks by HICL with a quantity limit of #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline for **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires a diagnosis of hepatitis C. The following criteria must also be met.

- Patient has genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient is at least 6 years old and weighs at least 17 kg (37 pounds)
- Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Documentation of HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)
- Pediatric patients age 6 and older who weigh between 17 kg (37 pounds) and 45 kg (99 pounds) with genotype 1, 2, 3, 4, 5, 6 and either no cirrhosis or compensated cirrhosis. (Please note: for pediatric patients weighing at least 45 kg, the preferred product is Mavyret).
- For patients with genotype 1, 2, 3, 4, 5, or 6 and decompensated cirrhosis, the patient must be using a ribavirin-containing regimen.
- Patient is post-liver transplant with genotype 2 or 3 and decompensated cirrhosis, will be taking a ribavirin-containing regimen, and is 18 years or older.

Epclusa will not be approved for the following patients:

- Patient using any of the following medications concurrently while on Epclusa: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

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PRIOR AUTHORIZATION GUIDELINES**SOFOSBUVIR/VELPATASVIR****RATIONALE**

Ensure appropriate utilization of Epclusa (sofosbuvir/velpatasvir).

FDA APPROVED INDICATIONS

For the treatment of chronic hepatitis C genotype 1-6 infection in adults.

REFERENCES

- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed January 2, 2019.
- Epclusa [Prescribing Information]. Foster City, CA: Gilead Sciences; June 2016.

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 01/2020	02/2020	04/01/2020
Revised 05/2020	05/2020	5/22/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

STATIN ZERO COST SHARE OVERRIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ROSUVASTATIN	CRESTOR, EZALLOR SPRINKLE		19153 20229 39996 38314	GPI-14 (39400060100305) (39400060100310) (39400060106805) (39400060106810)	
PRAVASTATIN	PRAVACHOL	06227		GPI-10 (3940006510)	
SIMVASTATIN	ZOCOR		26531 26532 26533 26534	GPI-14 (39400075000310) (39400075000320) (39400075000330) (39400075000340)	
ATORVASTATIN	LIPITOR		43720 43721	GPI-14 (39400010100310) (39400010100320)	
LOVASTATIN, LOVASTATIN EXTENDED- RELEASE	ALTOPREV	02793		GPI-10 (3940005000)	
FLUVASTATIN, FLUVASTATIN EXTENDED- RELEASE	LESCOL, LESCOL XL	08946		GPI-10 (3940003010)	
PITAVASTATIN CALCIUM	LIVALO	36983		GPI-10 (3940005810)	
PITAVASTATIN MAGNESIUM	ZYPITAMAG	44422		GPI-10 (3940005830)	

GUIDELINES FOR USE

1. Is the patient requesting a cost share exception for the requested low to moderate-intensity statin **AND** does the plan cover these agents at zero cost share (i.e., the plan follows Affordable Care Act [ACA] recommendations and is linked to MedImpact's Essential Health Benefit Tables)?

If yes, continue to #2.

If no, guideline does not apply.

CONTINUED ON NEXT PAGE

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****STATIN ZERO COST SHARE OVERRIDE****GUIDELINES FOR USE (CONTINUED)**

2. Does the patient's plan have specific procedures, instructions, and/or policies for cost share exception processes or for multi-source brand agent overrides (DAW1 override)?

If yes, guideline does not apply.

If no, continue to #3.

3. Is the patient between 40-75 years of age without a history of cardiovascular disease and has **NOT** used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on the patient's prescription claims profile or medical records?

- Aspirin/dipyridamole (Aggrenox)
- Clopidogrel (Plavix)
- Dipyridamole
- Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
- Prasugrel (Effient)
- Praluent Pen
- Repatha
- Ticagrelor (Brilinta)
- Ticlopidine
- Vorapaxar sulfate (Zontivity)

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the request for a single-source brand statin agent that has no preferred generic agents or therapeutically equivalent products available **AND** the physician has provided documentation confirming that the requested drug is considered as medically necessary (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)?

If yes, **approve for 12 months for the requested agent by GPID or GPI-14 at zero cost share.**

If no, continue to #5.

CONTINUED ON NEXT PAGE

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****STATIN ZERO COST SHARE OVERRIDE****GUIDELINES FOR USE (CONTINUED)**

5. Is the request for a brand agent (e.g., Atoprev, Zypitamag, Livalo, Lescol, Lescol XL, Lipitor, Zocor, Crestor, Ezallor Sprinkle, Pravachol) **AND** the physician has provided documentation that satisfies **ONE** of the following criteria?
- Two preferred products are medically inappropriate for the patient (alternatively, one if only one agent is available)
 - The patient has tried or has a documented medical contraindication to two preferred products (alternatively, a trial of one if only one agent is available)
 - The requested drug is considered as medically necessary (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)

If yes, **approve for 12 months for the requested agent by GPID or GPI-14 at zero cost share with the following quantity limits:**

- Atorvastatin (Lipitor): #1 per day.
- Fluvastatin (Lescol): #2 per day.
- Fluvastatin ER (Lescol XL): #1 per day.
- Lovastatin ER (Atoprev): #1 per day.
- Pitavastatin calcium (Livalo): #1 per day.
- Pitavastatin magnesium (Zypitamag): #1 per day.
- Pravastatin (Pravachol): #1 per day.
- Rosuvastatin (Crestor, Ezallor Sprinkle): #1 per day.
- Simvastatin (Zocor): #1 per day.

APPROVAL TEXT (applicable to multi-source brand agents only): Although your cost share has been reduced to zero-dollar, you may incur a dispense-as-written (DAW) penalty fee if you choose to fill a brand prescription instead of its generic equivalent.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

STATIN ZERO COST SHARE OVERRIDE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **STATIN ZERO COST SHARE OVERRIDE** requires that the following rules be met for approval:

- A. You are between 40 to 75 years of age without a history of cardiovascular disease (heart disease)
- B. You have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
 - 1. Aspirin/dipyridamole (Aggrenox)
 - 2. Clopidogrel (Plavix)
 - 3. Dipyridamole
 - 4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
 - 5. Prasugrel (Effient)
 - 6. Praluent Pen
 - 7. Repatha
 - 8. Ticagrelor (Brilinta)
 - 9. Ticlopidine
 - 10. Vorapaxar sulfate (Zontivity)
- C. **If the request is for a single-source brand (no generic available) statin that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:**
 - 1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)
- D. Your doctor provided documentation that satisfies **ONE** of the following:
 - 1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
 - 2. You have tried or have a documented medical contraindication (medical reason why you cannot take medication) to two preferred medications (or a trial of one if only one agent is available)
 - 3. The requested medication is considered medically necessary for you, (considerations may include severity of side effects and ability to adhere to the appropriate use of the item or service)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****STATIN ZERO COST SHARE OVERRIDE****RATIONALE**

This guideline applies to plans where the pharmacy benefit allows for coverage of low-to-moderate intensity statins at zero copay. The override criteria allow patient access to all FDA-approved statins at zero copay by waiving the applicable cost-sharing for branded or non-preferred branded statins.

In November 2016, the US Preventive Services Task Force (USPSTF) issued its final recommendations on statin use for the primary prevention of cardiovascular disease (CVD) in adults. CVD is a broad term that includes a number of conditions such as coronary heart disease and cerebrovascular disease, which ultimately manifest as heart attack and stroke, respectively. CVD is the leading cause of morbidity and mortality in the US, accounting for one out of every three deaths among adults.

Based on the well-established benefit of statin therapy in reducing the risk of CVD events and mortality, the USPSTF now recommends that adults without a history of CVD use a low- to moderate-dose statin for the primary prevention of CVD events and mortality when all of the following criteria are met (Grade B recommendation):

- (1) Age 40 to 75 years
- (2) One or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking)
- (3) Calculated 10-year risk of a cardiovascular event of 10% or greater

Under the Affordable Care Act (ACA), plans are required to cover USPSTF preventive recommendations that have an A or B rating.

In light of USPSTF recommendations, MedImpact has created an edit to allow for a zero copay to be approved for all low- to moderate-intensity statins for qualifying members. This edit is not applicable to Medicare Part D formularies.

REFERENCES

- U.S. Preventive Services Task Force [Final Summary]. Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication. Updated November 2016. Available at: <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/statin-use-in-adults-preventive-medication1>. Accessed December 2017.
- U.S. Department of Labor. Affordable Care Act Implementation Frequently Asked Questions. Available at: <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs>. Accessed December 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/08/20

Created: 12/17

Client Approval: 05/20

P&T Approval: 01/20



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

NIMODIPINE SOLUTION

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nymalize.

REFERENCES

- Nymalize [Prescribing Information]. Atlanta, GA: Arbor Pharmaceuticals, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 05/15/20

Created: 08/13

Client Approval: 09/17

P&T Approval: 07/20

PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

Generic	Brand	HICL	GCN	Exception/Other
IMMUNE GLOBULIN	BIVIGAM, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	04202 41798 41995		
IMMUNE GLOB, GAM CAPRYLATE	GAMUNEX-C, GAMMAKED	25631		
IMMUNE GLOBULIN / MALTOSE	OCTAGAM	33220		
IGG/HYALURONIDA SE, RECOMBINANT	HYQVIA	41391		
IMMUN GLOB G(IGG)/GLY/IGA OV50	CUVITRU	41796		
IMMUN GLOB G(IGG)- IFAS/GLYCINE	PANZYGA	45354		
IMMUN GLOB G(IGG)- HIPPI/MALTOSE	CUTAQUIG	45734		
IMMUNE GLOBULIN (HUMAN)-KLHW	XEMBIFY	45891		

This drug must be reviewed by a pharmacist.

GUIDELINES FOR USE

1. Is the request for use as a subcutaneous injection?

If yes, continue to #2.

If no, continue to #5.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

2. Is the request for Hizentra and will be used for **ONE** of the following diagnoses?

- Primary immunodeficiency disease (PID)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

If yes, **approve for 12 months by GPID.**

If no, continue to #3.

3. Is the request for Gammagard Liquid, Cuvitru, Gamunex-C, Gammaked, Hyqvia, Cutaquig, or Xembify? (**NOTE:** Gammagard Liquid, Gamunex-C and Gammaked may be given via SC or IV route.)

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a primary immunodeficiency disease (PID)?

If yes, **approve the requested agent for 12 months as follows:**

- **Gammagard Liquid, Gamunex-C or Gammaked: Approve by NDC.**
- **Cuvitru: Approve by HICL.**
- **Hyqvia, Cutaquig, or Xembify: Approve by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

5. Is the request for use as an intravenous (IV) injection or intramuscular (IM) injection?

If yes, continue to #6.

If no, guideline does not apply.

6. Is the request for Cuvitru, Hizentra, Hyqvia or Xembify? (**NOTE:** Cuvitru, Hizentra, Hyqvia and Xembify are indicated only for SC route)

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #7.

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PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

7. Is the request for Gamastan S/D? (**NOTE:** Gamastan S/D is indicated for intramuscular use only)

If yes, continue to #8.

If no, continue to #9.

8. Is Gamastan S/D being used for hepatitis A, measles, varicella, or rubella prophylaxis, or passive immunization?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

9. Does the patient have **ONE** of the following diagnoses?
- Primary Immunodeficiency Disease (PID)
 - Idiopathic Thrombocytopenic Purpura (ITP)
 - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
 - Multifocal Motor Neuropathy (MMN)
 - Kawasaki Syndrome
 - B-cell Chronic Lymphocytic Leukemia (CLL) with Hypogammaglobulinemia, Autoimmune Hemolytic Anemia (AIHA), Immune Thrombocytopenic Purpura (ITP), or pure Red Blood Cell Aplasia (PRCA)
 - Guillain-Barre Syndrome (GBS)
 - Myasthenia Gravis
 - Autoimmune Graves' Ophthalmopathy
 - Cytomegalovirus-induced Pneumonitis related to a solid organ transplant
 - Prevention of bacterial infection in an HIV-infected child
 - Reduction of secondary infections in pediatric HIV infections
 - Dermatomyositis or polymyositis
 - Autoimmune uveitis (Birdshot retinochoroidopathy)
 - Lambert-Eaton myasthenic syndrome
 - IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
 - Stiff-man syndrome
 - Neonatal sepsis
 - Rotaviral enterocolitis
 - Toxic shock syndrome
 - Enteroviral meningoencephalitis
 - Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
 - Autoimmune Mucocutaneous Blistering Disease (AMBD) (such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita)
 - Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
 - Pediatric acute-onset neuropsychiatric syndrome (PANS)

If yes, **approve the requested agent for 12 months as follows:**

- **Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Flebogamma DIF, Gammaplex, or Privigen: Approve by NDC.**
- **Gammagard S-D: Approve by NDC.**
- **Octagam: Approve by HICL**
- **Panzyga: Approve by HICL.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **IMMUNE GLOBULIN** requires the following rule(s) be met for approval:

- A. **For Gammagard Liquid, Gamunex-C, Gammaked, Bivigam, Flebogamma DIF, Gammagard S-D, Gammaplex, Privigen, Octagam, or Panzyga for intravenous (IV) injection**, approval requires you to have ONE of the following diagnoses:
1. Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
 2. Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
 3. Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
 4. Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)
 5. Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
 6. B-cell Chronic Lymphocytic Leukemia (blood and bone marrow cancer of immune cells) with Autoimmune Hemolytic Anemia (body destroys red blood cells more rapidly than it produces them), Immune Thrombocytopenic Purpura (decreased number of blood cells that prevent bleeding with increased easy bruising) OR Pure Red Cell Blood Aplasia (bone marrow stops making red blood cells)
 7. Guillain-Barre Syndrome (immune system attacks the nerves)
 8. Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
 9. Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
 10. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation) related to a solid organ transplant
 11. Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)-infected child
 12. Reduction of secondary infections in pediatric HIV infections
 13. Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
 14. Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
 15. Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
 16. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
 17. Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
 18. Neonatal sepsis (blood infection in infants)
 19. Rotaviral enterocolitis (severe diarrhea among infants and young children)



WELLFLEET
RX PLAN

PRIOR AUTHORIZATION GUIDELINES

20. Toxic shock syndrome (life-threatening complication of certain bacterial infections)
(Denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

IMMUNE GLOBULIN

GUIDELINES FOR USE (CONTINUED)

21. Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
 22. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
 23. Autoimmune Mucocutaneous Blistering Disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita
 24. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
 25. Pediatric acute-onset neuropsychiatric syndrome (PANS)
- B. For Gamastan S-D, approval requires:**
1. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella
- C. For Hizentra, approval requires:**
1. The medication is only for subcutaneous (under the skin) use
 2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak) OR chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
- D. For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:**
- The medication is only for subcutaneous (under the skin) use
 - You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)
- E. For Gammagard Liquid, Gamunex-C, or Gammaked for subcutaneous use, approval requires:**
1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES**IMMUNE GLOBULIN**

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monographs for the drugs listed in this guideline.

REFERENCES

- Bivigam [Prescribing Information]. Biotest Pharmaceuticals Co.: Boca Raton, FL. January 2017.
- Cuvitru [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. September 2016.
- Flebogamma 5% DIF [Prescribing Information]. Grifols: Barcelona, Spain. July 2017.
- Flebogamma 10% DIF [Prescribing Information]. Grifols: Barcelona, Spain. July 2017.
- Gamastan S/D [Prescribing Information]. Grifols: Research Triangle Park, NC. June 2017.
- Gammagard Liquid [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. March 2017.
- Gammagard S/D [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. March 2017.
- Gammaked [Prescribing Information]. Grifols: Research Triangle Park, NC. September 2016.
- Gammaplex 5% [Prescribing Information]. BPL Inc.: Durham, NC. December 2016.
- Gammaplex 10% [Prescribing Information]. BPL Inc.: Durham, NC. December 2016.
- Gamunex-C [Prescribing Information]. Grifols: Research Triangle Park, NC. March 2017.
- Hizentra [Prescribing Information]. CSL Behring LLC: Kankakee, IL. March 2018.
- Hyqvia [Prescribing Information]. Baxalta US Inc.: Westlake Village, CA. September 2016.
- Octagam 5% [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. April 2015.
- Octagam 10% [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. August 2015.
- Panzyga [Prescribing Information]. Octapharma USA Inc.: Hoboken, NJ. August 2018.
- Privigen [Prescribing Information]. CSL Behring LLC: Kankakee, IL. September 2017.
- Cutaquig [Prescribing Information]. Hoboken, NJ: Octapharma USA, Inc., May 2019.
- Xembify [Prescribing Information]. Research Triangle Park, NC: Grifols Therapeutics LLC; October 2019.



PRIOR AUTHORIZATION GUIDELINES

Created	FS Committee Approval	Effective
05/01/2020		5/22/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

Drugs listed in this document does not ensure coverage. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is intended for informational use only and is not intended to replace professional medical advice or treatment, or diagnose, treat, cure, or prevent any disease or medical condition. This document is subject to change.

CLOBAZAM-SYMPAZAN

Generic	Brand			
CLOBAZAM	SYMPAZAN			

GUIDELINES FOR USE

The guideline named CLOBAZAM-SYMPAZAN requires a diagnosis of Lennox-Gastaut Syndrome. The following criteria must also be met:

- ☐ The requested medication will be used for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (i.e., in combination with lamotrigine or topiramate)
- ☐ The patient is 2 years of age or older
- ☐ Physician attestation that the patient is unable to take tablets or suspension
- ☐ The patient has had a trial of or contraindication to generic/branded clobazam products (Onfi)

Commercial Effective: 04/01/19

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

APOMORPHINE – SL (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
APOMORPHINE	KYNMOBI	01934		GPI-10 (7320301010)	BRAND = KYNMOBI

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease AND meet the following criterion?

- Kynmobi is being used for the acute, intermittent treatment of "OFF" episodes

If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #5 per day.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for approval:

- You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
- The requested medication is being used for acute, intermittent treatment (sudden and periodic treatment) of "OFF" episodes (when symptoms return due to your medication for Parkinson's disease wearing off)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Kynmobi.

REFERENCES

Kynmobi [Prescribing Information]. Marlborough, MA: Sunovion Pharmaceuticals Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/19/20

Created: 06/20

Client Approval: 07/20

P&T Approval: 07/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEMPEDOIC ACID AND EZETIMIBE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEMPEDOIC ACID AND EZETIMIBE	NEXLIZET	46386		GPI-10 (3999100220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have **ONE** of the following diagnoses?
 - Established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)
 - Heterozygous familial hypercholesterolemia [HeFH]

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
 - The patient had a previous trial of ezetimibe
 - The patient has an LDL-cholesterol level greater than or equal to 70 mg/dL

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient meet **ONE** of the following criteria?
 - The patient had a trial of a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
 - The patient has been taking a maximally tolerated dose of any statin given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

If yes, continue to #4

If no, continue to #5.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BEMPEDOIC ACID AND EZETIMIBE****INITIAL CRITERIA (CONTINUED)**

4. Will the patient continue statin treatment as described above in combination with Nexlizet?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

APPROVAL TEXT: Renewal for established cardiovascular disease or heterozygous familial hypercholesterolemia [HeFH] requires the patient has experienced LDL-C lowering AND meets ONE of the following criteria: 1) The patient will continue therapy with a maximally tolerated dose of any statin, 2) The patient has an absolute contraindication to statin therapy, OR 3) The patient has complete statin intolerance.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?

