WELLFLEET

RX PLAN

# Prior Authorization Guidelines

## For Wellfleet Rx/KPP Only
## (ID Card BIN: 012882)

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

Revised: 6/1/2021

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

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## ABALOPARATIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| ABALOPARATIDE | TYMLOS | | | |

### GUIDELINES FOR USE

Our guideline named **ABALOPARATIDE (Tymlos)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak or brittle bones after menopause)
B. You have not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo
C. You meet ONE of the following (1, 2, or 3):
    1. You have high risk for fractures defined as ONE of the following:
        i. History of osteoporotic fracture(s) (cracked bones) due to trauma (injury) or fragility (weakness)
        ii. 2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density T-score (test to determine your risk for weak bones) less than or equal to -2.5, corticosteroid use, or use of GnRH (Gonadotropin-releasing hormone) analogs such as nafarelin, etc.
        iii. No prior treatment for osteoporosis AND FRAX (Fracture Risk Assessment Tool) score greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
    2. You are unable to use oral therapy due to upper gastrointestinal (stomach and intestine) problems, you cannot tolerate oral medication, you have lower gastrointestinal problems (unable to absorb oral medications), you have trouble remembering to take oral medications or cannot plan to use an oral bisphosphonate (such as alendronate, risedronate, ibandronate) with other oral medications in your daily routine
    3. You have had an adequate trial of, intolerance to, or a contraindication (medical reason why you cannot use) to bisphosphonates such as Fosamax, Actonel, Boniva

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## ABEMACICLIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ABEMACICLIB | VERZENIO | | | |

### GUIDELINES FOR USE

Our guideline named **ABEMACICLIB (Verzenio)** requires the following rules be met for approval:

A. You have advanced or metastatic breast cancer (cancer has spread to other parts of body) that is hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2)

B. You meet ONE of the following:

1. **If the medication will be used in combination with fulvestrant, approval also requires:**
   i. You are a female
   ii. Your disease has gotten worse after using endocrine therapy
   iii. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)
2. **If the medication will be used as monotherapy (used alone), approval also requires:**
   i. You are 18 years of age or older
   ii. Your disease has gotten worse after using endocrine therapy and before using chemotherapy in the metastatic setting
   iii. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)
3. **If the medication will be used in combination with an aromatase inhibitor (e.g. Anastrozole, letrozole), approval also requires:**
   i. You are a female and postmenopausal
   ii. You have NOT received prior endocrine therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   iii. The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
   iv. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)

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## ACALABRUTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ACALABRUTINIB | CALQUENCE | | | |

### GUIDELINES FOR USE

Our guideline named **ACALABRUTINIB (Calquence)** requires the following rules be met for approval:

A. You have a diagnosis of mantle cell lymphoma (MCL: a type of cancer), chronic lymphocytic leukemia (CLL: cancer of the blood and bone marrow), or small lymphocytic lymphoma (SLL: cancer of the blood and bone marrow)
B. You are 18 years of age or older
C. **If you have mantle cell lymphoma (MCL), approval also requires:**
    1. You have received at least one prior therapy for mantle cell lymphoma

Commercial Effective: 05/01/20

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## ACETAMINOPHEN DAILY LIMIT OVERRIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| N/A | N/A | | | |

### GUIDELINES FOR USE

Our guideline named **ACETAMINOPHEN DAILY LIMIT OVERRIDE** will cause a denied claim for acetaminophen when the total daily dose acetaminophen exceeds 4000mg. The claim will also deny if the requested drug is being used at the same time with other acetaminophen containing product(s) and the combination exceeds 4000mg of acetaminophen per day limit.

**Approval requires the following rule be met:**

A. You will discontinue the other acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

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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

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## AFATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| AFATINIB DIMALEATE | GILOTRIF | | | |

### GUIDELINES FOR USE

Our guideline named **AFATINIB (Gilotrif)** requires the following rule(s) be met for approval:

A. You have metastatic squamous non-small cell lung cancer (type of cancer that has spread) or metastatic non-small cell lung cancer (a different type of lung cancer that has spread)
B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
   1. Your disease has worsened after using platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)
C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumors have non-resistant epidermal growth factor receptor (EGFR; type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test

Commercial Effective: 05/01/20

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## ALECTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ALECTINIB | ALECENSA | | | |

### GUIDELINES FOR USE

Our guideline named **ALECTINIB (Alecensa)** requires the following rules be met for approval:

1. You have a diagnosis of metastatic non-small cell lung cancer (NSCLC; type of cancer that has spread)
2. You are positive for anaplastic lymphoma kinase (ALK; gene mutation) fusion oncogene as detected by an FDA (Food and Drug Administration) -approved test

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## ALLERGEN EXTRACT-HOUSE DUST MITE

| Generic | Brand | | | |
|---|---|---|---|---|
| HOUSE DUST MITE | ODACTRA | | | |

### GUIDELINES FOR USE

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

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites, with or without conjunctivitis (type of inflammation of eye and eyelid)
B. Your diagnosis is confirmed by in vitro testing (testing outside of your body in a tube) for IgE (Immunoglobulin E) antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
C. You are between 18 and 65 years old
D. The medication is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
G. You have a current claim or prescription for auto-injectable epinephrine within the past 365 days

### RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-HOUSE DUST MITE (Odactra)** requires the following rule is met for renewal:

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Commercial Effective: 05/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ALLERGEN EXTRACT-MIXED GRASS POLLEN

| Generic | Brand | | | |
|---|---|---|---|---|
| GR POL-ORC/SW VER/RYE/KENT/TIM | ORALAIR | | | |

### GUIDELINES FOR USE

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

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:

A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. Your diagnosis is confirmed by a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You 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: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You have a current claim or prescription for auto-injectable epinephrine
F. You are between 5 and 65 years of age

### RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rules be met for renewal:

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

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## ALLERGEN EXTRACT-SHORT RAGWEED POLLEN

| Generic | Brand | | | |
|---|---|---|---|---|
| WEED POLLEN-SHORT RAGWEED | RAGWITEK | | | |

### GUIDELINES FOR USE

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

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule(s) be met for approval:

A. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. Your diagnosis is confirmed by a positive skin prick test or in vitro testing (testing outside of your body in a tube) for pollen-specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You 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: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You are 18 years of age or older
F. You have a current claim or prescription for auto-injectable epinephrine

### RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-SHORT RAGWEED POLLEN (Ragwitek)** requires the following rule be met for renewal:

A. You have an improvement in signs and symptoms of allergic rhinitis from baseline

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## ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN

| Generic | Brand | | | |
|---|---|---|---|---|
| GRASS POLLEN-TIMOTHY, STD | GRASTEK | | | |

### GUIDELINES FOR USE

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

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule(s) be met for approval:

A. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. You have a positive skin prick test and/or a positive titre (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You 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: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You are at least 5 years old
F. You have a current claim or prescription for auto-injectable epinephrine

### RENEWAL CRITERIA

Our guideline named **ALLERGEN EXTRACT-TIMOTHY GRASS POLLEN (Grastek)** requires the following rule be met for renewal:

A. You have experienced an improvement in signs and symptoms of allergic rhinitis (itchy, watery eyes, sneezing) from baseline

Commercial Effective: 05/01/20

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## ALPELISIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ALPELISIB | PIQRAY | | | |

### GUIDELINES FOR USE

Our guideline named **ALPELISIB (Piqray)** requires the following rule(s) be met for approval:

A. You have a diagnosis of advanced or metastatic breast cancer (breast cancer that has spread to other parts of the body)
B. Your breast cancer is hormone receptor (HR: type of gene)-positive, human epidermal growth factor receptor 2 (HER2: type of gene)-negative
C. You are a postmenopausal female or a male
D. Piqray will be used in combination with Faslodex (fulvestrant)
E. You have presence of PIK3CA (type of gene)-mutation as detected by a Food and Drug Administration approved test
F. You have experienced disease progression on or after an endocrine-based regimen (your disease has worsened after using a type of hormone therapy)

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## AMIKACIN LIPOSOMAL INHALATION

| Generic | Brand | | | |
|---|---|---|---|---|
| AMIKACIN LIPOSOMAL/NEB. ACCESSR | ARIKAYCE | | | |

### GUIDELINES FOR USE

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

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:

A. You have *Mycobacterium avium complex* (MAC – group of bacteria that cause serious infections) lung disease with limited or no alternative treatment options
B. You are 18 years of age or older
C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
D. Arikayce will be used as part of a combination antibacterial drug regimen
E. Arikayce is being prescribed by or given in consultation with a pulmonologist (lung doctor) or infectious disease specialist physician

### RENEWAL CRITERIA

Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for renewal:

A. You have *Mycobacterium avium complex* (MAC- group of bacteria that cause serious infections) lung disease
B. You have not had a positive *Mycobacterium avium complex* sputum culture (mucus test) after repeated negative cultures
C. You have experienced an improvement in symptoms
D. You meet ONE of the following:
    1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture (mucus test) for *Mycobacterium avium complex* by 6 months of Arikayce treatment
    2. For second or later renewal requests, approval also requires documentation of at least THREE negative sputum cultures (mucus test) for *Mycobacterium avium complex* by 12 months of Arikayce treatment

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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

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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)

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## AMPHETAMINE SULFATE

| Generic | Brand | | | |
|---|---|---|---|---|
| AMPHETAMINE SULFATE | EVEKEO | | | |

### GUIDELINES FOR USE

Our guideline named **AMPHETAMINE SULFATE (Evekeo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Narcolepsy (condition where you suddenly fall asleep)
   2. Attention deficit disorder with hyperactivity (difficulty paying attention)
   3. Use for weight loss or exogenous obesity (overweight due to overeating)

B. **If you have narcolepsy, approval also requires:**
   1. You are 6 years of age or older

C. **If you have attention deficit disorder with hyperactivity, approval also requires:**
   1. You are 3 years of age or older
   2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)

D. **If the request is for weight loss or exogenous obesity, approval also requires:**
   1. You are 12 years of age or older
   2. You had a previous trial of other weight loss medications such as Contrave, Belviq, Qsymia, Xenical, phentermine, phendimetrazine, benzphetamine, diethylpropion

**Note:** The approval of Evekeo for use as a short-term adjunct (add-on) in a regimen of weight reduction is for a maximum duration of 12 weeks

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## ANABOLIC STEROIDS

| Generic | Brand | | | |
|---|---|---|---|---|
| OXYMETHOLONE | ANADROL-50 | | | |
| OXANDROLONE | OXANDRIN | | | |

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

**GUIDELINES FOR USE**

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

**ANADROL-50**

Our guideline named **ANABOLIC STEROIDS (Anadrol-50)** requires the following rule(s) be met for approval:

A. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
    3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
    4. Known or suspected hypercalcemia (high calcium levels)
    5. Severe hepatic (liver) dysfunction
D. **If you have anemia, approval also requires:**
    1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's
E. **If you have cachexia associated with AIDS, approval also requires:**
    1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
    2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
    3. Therapy is prescribed by or given in recommendation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS), or infectious disease specialist

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

## ANABOLIC STEROIDS

### INITIAL CRITERIA - ANADROL-50 (CONTINUED)

4. You meet ONE of the following:
    a. You have 10% unintentional weight loss over 12 months
    b. You have 7.5% unintentional weight loss over 6 months
    c. You have 5% body cell mass (BCM) loss within 6 months
    d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
    e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
    f. You have a BMI of less than 18.5 kg per meter squared

### OXANDRIN

Our guideline named **ANABOLIC STEROIDS (Oxandrin)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Weight loss
    2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
    3. Bone pain accompanying osteoporosis (weak and brittle bones)
    4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
    5. Turner's Syndrome (disorder where female has one X chromosome
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
    3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
    4. Known or suspected hypercalcemia (high calcium levels)
    5. Severe hepatic (liver) dysfunction
D. **If you have weight loss, approval also requires:**
    1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
    2. Medication is being used as add-on therapy to help weight gain

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

**INITIAL CRITERIA - OXANDRIN (CONTINUED)**

E. **If you have cachexia associated with AIDS, approval also requires:**
   1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
   2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
   3. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS) or infectious disease specialist
   4. You meet ONE of the following:
      a. You have 10% unintentional weight loss over 12 months
      b. You have 7.5% unintentional weight loss over 6 months
      c. You have 5% body cell mass (BCM) loss within 6 months
      d. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
      e. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
      f. You have a BMI of less than 18.5 kg per meter squared

**RENEWAL CRITERIA**

(**NOTE:** For the diagnosis of anemia, weight loss, protein catabolism associated with prolonged administration of corticosteroids, bone pain accompanying osteoporosis, or Turner's Syndrome, please refer to the Initial Criteria section)

**OXANDRIN and ANADROL-50**

Our guideline named **ANABOLIC STEROIDS (Oxandrin and Anadrol-50)** requires the following rule(s) be met for renewal:

A. You have cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
C. Your viral load (amount of virus in your blood) is less than 200 copies per mL within the past 3 months
D. You have a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
E. You have not received more than 24 weeks of therapy in a calendar year

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

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## APOMORPHINE

| Generic | Brand | | | |
|---|---|---|---|---|
| APOMORPHINE | APOKYN | | | |

### GUIDELINES FOR USE

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

Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for approval:

A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. The requested medication is being used for acute, intermittent treatment of hypomobility (short and sudden episodes where you have decreased ability to move), OFF episodes associated with advanced Parkinson's disease
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
D. Your physician has optimized your drug therapy as evidenced by BOTH of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. You have had a trial of or contraindication to (medical reason why you cannot use) at least TWO Parkinson disease agents from two different classes: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone)

### RENEWAL CRITERIA

Our guideline named **APOMORPHINE (Apokyn)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You have had improvement with motor fluctuations during OFF episodes with the use of Apokyn (such as 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)

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Commercial Effective: 07/01/20

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

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## APOMORPHINE - SL

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| APOMORPHINE | KYNMOBI | | | | |

### GUIDELINES FOR USE

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

Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist
D. The physician has optimized drug therapy as evidenced by **BOTH** of the following:
   1. Change in levodopa/carbidopa dosing strategy or formulation
   2. Trial of or contraindication to at least two Parkinson's agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitor (MAO-I) (i.e., selegiline, rasagiline), or catechol-o-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)
E. 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)

### RENEWAL CRITERIA

Our guideline named **APOMORPHINE (Kynmobi)** requires the following rule(s) be met for renewal:

A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as 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)