- The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
- The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

APPROVAL TEXT: Renewal for established cardiovascular disease or heterozygous familial hypercholesterolemia [HeFH] requires the patient has experienced LDL-C lowering AND meets ONE of the following criteria: 1) The patient will continue therapy with a maximally tolerated dose of any statin, 2) The patient has an absolute contraindication to statin therapy, OR 3) The patient has complete statin intolerance.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BEMPEDOIC ACID AND EZETIMIBE****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol]

B. You are 18 years of age or older

C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You previously had a trial of ezetimibe

E. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL

F. **If you are statin tolerant, approval also requires:**

1. You will continue statin treatment in combination with Nexlizet
2. You meet ONE of the following:
 - a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
 - b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Initial denial text continued on the next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BEMPEDOIC ACID AND EZETIMIBE****INITIAL CRITERIA (CONTINUED)****G. If you are statin intolerant, approval also requires ONE of the following:**

1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of established cardiovascular disease OR heterozygous familial hypercholesterolemia [HeFH] and meet the following criterion?
 - The patient has experienced LDL-C lowering

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
 - The patient has continued therapy with a maximally tolerated dose of any statin
 - The patient has an absolute contraindication to statin therapy
 - The patient has complete statin intolerance

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BEMPEDOIC ACID AND EZETIMIBE****RENEWAL CRITERIA (CONTINUED)**

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
 - 1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
 - 2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)
- B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering
- C. You meet ONE of the following:
 - 1. You have continued therapy with a maximally tolerated dose of any statin
 - 2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
 - 3. You have complete statin intolerance

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nexlizet.

REFERENCES

Nexlizet [Prescribing Information]. Ann Arbor, MI: Esperion Therapeutics Inc., February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/15/20

Created: 06/20

Client Approval: 06/20

P&T Approval: 01/20

LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

OPIOID-BUPRENORPHINE CONCURRENT USE

Generic	Brand	HICL	GCN	Exception/Other
N/A	N/A	N/A	N/A	N/A

GUIDELINES FOR USE

- Is the claim rejecting with **ONE** of the following error codes?
 - REJ-433-1200 (DUR CONCURRENT USE): CLAIM CONFLICTS IN THERAPY WITH MEMBER HISTORY**
 - REJ-1064 (DUR DD DENY): DRUG-DRUG INTERACTION FOUND**

If yes, continue to #2.

If no, guideline does not apply.

- Does the patient meet at least **ONE** of the following criteria?

- Patient has a diagnosis of active cancer
- Patient is in hospice care
- Patient is receiving palliative care or end-of-life care
- Patient is a resident of a long-term care facility

If yes, **approve for 12 months by HICL with ONE of the following overrides:**

- **For DUR_CONCURRENT_USE Rejection: Set DUR_CONCURRENT_OVR to 'OP_BUP'**
- **For DUR_DD_DENY Rejection: Set DUR_DD_DENY to 'Y' for Yes**

If the claim analysis continues to reject, follow the clinical coverage determination process.

If no, continue to #3.

- Has the prescriber provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and needs to resume chronic opioid treatment? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

If yes, **approve for 4 months by HICL with ONE of the following overrides:**

- **For DUR_CONCURRENT_USE Rejection: Set DUR_CONCURRENT_OVR to 'OP_BUP'**
- **For DUR_DD_DENY Rejection: Set DUR_DD_DENY to 'Y' for Yes**

If the claim analysis continues to reject, follow the clinical coverage determination process.

If no, continue to #4.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**OPIOID-BUPRENORPHINE CONCURRENT USE****GUIDELINES FOR USE**

4. Is the prescriber aware that the patient is currently receiving buprenorphine or buprenorphine-containing agents for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication? (**NOTE:** Consultation with an addiction medicine specialist is recommended)

If yes, **approve for 30 days by HICL with ONE of the following overrides:**

- **For DUR_CONCURRENT_USE Rejection: Set DUR_CONCURRENT_OVR to 'OP_BUP'**
- **For DUR_DD_DENY Rejection: Set DUR_DD_DENY to 'Y' for Yes**

If the claim analysis continues to reject, follow the clinical coverage determination process.

If no, do not approve.

OPTIONAL OPERATIONAL DENIAL TEXT FOR APPROVAL OF CLINICAL UM, BUT DENIAL OF THE OPIOID SAFETY EDIT: While your request for [enter approved UM] for [enter requested drug] has been granted, the drug has not been approved because of the use of an opioid drug and a buprenorphine-containing drug together. **[Proceed to enter Denial Text below]**

DENIAL TEXT: The guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** is for patients who are receiving an opioid with buprenorphine or a buprenorphine-containing agent. This guideline allows an approval for concurrent use of these medications when one of the following criteria is met:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility
- The prescriber is aware that the patient is currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has provided attestation to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended
- The prescriber has provided attestation that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and to proceed with opioid treatment. Consultation with an addiction medicine specialist is recommended

Please consult your physician and/or your pharmacist to discuss your options or if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES**OPIOID-BUPRENORPHINE CONCURRENT USE****RATIONALE**

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from CMS guidance. For further information, please refer to the Drug Monograph for Opioid-Buprenorphine Concurrent Use.

REFERENCES

- Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf> [Accessed 4/2/18].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/15/20

Created: 12/18

Client Approval: 06/20

P&T Approval: 10/18

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ABIRATERONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABIRATERONE ACETATE	ZYTIGA	37571		GPI-10 (2140601020)	
ABIRATERONE ACET, SUBMICRONIZED	YONSA	44946			

**** Please use the criteria for the specific drug requested ****

GUIDELINES FOR USE

ZYTIGA

1. Does the patient have **ONE** of the following diagnoses?

- Metastatic castration-resistant prostate cancer (mCRPC)
- Metastatic high-risk castration-sensitive prostate cancer (mCSPC)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the requested medication being used in combination with prednisone?

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**

- Zytiga 250mg: #8 per day.
- Zytiga 500mg: #4 per day.

If no, **approve for 12 months by GPID or GPI-14 with a quantity limit as follows:**

- Zytiga 250mg: #4 per day.
- Zytiga 500mg: #2 per day.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ABIRATERONE****GUIDELINES FOR USE - ZYTIGA (CONTINUED)**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE (Zytiga)** requires the following rule(s) be met for approval:

1. You have a diagnosis of metastatic castration-resistant prostate cancer (cancer that keeps growing after lowering testosterone levels in the body) **OR** metastatic high-risk castration-sensitive prostate cancer (cancer that spreads but may respond to lowering testosterone levels in the body)
2. The requested medication will be used in combination with prednisone

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

YONSA

1. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
 - The requested medication is being used in combination with methylprednisolone
 - The patient had a trial of or contraindication to Zytiga (abiraterone acetate)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the patient concomitantly using a strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital)?

If yes, **approve for 12 months by HICL or GPI-14 with a quantity limit of #8 per day.**

If no, **approve for 12 months by HICL or GPI-14 with a quantity limit of #4 per day.**

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****ABIRATERONE****GUIDELINES FOR USE - YONSA (CONTINUED)**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABIRATERONE (Yonsa)** requires the following rule(s) be met for approval:

1. You have metastatic castration-resistant prostate cancer (cancer that continues to spread after using hormone therapy)
2. The requested medication will be used in combination with methylprednisolone
3. You have previously tried or have a contraindication to (medical reason why you cannot use) Zytiga (abiraterone acetate)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Yonsa and Zytiga.

REFERENCES

- Yonsa [Prescribing Information]. Sun Pharma. Cranbury, NJ. June 2018.
- Zytiga [Prescribing Information]. Horsham, PA. Janssen Biotech; June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/13/20

Created: 06/11
Client Approval: 07/20

P&T Approval: 07/18

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

AVELUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AVELUMAB	BAVENCIO	44170		GPI-10 (2135302000)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic Merkel cell carcinoma (MCC) and meet the following criterion?

- The patient is 12 years or older

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #2.

- Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma (UC) and meet **ONE** of the following criteria?
 - The patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient does not have disease progression with first-line platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The requested medication will be used as first-line maintenance treatment

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #3.

- Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?
 - The requested medication will be used as first-line treatment
 - The requested medication will be used in combination with axitinib

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it

Our guideline named **AVELUMAB (Bavencio)** requires the following rules be met for approval:

A. You have **ONE** of the following diagnoses:

- Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
- Locally advanced or metastatic (disease that has spread) urothelial carcinoma (UC: type of urinary system cancer)
- Advanced renal cell carcinoma (RCC: type of kidney cancer)

(Denial text continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****AVELUMAB (NSA)****GUIDELINES FOR USE (CONTINUED)**

- B. If you have metastatic Merkel Cell Carcinoma, approval also requires:**
1. You are 12 years of age or older
- C. If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
1. Your disease has worsened during or after platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 2. Your disease has worsened within 12 months of neoadjuvant (treatment given before a main treatment) or adjuvant treatment (add-on to a main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 3. Your disease has not worsened with first-line platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 - a. The requested medication will be used as first-line maintenance treatment
- D. If you have advanced renal cell carcinoma, approval also requires:**
1. The requested medication will be used as first-line treatment
 2. The requested medication will be used in combination with axitinib

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bavencio.

REFERENCES

- Bavencio [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/13/20

Created: 04/17

Client Approval: 07/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE ACETATE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OCTREOTIDE ACETATE	BYNFEZIA		47454	GPI-10 (3017007010)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acromegaly and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication is being used to reduce blood levels of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C]
 - The patient had an inadequate response to or cannot be treated with **ALL** of the following
 - Surgical resection
 - Pituitary irradiation
 - Bromocriptine mesylate at maximally tolerated doses

If yes, **approve for 12 months by GPID.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic carcinoid tumors and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient is being treated for severe diarrhea and flushing episodes associated with metastatic carcinoid tumors

If yes, **approve 12 months by GPID.**

If no, continue to #3.

3. Does the patient have a diagnosis of vasoactive intestinal peptide tumors (VIPomas) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient is being treated for profuse watery diarrhea associated with VIP-secreting tumors

If yes, **approve 12 months by GPID.**

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

OCTREOTIDE ACETATE (INTERIM)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OCTREOTIDE ACETATE (Bynfezia)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
 2. Metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
 3. Vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)
- B. **If you have acromegaly, approval also requires:**
1. You are 18 years of age or older
 2. The requested medication is being used to reduce blood levels of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C]
 3. You had an inadequate response to or cannot be treated with **ALL** of the following:
 - i. Surgical resection (removal by surgery)
 - ii. Pituitary irradiation (radiation therapy directed at the pituitary)
 - iii. Bromocriptine mesylate at maximally tolerated doses
- C. **If you have metastatic carcinoid tumors, approval also requires:**
1. You are 18 years of age or older
 2. You are being treated for severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
- D. **If you have vasoactive intestinal peptide tumors (VIPomas), approval also requires:**
1. You are 18 years of age or older
 2. You are being treated for profuse watery diarrhea associated with VIP-secreting tumors

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bynfezia.

REFERENCES

Bynfezia [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries Inc., January 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Created: 06/20

Commercial Effective: 07/03/20

Client Approval: 07/20

P&T Approval: 07/20

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BUROSUMAB-TWZA (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUROSUMAB-TWZA	CRYSVITA	44867		GPI-10 (3090951060)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of X-linked hypophosphatemia (XLH) confirmed by **ONE** of the following criteria?
 - The patient has XLH symptoms (e.g., osteomalacia, excessive fractures, bowed legs, impaired growth) and **ONE** of the following:
 - The patient has a serum phosphate level of < 3.2 mg/dL in pediatric patients or <2.5 mg/dL in adults **with** normal vitamin D levels
 - The patient has shown hyperexpression of FGF23 protein on assay
 - The patient possesses family history of XLH
 - Genotyping confirmation of the *PHEX* mutation causative of XLH

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
 - The patient is 6 months of age or older
 - The patient is NOT on concurrent oral phosphate salt or active vitamin D analog supplementation
 - The medication is prescribed by or given in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #3mL per 14 days.**

APPROVAL TEXT: Renewal requires that the patient achieves normalized phosphate levels as defined by reference range for age.

If no, continue to #3.

3. Does the patient have a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - The disease is associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 14 days.**

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BUROSUMAB-TWZA (NSA)****INITIAL CRITERIA (CONTINUED)**

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **BUROSUMAB (Crysvita)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. X-linked hypophosphatemia (XLH: inherited disorder with low phosphate blood levels)
2. Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

B. **If you have X-linked hypophosphatemia (XLH), approval also requires:**

1. You are 6 months of age or older
2. You will not be taking oral phosphate salt or active vitamin D analog supplementation with requested medication
3. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformities), or medical geneticist
4. Your diagnosis is confirmed by ONE of the following:
 - a. You have XLH symptoms such as osteomalacia (bone softening), excessive fractures, bowed legs, impaired growth and ONE of the following:
 - i. If you are less than 18 years of age, your serum phosphate level is less than 3.2 mg/dL with normal vitamin D levels
 - ii. If you are 18 years of age or older, your serum phosphate level is less than 2.5 mg/dL with normal vitamin D levels
 - iii. You have more than normal amount of FGF23 protein on assay (type of lab analysis)
 - iv. You have a family history of X-linked hypophosphatemia
 - b. You have a *PHEX* mutation (Phosphate-regulating neutral endopeptidase, X-linked) confirmed by a genotyping (type of test)

C. **If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO), approval also requires:**

1. You are 2 years of age or older
2. Your disease is associated with phosphaturic mesenchymal tumors (tumors that overproduce fibroblast growth factor 23) that cannot be curatively resected (surgically removed) or localized

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BUROSUMAB-TWZA (NSA)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of X-linked hypophosphatemia (XLH) **AND** meet the following criterion?
 - The patient has achieved normal blood phosphate levels as defined by reference range for age

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3mL per 14 days.**
If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BUROSUMAB (Crysvita)** requires the following rules be met for renewal:

- A. You have a diagnosis of X-linked hypophosphatemia (XLH: inherited disorder with low phosphate blood levels)
- B. You have achieved normal blood phosphate levels as defined by the reference range for your age

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Crysvita.

REFERENCES

- Crysvita [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc. June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/13/20

Created: 08/18

Client Approval: 06/20

P&T Approval: 07/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

INEBILIZUMAB-CDON (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INEBILIZUMAB-CDON	UPLIZNA	46617		GPI-10 (9940504020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient is anti-aquaporin-4 (AQP4) antibody positive

If yes, **approve for 12 months by HICL or GPI-10 as follows:**

- **LOADING DOSE:** Approve for 1 month with a quantity limit of #60mL per 28 days.
- **MAINTENANCE DOSE:** Approve for 11 months with a quantity limit of #30mL per 180 days x 2 fills. (Please enter start date of 5 months after the end date of the first approval)

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** requires the following rule(s) be met for approval:

- A. You have neuromyelitis optica spectrum disorder (a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
- B. You are 18 years of age or older
- C. You are anti-aquaporin-4 (AQP4: type of protein) antibody positive

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Uplizna.

REFERENCES

Uplizna [Prescribing Information]. Gaithersburg, MD: Viela Bio, Inc., June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/03/20

Created: 06/20

Client Approval: 07/20

P&T Approval: 07/20

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PRIOR AUTHORIZATION GUIDELINES**LEDIPASVIR/SOFOSBUVIR**

Generic	Brand	HICL	GCN	Exception/Other
LEDIPASVIR/SOFOSBUVIR	HARVONI	41457		

*******Customer Service/PAC Alert*******
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

HEPATITIS C FORMULARY PREFERRED PRODUCT IS MAVYRET. PLEASE FOLLOW GUIDELINE LANGUAGE CLOSELY.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of chronic hepatitis C, with genotype 1, genotype 4, genotype 5, or genotype 6?

If yes, continue to #2.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.
2. Does the patient have a recent HCV infection documented by **ONE** detectable HCV RNA level within the last 6 months?

If yes, continue to #3.
If no, do not approve.
DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PRIOR AUTHORIZATION GUIDELINES**LEDIPASVIR/SOFOSBUVIR****GUIDELINES FOR USE (CONTINUED)**

3. Is the patient currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model?

If yes, continue to #4.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

4. Is the patient currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or tipranavir/ritonavir?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #5.

5. Does the patient have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation)?

If yes, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

If no, continue to #6.

6. Is the request for a pediatric patient aged 3 to 17 years weighing less than 35 kg?

If yes, continue to #7

If no, continue to #11

7. Does the patient meet ONE of the following:
- Genotype 1, 4, 5, or 6 and is treatment naïve with no cirrhosis or compensated (Child Pugh A) cirrhosis
 - Genotype 1, 4, 5, or 6 and is treatment experienced with no cirrhosis
 - Genotype 4, 5, or 6 and is treatment experienced with compensated (Child Pugh A) cirrhosis.

If yes, **approve based on patient weight**

If weight is 17 to 34 kg: approve Harvoni 45/200 mg (GPID 46868 or 46885) for 12 weeks for 1 tablet/packet per day.

If weight is less than 17 kg: approve Harvoni 33.75/150 (GPID 46886) for 12 weeks for 1 packet per day

If no, continue to #8



PRIOR AUTHORIZATION GUIDELINES

8. Does the patient meet ONE of the following:
- Genotype 1 and has decompensated (Child Pugh B or C) cirrhosis
 - Genotype 1 or 4; is status post liver transplant with no or compensated (Child Pugh A) cirrhosis

If yes, continue to #9

If no, continue to #10

9. Will the patient be using the requested medication with ribavirin?

If yes, **approve based on patient weight**

If weight is 17 to 34 kg: Approve Harvoni 45/200 mg (GPID 46868 or 46885) for 12 weeks for 1 tablet/packet per day.

If weight is less than 17 kg: Approve Harvoni 33.75/150 mg (GPID 46886) for 12 weeks for 1 packet per day.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

10. Does the patient have genotype 1 with compensated (Child Pugh A) cirrhosis, is treatment experienced, and will be taking the medication with ribavirin?

If yes, **approve based on patient weight**

If weight is 17 to 34 kg: Approve Harvoni 45/200 mg (GPID 46868 or 46885) for 12 weeks for 1 tablet/packet per day.

If weight is less than 17 kg: Approve Harvoni 33.75/150mg (GPID 46886) for 12 weeks for 1 packet per day

If no, **approve based on patient weight**

If weight is 17 to 34 kg: Approve Harvoni 45/200 mg (GPID 46868 or 46885) for 24 weeks for 1 tablet /packet per day.

If weight is less than 17 kg: Approve Harvoni 33.75/150mg (GPID 46886) for 24 weeks for 1 packet per day.