Commercial Effective: 10/01/20

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

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## ARIPIPRAZOLE SENSOR TABS

| Generic | Brand | | | |
|---|---|---|---|---|
| ARIPIPRAZOLE TABLETS WITH SENSOR | ABILIFY MYCITE | | | |

## GUIDELINES FOR USE

Our guideline named **ARIPIPRAZOLE SENSOR TABS (Abilify MyCite)** requires the following rule(s) be met for approval:

A. You have a diagnosis of schizophrenia, bipolar I disorder, or major depressive disorder
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a psychiatrist
D. You have a medical necessity for medication ingestion tracking
E. **If you have major depressive disorder (MDD),** approval also requires:
   a. The medication will be used as an adjunctive (add-on) treatment
F. **If you have bipolar I disorder,** approval also requires **ONE** of the following**:**
   1. The request is for acute (short-term) treatment of manic and mixed episodes as monotherapy, OR as an adjunct (add-on) to lithium or valproate
   2. The request is for maintenance treatment as monotherapy, OR as an adjunct to lithium or valproate

Commercial Effective: 07/01/20

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

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## ASFOTASE ALFA

| Generic | Brand | | | |
|---|---|---|---|---|
| ASFOTASE ALFA | STRENSIQ | | | |

### GUIDELINES FOR USE

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

Our guideline named **ASFOTASE ALFA (Strensiq)** requires the following rules be met for approval:

A. You have a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP; genetic disorder causing abnormal development of bones and teeth) or juvenile-onset hypophosphatasia (HPP).
B. **If you have perinatal/infantile-onset hypophosphatasia (HPP), all of the following criteria must be met:**
    1. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor)
    2. You were 6 months of age or younger at hypophosphatasia onset
    3. You are not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
    4. You are positive for a tissue non-specific alkaline phosphatase (a type of enzyme) (ALPL) gene mutation as confirmed by genetic testing **OR** you meet at least **TWO** of the following criteria:
    a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
    b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND you have not received vitamin B6 supplementation in the previous week
    c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
    d. Radiographic evidence of hypophosphatasia [e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), widened growth plates, areas of radiolucency (ability to see through with x-rays/ radiation) or sclerosis (hardening of an area)]
    e. Presence of **two or more** of the following:
        i. Rachitic chest deformity (chest bones are not normal)
        ii. Craniosynostosis (premature closure of skull bones)
        iii. Delay in skeletal growth resulting in delay of motor development
        iv. History of vitamin B6 dependent seizures
        v. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
        vi. History or presence of fracture after birth not due to injury or delayed fracture healing

***(Initial criteria continued on next page)***

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

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## ASFOTASE ALFA

### INITIAL CRITERIA (CONTINUED)

C. **If you have juvenile-onset hypophosphatasia (HPP), approval also requires:**
   1. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor)
   2. You were 18 years of age or younger at hypophosphatasia onset
   3. You are not currently receiving treatment with a bisphosphonate [e.g., Boniva (ibandronate), Fosamax (alendronate), Actonel (risedronate)]
   4. You are positive for a tissue non-specific alkaline phosphatase (TNSALP) (ALPL) gene mutation as confirmed by genetic testing **OR** meet at least **TWO** of the following criteria:
      a. Serum alkaline phosphatase (type of enzyme) level below that of normal range for your age
      b. Serum pyridoxal-5'-phosphate (PLP) levels elevated **AND** you have not received vitamin B6 supplementation in the previous week
      c. Urine phosphoethanolamine (PEA) level above that of normal range for your age
      d. Radiographic evidence of hypophosphatasia (e.g., flared and frayed metaphyses (narrow part of long bone), osteopenia (bone loss), osteomalacia (bone softening), widened growth plates, areas of radiolucency or sclerosis (hardening of an area)
      e. Presence of **two or more** of the following:
         i. Rachitic deformities (rachitic chest, bowed legs, knock-knees)
         ii. Premature loss of primary teeth prior to 5 years of age
         iii. Delay in skeletal growth leading to motor development delay
         iv. History or presence of fracture after birth not due to injury or delayed fracture healing

**Strensiq will not be approved for the following patients:**
1. Patients with serum calcium or phosphate levels below the normal range
2. Patients with a treatable form of rickets (A softening and weakening of bones in children, usually due to low Vitamin D)

### RENEWAL CRITERIA

Our guideline named **ASFOTASE ALFA (Strensiq)** requires that the following rule is met for renewal:

A. You have experienced improvement in the skeletal characteristics of hypophosphatasia (HPP: genetic disorder causing abnormal development of bones and teeth). Characteristics may include irregularity of the provisional zone of calcification (area on long bone for calcium build-up), physeal widening (area of bone that helps length growth), metaphyseal flaring (a narrow part of long bone grows), radiolucencies (ability to see with x-rays/ radiation), patchy osteosclerosis (parts of abnormal hardening of bone), ratio of mid-diaphyseal cortex to bone thickness, gracile (slender) bones, bone formation and fractures.

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

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## ASPIRIN ER

| Generic | Brand | | | |
|---|---|---|---|---|
| ASPIRIN ER | DURLAZA | | | |

### GUIDELINES FOR USE

Our guideline named **ASPIRIN ER (Durlaza)** requires the following rules be met for approval:

1. You have ONE of the following:
   a. Diagnosis of chronic coronary artery disease [damage or disease in the heart's major blood vessels; may include a history of myocardial infarction (heart attack) or unstable angina (chest pain when your heart doesn't get enough oxygen)] OR
   b. History of an ischemic stroke or transient ischemic attack (arteries to your brain become narrowed or blocked, causing blood flow loss).
2. You have previously tried aspirin over-the-counter (OTC)
3. Durlaza is NOT being used for acute treatment (short term treatment) of myocardial infarction (heart attack) or before percutaneous coronary intervention (non-surgical procedure used to treat narrowing of the coronary arteries of the heart)

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Commercial Effective: 07/01/20

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

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## ASPIRIN-OMEPRAZOLE

| Generic | Brand | | | |
|---|---|---|---|---|
| ASPIRIN-OMEPRAZOLE | YOSPRALA, ASPIRIN-OMEPRAZOLE | | | |

### GUIDELINES FOR USE

Our guideline named **ASPIRIN-OMEPRAZOLE (Yosprala)** requires the following rule(s) be met for approval:

A. The request is for secondary prevention of cardiovascular (related to heart and blood vessels) or cerebrovascular (related brain and blood vessels) events
B. You have ONE of the following:
   1. Ischemic stroke (arteries to your brain become narrowed or blocked, causing less blood flow)
   2. Transient ischemia of the brain due to fibrin platelet emboli (blood flow to your brain gets cut off for a short time due to temporary blockage)
   3. Previous myocardial infarction (heart attack)
   4. Unstable angina pectoris (chest pain when your heart doesn't get enough oxygen)
   5. Chronic stable angina pectoris (chest pain when your heart doesn't get enough oxygen)
   6. History of undergoing revascularization procedures (procedures that restore blood flow to heart such as coronary artery bypass graft, percutaneous transluminal coronary angioplasty)
C. You have a risk of developing aspirin associated gastrointestinal (GI) ulcers due to age (55 years or older) **AND** have a documented history of gastrointestinal (GI) ulcers
D. You have tried both aspirin over-the-counter (OTC) **AND** generic proton pump inhibitors (such as omeprazole, lansoprazole, pantoprazole, rabeprazole)

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)

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## AVATROMBOPAG

| Generic | Brand | | | |
|---|---|---|---|---|
| AVATROMBOPAG | DOPTELET | | | |