11. Is the patient a pediatric patient who weighs between 35 kg and 44 kg? **NOTE:** For pediatric patients weighing at least 45 kg (99 pounds) the preferred product is Mavyret.

If yes, continue to #12.

If no, continue to #15

12. Does the patient meet **ALL** the following criteria

- Treatment of genotype 1, 4, 5, or 6.
- Treatment naïve.
- Without cirrhosis **OR** with compensated cirrhosis (Child-Pugh A).

If yes, **approve Ledipasvir/Sofosbuvir 90/400 mg (GPID 37179) for 12 weeks for #1 tablet per day.**



WELLFLEET
RX PLAN

PRIOR AUTHORIZATION GUIDELINES

If no, continue to #13.

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PRIOR AUTHORIZATION GUIDELINES**LEDIPASVIR/SOFOSBUVIR****GUIDELINES FOR USE (CONTINUED)**

13. Does the patient meet **ONE** of the following?

- Genotype 1, treatment experienced with an interferon regimen, and no cirrhosis.
- Genotype 4, 5, or 6, treatment experienced with an interferon regimen without cirrhosis or with compensated cirrhosis (Child Pugh A).

If yes, **approve Ledipasvir/Sofosbuvir 90/400 mg (GPID 37179) for 12 weeks for #1 tablet per day.**

If no, continue to #14.

14. Does the patient meet all the following?

- Genotype 1.
- Treatment experienced with an interferon regimen.
- Compensated cirrhosis (Child Pugh A).

If yes, **approve Ledipasvir/Sofosbuvir 90/400 mg (GPID 37179) for 24 weeks for #1 tablet per day.**

If no, continue to #15.

15. Is the patient an adult and have hepatitis C post-liver transplant?

If yes, continue to #16.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

16. Does the patient have cirrhosis (compensated or decompensated)?

If yes, continue to #17.

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

17. Will the requested medication be taken in combination with ribavirin?

If yes, **approve Ledipasvir/Sofosbuvir 90/400 mg (GPID 37179) for 12 weeks for #1 tablet per day.**

If no, do not approve.

DENIAL TEXT: See denial text at the end of the guideline.

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PRIOR AUTHORIZATION GUIDELINES

LEDIPASVIR/SOFOSBUVIR

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires a diagnosis of hepatitis C. Please note that the preferred formulary product for patients weighing at least 45 kg (99 pounds) is Mavyret. The following criteria must also be met:

- Has genotype 1, genotype 4, genotype 5, or 6 hepatitis C
- The request is for one of the following:
 - a pediatric patient age 3 to 17 years weighing who is treatment naïve with no or compensated cirrhosis or is treatment experienced with no cirrhosis
 - a pediatric patient age 3 to 17 years with genotype 4, 5, or 6 who is treatment experienced with compensated cirrhosis
 - a pediatric patient age 3 to 17 years with genotype 1 who is treatment experienced with compensated cirrhosis and will be taking the medication with ribavirin
 - a pediatric patient age 3 to 17 years with genotype 1 who has decompensated cirrhosis and the requested medication will be taken in combination with ribavirin
 - a pediatric patient age 3 to 17 years with genotype 1 or 4 who is status post liver transplant with no or compensated cirrhosis and the requested medication will be taken in combination with ribavirin.
 - a pediatric patient weighing between 35 kg to 44 kg who is treatment naïve or treatment experienced with an interferon-containing regimen without cirrhosis or with compensated cirrhosis.
 - an adult with hepatitis C post-liver transplant with cirrhosis and the requested medication will be taken in combination with ribavirin.
- Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Documentation of HCV infection at least **ONE** detectable HCV RNA level within the last 6 months

Harvoni will not be approved for the following patients:

- Patient using any of the following medications concurrently while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or tipranavir/ritonavir
- Patient with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.

RATIONALE

Ensure appropriate utilization of Harvoni (sofosbuvir/ledipasvir).

LEDIPASVIR/SOFOSBUVIR

REFERENCES

- Afdhal N, Zeuzem S, Kwo P, Chojkier M, Gitlin N, et al. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. NEJM 2014; 370 (20): 1889-1898.

PRIOR AUTHORIZATION GUIDELINES

- Afdhal N, Reddy R, Nelson D, Lawitz E, Gordon S, et al. Ledipasvir and sofosbuvir for previously treated HCV genotype 1 infection. NEJM 2014; 370 (16): 1483-1493.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at <http://www.hcvguidelines.org/full-report-view> Accessed January 2, 2019.
- Harvoni [Prescribing Information]. Foster City, CA: Gilead Sciences; April 2017.
- Harvoni [Product Formulary Monograph]. Foster City, CA: Gilead Sciences; October 2014.
- Kowdley K, Gordon S, Reddy R, Rossaro L, Bernstein D, et al. Ledipasvir and sofosbuvir for 8 or 12 weeks for chronic HCV without cirrhosis. NEJM 2014; 370 (20): 1879-1888.

Created	FS Committee Approval	Effective
01/19	02/19	04/26/19
Revised 8/1/19	08/19	9/15/19
Revised 11/1/19	11/19	11/20/19
Revised 1/31/2020	02/2020	4/1/2020
Revised 6/10/2020		7/10/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

LURBINECTEDIN (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LURBINECTEDIN	ZEPZELCA	46626		GPI-10 (2110002400)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic small cell lung cancer (SCLC) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient experienced disease progression on or after platinum-based chemotherapy (e.g. carboplatin, cisplatin)

If yes, **approve for 12 months by HICL or GPI-10 for one fill per 21 days.**

If no, do not approve.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LURBINECTEDIN (Zepzelca)** requires the following rule(s) be met for approval:

- You have metastatic small cell lung cancer (SCLC: type of lung cancer that has spread to other parts of the body)
- You are 18 years of age or older
- You have experienced disease progression (worsening) on or after platinum-based chemotherapy (type of cancer medication)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zepzelca.

REFERENCES

Zepzelca [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/04/20

Created: 06/20

Client Approval: 07/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ELAGOLIX/ESTRADIOL/NORETHINDRONE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELAGOLIX AND ESTRADIOL AND NORETHINDRONE	ORIAHNN	46577		GPI-10 (2499350340)	

GUIDELINES FOR USE

1. Is the request for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND** the patient meets the following criterion?
 - The patient is premenopausal

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**
If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (OriaHnn)** requires the following rule(s) be met for approval:

- A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
- B. You are premenopausal

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for OriaHnn.

REFERENCES

OriaHnn [Prescribing Information]. North Chicago, IL: AbbVie Inc., May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/12/20

Created: 06/20

Client Approval: 07/20

P&T Approval: 07/20

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

OZANIMOD

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OZANIMOD	ZEPOSIA	46431		GPI-10 (6240705020)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient had a previous trial of ONE sphingosine-1-phosphate receptor modulator (e.g., Gilenya, Mayzent) **AND** any ONE agent indicated for the treatment of multiple sclerosis (MS)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **OZANIMOD (Zeposia)** requires the following rule(s) be met for approval:

- You have a relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
- You are 18 years of age or older
- You had a previous trial of ONE sphingosine-1-phosphate receptor modulator (such as Gilenya or Mayzent) **AND** any ONE agent indicated for the treatment of multiple sclerosis (**Please note:** Other multiple sclerosis agents may also require prior authorization)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Zeposia.

REFERENCES

- Zeposia [Prescribing Information]. Summit, NJ: Celgene Corporation, March 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 06/15/20

Created: 06/20

Client Approval: 06/20

P&T Approval: 01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES
PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PERTUZUMAB- TRASTUZUMAB-HY-ZZXF	PHESGO	46674		GPI-10 (2199000355)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of locally advanced, inflammatory, or early breast cancer (either greater than 2 cm in diameter or node positive) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient's breast cancer is HER2-positive
 - The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of early breast cancer at high risk of recurrence and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient's breast cancer is HER2-positive
 - The requested medication will be used in combination with chemotherapy in the adjuvant setting

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of metastatic breast cancer and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient's breast cancer is HER2-positive
 - The patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease
 - The requested medication is being used in combination with docetaxel

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #15mL per 21 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA) (INTERIM)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (Phesgo)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Locally advanced, inflammatory, or early breast cancer (tumor is greater than 2 cm in diameter or node positive)
 - 2. Early breast cancer at high risk of recurrence (returning)
 - 3. Metastatic breast cancer (breast cancer has spread to other parts of the body)
- B. **If you have locally advanced, inflammatory or early breast cancer (tumor is greater than 2 cm in diameter or node positive), approval also requires:**
 - 1. You are 18 years of age or older
 - 2. Your breast cancer is HER2-positive
 - 3. The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting (given before surgery)
- C. **If you have early breast cancer at high risk of recurrence, approval also requires:**
 - 1. You are 18 years of age or older
 - 2. Your breast cancer is HER2-positive
 - 3. The requested medication will be used in combination with chemotherapy in the adjuvant setting (given as add-on treatment)
- D. **If you have metastatic breast cancer, approval also requires:**
 - 1. You are 18 years of age or older
 - 2. Your breast cancer is HER2-positive
 - 3. You have not previously received anti-HER2 therapy or chemotherapy for metastatic disease
 - 4. The requested medication is being used in combination with docetaxel

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Phesgo.

REFERENCES

Phesgo [Prescribing Information]. South San Francisco, CA: Genentech, Inc., June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/10/20

Created: 07/20

Client Approval: 10/20

P&T Approval: 10/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

SELINEXOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELINEXOR	XPOVIO	45854		GPI-10 (2156006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma (RRMM) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The requested medication will be used in combination with dexamethasone
- The patient has received at least four prior therapies for the treatment of RRMM
- The patient's RRMM is refractory to **ALL** of the following:
 - Two proteasome inhibitors (e.g., bortezomib, carfilzomib)
 - Two immunomodulatory agents (e.g., lenalidomide, pomalidomide)
 - One anti-CD38 monoclonal antibody (e.g., daratumumab)

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Xpovio 60mg weekly dose: #12 per 28 days.
- Xpovio 80mg weekly dose: #16 per 28 days.
- Xpovio 100mg weekly dose: #20 per 28 days.
- Xpovio 160mg weekly dose: #32 per 28 days.

If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has received at least two lines of systemic therapy

If yes, approve for 12 months by GPID or GPI-14 for all strengths as follows:

- Xpovio 40mg weekly dose: #8 per 28 days
- Xpovio 60mg weekly dose: #12 per 28 days.
- Xpovio 80mg weekly dose: #16 per 28 days.
- Xpovio 120mg weekly dose: #24 per 28 days.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****SELINEXOR****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Relapsed or refractory multiple myeloma (RRMM: cancer of a type of white blood cells called plasma cells, that has return or did not respond to treatment)
 2. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of cancer that starts in the immune system), including DLBCL arising from follicular lymphoma
- B. You are 18 years of age or older
- C. **If you have relapsed or refractory multiple myeloma, approval also requires:**
1. The requested medication will be used in combination with dexamethasone
 2. You have received at least four prior therapies for the treatment of RRMM)
 3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
 - i. Two proteasome inhibitors (such as bortezomib, carfilzomib)
 - ii. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
 - iii. One anti-CD38 monoclonal antibody (such as daratumumab)
- D. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), approval also requires:**
1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xpovio.

REFERENCES

- Xpovio [Prescribing Information]. Newton, MA: Karyopharm Therapeutics Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/13/20

Created: 07/19

Client Approval: 07/20

P&T Approval: 07/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

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ACNE AGE RESTRICTION OVERRIDE

Generic	Brand				
ADAPALENE	DIFFERIN, PLIXDA				
ADAPALENE/BENZOYL PEROXIDE	EPIDUO, EPIDUO FORTE				
TRETINOIN	ATRALIN, AVITA, RETIN-A, TRETIN-X, ALTRENO				
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP				
TRIFAROTENE	AKLIEF				
TAZAROTENE	FABIOR, ARAZLO				

GUIDELINES FOR USE

Our guideline named ACNE AGE RESTRICTION OVERRIDE requires the following rule(s) be met for approval:

- A. You are 26 years of age or older
- B. The request is for a non-cosmetic (not for appearance) diagnosis.
- C. Approval may also require that you have tried preferred agent(s), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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AVAPRITINIB

Generic	Brand				
AVAPRITINIB	AYVAKIT				

GUIDELINES FOR USE

Our guideline named AVAPRITINIB (Ayvakit) requires the following rule(s) be met for approval:

- A. You have unresectable (cannot be removed completely through surgery) or metastatic (cancer that has spread to other parts of the body) gastrointestinal stromal tumor (GIST: type of growth in the digestive system tract, most commonly in the stomach or small intestine)
- B. You are 18 years of age or older
- C. You have a platelet-derived growth factor receptor alpha (PDGFRA: a type of gene/protein) exon 18 mutation, including PDGFRA D842V mutations (a change in your DNA that make up your gene)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

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BENRALIZUMAB

Generic	Brand			
BENRALIZUMAB	FASENRA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named BENRALIZUMAB (Fasenra) requires the following rule(s) be met for approval:

- A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
- B. You are 12 years of age or older
- C. Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
- D. Fasenra will be used as add-on maintenance treatment
- E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
- F. You had a prior therapy with medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as tiotropium), leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
- G. You have experienced at least ONE asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 or more days)
- H. You are NOT receiving concurrent treatment with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Cinqair)

RENEWAL CRITERIA

Our guideline named BENRALIZUMAB (Fasenra) requires the following rule(s) be met for renewal:

1. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
2. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
3. You have shown a clinical response as evidenced by ONE of the following:
 1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
 2. Decreased use of rescue medications
 3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
 4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

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BEXAROTENE

Generic	Brand				
BEXAROTENE SOFTGEL	TARGRETIN				
BEXAROTENE 1% TOPICAL GEL	TARGRETIN				

GUIDELINES FOR USE

Our guideline named BEXAROTENE (Targretin) requires the following rule to be met for approval:

- A. You have cutaneous T-cell lymphoma (CTCL: a type of cancer that starts in white blood cells and attacks the skin)
- B. If the request is for bexarotene capsules, approval also requires:
 1. Your condition is refractory (resistant) to previous systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or Velcade
- C. If the request is for topical bexarotene treatment, approval also requires:
 1. You have cutaneous T-cell lymphoma (CTCL) Stage IA or IB
 2. You meet ONE of the following:
 - a. Your condition is refractory or persistent after previous therapy
 - b. You have not tolerated previous therapy

Commercial Effective: 07/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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CAPECITABINE

Generic	Brand			
CAPECITABINE	XELODA			

GUIDELINES FOR USE

Our guideline named CAPECITABINE (Xeloda) requires the following rule(s) to be met for approval:

A. You have ONE of the following diagnoses:

1. Stage III (Duke's C) colon cancer (cancer has spread to lymph nodes)
2. Metastatic colorectal cancer (colon cancer that has spread)
3. Metastatic breast cancer (breast cancer that has spread)

B. If you have metastatic colorectal cancer, approval also requires:

1. Capecitabine is being used by itself OR in combination with oxaliplatin (CapeOX or XELOX regimen)

C. If you have metastatic breast cancer, approval also requires ONE of the following:

1. You have previously failed a trial of both paclitaxel AND an anthracycline -containing regimen
2. You have previously failed a trial of an anthracycline-containing regimen and capecitabine is being used in combination with docetaxel

Note: Required alternative regimens listed above may require prior authorization and may be covered under the medical benefit.

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

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CORTICOTROPIN

Generic	Brand				
CORTICOTROPIN	ACTHAR				

GUIDELINES FOR USE

Our guideline named CORTICOTROPIN (Acthar Gel) requires the following rule(s) be met for approval:

- A. You have infantile spasms (type of seizure disorder in young children)
- B. You are less than 2 years of age

For all other indications, consider the use of intravenous (IV) corticosteroids.

Other approved indications include:

1. Acute exacerbation (sudden worsening of symptoms) of multiple sclerosis
2. Rheumatic disorders (disease affecting joints in the body)
 - a. Psoriatic arthritis (joint pain and swelling with red scaly skin patches)
 - b. Rheumatoid arthritis (including juvenile rheumatoid arthritis)
 - c. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
3. Collagen disease (diseases associated with defects in collagen)
 - a. Systemic lupus erythematosus (condition where immune system attacks healthy tissue)
 - b. Systemic dermatomyositis (polymyositis; inflammatory disease with muscle weakness and skin rash)
4. Dermatologic disease (diseases relating to the skin)
 - a. Severe erythema multiforme (disorder affecting skin, mucous membranes, genitals and eyes)
 - b. Stevens-Johnson syndrome (rare, serious skin disorder)
5. Allergic disease
 - a. Serum sickness (immune system reaction to non-human proteins)
6. Ophthalmic disease (diseases involving the eye)
 - a. Severe acute and chronic allergic and inflammatory processes involving the eye and its parts (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)
7. Respiratory disease (disease involving the lungs)
 - a. Symptomatic sarcoidosis (abnormal collections of inflammatory cells in the lungs, skin or lymph nodes)
8. Edematous state (accumulation of excessive amount of fluid)
 - a. To induce a diuresis (increase urine production) or a remission (reduction) of proteinuria (protein in urine) in the nephrotic syndrome (kidney disorder that causes the body to pass too much protein in the urine) without uremia of the idiopathic type (high levels of waste products in the blood with no known cause), or that due to lupus erythematosus

Commercial Effective: 07/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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MEPOLIZUMAB

Generic	Brand			
MEPOLIZUMAB	NUCALA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named MEPOLIZUMAB (Nucala) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Severe asthma with an eosinophilic phenotype (inflammatory type)
 - 2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
- B. If you have eosinophilic granulomatosis with polyangiitis (EGPA), approval also requires:
 - 1. You are 18 years of age or older
- C. If you have severe asthma with an eosinophilic phenotype, approval also requires:
 - 1. You are 6 years of age or older
 - 2. Therapy is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/ breathing) medicine or allergy medicine
 - 3. Nucala will be used as add-on maintenance treatment
 - 4. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
 - 5. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
 - 6. You have experienced at least ONE asthma exacerbation (worsening of symptoms) within the past 12 months. Exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days
 - 7. You are not being treated on the requested medication concurrently (at the same time) with Xolair, Dupixent, or another anti-IL-5 asthma biologic (such as Cinqair, Fasenra)

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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MEPOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named MEPOLIZUMAB (Nucala) requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
 - 1. Severe asthma with an eosinophilic phenotype
 - 2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
- B. If you have severe asthma with an eosinophilic phenotype, renewal also requires:
 - 1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
 - 2. You have shown a clinical response as evidenced by ONE of the following:
 - a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
 - b. Decreased use of rescue medications
 - c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
 - d. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

Commercial Effective: 07/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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NINTEDANIB

Generic	Brand			
NINTEDANIB	OFEV			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named NINTEDANIB (Ofev) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. If you have idiopathic pulmonary fibrosis (IPF), approval also requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline
6. You are NOT receiving treatment with Esbriet

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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NINTEDANIB

INITIAL CRITERIA (CONTINUED)

- C. If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:
1. You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
 2. You are 18 years of age or older
 3. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
 4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT)
 5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40% of predicted value
 6. Other causes of interstitial lung disease are ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)
- D. If you have chronic fibrosing interstitial lung disease with progressive phenotype (PF-ILD), approval also requires:
1. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (ILD) (not caused by comorbidities such as infection, heart failure)
 2. You are 18 years of age or older
 3. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
 4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
 5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45% of predicted value

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STANDARD COMMERCIAL DRUG FORMULARY
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NINTEDANIB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

Our guideline named NINTEDANIB (Ofev) requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

Commercial Effective: 07/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE

Generic	Brand				
EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	TRUVADA				
EMTRICITABINE/TENOFOVIR ALAFENAMIDE FUMARATE	DESCOVY				
TENOFOVIR DISOPROXIL FUMARATE	VIREAD				
EMTRICITABINE	EMTRIVA				

GUIDELINES FOR USE

Our guideline named PRE-EXPOSURE PROPHYLAXIS ZERO COST SHARE OVERRIDE requires the following rule(s) be met for approval:

- A. The requested pre-exposure prophylaxis (PrEP) medication is FDA (Food and Drug Administration) approved for PrEP or recommended by the CDC (Centers for Disease Control and Prevention) PrEP Guidelines
- B. If the request is for a single-source brand (no generic available) PrEP medication that has no preferred generic drugs or therapeutically equivalent (drugs with similar effect) drugs available, approval also requires:
 1. Your doctor has provided documentation confirming the requested drug is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)
- C. Your doctor has provided documentation supporting ONE of the following:
 1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
 2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
 3. The requested medication is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)

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TEDUGLUTIDE

Generic	Brand			
TEDUGLUTIDE	GATTEX			

GUIDELINES FOR USE

Our guideline named TEDUGLUTIDE (Gattex) requires the following rule(s) be met for approval:

- A. You have short bowel syndrome (SBS; your body is unable to absorb nutrients from the foods you eat due to a lack of a functional small intestine)
- B. You are 1 year of age or older
- C. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

Commercial Effective: 07/01/20



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BEMPEDOIC ACID

Generic	Brand				
BEMPEDOIC ACID	NEXLETOL				

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named BEMPEDOIC ACID (Nexletol) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque build up causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])

B. You are 18 years of age or older

C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You previously had a trial of or contraindication (a medical reason why you cannot use) to ezetimibe

E. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL

F. If you are statin tolerant, approval also requires:

1. You will continue statin treatment in combination with Nexletol
2. You meet ONE of the following:
 - a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
 - b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

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STANDARD COMMERCIAL DRUG FORMULARY
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BEMPEDOIC ACID

INITIAL CRITERIA (CONTINUED)

- G. If you are statin intolerant, approval also requires ONE of the following:
1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
 2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named BEMPEDOIC ACID (Nexletol) requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
 2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)
- B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering
- C. You meet ONE of the following:
1. You have continued therapy with a maximally tolerated dose of any statin
 2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
 3. You have complete statin intolerance

Commercial Effective: 07/01/20

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BRIGATINIB

Generic	Brand			
BRIGATINIB	ALUNBRIG			

GUIDELINES FOR USE

Our guideline named BRIGATINIB (Alunbrig) requires the following rule(s) be met for approval:

- A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
- B. You are 18 years of age or older
- C. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA) as detected by a Food and Drug Administration (FDA)-approved test

Commercial Effective: 07/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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OLAPARIB

Generic	Brand			
OLAPARIB	LYNPARZA			

GUIDELINES FOR USE

Our guideline named OLAPARIB (Lynparza) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Advanced ovarian cancer
2. Recurrent or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal (abdomen) cancer
3. HER2-negative (you do not have a certain gene mutation) metastatic breast cancer (breast cancer that has spread to other parts of the body)
4. Metastatic pancreatic adenocarcinoma (cancer of the pancreas that has spread to other parts of the body)
5. Metastatic castration-resistant prostate cancer (mCRPC) (cancer of the prostate that has spread to other parts of the body and does not respond to hormone therapy)

B. If you have advanced ovarian cancer, approval also requires:

1. You are 18 years of age or older
2. The requested medication will be used as monotherapy (used alone for treatment)
3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
4. You have been treated with at least three prior lines of chemotherapy (such as, paclitaxel, docetaxel, cisplatin, carboplatin)

C. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. The requested medication will be started no later than 8 weeks after your most recent platinum-containing regimen
3. You are in complete or partial response to your most recent platinum-based chemotherapy
4. You have completed at least two or more lines of platinum-based chemotherapy
5. The requested medication will be used alone for maintenance treatment

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

- D. If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
1. You are 18 years of age or older
 2. The requested medication will be used for maintenance treatment
 3. You are in complete or partial response to first-line platinum-based chemotherapy
 4. You meet ONE of the following:
 - a. You have a deleterious or suspected deleterious germline or somatic BRCA mutation (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
 - b. Your cancer is homologous recombination deficiency (HRD: type of gene mutation) positive
 - i. HRD status is defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
 - ii. Lynparza will be used in combination with bevacizumab
- E. If you have HER2-negative (you do not have a certain gene mutation) metastatic breast cancer, approval also requires:
1. You are 18 years of age or older
 2. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
 3. You have been treated with chemotherapy in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
 4. If you have hormone receptor (HR)-positive breast cancer, you must have had prior treatment with endocrine (hormone) therapy or be considered inappropriate for endocrine therapy
- F. If you have metastatic pancreatic adenocarcinoma (type of cancer), approval also requires:
1. You are 18 years of age or older
 2. The requested medication will be used for maintenance treatment
 3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
 4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen
- (Criteria continued on next page)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

- G. If you have metastatic castration-resistant prostate cancer, approval also requires:
1. You are 18 years of age or older
 2. You have a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation that causes a change in your DNA that make up your gene) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
 3. Your disease has progressed following prior treatment with enzalutamide or abiraterone

Commercial Effective: 07/01/20



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RUCAPARIB

Generic	Brand			
RUCAPARIB	RUBRACA			

GUIDELINES FOR USE

Our guideline named RUCAPARIB (Rubraca) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that affects the abdomen or a woman's sex organs)
2. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer returns and affects the abdomen or a woman's sex organs)
3. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic) confirmed by Food and Drug Administration (FDA)-approved test for Rubraca
3. You have been treated with two or more chemotherapies such as paclitaxel, docetaxel, cisplatin, carboplatin

C. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. You are in a complete or partial response to platinum based-chemotherapy
3. The requested medication will be used for maintenance treatment

D. If you have metastatic castration-resistant prostate cancer (mCRPC), approval also requires:

1. You are 18 years of age or older
2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic)
3. You have been treated with androgen receptor-directed therapy AND a taxane-based chemotherapy

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY
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AXITINIB

Generic	Brand			
AXITINIB	INLYTA			

GUIDELINES FOR USE

Our guideline named AXITINIB (Inlyta) requires the following rule(s) be met for approval:

- A. You have advanced renal cell carcinoma (RCC; type of kidney cancer)
- B. You also meet ONE of the following:
 - 1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
 - 2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
 - 3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

Commercial Effective: 07/01/20



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POMALIDOMIDE

Generic	Brand			
POMALIDOMIDE	POMALYST			

GUIDELINES FOR USE

Our guideline named POMALIDOMIDE (Pomalyst) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Multiple myeloma (MM: cancer that forms in your white blood cells)
 - 2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)
- B. If you have multiple myeloma, approval also requires:
 - 1. You are 18 years of age or older
 - 2. The requested medication is used in combination with dexamethasone
 - 3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])
- C. If you have Kaposi sarcoma, approval also requires:
 - 1. You are 18 years of age or older
 - 2. You meet ONE of the following:
 - a. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
 - b. You are human immunodeficiency virus (HIV)-negative

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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AFAMELANOTIDE (NSA)

Generic	Brand				
AFAMELANOTIDE	SCENESSE				

GUIDELINES FOR USE

Our guideline named AFAMELANOTIDE (Scenesse) requires the following rule(s) be met for approval:

- A. You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
- B. You are 18 years of age or older
- C. You have a history of phototoxic reactions (damage to the skin)
- D. The requested medication will be used to increase pain free light exposure

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
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ISATUXIMAB-IRFC (NSA)

Generic	Brand				
ISATUXIMAB-IRFC	SARCLISA				

GUIDELINES FOR USE

Our guideline named ISATUXIMAB-IRFC (Sarclisa) requires the following rule(s) be met for approval:

- A. You have multiple myeloma (plasma cell cancer)
- B. You are 18 years of age or older
- C. The requested medication will be used in combination with pomalidomide and dexamethasone
- D. You have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as ixazomib, carfilzomib)

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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NUSINERSEN (NSA)

Generic	Brand			
NUSINERSEN	SPINRAZA			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named NUSINERSEN (Spinraza) requires the following rule(s) be met for approval:

- A. You have Spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
- B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of gene mutation analysis with bi-allelic survival motor neuron (SMN1: type of protein in spinal cord) mutations such as deletions and/or point mutations
- C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
- D. If you are presymptomatic (symptoms have not yet appeared), approval also requires:
 1. There is documentation showing you have up to three copies of survival motor neuron (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
- E. If you are symptomatic, approval also requires:
 1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
 2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
 3. For patients who had previous gene therapy: you experienced less than expected clinical benefit with gene therapy

RENEWAL CRITERIA

Our guideline named NUSINERSEN (Spinraza) requires the following rule(s) be met for renewal:

- A. You have Spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
- B. You meet ONE of the following:
 1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
 2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

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RESLIZUMAB (NSA)

Generic	Brand			
RESLIZUMAB	CINQAIR			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named RESLIZUMAB (Cinqair) requires the following rule(s) be met for approval:

- A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
- B. You are 18 years of age or older
- C. Cinqair is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
- D. Cinqair will be used as add-on maintenance treatment
- E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
- F. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
- G. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- H. You are not being treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Fasenra) at the same time with requested medication

RENEWAL CRITERIA

Our guideline named RESLIZUMAB (Cinqair) requires the following rule(s) be met for renewal:

- A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
- B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
- C. You have shown a clinical response as evidenced by ONE of the following:
 1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
 2. Decreased use of rescue medications
 3. Increase in percent predicted FEV1 (type of lung test) from pretreatment baseline
 4. Reduction in severity or frequency of asthma-related symptoms such as wheezing, shortness of breath, coughing, etc.

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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TEPROTUMUMAB-TRBW (NSA)

Generic	Brand				
TEPROTUMUMAB-TRBW	TEPEZZA				

GUIDELINES FOR USE

Our guideline named TEPROTUMUMAB-TRBW (Tepezza) requires the following rule(s) be met for approval:

- A. You have thyroid eye disease (a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards)

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

Generic	Brand			
TRASTUZUMAB	HERCEPTIN			
TRASTUZUMAB-HYALURONIDASE-OYSK	HERCEPTIN HYLECTA			

GUIDELINES FOR USE

Our guideline named TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (Herceptin, Herceptin Hylecta) requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
 2. Breast cancer
 3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)
- B. If you have metastatic breast cancer, approval also requires:
 1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
 2. You meet ONE of the following:
 - a. The requested medication is being used in combination with paclitaxel for first-line treatment
 - b. The requested medication is being used as a single agent if you have previously tried chemotherapy for metastatic disease (disease has spread to other areas of body)
 3. If you are requesting Herceptin Hylecta, you must be 18 years of age or older
 4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri
- C. If you have breast cancer, approval also requires:
 1. The request is for adjuvant therapy (add-on therapy to main treatment)
 2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) tumor as detected by a Food and Drug Administration (FDA)-approved test
 3. You meet ONE of the following:
 - a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
 - c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
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TRASTUZUMAB/TRASTUZUMAB-HYALURONIDASE (NSA)

GUIDELINES FOR USE (CONTINUED)

4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri
5. If you are requesting Herceptin Hylecta, you must be 18 years of age or older
- D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma (stomach-throat cancer that has spread), approval also requires:
 1. The request is for Herceptin (not Herceptin Hylecta)
 2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) metastatic breast cancer as detected by a Food and Drug Administration (FDA)-approved test
 3. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 4. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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TRASTUZUMAB-DTTB (NSA)

Generic	Brand				
TRASTUZUMAB-DTTB	ONTRUZANT				

GUIDELINES FOR USE

Our guideline named TRASTUZUMAB- DTTB (Ontruzant) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Breast cancer
2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:

1. The request is for adjuvant (add-on) therapy
2. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
 - a. The requested medication is being used as part of a treatment plan that contains doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
 - c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

C. If you have metastatic breast cancer, approval also requires:

1. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
2. You meet ONE of the following:
 - a. The requested medication is being used in combination with paclitaxel for first-line treatment
 - b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-DTTB (NSA)

GUIDELINES FOR USE (CONTINUED)

- D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You have HER2-positive tumor (type of protein present in stomach cancer) as detected by a Food and Drug Administration-approved test
 2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

Commercial Effective: 07/01/20



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TRASTUZUMAB-PKRB (NSA)

Generic	Brand				
TRASTUZUMAB-PKRB	HERZUMA				

GUIDELINES FOR USE

Our guideline named TRASTUZUMAB-PKRB (Herzuma) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Breast cancer
2. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

B. If you have breast cancer, approval also requires:

1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
2. The request is for adjuvant (add-on) treatment
3. You meet ONE of the following:
 - a. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - b. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
 - c. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
4. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

C. If you have metastatic breast cancer, approval also requires:

1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
2. You meet ONE of the following:
 - a. The requested medication is being used in combination with paclitaxel for first-line treatment
 - b. The requested medication is being used as a single agent if you have previously received ONE or more chemotherapy regimens for metastatic disease (disease has spread to other parts of the body)
3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

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TRASTUZUMAB-PKRB (NSA)

GUIDELINES FOR USE (CONTINUED)

- D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
1. You have HER2-positive tumor (type of protein found in stomach cancer) as detected by a Food and Drug Administration (FDA)-approved test
 2. The requested medication is being used in combination with cisplatin and capecitabine or 5-fluorouracil
 3. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
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VESTRONIDASE ALFA-VJBK (NSA)

Generic	Brand			
VESTRONIDASE ALFA-VJBK	MEPSEVII			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named VESTRONIDASE ALFA-VJBK (Mepsevii) requires the following rule(s) be met for approval:

- A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
- B. The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders
- C. You have a documented urinary GAG (glycosaminoglycan: type of chemical that builds up when your body cannot break it down) level of greater than three times the upper level of normal based on the laboratory test
- D. Your diagnosis of Mucopolysaccharidosis VII is confirmed by documentation of beta-glucuronidase enzyme activity deficiency (you don't have a protein that breaks down a chemical) or genetic testing
- E. You have at least ONE of the following clinical signs of Mucopolysaccharidosis VII:
 - 1.Enlarged liver and spleen
 - 2.Joint limitations
 - 3.Airway obstructions or pulmonary (lung/breathing) dysfunction
- F. You have not undergone successful bone marrow or stem cell treatment for Mucopolysaccharidosis VII
- G. You have limitation in mobility, but you still have ambulatory (walking) capacity for the six-minute walk test (6MWT) to be measured and evaluated

RENEWAL CRITERIA

Our guideline named VESTRONIDASE ALFA-VJBK (Mepsevii) requires the following rule(s) be met for renewal:

- A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
- B. You have improved, maintained, or demonstrated less than expected decline in ambulatory (walking) ability based on a six-minute walk test compared to baseline

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
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VINCRIStINE LIPOSOMAL (NSA)

Generic	Brand			
VINCRIStINE SULFATE LIPOSOMAL	MARQIBO			

GUIDELINES FOR USE

Our guideline named VINCRIStINE SULFATE LIPOSOMAL (Marqibo) requires the following rule(s) be met for approval:

- A. You have Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (a type of cancer that does not have a certain gene mutation)
- B. You meet ONE of the following criteria:
 - 1. You have experienced a relapse (disease returns) two or more times
 - 2. You have experienced disease progression after treatment with two or more anti-leukemia therapies

Commercial Effective: 07/01/20



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ATEZOLIZUMAB (NSA)

Generic	Brand			
ATEZOLIZUMAB	TECENTRIQ			

GUIDELINES FOR USE

Our guideline named ATEZOLIZUMAB (Tecentriq) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Locally advanced or metastatic (disease has spread to other parts of the body) urothelial carcinoma (cancer that occurs in the urinary system)
2. Metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
3. Unresectable locally advanced/metastatic triple-negative breast cancer (breast cancer that does not have estrogen receptor, progesterone receptor, or human epidermal growth factor receptor 2 [HER-2) protein, and cannot be removed by surgery or has spread to other parts of the body)
4. Extensive-stage small cell lung cancer (ES-SCLC: type of lung cancer)
5. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)

B. If you have locally advanced or metastatic urothelial carcinoma, approval also requires:

1. You are 18 years of age or older
2. You meet ONE of the following:
 - a. You are not eligible to receive cisplatin-containing chemotherapy AND has a tumor that expresses PD-L1 (Programmed death-ligand 1 sustained tumor-infiltrating immune cells [IC] covering 5% or more of the tumor area), as determined by a Food and Drug Administration approved test
 - b. You are not eligible to receive any platinum containing chemotherapy regardless of PD-L1 status
 - c. Your disease gets worse on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 - d. Your disease gets worse within 12 months of neoadjuvant (treatment given as a first step to shrink a tumor before the main treatment) or adjuvant treatment (therapy applied after initial treatment for cancer) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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ATEZOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- C. If you have metastatic non-squamous non-small cell lung cancer (NSq NSCLC), approval also requires:
1. You are 18 years of age or older
 2. You do not have EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) genomic tumor abnormalities
 3. The requested medication will be given in combination with ONE of the following regimens as a first-line treatment:
 - a. Bevacizumab, paclitaxel, and carboplatin, OR
 - b. Paclitaxel protein-bound and carboplatin
- D. If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:
1. You are 18 years of age or older
 2. The requested medication will be used as a single-agent
 3. You meet ONE of the following:
 - a. You do not have an EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) mutation AND your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 - b. You do not have an EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) mutation, the requested medication will be used as first line treatment, AND you have tumors that have high PD-L1 (programmed death-ligand 1: type of protein) expression (PD-L1 stained 50% or more of tumor cells, or PD-L1 stained tumor infiltrating immune cells covering 10% or more of the tumor area) as determined by an Food and Drug Administration (FDA) approved test
 - c. You have an ALK mutation and your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND ALK-directed therapy [such as Xalkori (crizotinib), Zykadia (ceritinib)]
 - d. You have an EGFR mutation and your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) AND EGFR-directed therapy [such as Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]
- E. If you have unresectable locally advanced or metastatic triple-negative breast cancer (TNBC), approval also requires:
1. You are 18 years of age or older
 2. The requested medication will be used in combination with paclitaxel protein-bound
 3. Your tumor expresses PD-L1 (programmed death ligand 1 stained tumor-infiltrating immune cells [IC] of any intensity covering 1% or more of the tumor area), as determined by a Food and Drug Administration (FDA) approved test
- (Criteria continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
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ATEZOLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- F. If you have extensive-stage small cell lung cancer (ES-SCLC), approval also requires:
 - 1. You are 18 years of age or older
 - 2. The requested medication will be used in combination with carboplatin and etoposide as a first-line treatment
- G. If you have unresectable or metastatic hepatocellular carcinoma (HCC), approval also requires:
 - 1. You have not previously been treated with systemic therapy
 - 2. The requested medication will be used in combination with bevacizumab