### GUIDELINES FOR USE

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

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   a. Thrombocytopenia (low amount of a type of blood cell that prevents bleeding)
   b. Chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)

B. **If you have thrombocytopenia, approval also requires:**
   1. You are 18 years of age or older
   2. You have chronic liver disease
   3. You are scheduled to undergo a procedure 10 to 13 days after starting Doptelet therapy
   4. You have a platelet (type of blood cell that prevents bleeding) count of less than 50 x 10(9)/L measured within the last 30 days
   5. Therapy is prescribed by or given in consultation with a hematologist (blood specialist), gastroenterologist (digestive system doctor), hepatologist (liver specialist), immunologist (allergy/immune system specialist), or endocrinologist (hormone doctor)
   6. You are not receiving other thrombopoietin receptor agonist therapy such as Promacta

C. **If you have chronic immune thrombocytopenia (cITP), approval also requires:**
   1. You are 18 years of age or older
   2. You have previously tried corticosteroids or immunoglobulins, unless there is a medical reason why you cannot (contraindication) **OR** you had an insufficient response to splenectomy (surgical removal of spleen)
   3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system specialist)

### RENEWAL CRITERIA

Our guideline named **AVATROMBOPAG (Doptelet)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of thrombocytopenia (low amount of a type of blood cell that prevents bleeding) or chronic immune thrombocytopenia (condition where your body fights against a type of blood cell that prevents bleeding)
B. You had a clinical response to therapy as defined by an increase in platelet count to at least 50 x 10(9)/L (at least 50,000 per microliter), compared to baseline.

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

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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

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## AZTREONAM INHALED

| Generic | Brand | | | |
|---|---|---|---|---|
| AZTREONAM LYSINE | CAYSTON | | | |

### GUIDELINES FOR USE

Our guideline named **AZTREONAM INHALED** requires the following rule(s) be met for approval:

A. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 7 years of age or older
C. You have a lung infection with a Gram negative species such as *Pseudomonas aeruginosa*

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## BACLOFEN ORAL SOLUTION

| Generic | Brand | | | |
|---|---|---|---|---|
| BACLOFEN | OZOBAX | | | |

### GUIDELINES FOR USE

Our guideline named **BACLOFEN ORAL SOLUTION (Ozobax)** requires the following rule be met for approval:

A. You are unable to swallow oral baclofen tablets at the prescribed dosing.

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Commercial Effective: 07/01/20

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

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## BEDAQUILINE FUMARATE

| Generic | Brand | | | |
|---|---|---|---|---|
| BEDAQUILINE FUMARATE | SIRTURO | | | |

### GUIDELINES FOR USE

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

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Commercial Effective: 08/01/20

**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.)

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

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## BEROTRALSTAT

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| BEROTRALSTAT HYDROCHLORIDE | ORLADEYO | | | | |

### GUIDELINES FOR USE

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

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Orladeyo together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

### RENEWAL CRITERIA

Our guideline named **BEROTRALSTAT (Orladeyo)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

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Commercial Effective: 01/01/21

**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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## BINIMETINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| BINIMETINIB | MEKTOVI | | | |

### GUIDELINES FOR USE

Our guideline named **BINIMETINIB (Mektovi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of unresectable (cannot completely remove by surgery) or metastatic (disease that has spread) melanoma (skin cancer)
B. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by a Food and Drug Administration-approved test
C. The medication will be used in combination with Braftovi (encorafenib)

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Commercial Effective: 07/01/20

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

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## BOSUTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| BOSUTINIB | BOSULIF | | | |

### GUIDELINES FOR USE

Our guideline named **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+; small abnormal chromosome found in leukemia) chronic myelogenous leukemia (CML; blood-cell cancer that begins in the bone marrow)
   2. Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML; blood-cell cancer that begins in the bone marrow)

B. You are 18 years of age or older

C. **If you have chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+; small abnormal chromosome found in leukemia) chronic myeloid leukemia (CML; blood-cell cancer that begins in the bone marrow), approval also requires:**
   1. You have previously tried or have a contraindication to (a medical reason why you cannot use) other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)
   2. You do NOT have the T315I, V299L, G250E, or F317L mutations as shown by Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (type of lab test)

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## BREMELANOTIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| BREMELANOTIDE | VYLEESI | | | |

### GUIDELINES FOR USE

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

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You had a previous trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are **NOT** currently using Addyi (flibanserin)

### RENEWAL CRITERIA

Our guideline named **BREMELANOTIDE (Vyleesi)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD; also referred to as female sexual interest/arousal disorder [FSIAD] where you do not desire sexual activity), as defined by **ALL** of the following:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. HSDD is **NOT** a result of a co-existing medical or psychiatric (mental) condition, a problem within the relationship or the effects of a medication or drug substance
   3. HSDD symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are **NOT** currently using Addyi (flibanserin)
D. You have experienced continued improvement in symptoms of HSDD/FSIAD such as increased sexual desire, lessened distress)

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

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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

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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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## CAPLACIZUMAB-YHDP

| Generic | Brand | | | |
|---|---|---|---|---|
| CAPLACIZUMAB-YHDP | CABLIVI | | | |

### GUIDELINES FOR USE

Our guideline named **CAPLACIZUMAB-YHDP (Cablivi**) requires the following rule(s) be met for approval:

A. You have a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP- a type of blood disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
D. You have NOT experienced more than two recurrences of acquired thrombotic thrombocytopenia purpura, while on Cablivi therapy. For example there's a new drop in platelet count requiring repeat plasma exchange during 30 days post-plasma exchange therapy (process of replacing a liquid part of the blood) and up to 28 days of extended therapy
E. You also meet ONE of the following:
    1. Your request is for continuation of Cablivi therapy from inpatient (hospital) setting and you previously received plasma exchange and immunosuppressive therapy (treatment that weakens your immune system) within the inpatient setting
    2. Your request is for continuation of Cablivi therapy from the initial 30 days treatment course (no break in therapy) AND:
        a. You are receiving immunosuppressive therapy, and
        b. You are experiencing signs of persistent underlying disease (such as suppressed ADAMTS13 [a disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13: type of blood clot disorder] activity level remain present)

Commercial Effective: 07/01/20

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

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## CAPMATINIB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| CAPMATINIB | TABRECTA | | | | |

### GUIDELINES FOR USE

Our guideline named **CAPMATINIB (Tabrecta)** 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. 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

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Commercial Effective: 10/01/20

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

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## CAPSAICIN

| Generic | Brand | | | |
|---|---|---|---|---|
| CAPSAICIN 8% PATCH | QUTENZA | | | |

## GUIDELINES FOR USE

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.