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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IPILIMUMAB (NSA)

Generic	Brand			
IPILIMUMAB	YERVOY			

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named IPILIMUMAB (Yervoy) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed with surgery or has spread)
2. Cutaneous melanoma (type of skin cancer)
3. Advanced renal cell carcinoma (type of kidney cancer)
4. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (types of colon cancer)
5. Hepatocellular carcinoma (liver cancer)
6. Metastatic or recurrent non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body or has returned)

B. If you have unresectable or metastatic melanoma, approval also requires:

1. You are 12 years of age or older

C. If you have cutaneous melanoma, approval also requires:

1. The requested medication will be used for adjuvant (add-on) treatment
2. There is pathologic (disease) involvement of regional lymph nodes of more than 1mm
3. You have undergone complete resection (surgery to completely remove cancer), including total lymphadenectomy (lymph glands are surgically removed)

D. If you have advanced renal cell carcinoma, approval also requires:

1. The requested medication will be used in combination with Opdivo (nivolumab)
2. You have intermediate or poor risk disease
3. You have not received prior treatment for advanced renal cell carcinoma

E. If you have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval also requires:

1. You are 12 years of age or older
2. The requested medication will be used in combination with Opdivo (nivolumab)
3. You have disease progression (disease gets worse) following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

F. If you have hepatocellular carcinoma, approval also requires:

1. The requested medication will be used in combination with Opdivo (nivolumab)
2. You have previously been treated with Nexavar (sorafenib)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
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IPILIMUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

- G. If you have metastatic or recurrent non-small cell lung cancer (NSCLC), approval also requires:
1. You are 18 years of age or older
 2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (changes in your gene structure)
 3. The requested medication is used as first-line treatment
 4. You have NOT received Yervoy for more than 2 years
 5. You meet ONE of the following:
 - a. For metastatic NSCLC, the requested medication will be used in combination with Opdivo (nivolumab) AND your tumor express programmed death-ligand 1 (PD-L1: type of protein) at greater than or equal to 1% as determined by an FDA (Food and Drug Administration)-approved test
 - b. For metastatic or recurrent NSCLC, the requested medication will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)

RENEWAL CRITERIA

- Our guideline named IPILIMUMAB (Yervoy) requires the following rule(s) be met for renewal:
- A. The request is for adjuvant (add-on) treatment of cutaneous melanoma (type of skin cancer)
 - B. You do not have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant)
 - C. You have not been treated with Yervoy for more than 3 years

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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RAMUCIRUMAB (NSA)

Generic	Brand			
RAMUCIRUMAB	CYRAMZA			

GUIDELINES FOR USE

Our guideline named RAMUCIRUMAB (Cyramza) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Advanced or metastatic (cancer that has spread to other parts of the body), gastric cancer or gastro-esophageal junction adenocarcinoma (cancer of the stomach or cancer of the esophagus [tube that connects mouth and stomach])
2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of your body)
3. Metastatic colorectal cancer (type of colon or rectum cancer that has spread to other parts of the body)
4. Hepatocellular carcinoma (type of liver cancer)

B. If you have advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval also requires:

1. The requested medication will be used as a single agent or in combination with paclitaxel
2. You have experienced disease progression (disease has worsened) on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

C. If you have metastatic non-small cell lung cancer (NSCLC), approval also requires ONE of the following:

1. The requested medication will be used in combination with docetaxel and you meet ONE of the following:
 - a. You have experienced disease progression (disease has worsened) on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin)
 - b. You have an epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK : type of enzyme) genomic tumor abnormality AND your disease has gotten worse on an Food and Drug Administration (FDA)-approved therapy (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza
2. The requested medication will be used in combination with erlotinib as first-line treatment AND your tumors have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 (L858R) substitution mutations

(Criteria continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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RAMUCIRUMAB (NSA)

GUIDELINE FOR USE (CONTINUED)

- D. If you have metastatic colorectal cancer, approval also requires:
 - 1. The requested medication will be used in combination with FOLFIRI (drug combination of irinotecan, folinic acid, and 5-fluorouracil)
 - 2. You have experienced disease progression (disease has worsened) on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)
- E. If you have hepatocellular carcinoma, approval also requires:
 - 1. The requested medication will be used as a single agent
 - 2. You have an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
 - 3. You have been treated with sorafenib (Nexavar)

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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GEMTUZUMAB OZOGAMICIN (NSA)

Generic	Brand			
GEMTUZUMAB OZOGAMICIN	MYLOTARG			

GUIDELINES FOR USE

Our guideline named GEMTUZUMAB OZOGAMICIN (Mylotarg) requires that ONE of the following rule(s) be met for approval:

1. You have newly-diagnosed CD33 (type of molecule that is used as a marker to diagnose AML) –positive acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many immature white blood cells) AND you are 1 month of age or older
2. You have relapsed (returning) or refractory (resistant) CD33 (type of molecule that is used as a marker to diagnose AML) -positive acute myeloid leukemia (AML) AND you are 2 years of age or older

Commercial Effective: 07/01/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

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NIVOLUMAB (NSA)

Generic	Brand			
NIVOLUMAB	OPDIVO			

GUIDELINES FOR USE

Our guideline named NIVOLUMAB (Opdivo) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Unresectable or metastatic melanoma (type of skin cancer that has spread or cannot be completely removed with surgery)
2. Melanoma with lymph node involvement or metastatic (cancer that has spread to other parts of the body) disease
3. Metastatic or recurrent non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body or has returned)
4. Metastatic small cell lung cancer (type of lung cancer that has spread to other parts of the body)
5. Advanced renal cell carcinoma (RCC: type of kidney cancer)
6. Classical Hodgkin lymphoma (cHL: a type of immune system cancer)
7. Recurrent (returning) or metastatic squamous cell carcinoma of the head and neck (SCCHN: type of head/neck cancer that has spread to other parts of the body)
8. Locally advanced, or metastatic urothelial carcinoma (urinary system cancer)
9. Microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer
10. Hepatocellular carcinoma (HCC: liver cancer)
11. Unresectable (cannot be removed by surgery) advanced, recurrent (returning) or metastatic esophageal squamous cell carcinoma (ESCC: type of cancer that affects the esophagus [tube that runs from the throat to the stomach] and has spread to other parts of the body)

B. If you have unresectable or metastatic melanoma, approval also requires:

1. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
2. You will not be using the requested medication with Tafinlar (dabrafenib), Mekinist (trametinib), Zelboraf (vemurafenib) or Cotellic (cobimetinib)

C. If you have melanoma with lymph node involvement or metastatic disease, approval also requires:

1. You have undergone complete resection (completely removed by surgery)
2. The requested medication will be used as an adjuvant (add-on) treatment

(Criteria continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- D. If you have metastatic or recurrent non-small cell lung cancer, approval also requires:
1. You are 18 years of age or older
 2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (changes in your gene structure)
 3. The requested medication is used as first-line treatment
 4. You have NOT received Opdivo for more than 2 years
 5. You meet ONE of the following:
 - a. For metastatic NSCLC: the requested medication will be used in combination with Yervoy (ipilimumab) AND your tumor express programmed death-ligand 1 (PD-L1: type of protein) at greater than or equal to 1% as determined by an FDA (Food and Drug Administration)-approved test
 - b. For metastatic or recurrent NSCLC: the requested medication will be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)
- E. If you have metastatic non-small cell lung cancer, approval also requires:
1. Your disease has worsened while on or after platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 2. If you have ALK mutations (type of gene mutation), your disease must have worsened after using an FDA-approved ALK-directed therapy (such as crizotinib, ceritinib)
 3. If you have EGFR mutations (type of gene mutation), your disease must have worsened after using an FDA-approved EGFR-directed therapy (such as erlotinib, gefitinib, afatinib)
- F. If you have metastatic small cell lung cancer (SCLC), approval also requires:
1. Your disease has gotten worse after platinum-based chemotherapy (such as cisplatin, carboplatin) and at least one other line of therapy
- G. If you have advanced renal cell carcinoma (RCC), approval also requires ONE of the following:
1. Opdivo will be used alone and you have previously received one prior anti-angiogenic therapy (drugs that stop tumors from growing their own blood vessels such as Sutent (sunitinib), Votrient (pazopanib), Cabometyx (cabozantinib), Inlyta (axitinib), Nexavar (sorafenib)
 2. Opdivo will be used in combination with Yervoy (ipilimumab) AND meet the following:
 - a. You have intermediate or poor risk disease
 - b. You have not received prior treatment for advanced renal cell carcinoma

(Criteria continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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NIVOLUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- H. If you have classical Hodgkin lymphoma (cHL), approval also requires:
 - 1. You are 18 years of age or older
 - 2. Your disease has relapsed or worsened after ONE of the following:
 - a. Autologous hematopoietic stem cell transplantation (cells from your own body are used) and Adcetris (brentuximab vedotin)
 - b. Three or more lines of systemic therapy that includes autologous hematopoietic stem cell transplantation
- I. If you have recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC), approval also requires:
 - 1. Your disease has worsened on or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- J. If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:
 - 1. Your disease has worsened during or following platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
 - 2. Your disease has worsened within 12 months of neoadjuvant or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
- K. If you have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval also requires:
 - 1. You are 12 years of age or older
 - 2. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
 - 3. Your disease has worsened after treatment with a fluoropyrimidine, oxaliplatin, and irinotecan
- L. If you have hepatocellular carcinoma (HCC), approval also requires:
 - 1. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
 - 2. You have been previously treated with Nexavar (sorafenib)
- M. If you have esophageal squamous cell carcinoma (ESCC), approval also requires:
 - 1. You have previously received treatment with fluoropyrimidine and platinum-based chemotherapy (type of cancer medications)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DUPILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DUPILUMAB	DUPIXENT	44180		GPI-10 (9027302000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
 - The patient meets at least **ONE** of the following for disease severity:
 - Atopic dermatitis involving at least 10% of body surface area (BSA) **OR**
 - Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
 - The patient has at least **TWO** of the following:
 - Intractable pruritus
 - Cracking and oozing/bleeding of affected skin
 - Impaired activities of daily living
 - Therapy is prescribed by or given in consultation with a dermatologist or allergist/immunologist
 - The patient had an inadequate response or contraindication to **ONE** of the following: topical corticosteroids, topical calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], or phototherapy

If yes, continue to #2.

If no, continue to #4.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****DUPILUMAB****INITIAL CRITERIA (CONTINUED)****2. Is the patient between 6 to 17 years of age?**

If yes, please enter **TWO** approvals by GPID or GPI-14 with a quantity limit based on the patient's weight as follows:

- **FIRST APPROVAL:**
 - If weight is 15kg to less than 30kg: Approve a quantity of #4mL (#2 300mg/2mL) with an end date of 1 month.
 - If weight is 30kg to less than 60kg: Approve a quantity of #4.56mL (#4 200mg/1.14mL) with an end date of 1 month.
 - If weight is 60kg or more: Approve a quantity of #8mL (#4 300mg/2mL) with an end date of 1 month.
- **SECOND APPROVAL:**
 - If weight is 15kg to less than 30kg: Approve for 5 months with a quantity limit of #4mL (#2 300mg/2mL) per 56 days (enter a start date 3 weeks after the start date of the first approval).
 - If weight is 30kg to less than 60kg: Approve for 5 months with a quantity limit of #2.28mL (#2 200mg/1.14mL) per 28 days (enter a start date of 1 week after the end of the first approval).
 - If weight is 60kg or more: Approve for 5 months with a quantity limit of #4mL (#2 300mg/2mL) per 28 days (enter a start date of 1 week after the end of the first approval).

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained improvement in at least two of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living.

If no, continue to #3.

3. Is the patient 18 years of age or older?

If yes, please enter **TWO** approvals by GPID or GPI-14 as follows:

- **FIRST APPROVAL:** Approve a quantity of #8mL (#4 300mg/2mL) with an end date of 1 month.
- **SECOND APPROVAL:** Approve for 5 months with a quantity limit of #4mL (#2 300mg/2mL) per 28 days (enter a start date of 1 week after the end of the first approval).

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained improvement in at least two of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living.

If no, do not approve.

DENIALTEXT: See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DUPIUMAB

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype **AND** meet the following criterion?
- The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months

If yes, continue to #6.

If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma?

If yes, continue to #6.

If no, continue to #7.

6. Does the patient meet **ALL** of the following criteria?

- The patient is 12 years of age or older
- The patient had a prior therapy with medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide, etc.] **AND** at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [such as salmeterol, formoterol, etc.], long-acting muscarinic antagonist [such as aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton, etc.], theophylline)
- The patient has experienced at least **ONE** asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- Dupixent will be used as an add-on maintenance treatment
- The patient is not being concurrently treated with Xolair or an anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
- Therapy is prescribed by or given in consultation with a physician specializing in pulmonary or allergy medicine

If yes, please enter **TWO** approvals by GPID or GPI-14 for the requested medication as follows:

- **FIRST APPROVAL:** approve a quantity of #8mL (#4 300mg/2mL) OR #4.56mL (#4 200mg/1.14mL) with an end date of 1 month.
- **SECOND APPROVAL:** approve for 11 months with a quantity limit of #4mL (#2 300mg/2mL) OR #2.28mL (#2 200mg/1.14mL) per 28 days (enter a start date of 1 week after the end of the first approval).

APPROVAL TEXT: See the approval text on the next page.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****DUPILUMAB****INITIAL CRITERIA (CONTINUED)**

APPROVAL TEXT: Renewal requires ALL of the following: i) the patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers, ii) the patient has shown a clinical response as evidenced by one of the following: a) reduction in asthma exacerbation from baseline, b) decreased utilization of rescue medications, c) increase in percent predicted FEV1 from pretreatment baseline, or d) reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

7. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
 - The patient has inadequately controlled disease as determined by **ONE** of the following:
 - Use of systemic steroids in the past 2 years
 - Endoscopic sinus surgery
 - Dupixent will be used as add-on maintenance treatment (i.e., in conjunction with maintenance intranasal steroids)
 - Therapy is prescribed by or given in consultation with an otolaryngologist or allergist/immunologist

If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of #4mL (#2 300mg/2mL) per 28 days.**

APPROVAL TEXT: Renewal requires the patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps).

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
2. Moderate to severe asthma
3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**

1. You meet at least ONE of the following for disease severity:
 - a. Atopic dermatitis involving at least 10% of body surface area (BSA)
 - b. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc)
2. You have at least TWO of the following:
 - a. Intractable pruritus (severe itching)
 - b. Cracking and oozing/bleeding of affected skin
 - c. Impaired activities of daily living
3. The medication is prescribed by or given in consultation with a dermatologist (skin doctor) or allergist/immunologist (allergy doctor)
4. You are 6 years of age or older
5. You had an inadequate response or contraindication to (a medical reason why you cannot use) ONE of the following: topical corticosteroids, topical calcineurin inhibitors [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [Eucrisa (crisaborole)], or phototherapy (light therapy)

C. **If you have moderate to severe asthma, approval also requires:**

1. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) with a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months **OR** oral corticosteroid-dependent asthma
2. You are 12 years of age or older
3. You had prior therapy with medium, high-dose, or maximally tolerated inhaled corticosteroid [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide] **AND** at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
4. You have experienced at least ONE asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
5. Dupixent will be used as an add-on maintenance treatment

(Initial denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****DUPILUMAB****INITIAL CRITERIA (CONTINUED)**

6. You are not being concurrently treated with Xolair or an anti-IL5 asthma biologic such as Nucala, Cinqair, Fasenra
7. The medication is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/breathing) or allergy medicine
- D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
 1. You are 18 years of age or older
 2. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
 3. You have inadequately controlled disease as determined by **ONE** of the following:
 - a. Use of systemic steroids in the past 2 years
 - b. Endoscopic sinus surgery (using a small camera to help in surgery)
 4. Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
 5. The medication is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis **AND** meet the following criterion?
 - The patient has experienced or maintained improvement in at least two of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living

If yes, continue to #2.

If no, continue to #4.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DUPIUMAB

RENEWAL CRITERIA (CONTINUED)

2. Is the patient between 6 to 17 years of age?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit based on the patient's weight, as follows:**

- If weight is 15kg to less than 30kg: Approve with a quantity limit of #4mL (#2 300mg/2mL) per 56 days.
- If weight is 30kg to less than 60kg: Approve with a quantity limit of #2.28mL (#2 200mg/1.14mL) per 28 days.
- If weight is 60kg or more: Approve with a quantity limit of #4mL (#2 300mg/2mL) per 28 days.

If no, continue to #3.

3. Is the patient 18 years of age or older?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4mL (#2 300mg/2mL) per 28 days.**

If no, do not approve.

DENIALTEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe asthma and meet **ALL** of the following criteria?

- The patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
- The patient has shown a clinical response as evidenced by **ONE** of the following:
 - Reduction in asthma exacerbation from baseline
 - Decreased utilization of rescue medications
 - Increase in percent predicted FEV1 from pretreatment baseline
 - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

If yes, **approve for 12 months by GPID or GPI-14 for the requested medication with a quantity limit of #4mL (#2 300mg/2mL) OR #2.28mL (#2 200mg/1.14mL) per 28 days.**

If no, continue to #5.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet the following criterion?
- The patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4mL (#2 300mg/2mL) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
2. Moderate to severe asthma
3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have moderate to severe atopic dermatitis, renewal also requires:**

1. You have experienced or maintained improvement in at least two of the following:
 - a. Intractable pruritus (severe itching)
 - b. Cracking and oozing/bleeding of affected skin
 - c. Impaired activities of daily living
2. You are 6 years of age or older

C. **If you have moderate to severe asthma, renewal also requires:**

1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
2. You have shown a clinical response as evidenced by ONE of the following:
 - a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
 - b. Decreased use of rescue medications
 - c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
 - d. Reduction in severity or frequency of asthma-related symptoms such as less wheezing, shortness of breath, coughing, etc.

D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**

1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

DUPILUMAB

RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Dupixent.

REFERENCES

- Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/13/20

Created: 01/17

Client Approval: 07/20

P&T Approval: 04/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

TAZEMETOSTAT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAZEMETOSTAT	TAZVERIK	46312		GPI-10 (2153367520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic or locally advanced epithelioid sarcoma and meet **ALL** of the following criteria?

- The patient is 16 years of age or older
- The patient is not eligible for complete resection

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
If no, continue to #2.

2. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, continue to #3.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient meet **ALL** of the following criteria?

- The tumors are positive for an EZH2 mutation as detected by an FDA-approved test
- The patient has received at least 2 prior systemic therapies

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
If no, continue to #4.

4. Does the patient have no satisfactory alternative treatment options?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****TAZEMETOSTAT****GUIDELINES FOR USE (CONTINUED)**

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TAZEMETOSTAT (Tazverik)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Metastatic or locally advanced (cancer that has spread to other parts of the body or has grown outside the organ it started in, but has not yet spread to distant parts of the body) epithelioid sarcoma (rare type of soft tissue cancer)
 2. Relapsed or refractory follicular lymphoma (cancer of the white blood cells that has returned or is resistant to previous treatment)
- B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
1. You are 16 years of age or older
 2. You are not eligible for complete resection (surgically removing all of a tissue/organ)
- C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
1. You are 18 years or older
 2. You meet ONE of the following:
 - a. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (medication/treatment that spreads throughout your body)
 - b. You have no satisfactory alternative treatment options

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tazverik.

REFERENCES

- Tazverik [Prescribing Information]. Cambridge, MA: Epizyme, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/13/20

Created: 05/20

Client Approval: 06/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

FENFLURAMINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FENFLURAMINE	FINTEPLA	02116		GPI-10 (7260002810)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - Therapy is prescribed by or given in consultation with a neurologist
 - The patient had a trial of or contraindication to clobazam **AND** valproic acid derivatives

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**

If no, do not approve.

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:

- A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
- B. You are 2 years of age or older
- C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spine, and nerves)
- D. You had a previous trial of clobazam AND valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****FENFLURAMINE****GUIDELINES FOR USE (CONTINUED)****RENEWAL CRITERIA**

1. Does the patient have a diagnosis of seizures associated with Dravet syndrome **AND** meet the following criterion?
 - The patient has shown continued clinical benefit (e.g., reduction of seizures, reduced length of seizures, seizure control maintained)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #11.8mL per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **FENFLURAMINE (Fintepla)** requires the following rule(s) be met for approval:

- A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
- B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fintepla.

REFERENCES

- Fintepla [Prescribing Information]. Emeryville, CA: Zogenix, Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/01/20

Created: 07/20

Client Approval: 07/20

P&T Approval: 04/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEDAQUILINE FUMARATE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO	39895		GPI-10 (0900001510)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of *M. tuberculosis* that is resistant to at least isoniazid and rifampin) and meet **ALL** of the following criteria?

- The patient meets **ONE** of the following:
 - The patient is 5 to less than 18 years of age **AND** weighs at least 15kg
 - The patient is 18 years of age or older
- Sirturo will be used in combination with at least 3 other antibiotics

If yes, **approve for a total of 24 weeks by GPID or GPI-14 as follows:**

For pediatric patients weighing 15kg to less than 30kg:

- FIRST APPROVAL:** Approve for 4 weeks for the requested strength as follows:
 - Sirturo 20mg: #170 per 28 days.
 - Sirturo 100mg: #34 per 28 days.
- SECOND APPROVAL:** Approve for 20 weeks (total fill count 5) for the requested strength as follows:
 - Sirturo 20mg: #60 per 28 days.
 - Sirturo 100mg: #12 per 28 days.

Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

(Note: The total duration of treatment with Sirturo is 24 weeks)

For pediatric patients weighing 30kg or greater and adult patients:

- FIRST APPROVAL:** Approve for 4 weeks for the requested strength as follows:
 - Sirturo 20mg: #340 per 28 days.
 - Sirturo 100mg: #68 per 28 days.
- SECOND APPROVAL:** Approve for 20 weeks (total fill count 5) for the requested strength as follows:
 - Sirturo 20mg: #120 per 28 days.
 - Sirturo 100mg: #24 per 28 days.

Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

(Note: The total duration of treatment with Sirturo is 24 weeks)

If no, continue to #2.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****BEDAQUILINE FUMARATE****GUIDELINES FOR USE (CONTINUED)**

2. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of *M. tuberculosis* that is resistant to at least isoniazid and rifampin) **OR** pulmonary extensively drug resistant tuberculosis (XDR-TB) (i.e., an isolate of *M. tuberculosis* that is resistant to at least isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside) and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- Sirturo will be used in combination with pretomanid and linezolid

If yes, **approve for a total of 26 weeks for Sirturo 100mg by GPID or GPI-14 as follows:**

- **FIRST APPROVAL:** Approve for 4 weeks with a quantity limit of #68 per 28 days.
- **SECOND APPROVAL:** Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

(**Note:** The total duration of treatment with Sirturo is 26 weeks)

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **BEDAQUILINE FUMARATE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. If you have pulmonary multi-drug resistant tuberculosis (MDR-TB), approval also requires ONE of the following:

1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. If you have pulmonary extensively drug resistant tuberculosis (XDR-TB), approval also requires:

1. You are 18 years of age or older
2. You will be using Sirturo in combination with pretomanid and linezolid

(Denial text continued on next page)

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEDAQUILINE FUMARATE

GUIDELINES FOR USE (CONTINUED)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo.

REFERENCES

- Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/01/20

Created: 05/13

Client Approval: 07/20

P&T Approval: 07/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CANAKINUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CANAKINUMAB/PF	ILARIS	36497		GPI-10 (6646002000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
 - The patient is 2 years of age or older
 - Therapy is prescribed by or given in consultation with a rheumatologist
 - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 - The patient had a previous trial of or contraindication to the following preferred immunomodulator: Actemra [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 vials (300mg) per 28 days.**

APPROVAL TEXT: Renewal for systemic juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

If no, continue to #2.

- Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) and meet **ALL** of the following criteria?
 - The patient is 4 years of age or older
 - Therapy is prescribed by or in consultation with a rheumatologist

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial (150mg) per 56 days.**

If no, continue to #3.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****CANAKINUMAB (NSA)****INITIAL CRITERIA (CONTINUED)**

3. Does the patient have a diagnosis of **ONE** of the following periodic fever syndromes?
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
 - Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
 - Familial Mediterranean Fever (FMF)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 vials (300mg) per 28 days.**

If no, continue to #4.

4. Does the patient have a diagnosis of Adult-Onset Still's Disease (AOSD)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 vials (300mg) per 28 days.**

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Systemic Juvenile Idiopathic Arthritis (SJIA: inflammation and stiffness in joints of children)
2. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
3. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
4. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic disorders that have recurrent fever episodes and inflammation)
5. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

(Initial denial text continued on next page)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CANAKINUMAB (NSA)

INITIAL CRITERIA (CONTINUED)

- B. If you have Systemic Juvenile Idiopathic Arthritis (SJIA), approval also requires:**
1. You are 2 years of age or older
 2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
 3. You had a previous trial of at least ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
 4. You had a previous trial of the preferred immunomodulator: Actemra, unless there is a medical reason why you cannot (contraindication)
- C. If you have Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:**
1. You are 4 years of age or older
 2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) **AND** meet the following criterion?
 - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 vials (300mg) per 28 days.**

If no, continue to #2.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

CANAKINUMAB (NSA)

RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)?

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial (150mg) per 56 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of **ONE** of the following periodic fever syndromes?

- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
- Familial Mediterranean Fever (FMF)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 vials (300mg) per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Systemic Juvenile Idiopathic Arthritis (SJIA: inflammation and stiffness in joints of children)
2. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
3. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
4. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic disorders that have recurrent fever episodes and inflammation)
5. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)

B. **If you have systemic juvenile idiopathic arthritis (SJIA), renewal also requires:**

1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CANAKINUMAB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ilaris.

REFERENCES

- Ilaris [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/01/20

Created: 08/13

Client Approval: 07/20

P&T Approval: 07/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEVACIZUMAB	AVASTIN	25963		GPI-10 (2133502000) (8665502000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) **AND** meet the following criterion?
 - The requested medication is being used in combination with intravenous 5-fluorouracil based chemotherapy for first or second-line treatment
 - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi or Zirabev

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #2.

2. Does the patient have a diagnosis of metastatic colorectal cancer (mCRC) and meet **ALL** of the following criteria?
 - The patient has progressed on a first-line Avastin-containing regimen
 - The requested medication is being used in combination with fluoropyrimidine- irinotecan- (i.e., FOLFIRI) or fluoropyrimidine-oxaliplatin- (i.e., FOLFOX, CapeOx) based chemotherapy as a second-line treatment
 - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi or Zirabev

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #3.

3. Does the patient have a diagnosis of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC) **AND** meet the following criterion?
 - The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment
 - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi or Zirabev

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #4.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of recurrent glioblastoma (GBM) **AND** meet the following criteria?
- The patient is 18 years of age or older
 - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi or Zirabev

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #5.

5. Does the patient have a diagnosis of metastatic renal cell carcinoma (RCC) **AND** meet the following criterion?
- The requested medication is being used in combination with interferon alfa
 - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi or Zirabev

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #6.

6. Is Avastin being used to treat any ophthalmic indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb **AND** meet the following criterion?
- The requested medication is prescribed by an ophthalmologist and/or retina specialist

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #7.

7. Does the patient have a diagnosis of persistent, recurrent, or metastatic cervical cancer **AND** meet the following criterion?
- The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
 - The patient had a trial of or contraindication to **ONE** of the following preferred agents: Mvasi or Zirabev

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #8.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ALL** of the following criteria?
- The requested medication is being used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
 - The patient has received no more than 2 prior chemotherapy regimens

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #9.

9. Does the patient have a diagnosis of platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer and meet **ONE** of the following criteria?
- The requested medication is being used in combination with carboplatin and paclitaxel
 - The requested medication is being used in combination with carboplatin and gemcitabine
 - The requested medication is being used as a single agent after prior use in combination with one of the carboplatin-containing chemotherapy regimens listed above

If yes, **approve for 12 months by HICL or GPI-10.**

If no continue to #10.

10. Does the patient have a diagnosis of stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
- The requested medication is being used following initial surgical resection
 - The requested medication is being used in combination with carboplatin and paclitaxel, **OR** as a single agent after prior use in combination with carboplatin and paclitaxel

If yes, **approve for 12 months by HICL or GPI-10.**

If no, continue to #11.

11. Does the patient have a diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) and meet **ALL** of the following criteria?
- The requested medication will be used in combination with atezolizumab
 - The patient has not received prior systemic therapy

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEVACIZUMAB (Avastin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
3. Recurrent glioblastoma (GBM: type of brain tumor)
4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
5. An ophthalmic (eye) indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb
6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
7. Platinum-resistant recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
8. Platinum-sensitive recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
9. Stage III or IV epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

B. **If you have metastatic colorectal cancer, approval also requires:**

1. You meet ONE of the following:
 - i. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
 - ii. Your disease has progressed (gotten worse) on a first-line Avastin product-containing regimen AND the requested medication is being used in combination with fluoropyrimidine- irinotecan- (for example FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example FOLFOX, CapeOx) based chemotherapy as a second-line treatment
2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**

1. The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment
2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

(Denial text continued on next page)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BEVACIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- D. **If you have recurrent glioblastoma, approval also requires:**
1. You are 18 years of age or older
 2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
- E. **If you have metastatic renal cell carcinoma, approval also requires:**
1. The requested medication is being used in combination with interferon-alfa
 2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
- F. **If you have any ophthalmic indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb, approval also requires:**
1. The requested medication is prescribed by an ophthalmologist (eye doctor) and/or retina specialist (a special type of eye doctor)
- G. **If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:**
1. The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
 2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
- H. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
1. The requested medication is being used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
 2. You have received no more than two prior chemotherapy regimens
- I. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:**
1. The requested medication is being used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
 2. The requested medication is being used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
- J. **If you have Stage III or IV epithelial ovarian/fallopian tube or primary peritoneal cancer, approval also requires:**
1. The requested medication is being used following initial surgical resection (removal)
 2. The requested medication is being used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel
- K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
1. The requested medication will be used in combination with atezolizumab
 2. You have not received prior systemic therapy (treatment that spreads throughout the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

BEVACIZUMAB (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Avastin.

REFERENCES

- Avastin [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/20/20

Created: 02/13

Client Approval: 07/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BUDESONIDE	ORTIKOS		46496 46497	GPI-14 (22100012007025) (22100012007030)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of mild to moderate active Crohn's Disease and meet **ALL** of the following criteria?
 - The patient is 8 years of age or older
 - Crohn's disease involves the ileum and/or the ascending colon

If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**

If no, continue to #2.

2. Does the patient have a diagnosis of mild to moderate Crohn's Disease and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - Crohn's disease involves the ileum and/or the ascending colon
 - The requested medication is being used for the maintenance of clinical remission

If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **BUDESONIDE ER (Ortikos)** requires the following rule(s) be met for approval:

- A. You have mild to moderate Crohn's Disease involving the ileum and/or the ascending colon (inflammation of the digestive tract that affects a part of your small intestines and/or the beginning of the colon which can lead to stomach pain, diarrhea, weight loss, or malnutrition)
- B. **If you have mild to moderate active Crohn's Disease, approval also requires:**
 1. You are 8 years of age or older
- C. **If you have mild to moderate Crohn's Disease, approval also requires:**
 1. You are 18 years of age or older
 2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BUDESONIDE (INTERIM)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ortikos.

REFERENCES

Ortikos [Prescribing Information]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 7/31/20

Created: 07/20

Client Approval: 10/20

P&T Approval: 10/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

Drugs listed in this document does not ensure coverage. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is intended for informational use only and is not intended to replace professional medical advice or treatment, or diagnose, treat, cure, or prevent any disease or medical condition. This document is subject to change.

PLERIXAFOR (NSA)

Generic	Brand			
PLERIXAFOR	MOZOBIL			

GUIDELINES FOR USE

Our guideline named **PLERIXAFOR (Mozobil)** requires you meet the following rule(s) for approval:

- A. You have Non-Hodgkin's lymphoma (cancer of a part of the immune system called the lymph system) or multiple myeloma (cancer that forms in a type of white blood cell called a plasma cell)
- B. The medication is prescribed by or given in consultation with a hematologist or oncologist (blood or cancer doctor)

Commercial Effective: 07/01/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

FOSTEMSAVIR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
FOSTEMSAVIR	RUKOBIA	46684		GPI-10 (1210233040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication will be used in combination with other antiretroviral(s)
 - The patient is treatment experienced
 - The patient has multidrug-resistant HIV-1 infection
 - The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **FOSTEMSAVIR (Rukobia)** requires the following rule(s) be met for approval:

- A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
- B. You are 18 years of age or older
- C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
- D. You are treatment experienced (previously treated)
- E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
- F. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

FOSTEMSAVIR

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Rukobia.

REFERENCES

- Rukobia [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective:08/01/20

Created: 07/20

Client Approval: 07/20

P&T Approval:07/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEMBROLIZUMAB	KEYTRUDA	41369		GPI-10 (2135305300)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma?

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #2.

2. Does the patient have a diagnosis of melanoma with involvement of lymph node(s) following complete resection and meet the following criterion?

- The requested medication will be used as an adjuvant treatment

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #3.

3. Does the patient have a diagnosis of metastatic nonsquamous (e.g., adenocarcinoma, large cell carcinoma) non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?

- The patient has not received prior systemic chemotherapy treatment for metastatic NSCLC (i.e., used as first-line treatment)
- The medication is used in combination with pemetrexed and platinum chemotherapy
- The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

If yes, **approve for 12 months by GPID OR GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #4.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
- The patient has not received prior systemic chemotherapy treatment for metastatic NSCLC (i.e., used as first-line treatment)
 - The medication is used in combination with carboplatin and either paclitaxel or nab-paclitaxel

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #5.

5. Does the patient have a diagnosis of non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
- The patient has not received prior systemic chemotherapy treatment for NSCLC (i.e., used as first-line treatment)
 - The medication will be given as a single agent (i.e., not in combination with chemotherapy)
 - NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) ≥1%] as determined by an FDA-approved test
 - The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
 - The patient meets **ONE** of the following:
 - The patient has stage III NSCLC **AND** is not a candidate for surgical resection or definitive chemoradiation
 - The patient has metastatic NSCLC

If yes, **approve for 12 months by GPID OR GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #6.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
- The medication will be given as a single agent (i.e., not in combination with chemotherapy)
 - NSCLC tumors express programmed death-ligand 1 (PD-L1) [Tumor Proportion Score (TPS) $\geq 1\%$] as determined by an FDA-approved test
 - The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient meets **ONE** of the following:
 - The patient does not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
 - The patient has an anaplastic lymphoma kinase (ALK) genomic tumor aberration **AND** disease progression on or after ALK-directed therapy [e.g., Xalkori (crizotinib), Zykadia (ceritinib)]
 - The patient has an epidermal growth factor receptor (EGFR) genomic tumor aberration **AND** disease progression on or after EGFR-directed therapy [e.g., Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

If yes, approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #7.

7. Does the patient have a diagnosis of metastatic small cell lung cancer (SCLC) and meet **ALL** of the following criteria?
- The patient has disease progression on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The patient has received at least one other prior line of therapy

If yes, approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #8.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

8. Does the patient have a diagnosis of metastatic or unresectable, recurrent head and neck squamous cell carcinoma (HNSCC) and meet **ALL** of the following criteria?
- The medication is used as a first line treatment
 - The patient meets **ONE** of the following:
 - The medication will be given in combination with platinum and fluorouracil (FU)
 - The medication will be given as a single agent **AND** the tumors express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #9.

9. Does the patient have a diagnosis of recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) and meet **ALL** of the following criteria?
- The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
 - The medication will be given as a single agent

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #10.

10. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) and meet **ONE** of the following criteria?
- The patient has refractory classical Hodgkin lymphoma (cHL)
 - The patient has relapsed after 3 or more prior lines of therapy

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #11.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

11. Does the patient have a diagnosis of primary mediastinal large B-cell lymphoma (PMBCL) and meet **ONE** of the following criteria?

- The patient has refractory PMBCL
- The patient has relapsed after 2 or more prior lines of therapy

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #12.

12. Does the patient have a diagnosis of locally advanced or metastatic urothelial carcinoma and meet **ONE** of the following criteria?

- The patient is not eligible to receive cisplatin-containing chemotherapy **AND** patient's tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by an FDA approved test
- The patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status
- The patient has disease progression on or after treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
- The patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #13.

13. Does the patient have a diagnosis of bladder cancer and meet **ALL** of the following criteria?

- The patient has Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors
- The patient is ineligible for or has elected not to undergo cystectomy

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #14.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

14. Does the patient have a diagnosis of an unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and meet **ONE** of the following criteria?

- The patient has a solid tumor that has progressed following prior treatment and has no satisfactory alternative treatment options
- The patient has colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #15.

15. Does the patient have a diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?

- The patient has tumors that express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test
- The patient has disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #16.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

16. Does the patient have a diagnosis of recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus and meet **ALL** of the following criteria?