Commercial Effective: 08/24/20

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

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## CARBIDOPA-LEVODOPA

| Generic | Brand | | | |
|---|---|---|---|---|
| CARBIDOPA/LEVODOPA | DUOPA | | | |

### GUIDELINES FOR USE

Our guideline named **CARBIDOPA-LEVODOPA (Duopa)** requires the following rule be met for approval:

A. You have a diagnosis of advanced Parkinson's disease (nerve system disorder that affects movement)

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Commercial Effective: 07/01/20

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

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## CENEGERMIN-BKBJ

| Generic | Brand | | | |
|---|---|---|---|---|
| CENEGERMIN-BKBJ | OXERVATE | | | |

### GUIDELINES FOR USE

Our guideline named **CENEGERMIN-BKBJ (Oxervate)** requires the following rule(s) be met for approval:

A. You have a diagnosis of neurotrophic keratitis (an eye disease due to a damaged eye nerve)
B. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor)
C. You have a medical history that supports a cause for trigeminal nerve damage (damage to a nerve in the head) such as herpes zoster infection (shingles virus), multiple sclerosis (disorder where immune system attacks nerves), diabetes, ocular surgical (eye surgery) damage
D. You have loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
E. You are refractory (not fully responsive) to conservative management that includes artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses

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Commercial Effective: 09/04/20

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

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## CERITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| CERITINIB | ZYKADIA | | | |

## GUIDELINES FOR USE

Our guideline named **CERITINIB (Zykadia)** requires the following rule(s) be met for approval:

A. You have a diagnosis of metastatic non-small cell lung cancer (type of lung cancer that has spread)
B. Your tumor is anaplastic lymphoma kinase (ALK: a type of enzyme) positive as confirmed by a Food and Drug Administration-approved test

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## CHENODIOL

| Generic | Brand | | | |
|---|---|---|---|---|
| CHENODIOL | CHENODAL | | | |

### GUIDELINES FOR USE

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

Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for approval:

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
B. **If you have radiolucent gallstones, approval also requires:**
   1. You have tried ursodiol, unless there is a medical reason why you cannot (contraindication)
   2. You have not received previous chenodiol therapy for more than a total of 24 months

### RENEWAL CRITERIA

Our guideline named **CHENODIOL (Chenodal)** requires the following rule(s) be met for renewal:

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)
B. **If you have radiolucent gallstones, renewal also requires:**
   1. You have **NOT** had chenodiol therapy for more than a total of 24 months
   2. You do **NOT** have complete or no gallstone dissolution (disappearance) seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
   3. You have partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
C. **If you have cerebrotendinous xanthomatosis, renewal also requires you have experienced an improvement** in **ONE** of the following:
   1. Normalization of elevated serum or urine bile alcohols
   2. Normalization of elevated serum cholestanol levels
   3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

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

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## CHOLIC ACID

| Generic | Brand | | | |
|---|---|---|---|---|
| CHOLIC ACID | CHOLBAM | | | |

### GUIDELINES FOR USE

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

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for approval:

A. You show signs of liver disease, steatorrhea (excess fat in feces), or complications from your body not being able to absorb fat-soluble vitamins that occur from ONE of the following conditions:
   1. Bile acid synthesis disorders (your body has a problem making bile acid)
   2. Peroxisomal disorders (Zellweger spectrum disorders) (problems with a part of a cell that contains enzymes)

### RENEWAL CRITERIA

Our guideline named **CHOLIC ACID (Cholbam)** requires the following rule(s) be met for renewal:

A. You have experienced an improvement in your liver function as defined by at least ONE of the following criteria:
   1. ALT (alanine aminotransferase) or AST (aspartate transaminase) (types of liver enzymes) values have been lowered to less than 50 U/L or baseline levels reduced by 80%
   2. Total bilirubin values reduced to less than 1 mg/dL
   3. No evidence of cholestasis (condition where bile cannot flow from liver) on liver biopsy

Commercial Effective: 07/01/20

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

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## CLASCOTERONE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| CLASCOTERONE | WINLEVI | | | | |

### GUIDELINES FOR USE

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

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:

A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
B. You are 12 years of age or older
C. Therapy is prescribed by or given in consultation with a dermatologist (skin doctor)
D. You have previously tried BOTH of the following unless there is a medical reason why you cannot (contraindication):
    1. ONE oral acne agent (such as oral antibiotics or oral isotretinoin)
    2. TWO topical acne agents (such as topical retinoids, topical antibiotics, benzoyl peroxide)

### RENEWAL CRITERIA

Our guideline named **CLASCOTERONE (Winlevi)** requires the following rule(s) be met for approval:

A. You have acne vulgaris (skin condition in which hair follicles become plugged with oil and dead skin cells)
B. You had improvement of acne lesions

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Commercial Effective: 01/01/21

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

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## CLOBAZAM-SYMPAZAN

| Generic | Brand | | | |
|---|---|---|---|---|
| CLOBAZAM | SYMPAZAN | | | |

### GUIDELINES FOR USE

Our guideline named **CLOBAZAM-SYMPAZAN** requires the following rule(s) be met for approval:

A. You have Lennox-Gastaut Syndrome (type of severe seizure)
B. The requested medication will be used for adjunctive (add-on) treatment of seizures associated with Lennox-Gastaut syndrome (type of severe seizure) such as in combination with lamotrigine or topiramate
C. You are 2 years of age or older
D. You are unable to take tablets or suspension
E. You had a trial of or contraindication to (medical reason why you cannot use) generic/branded clobazam products (Onfi)

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Commercial Effective: 07/01/20

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

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## COBIMETINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| COBIMETINIB FUMARATE | COTELLIC | | | |

### GUIDELINES FOR USE

Our guideline named **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:

A. You have unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
B. You are positive for BRAF V600E OR V600K (types of genes) mutation
C. Cobimetinib will be used in combination with vemurafenib (Zelboraf)

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Commercial Effective: 07/01/20

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

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## CONTRACEPTIVE ZERO COST SHARE OVERRIDE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| CONTRACEPTIVES, ORAL | | | | | |
| CONTRACEPTIVES, TRANSDERMAL | | | | | |
| CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC | | | | | |
| INTRA-UTERINE DEVICES (IUD'S) | | | | | |
| CONTRACEPTIVES, INJECTABLE | | | | | |
| CONTRACEPTIVES, IMPLANTABLE | | | | | |
| CONTRACEPTIVE, INTRAVAGINAL | | | | | |
| DIAPHRAGMS/CERVICAL CAP | | | | | |

### GUIDELINES FOR USE

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)

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)

**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

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

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## CRIZOTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| CRIZOTINIB | XALKORI | | | |

## GUIDELINES FOR USE

Our guideline named **CRIZOTINIB (Xalkori)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic non-small cell lung cancer (type of lung cancer that has spread) with anaplastic lymphoma kinase (ALK; a type of enzyme)-positive tumors
   2. Metastatic non-small cell lung cancer with ROS1 (a type of enzyme) -positive tumors.

Commercial Effective: 07/01/20

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

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## CYSTEAMINE BITARTRATE

| Generic | Brand | | | |
|---|---|---|---|---|
| CYSTEAMINE BITARTRATE | PROCYSBI | | | |

### GUIDELINES FOR USE

Our guideline named **CYSTEAMINE BITARTRATE (Procysbi)** requires the following rule(s) be met for approval:

A. You have nephropathic cystinosis (rare genetic, metabolic disease which results in an abnormal accumulation of a protein known as cysteine)
B. You are 1 year of age or older
C. You have previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## CYSTEAMINE HYDROCHLORIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| CYSTEAMINE HCL | CYSTARAN | | | |

### GUIDELINES FOR USE

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)

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Commercial Effective: 10/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## DABRAFENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| DABRAFENIB MESYLATE | TAFINLAR | | | |

### GUIDELINES FOR USE

Our guideline named **DABRAFENIB (Tafinlar)** requires the following rule(s) be met for approval:

A. You have unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread), metastatic non-small cell lung cancer, melanoma (skin cancer), or locally advanced or metastatic anaplastic thyroid cancer.
B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used as a single agent (by itself)
C. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mekinist (trametinib)
D. **If you have melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication has not previously been used for more than one year
   3. The medication will be used in combination with Mekinist (trametinib) for adjuvant (add-on) treatment
   4. There is involvement of lymph node(s) following complete resection (removal of a tumor and normal tissue around it)
E. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You have BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mekinist (trametinib)
F. **If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

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

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## DACLATASVIR

| Generic | Brand | | | |
|---|---|---|---|---|
| DACLATASVIR DIHYDROCHLORIDE | DAKLINZA | | | |

## GUIDELINES FOR USE

Our guideline named **DACLATASVIR (Daklinza)** requires the following rule(s) be met for approval:

A. You have hepatitis C, with genotype 1 or genotype 3 infection
B. You are 18 years of age or older
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. You have documentation showing at least ONE detectable HCV (hepatitis C virus) RNA level (amount of virus in your blood) within the past 6 months as evidence of a current and chronic HCV infection.
E. You must be taking Daklinza in combination with Sovaldi, and must meet all required criteria for Sovaldi
F. **For Genotype 1 infection we also require:**
    1. *Patients without cirrhosis (liver scarring):*
        a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
        b. You have previously tried Epclusa, Harvoni or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa, Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
    2. *Patients with decompensated cirrhosis (you have symptoms related to liver scarring):*
        a. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
        b. Concurrent (used at the same time with) ribavirin use required
    3. *Patients status post liver transplant:*
        a. You have previously tried Harvoni or Mavyret and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Harvoni and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
        b. Concurrent (used at the same time with) ribavirin use required

***(Criteria continued on next page)***

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

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**CONTINUED ON NEXT PAGE**

**GUIDELINES FOR USE (CONTINUED)**

G. **For Genotype 3 infection we also require:**
   1. *Patients without cirrhosis:*
      a. You are treatment naïve (never previously treated) or treatment experienced with a peginterferon and ribavirin regimen
      b. You have previously tried Epclusa or Mavyret and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
   2. *Patients with decompensated cirrhosis (Child-Pugh B or C; you have symptoms related to liver scarring):*
      a. You have previously tried Epclusa and you had adverse effect, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
   b. Concurrent (used at the same time with) ribavirin use required
   3. *Post-liver transplant, without cirrhosis:*
      a. Previous trial of Mavyret required and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) therapy; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required
   4. *Post-liver transplant, with compensated cirrhosis*
      a. Previous trial of Epclusa or Mavyret required and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa and Mavyret; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response) will not be approved]
      b. Concurrent (used at the same time with) ribavirin use required

**Daklinza will not be approved if you meet ANY of the following:**
- You are using any of the following medications at the same time while on Daklinza: amiodarone, carbamazepine, phenytoin, or rifampin
- You are using any of the following medications at the same time while on Sovaldi: phenobarbital, oxcarbazepine, rifabutin, rifapentine, or tipranavir/ritonavir
- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)
- You have compensated cirrhosis (Child-Pugh A; you have no symptoms related to liver damage) and are not status post liver transplant (you have not had a liver transplant)

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

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## DACOMITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| DACOMITINIB | VIZIMPRO | | | |

### GUIDELINES FOR USE

Our guideline named **DACOMITINIB (Vizimpro)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (type of cancer that has spread)
B. You have epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
C. The requested medication will be used as first-line treatment

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Commercial Effective: 07/01/20

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

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## DALFAMPRIDINE

| Generic | Brand | | | |
|---|---|---|---|---|
| DALFAMPRIDINE | AMPYRA | | | |

### GUIDELINES FOR USE

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

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for approval:

A. You have multiple sclerosis (disease in which the immune system eats away at the protective covering of nerves)
B. The medication is prescribed by or recommended by a neurologist (doctor who specializes in disorders of the nervous system)
C. You have symptoms of a walking disability

### RENEWAL CRITERIA

Our guideline named **DALFAMPRIDINE (Ampyra)** requires the following rule(s) be met for renewal:

A. You have experienced or maintained at least a 15% improvement in walking ability.

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Commercial Effective: 07/01/20

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

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## DASATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| DASATINIB | SPRYCEL | | | |

### GUIDELINES FOR USE

Our guideline named **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:

A. You have Philadelphia chromosome-positive (Ph+; type of gene mutation) chronic myeloid leukemia (CML; slowly progressing type of blood-cell cancer that begins in the bone marrow) in chronic, accelerated, or myeloid or lymphoid blast phase, OR Philadelphia chromosome-positive acute lymphoblastic leukemia (ALL; type of cancer of the blood and bone marrow that affects white blood cells).

B. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND are newly diagnosed
   2. You are between 1 and 17 years of age

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance or intolerance to prior therapy including imatinib (Gleevec)
   3. You have had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that you do not have the following mutations: T315I, V299L, T315A, or F317L/V/I/C

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance or intolerance to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are newly diagnosed, between 1 and 17 years of age, AND using Sprycel in combination with chemotherapy

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

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## DEFERASIROX

| Generic | Brand | | | |
|---|---|---|---|---|
| DEFERASIROX | EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX | | | |

**GUIDELINES FOR USE**

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

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** 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 taken within 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 need at least 2 lab values taken within 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 require a trial of equivalent generic Exjade or Jadenu tablets

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## DEFERASIROX

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** 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 taken within 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 need at least 2 lab values taken within the previous 3 months)
   2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

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Commercial Effective: 09/07/20

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

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## DEFERIPRONE

| Generic | Brand | | | |
|---|---|---|---|---|
| DEFERIPRONE | FERRIPROX | | | |

### 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)

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Commercial Effective: 10/12/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## DEFEROXAMINE

| Generic | Brand | | | |
|---|---|---|---|---|
| DEFEROXAMINE MESYLATE | DESFERAL, DEFEROXAMINE MESYLATE | | | |

### GUIDELINES FOR USE

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

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rule(s) be met for approval:

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
C. You are 3 years of age or older
D. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 1000mcg/L (shown by at least 2 lab values in the previous 3 months)

### RENEWAL CRITERIA

Our guideline named **DEFEROXAMINE (Desferal)** requires the following rules be met for renewal:

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
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)

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Commercial Effective: 07/01/20

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

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## DEFLAZACORT

| Generic | Brand | | | |
|---|---|---|---|---|
| DEFLAZACORT | EMFLAZA | | | |

### GUIDELINES FOR USE

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

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for approval:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that gets worse)
B. You are 2 years of age or older
C. You doctor confirms your diagnosis with genetic testing
D. The drug is prescribed by or recommended by a neurologist (nerve system doctor) specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
E. You have tried prednisone or prednisolone for at least 6 months and meet one of the following:
    1. Prednisone or prednisolone did not work and you meet ALL of the following criteria:
        a. You are not in Stage 1: pre-symptomatic phase
        b. There is no steroid myopathy (muscle disease due to steroid)
        c. You have documentation that your disease is advanced– you cannot walk, cannot function, cannot breathe using standard measures over time, consistent with advancing disease (stage 2 or higher). Acceptable standard measures include: 6-minute walk distance (6MWD), time to ascend/descend 4 stairs, rise from floor time (Gower'smaneuver), 10-meter run/walk time, or North Star Ambulatory Assessment (NSAA), Physician global assessments (PGA), pulmonary function (forced vital capacity, lung function tests), upper limb strength (propelling a wheelchair 30 feet)
    2. You had adverse side effects while on prednisone or prednisolone and there is documentation of literature-based evidence provided supporting Emflaza's decreased effect for that side effect
       Note: Requests due to side effects while on prednisone or prednisolone that are named or listed in the prescribing information of Emflaza will not be approved