- The tumors express PD-L1 (Combined Positive Score (CPS) ≥ 10) as determined by an FDA-approved test
- The patient has disease progression after one or more prior lines of systemic therapy

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #17.

17. Does the patient have a diagnosis of recurrent or metastatic cervical cancer and meet **ALL** of the following criteria?

- The patient has disease progression on or after chemotherapy
- The patient has tumors that express PD-L1 [Combined Positive Score (CPS) ≥ 1] as determined by an FDA-approved test

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #18.

18. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?

- The patient has previously been treated with sorafenib

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #19.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

19. Does the patient have a diagnosis of recurrent locally advanced or metastatic Merkel cell carcinoma?

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #20.

20. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ALL** of the following criteria?

- The patient has not received prior systemic chemotherapy treatment for renal cell carcinoma (i.e., used as first-line treatment)
- The medication is used in combination with axitinib

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #21.

21. Does the patient have a diagnosis of advanced endometrial carcinoma and meet **ALL** of the following criteria?

- The medication is used in combination with lenvatinib (Lenvima)
- The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
- The patient has experienced disease progression following prior systemic therapy
- The patient is not a candidate for curative surgery or radiation

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #22.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

22. Does the patient have a diagnosis of unresectable or metastatic solid tumors and meet **ALL** of the following criteria?

- The solid tumors are tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)], as determined by an FDA-approved test
- The patient has disease progression following prior treatment and has no satisfactory alternative treatment options

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #23.

23. Does the patient have a diagnosis of recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) and meet the following criterion?

- The disease is not curable by surgery or radiation

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, continue to #24.

24. Does the patient have a diagnosis of unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) and meet the following criterion?

- The requested medication is being used as first-line treatment

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:**

- **50mg powder: 4 vials per 21 days OR 8 vials per 42 days.**
- **100mg/4mL: 8mL per 21 days OR 16mL per 42 days.**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline for the drug named **PEMBROLIZUMAB (Keytruda)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Unresectable or metastatic melanoma (type of skin cancer that has spread to other parts of the body or cannot be completely removed with surgery)
2. Melanoma with involvement of lymph node(s) following complete resection (you have a type of skin cancer that involves the immune system after surgical removal)
3. Non-small cell lung cancer
4. Metastatic small cell lung cancer (type of lung cancer that has spread to other parts of the body)
5. Head and neck squamous cell carcinoma (type of neck cancer)
6. Classical Hodgkin Lymphoma (type of immune system cancer)
7. Primary mediastinal large B-cell lymphoma (type of immune system cancer)
8. Locally advanced or metastatic (disease has spread to other parts of the body) urothelial carcinoma (type of urinary system cancer)
9. Unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (type of cancer with genetic abnormalities that cannot be removed by surgery or has spread to other parts of the body)
10. Recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma (type of cancer in the stomach/lower part of throat)
11. Recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus (type of throat/esophagus cancer)
12. Recurrent or metastatic cervical cancer
13. Hepatocellular carcinoma (liver cancer)
14. Recurrent locally advanced or metastatic Merkel cell carcinoma (type of skin cancer)
15. Advanced renal cell carcinoma (kidney cancer)
16. Advanced endometrial carcinoma (type of cancer that starts in the uterus)
17. Bladder cancer
18. Unresectable or metastatic solid tumors (type of cancer that cannot be removed with surgery or has spread to other parts of the body)
19. Recurrent or metastatic cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned or has spread to other parts of the body)
20. Unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC: type of colon or rectal cancer with genetic abnormalities that cannot be removed by surgery or has spread to other parts of the body)

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- B. If you have melanoma (skin cancer) with involvement of lymph node(s) after complete surgical removal, approval also requires:**
1. The requested drug will be used as add-on (adjuvant) treatment
- C. If you have metastatic nonsquamous non-small cell lung cancer (NSCLC), approval also requires:**
1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for metastatic NSCLC (it is being used as first-line treatment)
 2. The medication is used in combination with pemetrexed and platinum chemotherapy
 3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
- D. If you have metastatic squamous non-small cell lung cancer (NSCLC), approval also requires:**
1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for metastatic NSCLC (it is being used as first-line treatment)
 2. The medication is used in combination with carboplatin and either paclitaxel or nab-paclitaxel
- E. If you have non-small cell lung cancer (NSCLC), approval also requires:**
1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for NSCLC (it is being used as first-line treatment)
 2. The medication will be given as a single agent (not given in combination with chemotherapy)
 3. Non-small cell lung cancer tumors have programmed death-ligand 1 Tumor Proportion Score greater than or equal to 1% (you have a certain amount of a type of protein that is present in lung cancer) as determined by a Food and Drug Administration (FDA)-approved test
 4. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
 5. You meet **ONE** of the following:
 - i. You have stage III non-small cell lung cancer AND are not a candidate for surgical resection (removal) or definitive chemoradiation
 - ii. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

F. If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:

1. The medication will be given as a single agent (it is not given in combination with chemotherapy)
2. Non-small cell lung cancer tumors have programmed death-ligand 1 Tumor Proportion Score greater than or equal to 1% (you have a certain amount of a type of protein that is present in lung cancer) as determined by a Food and Drug Administration (FDA)-approved test
3. You experienced disease progression (disease has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
4. You meet **ONE** of the following:
 - i. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (gene mutations)
 - ii. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (gene mutation) AND experienced disease progression (has gotten worse) on or after ALK-directed therapy such as Xalkori (crizotinib) or Zykadia (ceritinib)
 - iii. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (gene mutation) AND experienced disease progression (has gotten worse) on or after EGFR-directed therapy such as Tarceva (erlotinib), Iressa (gefitinib) or Gilotrif (afatinib)

G. If you have metastatic small cell lung cancer (SCLC), approval also requires:

1. You experienced disease progression (has gotten worse) on or after platinum-based chemotherapy such as cisplatin, carboplatin, oxaliplatin
2. You have received at least one other prior line of therapy

H. If you have metastatic or unresectable, recurrent head and neck squamous cell carcinoma (HNSCC), approval also requires:

1. The medication is used as a first line treatment
2. You meet **ONE** of the following:
 - i. The medication will be given in combination with platinum and fluorouracil (FU)
 - ii. The medication will be given as a single agent AND the tumors have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test

I. If you have recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), approval also requires:

1. You experienced disease progression (has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
2. The medication will be given as a single agent

J. If you have classical Hodgkin lymphoma (cHL), approval also requires ONE of the following:

1. You have refractory classical Hodgkin lymphoma (disease is resistant to treatment)
2. You have relapsed (disease has returned) after 3 or more prior lines of therapy

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- K. If you have primary mediastinal large B-cell lymphoma (PMBCL), approval also requires ONE of the following:**
1. You have refractory primary mediastinal large B-cell lymphoma (type of immune system cancer that is resistant to treatment)
 2. You have relapsed (disease has returned) after 2 or more prior lines of therapy
- L. If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
1. You are not eligible to receive cisplatin-containing chemotherapy and your tumors have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test
 2. You are not eligible for any platinum-containing chemotherapy regardless of PD-L1 (type of protein) status
 3. You experienced disease progression (has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
 4. You experienced disease progression (has gotten worse) within 12 months of neoadjuvant or adjuvant (add-on) treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
- M. If you have bladder cancer, approval also requires:**
1. You have Bacillus Calmette-Guerin (BCG; a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a group of abnormal cells that have not spread) with or without papillary tumors
 2. You are ineligible for or have chosen not to undergo cystectomy (surgery to remove part of or all of the urinary bladder)
- N. If you have unresectable or metastatic tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient, approval also requires ONE of the following:**
1. You have a solid tumor that has progressed (gotten worse) after using prior treatment and have no satisfactory alternative treatment options
 2. You have colorectal cancer that has progressed (gotten worse) following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan
- O. If you have recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
1. You have tumors that have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test
 2. You experienced disease progression (has gotten worse) on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy (treatment for a type of protein present in the cancer)

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STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEMBROLIZUMAB (NSA)

GUIDELINES FOR USE (CONTINUED)

- P. If you have recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus, approval also requires:**
1. You have tumors that have PD-L1 (programmed death-ligand 1; a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test
 2. You experienced disease progression (has gotten worse) after one or more prior lines of systemic therapy (treatment that spreads throughout the bloodstream)
- Q. If you have recurrent or metastatic cervical cancer, approval also requires:**
1. You experienced disease progression (has gotten worse) on or after chemotherapy
 2. You have tumors that have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test
- R. If you have hepatocellular carcinoma, approval also requires:**
1. You have previously been treated with sorafenib
- S. If you have advanced renal cell carcinoma (RCC), approval also requires:**
1. You have not received prior systemic chemotherapy treatment (therapy that travels throughout the bloodstream) for renal cell carcinoma (it is used as first line treatment)
 2. The medication is used in combination with axitinib
- T. If you have advanced endometrial carcinoma, approval also requires:**
1. The medication is used in combination with lenvatinib (Lenvima)
 2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
 3. You experienced disease progression following prior systemic therapy (disease has gotten worse after previous treatment)
 4. You are not a candidate for curative surgery or radiation
- U. If you have unresectable or metastatic solid tumors, approval also requires:**
1. Your solid tumors are tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food and Drug Administration (FDA)-approved test
 2. Your disease has worsened following prior treatment and you have no alternative treatment options
- V. If you have recurrent or metastatic cutaneous squamous cell carcinoma, approval also requires:**
1. Your disease is not curable by surgery or radiation
- W. If you have unresectable or metastatic MSI-H or dMMR colorectal cancer, approval also requires:**
1. Keytruda is being used as first-line treatment

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****PEMBROLIZUMAB (NSA)****RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Keytruda.

REFERENCES

- Keytruda [Prescribing Information]. Whitehouse Station, NJ: Merck & Co, Inc.; June 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 07/20/20

Created: 09/14

Client Approval: 07/20

P&T Approval: 07/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ESKETAMINE (NSA)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ESKETAMINE	SPRAVATO	41003		GPI-10 (5811002010)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The requested medication will be used in combination with an oral antidepressant
 - Therapy is prescribed by or given in consultation with a psychiatrist
 - The patient has non-psychotic, unipolar depression
 - The patient does NOT have active substance abuse
 - The patient had a trial of **TWO** oral anti-depressants from different classes for the treatment of depression (e.g., SSRIs, SNRIs, bupropion, mirtazapine, serotonin modulator, TCAs, optional MAOI) for an adequate time period defined as at least 6 weeks (unless the patient has shown little to no improvement after 4 weeks)

If yes, **approve for a total of 3 months by HICL or GPI-10 as follows:**

- **INDUCTION DOSE:** Approve for 1 month with a quantity limit of #23 per 28 days with no fill count.
- **MAINTENANCE DOSE:** Approve for 2 months with a quantity limit of #12 per 28 days (Enter a start date of 28 days from the first date of the induction dose approval).

APPROVAL TEXT: Renewal requires that the patient has demonstrated clinical benefit (improvement in depression) compared to baseline.

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:

- A. You have treatment-resistant depression (symptoms of depression have not improved after treatment)
 - B. You are 18 years of age or older
 - C. The requested medication will be used in combination with an oral antidepressant
 - D. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
 - E. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
 - F. You do NOT have active substance abuse
- (Initial denial text continued on next page)**

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ESKETAMINE (NSA)

INITIAL CRITERIA (CONTINUED)

- G. You had a trial of **TWO** oral anti-depressants from different classes for the treatment of depression. Classes of anti-depressants include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), bupropion, mirtazapine, serotonin modulator, tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs) are optional. You must have used the drugs for an adequate time period defined as at least 6 weeks (unless the patient has shown little to no improvement after 4 weeks)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of treatment-resistant depression (TRD) **AND** meet the following criterion?
 - The patient has demonstrated clinical benefit (improvement in depression) compared to baseline

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #12 per 28 days.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:

- A. You have treatment-resistant depression (symptoms of depression have not improved after treatment)
- B. You have demonstrated clinical benefit (improvement in depression) compared to baseline

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ESKETAMINE (NSA)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Spravato.

REFERENCES

- Spravato [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc., May 2019.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/01/20

Created: 05/19

Client Approval: 07/20

P&T Approval: 04/19



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

TRiheptanoin (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRiheptanoin	DOJOLVI	46676		GPI-10 (8020008000)	

GUIDELINES FOR USE

1. Does the patient have a confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD)?

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRiheptanoin (Dojolvi)** requires the following rule(s) be met for approval:

- A. You have a confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Dojolvi.

REFERENCES

Dojolvi [Prescribing Information]. Novato, CA: Ultragenyx Pharmaceutical Inc., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/24/20

Created: 07/20

Client Approval: 10/20

P&T Approval: 10/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BREXUCABTAGENE AUTOLEUCEL (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BREXUCABTAGENE AUTOLEUCEL	TECARTUS	46733			

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL) and meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by HICL.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BREXUCABTAGENE AUTOLEUCEL (Tecartus)** requires the following rule(s) be met for approval:

- A. You have relapsed or refractory mantle cell lymphoma (MCL: type of white blood cell cancer that has returned or does not respond to treatment)
- B. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tecartus.

REFERENCES

Tecartus [Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc., July 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/07/20

Created: 07/20

Client Approval: 10/20

P&T Approval: 10/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

TAFASITAMAB-CXIX (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TAFASITAMAB-CXIX	MONJUVI	46758		GPI-10 (2135306720)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) **OR** DLBCL arising from low grade lymphoma and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The requested medication will be used in combination with lenalidomide
- The patient is not eligible for autologous stem cell transplant (ASCT)

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of white blood cancer that has returned or did not respond to previous treatment)
2. Diffuse large B-cell lymphoma arising from low grade lymphoma (type of slow growing white blood cell cancer)

B. You are 18 years of age or older

C. The requested medication will be used in combination with lenalidomide

D. You are not eligible for autologous stem cell transplant (ASCT: stem cell transplant transferred from your own body)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Monjuvi.

REFERENCES

Monjuvi [Prescribing Information]. Boston, MA: MorphoSys US Inc., July 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/14/20

Created: 08/20

Client Approval: 10/20

P&T Approval: 10/20

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LIBRARY OF PRIOR AUTHORIZATION GUIDELINES

CAPSAICIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CAPSAICIN 8% PATCH	QUTENZA	36916		GPI-10 (9085002530)	

GUIDELINES FOR USE

1. Does the patient have neuropathic pain associated with **ONE** of the following conditions?

- Postherpetic neuralgia (PHN)
- Diabetic peripheral neuropathy (DPN) of the feet

If yes, **approve for 12 months by HICL or GPI-10 for 4 fills with a quantity limit of up to #4 patches per fill (maximum dose is 4 patches every 3 months).**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **CAPSAICIN (Qutenza)** requires the following rule be met for approval:

A. You have a diagnosis of neuropathic pain associated with ONE of the following conditions:

- Postherpetic neuralgia (PHN) (painful condition that affects the nerve fibers and skin after having shingles)
- Diabetic peripheral neuropathy (DPN) of the feet (numbness of the feet that is caused by diabetes)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Qutenza.

REFERENCES

- Qutenza [Prescribing Information]. Ardsley, NY. Acorda Therapeutics, Inc. July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/24/20

Created: 05/10

Client Approval: 07/20

P&T Approval: 10/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

MONOMETHYL FUMARATE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MONOMETHYL FUMARATE	BAFIERTAM	46576		GPI-10 (6240555000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, **AND** meet the following criterion?
 - The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:

- A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
- B. You are 18 years of age or older

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Bafiertam.

REFERENCES

Bafiertam [Prescribing Information]. High Point, NC: Banner Life Sciences LLC; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/14/20

Created: 08/20

Client Approval: 10/20

P&T Approval: 10/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

BELANTAMAB MAFODOTIN-BLMF (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BELANTAMAB MAFODOTIN-BLMF	BLENREP	46762		GPI-10 (2135501520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory multiple myeloma and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient has received at least four prior therapies, including the following:
 - Anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab)
 - Proteasome inhibitor (e.g., ixazomib, carfilzomib)
 - Immunomodulatory agent (e.g., lenalidomide, pomalidomide)

If yes, **approve for 12 months by HICL or GPI-10 for #1 fill every 21 days.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **BELANTAMAB MAFODOTIN-BLMF (Blenrep)** requires the following rule(s) be met for approval:

- A. You have relapsed or refractory multiple myeloma (type of blood cancer that has returned or did not respond to previous treatment)
- B. You are 18 years of age or older
- C. You have received at least four prior therapies, including an anti-CD38 monoclonal antibody (such as daratumumab, isatuximab), a proteasome inhibitor (such as ixazomib, carfilzomib), and an immunomodulatory agent (such as lenalidomide, pomalidomide)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Blenrep.

REFERENCES

Blenrep [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; August 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/21/20

Created: 07/20

Client Approval: 10/20

P&T Approval: 10/20

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DECITABINE/CEDAZURIDINE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DECITABINE/ CEDAZURIDINE	INQOVI	46686		GPI-10 (2199000225)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of myelodysplastic syndromes (MDS) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has **ONE** of the following International Prognostic Scoring System groups: intermediate-1, intermediate-2, or high-risk

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
If no, continue to #2.

2. Does the patient have a diagnosis of chronic myelomonocytic leukemia (CMML) **AND** meet the following criterion?
 - The patient is 18 years of age or older

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #5 per 28 days.**
If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DECITABINE/CEDAZURIDINE (Inqovi)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 1. Myelodysplastic syndromes (MDS: type of blood cancer)
 2. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)
- B. You are 18 years of age or older
- C. **If you have myelodysplastic syndromes (MDS), approval also requires:**
 1. You meet ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
 - a. Intermediate-1
 - b. Intermediate-2
 - c. High-risk

(Denial text continued on the next page)

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DECITABINE/CEDAZURIDINE (INTERIM)

GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Inqovi.

REFERENCES

Inqovi [Prescribing Information]. Pleasanton, CA: Astex Pharmaceuticals, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 08/21/20

Created: 08/20

Client Approval: 10/20

P&T Approval: 10/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
AZACITIDINE	ONUREG		48545 48540	GPI-14 (21300003000330) (21300003000320)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of acute myeloid leukemia and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
 - The patient is not able to complete intensive curative therapy

If yes, **approve for 12 months for all strengths by GPID or GPI-14 with a quantity limit of #14 per 28 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **AZACITIDINE (Onureg)** requires the following rule(s) be met for approval:

- A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
- B. You are 18 years of age or older
- C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
- D. You are not able to complete intensive curative therapy (treatment to cure the disease)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

AZACITIDINE (INTERIM)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Onureg.

REFERENCES

Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 9/11/20

Created: 09/20

Client Approval: 10/20

P&T Approval: 10/20

PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS

Generic	Brand	HICL	GCN	Exception/Other
BLOOD-GLUCOSE METER, CONTINUOUS	DEXCOM, DEXCOM G4, DEXCOM G5, DEXCOM G6	36756		
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, DEXCOM G6			NDC = 08627-0013-01 NDC = 08627-0014-01 NDC = 08627-0016-01
BLOOD-GLUCOSE SENSOR	DEXCOM G6, DEXCOM G5-G4 SENSOR			NDC = 08627-0051-04 NDC = 08627-0053-03
FLASH GLUCOSE SCANNING READER	FREESTYLE LIBRE READER FREESTYLE LIBRE 2 READER	44578		
FLASH GLUCOSE SENSOR	FREESTYLE LIBRE SENSOR FREESTYLE LIBRE 2 SENSOR	44576		NDC = 57599-0800-00

GUIDELINES FOR USE

- Does the patient have coverage for CGM products and/or CGM related accessories via the medical benefit, manufacturer program, or patient assistance program?

[Note: Guideline applies for patients with coverage of CGMs and/or CGM related accessories through the pharmacy benefit. Coverage of CGMs and/or CGM related accessories via the medical benefit, manufacturer program or patient assistance programs should be paid under the aforementioned benefits/programs and should not undergo PA review.]

If yes, guideline does not apply.
If no, continue to #2.

- Does the patient have a diagnosis of type 1 diabetes **OR** type 2 diabetes and insulin dependent?

If yes, continue to #3.
If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS

GUIDELINES FOR USE (CONTINUED)

3. Is the request for FreeStyle Libre System (i.e., Reader, Sensor) and meet **ALL** of the following criteria?

- Patient is 18 years of age or above
- The patient is currently performing at least 4 finger-stick glucose tests daily
- The patient's insulin treatment plan requires frequent adjustment of insulin dosing

If yes, **approve for 12 months by NDC for all of the following:**

- **Freestyle Libre Reader or Freestyle Libre 2 Reader: #1 reader per 12 months.**
- **Freestyle Libre 14 Day Sensor or Freestyle Libre 2 Sensor: #2 sensors per 28 days.**
- **Freestyle Libre 10 Day Sensor: #3 sensors per 30 days.**

If no, continue to #4.

4. Is the request for Dexcom continuous glucose monitoring system (i.e., Meter, Transmitter, Sensor) and meet **ALL** of the following criteria?

- Patient is 2 years of age or above
- The patient is currently performing at least 4 finger-stick glucose tests daily
- The patient's insulin treatment plan requires frequent adjustment of insulin dosing

If yes, **approve for 12 months for all the following:**

- **Dexcom System Meter (HICL 36756)**
- **Transmitter:**
 - **Dexcom G4: (NDC 08627-0013-01)**
 - **Dexcom G5: (NDC 08627-0014-01)**
 - **Dexcom G6: (NDC 08627-0016-01)**
- **Sensor:**
 - **Dexcom G4-5: (NDC 08627-0051-04)**
 - **Dexcom G6: (NDC 08627-0053-03)**

If no, do not approve.

DENIAL TEXT: The guideline named **Continuous Glucose Monitors** requires a diagnosis of type 1 diabetes or type 2 diabetes and insulin dependent. In addition, the following must be met:

For request of FreeStyle Libre System (i.e., Reader, Sensor), approval requires:

- Patient is 18 years of age or above
- The patient is currently performing at least 4 finger-stick glucose tests daily
- The patient's insulin treatment plan requires frequent adjustment of insulin dosing

For request of Dexcom continuous glucose monitoring system (i.e., Meter, Transmitter, Sensor), approval requires:

- Patient is 2 years of age or above
- The patient is currently performing at least 4 finger-stick glucose tests daily
- The patient's insulin treatment plan requires frequent adjustment of insulin dosing

CONTINUED ON NEXT PAGE



PRIOR AUTHORIZATION GUIDELINES

CONTINUOUS GLUCOSE MONITORS

RATIONALE

This guideline is to ensure approval of Real-Time Continuous Glucose Monitors (RT-CGM) to patients that meet the specified criteria.

RT-CGM is a glucose monitoring technology that continuously measures and displays interstitial glucose levels. Alarms and alerts are used to notify members when their blood glucose level is exceeding or falling below specified thresholds. This information is used by members to self-manage their diabetes.

Dexcom continuous glucose monitoring systems (CGM) require step therapy through the FreeStyle Libre system to promote overall low net cost. To date, FreeStyle Libre system is FDA approved in adults 18 years of age and older, while Dexcom CGM systems are approved in children and adults. Therefore, the step will not apply to persons less than 18 years of age. The FreeStyle Libre System does not have alarms that will automatically notify a patient during a severe low (hypoglycemic) or high (hyperglycemic) glucose event unless scanned with the Sensor. For example, the System does not have an alarm that can alert or wake a patient when asleep in the case of low or high glucose. Given this difference from Dexcom CGM systems, FreeStyle Libre will not require the patient is able to, or has a caregiver who is able, to hear and view Real-Time Continuous Glucose Monitors (RT-CGM) alerts and respond appropriately.

REFERENCES

- New York State Department of Health Medical Update October 2017 Volume 33 Number 10. https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-10.htm.
- FreeStyle Libre Flash Glucose Monitoring System. Abbott Laboratories. Indications and Safety Information. Access here: <https://www.freestylelibre.us/safety-information>
- Dexcom Continuous Glucose Monitoring Products. Dexcom, Inc. Access here: <https://www.dexcom.com/>
- Cefalu WT, et al. American Diabetes Association: Standards of Medical Care in Diabetes 2017. Diabetes Care 2017;40 (Suppl. 1):S1-S2.

Created: 10/18

Effective: 09/01/20

Client Approval: 08/10/20

P&T Approval: N/A

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPICAPONE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OPICAPONE	ONGENTYS	45536		GPI-10 (7315306000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Parkinson's disease and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient is experiencing "OFF" episodes
- The patient is currently being treated with carbidopa/levodopa
- The patient had a previous trial of, failure of, or contraindication to **TWO** Parkinson's disease agents from **TWO** different classes of the following:
 - Dopamine agonist (e.g., ropinirole, pramipexole, rotigotine)
 - Monoamine oxidase-inhibitors (MAO-I) (e.g., selegiline, rasagiline)
 - Adenosine receptor antagonist A2A (e.g., istradefylline)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **OPICAPONE (Ongentys)** requires the following rule(s) be met for approval:

- A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
- B. You are 18 years of age or older
- C. You are experiencing OFF episodes (times when you have symptoms return due to medication wearing off)
- D. You are currently being treated with carbidopa/levodopa
- E. You have tried or failed or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
 1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
 2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
 3. Adenosine receptor antagonist A2A (such as istradefylline)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OPICAPONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ongentys.

REFERENCES

- Ongentys [Prescribing Information]. San Diego, CA: Neurocrine Biosciences, Inc.; April 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 9/11/20

Created: 09/20

Client Approval: 04/20

P&T Approval: 04/20



STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

VILTOLARSEN (NSA) (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VILTOLARSEN	VILTEPSO	46773		GPI-10 (7460008000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Duchenne muscular dystrophy (DMD) **AND** meet the following criterion?

- The patient has a confirmed mutation of the DMD gene that is amenable to exon 53 skipping

If yes, **approve for 12 months by HICL or GPI-10.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **VILTOLARSEN (Viltepso)** requires the following rule(s) be met for approval:

- A. You have Duchenne muscular dystrophy (DMD; inherited disorder where your muscles get weaker over time)
- B. You have a confirmed mutation of the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Viltepso.

REFERENCES

- Viltepso [Prescribing Information]. Paramus, NJ: NS Pharma, Inc.; August 2020.

Library	Commercial	NSA
Yes	No	Yes

Part D Effective: N/A

Commercial Effective: 08/28/20

Created: 07/20

Client Approval: 10/20

P&T Approval: 10/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CYSTEAMINE HYDROCHLORIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
CYSTEAMINE HCL	CYSTARAN CYSTADROPS		33485 40466	GPI-10 (8680552510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystinosis?

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Does the patient require treatment for corneal cystine crystal accumulation or deposits?

If yes, **approve for 12 months for the requested drug by GPID or GPI-14 with a quantity limit as follows:**

- **Cystaran: #15mL (4 bottles) per 28 days.**
- **Cystadrops: #5mL (4 bottles) per 28 days.**

If no, do not approve.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:

- A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
- B. You require treatment for corneal cystine crystal accumulation or deposits (build up of cysteine in the eye)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

CYSTEAMINE HYDROCHLORIDE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Cystaran/Cystadrops.

REFERENCES

- Cystaran [Prescribing Information]. Gaithersburg, MD: Leadiant Biosciences, Inc.; May 2018.
- Cystadrops [Prescribing Information]. Lebanon, NJ: Recordati Rare Diseases Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/18/20

Created: 05/13

Client Approval: 08/13

P&T Approval: 05/13

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PRALSETINIB (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PRALSETINIB	GAVRETO	46818		GPI-10 (2153407600)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of metastatic non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has *RET* fusion-positive tumors as detected by an FDA approved test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
 If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

- You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
- You have rearranged during transfection (*RET*: type of gene) fusion-positive tumors that have been detected by an Food and Drug Administration (FDA) – approved test
- You are 18 years of age or older

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gavreto.

REFERENCES

Gavreto [Prescribing Information]. Cambridge, MA: Blueprint Medicines Corporation; September 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 9/18/20

Created: 09/20

Client Approval: 10/20

P&T Approval: 10/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

METOCLOPRAMIDE (INTERIM)

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
METOCLOPRAMIDE	GIMOTI		48272	GPI-14 (52300020102080)	

GUIDELINES FOR USE

- Does the patient have a diagnosis of acute and recurrent diabetic gastroparesis **AND** meet the following criterion?

- The patient is 18 years of age or older

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #9.8 mL per 28 days.**

If no, do not approve.

DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:

- You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (disorder that causes delayed emptying of food from the stomach)
- You are 18 years of age or older

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Gimoti.

REFERENCES

Gimoti [Prescribing Information]. Solana Beach, CA: Evoke Pharma, Inc.; June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 9/18/20

Created: 09/20

Client Approval: 10/20

P&T Approval: 10/20

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

RISDIPLAM

Generic	Brand	Exception/Other
RISDIPLAM	EVRYSDI	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for approval:

- A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
- B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
- C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
- D. **If you are presymptomatic (symptoms have not yet appeared), approval also requires:**
 1. There is documentation showing you have up to three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
- E. **If you are symptomatic (symptoms have appeared), approval also requires:**
 1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
 2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
 3. If you previously had gene therapy, you had less than expected clinical benefit

RENEWAL CRITERIA

Our guideline named **RISDIPLAM (Evrysdi)** requires the following rule(s) be met for renewal:

- A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
- B. You meet ONE of the following:
 1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
 2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

RISDIPLAM

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Evrysdi.



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

REFERENCES

- Evrysdi [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/07/20

Created: 08/20

Client Approval: 08/20

P&T Approval: 04/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

DEFERIPRONE

Generic	Brand	Exception/Other
DEFERIPRONE	FERRIPROX DEFERIPRONE	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for approval:

- A. You have transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
- B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
- C. You have tried Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
- D. You meet ONE of the following:
 1. You are experiencing intolerable toxicities, clinically significant adverse effects, or have a contraindication to (medical reason why you cannot use) current chelation therapy (process of removing metals from the blood) with Exjade, Jadenu, or Desferal
 2. Chelation therapy (with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough as shown by ONE of the following:
 - a. Serum ferritin levels (amount of iron-containing blood cell proteins) stay above 2500mcg/L (at least 2 lab values in the previous 3 months)
 - b. You have evidence of cardiac iron accumulation (iron build up in your heart) as defined by cardiac T2* MRI less than 10 milliseconds, iron induced cardiomyopathy (heart disease), fall in left ventricular ejection fraction (LVEF: amount of blood your heart pumps out), arrhythmia indicating inadequate chelation (irregular heartbeat because iron was not lowered enough in body)

RENEWAL CRITERIA

Our guideline named **DEFERIPRONE (Ferriprox)** requires the following rule(s) be met for renewal:

- A. You have transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
- B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ferriprox.

REFERENCES

- Ferriprox [Prescribing Information]. Weston, FL: ApoPharma USA, Inc.; February 2020.



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/02/20

Created: 08/17

Client Approval: 08/17

P&T Approval: 07/17



PRIOR AUTHORIZATION GUIDELINES

APREMILAST

Generic	Brand	HICL	GCN	Exception/Other
APREMILAST	OTEZLA	40967		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- A. The guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval: You have ONE of the following diagnoses:
1. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
 2. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
 3. Behçet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
- B. **If you have psoriatic arthritis (PsA), approval also requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
 3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
 4. The patient had a previous trial of or contraindication to any ONE of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]
- C. **For patients with moderate to severe plaque psoriasis, approval requires:**
1. You are 18 years of age or older
 2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
 3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of your body surface area (BSA) or psoriatic lesions (rashes) affecting your face, hands, feet, or genital area
 4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

For the diagnosis of oral ulcers associated with Behçet's disease, approval requires:

1. You are 18 years of age or older
2. The medication is prescribed by or given in consultation with a rheumatologist (joint pain and inflammation doctor)

PRIOR AUTHORIZATION GUIDELINES

3. You have previously tried ONE or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:

- A. You have psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches), moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales) or Behcet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms
- B. **If you have psoriatic arthritis (PsA), renewal also requires:**
 1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
- C. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
 1. You have achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
- D. **If you have Behcet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
 1. You have achieved or maintained clinical benefit compared to baseline such as an improvement in pain scores, number of ulcers, etc.

APREMILAST

RATIONALE

To ensure appropriate diagnostic, utilization and safety criteria are used for the management of prior authorization requests for apremilast.

REFERENCES

- Otezla [Prescribing Information]. Summit, NJ: Celgene Corporation; June 2017.

Created	FS Committee Approval	Effective
4/2019	4/2019	05/1/19
Revised 08/01/19	08/19	09/15/19
Revised 9/2019		10/21/19
Revised 5/2020	5/2020	5/22/2020
Revised 8/2020	8/2020	9/15/2020

Library	Commercial	Non Self-Administered Product
Yes	Yes	No



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

LEVAMLODIPINE (INTERIM)

Generic	Brand	Exception/Other
LEVAMLODIPINE MALEATE	CONJUPRI	

GUIDELINES FOR USE

Our guideline named **LEVAMLODIPINE (Conjupri)** requires the following rule(s) be met for approval:

- A. You have hypertension (high blood pressure)
- B. You are 6 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Conjupri.

REFERENCES

Conjupri [Prescribing Information]. Hong Kong: CSPC Ouyi Pharmaceutical Co., Ltd.; December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/02/20

Created: 09/20

Client Approval: 10/20

P&T Approval: 10/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

OCTREOTIDE - ORAL

Generic	Brand	Exception/Other
OCTREOTIDE	MYCAPSSA	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **OCTREOTIDE (Mycapssa)** requires the following rule(s) be met for approval:

- A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
- B. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
- C. You have responded to and are currently stable on an injectable somatostatin analog therapy (such as octreotide, lanreotide, or pasireotide)

RENEWAL CRITERIA

Our guideline named **OCTREOTIDE (Mycapssa)** requires the following rule(s) be met for renewal:

- A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
- B. You have had reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
- C. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Mycapssa.

REFERENCES

- Mycapssa [Prescribing Information]. Scotland, UK: MW Encap Ltd., June 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/07/20

Created: 08/20

Client Approval: 08/20

P&T Approval: 04/20



PRIOR AUTHORIZATION GUIDELINES

GUSELKUMAB

Generic	Brand	Exception/Other
GUSELKUMAB	TREMFYA	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **GUSELKUMAB (Tremfya)** requires a diagnosis of moderate to severe psoriasis or psoriatic arthritis. In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

- Therapy is prescribed by or given in consultation with a dermatologist
- The patient has psoriatic lesions involving at least 10% of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, or genital area
- The patient has had a previous trial of at least one or more forms of preferred therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- The patient is 18 years of age or older

For patients with psoriatic arthritis (PsA), approval requires:

- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
- The patient had a previous trial of or contraindication to at least ONE DMARDs (disease modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of or contraindication to any TWO of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

RENEWAL CRITERIA

Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

- A. You have ONE of the following diagnoses:
 1. Moderate to severe plaque psoriasis (PsO; dry, itchy skin patches with scales)
 2. Psoriatic arthritis (PsA; joint pain and swelling)
- B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
 1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
- C. **If you have psoriatic arthritis (PsA), renewal also requires:**
 1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

PRIOR AUTHORIZATION GUIDELINES

GUSELKUMAB

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for GUSELKUMAB.

REFERENCES

- Tremfya [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2017.

Created	FS Committee Approval	Effective
8/2019	8/2019	9/15/19
Revisions		
9.7.2020	8/2020	9/15/2020

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Library	Commercial	Non Self-Administered Product
Yes	Yes	No

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

TOBRAMYCIN INHALED

Generic	Brand	Exception/Other
TOBRAMYCIN	BETHKIS, TOBRAMYCIN	
TOBRAMYCIN IN 0.225% NACL	TOBI TOBRAMYCIN	
TOBRAMYCIN	TOBI PODHALER	
TOBRAMYCIN/NEBULIZER	KITABIS PAK	

GUIDELINES FOR USE

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

- A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
- B. You are 6 years of age or older
- C. You have a lung infection with a gram-negative species (type of bacteria that does not stain a purple color)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tobi, Bethkis or Kitabis.

REFERENCES

- Tobi [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
- Tobi Podhaler [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
- Bethkis [Prescribing Information]. Woodstock, IL: Chiesi USA, Inc.; December 2019.
- Kitabis Pak [Prescribing Information]. Midlothian, VA: PARI Respiratory Equipment, Inc.; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/25/20

Created: 05/12

Client Approval: 07/20

P&T Approval: 10/20

**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES****SATRALIZUMAB-MWGE**

Generic	Brand	Exception/Other
SATRALIZUMAB-MWGE	ENSPRYNG	

GUIDELINES FOR USE**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:

- A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
- B. You are 18 years of age or older
- C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
- D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
- E. You have at least ONE of the following core clinical characteristics:
 1. Optic neuritis (inflammation that damages an eye nerve)
 2. Acute myelitis (sudden and severe inflammation of the spinal cord)
 3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
 4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
 5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
 6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
- F. You will NOT use rituximab, inebilizumab, or eculizumab together with Enspryng

RENEWAL CRITERIA

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:

- A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
- B. You had a reduction in relapse frequency from baseline

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Enspryng.

REFERENCES

- Enspryng [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; August 2020.



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 09/07/20

Created: 08/20

Client Approval: 08/20

P&T Approval: 07/20



STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

SODIUM/CALCIUM/MAG/POT OXYBATE (INTERIM)

Generic	Brand	Exception/Other
SODIUM, CALCIUM, MAG, POT OXYBATE	XYWAV	

GUIDELINES FOR USE

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:

- A. You have narcolepsy with cataplexy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder) or excessive daytime sleepiness in narcolepsy (sleep disorder)
- B. You are 7 years of age or older

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xywav.

REFERENCES

Xywav [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; July 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 10/02/20

Created: 09/20

Client Approval: 10/20

P&T Approval: 10/20