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

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## DEFLAZACORT

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **DEFLAZACORT (Emflaza)** requires the following rules be met for renewal:

A. You have Duchenne muscular dystrophy (inherited muscular weakness that worsens)
B. You meet ONE of the following criteria:
   i. **If you are currently ambulatory (can walk), renewal also requires:**
      a. You have shown function, stabilization or improvement in a standard set of ambulatory or functional status measures since being on Emflaza. These measures must be monitored, tracked, and documented consistently. Acceptable standard measures include: 6-minute walk distance, time to ascend/descend 4 stairs, rise from floor time (Gower's maneuver), 10-meter run/walk time, North Star Ambulatory Assessment, Physician Global Assessments
   ii. **If you are currently non-ambulatory (cannot walk), renewal also requires:**
      a. You have maintained or have a less than expected decrease in pulmonary (breathing) function and/or upper limb strength assessed by standard measures since being on Emflaza. These measures must be monitored, tracked, and documented consistently. Acceptable standard measures include: pulmonary function (force vital capacity, pulmonary function tests), upper limb strength measures (propelling a wheelchair 30 feet), Physician Global Assessments

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

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## DELAFLOXACIN

| Generic | Brand | | | |
|---|---|---|---|---|
| DELAFLOXACIN | BAXDELA | | | |

## GUIDELINES FOR USE

Our guideline named **DELAFLOXACIN (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, decubitis 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)***

**CONTINUED ON NEXT PAGE**

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

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## DELAFLOXACIN

**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 pneumonia, 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)

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Commercial Effective: 04/01/20

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

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## DESIRUDIN

| Generic | Brand | | | |
|---|---|---|---|---|
| DESIRUDIN | IPRIVASK | | | |

### GUIDELINES FOR USE

Our guideline named **DESIRUDIN (Iprivask)** requires that you are receiving Iprivask for the prevention of deep vein thrombosis (DVT; blood clot in a deep vein, usually in the legs) and you are undergoing elective hip replacement surgery.

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Commercial Effective: 07/01/20

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

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## DEUTETRABENAZINE

| Generic | Brand | | | |
|---|---|---|---|---|
| DEUTETRABENAZINE | AUSTEDO | | | |

### GUIDELINES FOR USE

Our guideline named **DEUTETRABENAZINE (Austedo)** requires the following rule(s) be met for approval:

A. You have chorea (involuntary movements) associated with Huntington's disease or moderate to severe tardive dyskinesia (involuntary, repetitive body movements)
B. **If you have chorea associated with Huntington's disease, approval also requires:**
   1. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system) or movement disorder specialist
C. **If you have moderate to severe tardive dyskinesia, approval also requires:**
   1. Moderate to severe tardive dyskinesia has been present for at least 3 months
   2. You are at least 18 years of age
   3. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system), movement disorder specialist, or psychiatrist (mental health doctor)
   4. You have a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in the prescription claims history

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## DEXTROMETHORPHAN with QUINIDINE

| Generic | Brand | | | |
|---|---|---|---|---|
| DEXTROMETHORPHAN/ QUINIDINE | NUEDEXTA | | | |

### GUIDELINES FOR USE

Our guideline named **DEXTROMETHORPHAN with QUINIDINE (Nuedexta)** requires you have a pseudobulbar affect (sudden, uncontrollable laughter) for approval.

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## DIABETIC TEST STRIPS

| Generic | Brand | | | |
|---|---|---|---|---|
| BLOOD SUGAR DIAGNOSTIC<br>BLOOD SUGAR DIAGNOSTIC, DISC<br>BLOOD SUGAR DIAGNOSTIC, DRUM | DIABETIC TEST STRIPS<br>VARIOUS | | | |

### GUIDELINES FOR USE

Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:

A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott
B. You require a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment (problems with sight and/or memory and thinking)
C. You require a non-preferred blood glucose test strip because you use another manufacturer's companion insulin pump

Request for non-preferred test strips will not be approved if due to a need for data management software. Please note that data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

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Commercial Effective: 06/01/20

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

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## DICHLORPHENAMIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| DICHLORPHENAMIDE | KEVEYIS | | | |

### GUIDELINES FOR USE

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

Our guideline named **DICHLORPHENAMIDE (Keveyis)** requires the following rule(s) be met for approval:

A. You have a primary hypokalemic periodic paralysis (extreme muscle weakness with low potassium levels in your blood), primary hyperkalemic periodic paralysis (extreme muscle weakness with high potassium levels in your blood), or Paramyotonia Congenita (disorder that causes muscles stiffness)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a neurologist (nerve system doctor)
D. You do not have hepatic insufficiency (liver failure), pulmonary obstruction (difficulty breathing due to blockage of airflow, or a health condition that warrants concurrent use of high-dose aspirin
E. **If you have primary hypokalemic periodic paralysis, approval also requires:**
    1. You have tried acetazolamide AND a potassium-sparing diuretic (spironolactone, triamterene)
F. **If you have primary hyperkalemic periodic paralysis or Paramyotonia Congenita, approval also requires:**
    1. You have tried acetazolamide AND a thiazide diuretic (hydrochlorothiazide)

### RENEWAL CRITERIA

Our guideline named **DICHLORPHENAMIDE (Keveyis)** requires that you have experienced at least two fewer attacks per week from baseline (measurement before you started treatment) for renewal.

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
**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

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Commercial Effective: 04/01/20

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

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## DICLOFENAC TOPICAL

| Generic | Brand | | | |
|---|---|---|---|---|
| DICLOFENAC SODIUM 3% | SOLARAZE | | | |

## GUIDELINES FOR USE

Our guideline named **DICLOFENAC TOPICAL (Solaraze)** requires the following rule(s) be met for approval:

A. You have actinic keratosis (rough, scaly patch on the skin caused by years of sun exposure)
B. You had a previous trial of topical fluorouracil (such as Efudex, Fluoroplex, Carac), unless there is a medical reason why you cannot (contraindication)
C. The medication is prescribed by or given in consultation with a dermatologist (skin doctor) or oncologist (cancer/tumor doctor)

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## DORNASE ALFA

| Generic | Brand | | | |
|---|---|---|---|---|
| DORNASE ALFA | PULMOZYME | | | |

### GUIDELINES FOR USE

Our guideline named **DORNASE ALFA (Pulmozyme)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (CF: an inherited disorder that damages lung and digestive system with fluid build up)
B. If you are requesting twice daily dosing, we require that you have tried and failed once daily dosing

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Commercial Effective: 07/01/20

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

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## DUPILUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| DUPILUMAB | DUPIXENT | | | |

## GUIDELINES FOR USE

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

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

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

**INITIAL CRITERIA (CONTINUED)**

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
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

**CONTINUED ON NEXT PAGE**

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## DUPILUMAB

### GUIDELINE FOR USE (CONTINUED)

### RENEWAL CRITERIA

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)

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

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## DUVELISIB

| Generic | Brand | | | |
|---|---|---|---|---|
| DUVELISIB | COPIKTRA | | | |

### GUIDELINES FOR USE

Our guideline named **DUVELISIB (Copiktra)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory chronic lymphocytic leukemia (CLL: blood and bone marrow cancer that does not fully respond to treatment), small lymphocytic lymphoma (SLL: a type of white blood cell cancer), or follicular lymphoma (FL: type of cancer with abnormal immune system cells)
B. You are 18 years of age or older
C. **If you have relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
   1. You have received at least two prior therapies for CLL or SLL
D. **If you have relapsed or refractory follicular lymphoma (FL), approval also requires:**
   1. You have received at least two prior systemic therapies for FL

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## EFINACONAZOLE

| Generic | Brand | | | |
|---|---|---|---|---|
| EFINACONAZOLE | JUBLIA | | | |

### GUIDELINES FOR USE

Our guideline named **EFINACONAZOLE (Jublia)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenail(s) (toenail fungus)
B. You have previously tried the following unless contraindicated (a medical reason why you cannot use): ciclopirox topical solution AND either oral terbinafine OR oral itraconazole
C. You have at least ONE of the following conditions:
    1. Diabetes, peripheral vascular disease (narrowed blood vessels reduce blood flow to the limbs), or immunosuppression (weakened immune system)
    2. Pain surrounding the nail or soft tissue involvement

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ELAGOLIX

| Generic | Brand | | | |
|---|---|---|---|---|
| ELAGOLIX | ORILISSA | | | |

### GUIDELINES FOR USE

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

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for approval:
A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
D. You had a previous trial of or contraindication to (a medical reason why you cannot use) a nonsteroidal anti-inflammatory drug (NSAID; such as ibuprofen, meloxicam, naproxen) **AND** a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
E. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

### RENEWAL CRITERIA

Our guideline named **ELAGOLIX (Orilissa)** requires the following rule(s) be met for renewal:
A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Requests will not be approved if you meet ONE of the following conditions:
A. You have received a 6-month course of Orilissa 200mg twice daily
B. You have received a 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
C. You have received a 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

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Commercial Effective: 10/08/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ELAPEGADEMASE-LVLR

| Generic | Brand | | | |
|---|---|---|---|---|
| ELAPEGADEMASE-LVLR | REVCOVI | | | |

### GUIDELINES FOR USE

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

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system) as shown by ONE of the following:
   1. Confirmatory generic test
   2. Suggestive laboratory findings such as elevated deoxyadenosine nucleotide levels or lymphopenia (not enough of a type of white blood cell) AND you have hallmark signs/symptoms such as recurrent infections, failure to thrive, persistent diarrhea

B. The requested medication is prescribed by or given in consultation with an immunologist (immune system doctor), hematologist/oncologist (blood/cancer doctor), or physician specializing in inherited metabolic disorders

C. You have failed or are not a candidate for hematopoietic cell transplant (blood cell transplant from bone marrow), OR the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

### RENEWAL CRITERIA

Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for renewal:

A. You have adenosine deaminase severe combined immune deficiency (type of inherited disorder that damages immune system)

B. You have documentation of trough plasma adenosine deaminase activity greater than or equal to 30 mmol/hr/L AND trough deoxyadenosine nucleotide levels less than 0.02 mmol/L

C. You have improvement in/maintenance of immune function from baseline (such as decrease in number and severity of infections), AND you have not received successful hematopoietic cell transplantation (HCT) or gene therapy

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ELIGLUSTAT TARTRATE

| Generic | Brand | | | |
|---|---|---|---|---|
| ELIGLUSTAT TARTRATE | CERDELGA | | | |

### GUIDELINES FOR USE

Our guideline named **ELIGLUSTAT TARTRATE (Cerdelga)** requires the following rule(s) be met for approval:

A. You have type 1 (non-neuronopathic) Gaucher disease (genetic disorder where a type of fatty substance builds up in the body but does not affect the brain or spinal cord)
B. You are 18 years of age or older
C. Twice daily dosing will be approved if you are an extensive or immediate metabolizer of CYP2D6 (cytochrome P450 2D6; a type of enzyme) inhibitors
D. Once daily dosing will be approved if you are a poor metabolizer of CYP2D6 (cytochrome P450 2D6; a type of enzyme)

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Commercial Effective: 07/01/20

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

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## ELTROMBOPAG

| Generic | Brand | | | |
|---|---|---|---|---|
| ELTROMBOPAG | PROMACTA | | | |

### GUIDELINES FOR USE

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

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

**CONTINUED ON NEXT PAGE**

**STANDARD COMMERCIAL DRUG FORMULARY**
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## 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.

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 50X10(9)/L (at least 50,000 per microliter)

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Commercial Effective: 04/20/20

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

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## EMICIZUMAB-KXWH

| Generic | Brand | | | |
|---|---|---|---|---|
| EMICIZUMAB-KXWH | HEMLIBRA | | | |

### GUIDELINES FOR USE

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

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:

A. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
B. The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor)
D. Patients with Factor VIII inhibitors must have a history of a high titer (concentration) of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
E. Patients without Factor VIII inhibitors must meet one of the following criteria:
    1. You have severe hemophilia A defined as less than 1% factor VIII activity compared to normal
    2. You have *mild* or *moderate* hemophilia A and a history of 2 or more bleeds per year

### RENEWAL CRITERIA

Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:

A. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
B. You had a clinical benefit after using the medication compared to baseline

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ENASIDENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ENASIDENIB | IDHIFA | | | |

### GUIDELINES FOR USE

Our guideline named **ENASIDENIB (Idhifa)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory acute myeloid leukemia (a type of blood and bone marrow cancer that has returned after or is resistant to treatment)
B. You are 18 years of age or older
C. You are isocitrate dehydrogenase-2 (a type of enzyme) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

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Commercial Effective: 07/01/20

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## ENCORAFENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ENCORAFENIB | BRAFTOVI | | | |

### GUIDELINES FOR USE

Our guideline named **ENCORAFENIB (Braftovi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (a type of skin cancer that has spread or cannot be completely removed with surgery)
   2. Metastatic colorectal cancer (a type of cancer that affects the colon and the rectum and has spread to other parts of the body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have a BRAF V600E or V600K mutation (types of gene mutations) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mektovi (binimetinib)

C. **If you have metastatic colorectal cancer, approval also requires:**
   1. You have a BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Erbitux (cetuximab)
   3. You have previously received treatment

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Commercial Effective: 05/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ENTRECTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ENTRECTINIB | ROZLYTREK | | | |

### GUIDELINES FOR USE

Our guideline named **ENTRECTINIB (Rozlytrek)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of body) OR a solid tumor
B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. You have *ROS1*-positive tumors (you have a type of gene mutation)
C. **If you have a solid tumor, approval also requires:**
   1. You are 12 years of age or older
   2. The tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation (you have a type of gene mutation that doesn't have any known resistance)
   3. The tumor is metastatic (has spread to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (disease)
   4. There are no satisfactory alternative treatments, or you have progressed (gotten worse) after treatment

Commercial Effective: 07/01/20

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## ERDAFITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ERDAFITINIB | BALVERSA | | | |

### GUIDELINES FOR USE

Our guideline named **ERDAFITINIB (Balversa)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic urothelial carcinoma (type of bladder cancer that has spread)
B. You are 18 years of age or older
C. You have susceptible fibroblast growth factor receptor (FGFR3 or FGFR2) genetic alterations (abnormalities) as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
D. You meet ONE of the following:
    1. You have progressed (worsened disease) during or following at least one line of prior platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. You have progressed within 12 months of neoadjuvant (treatment given before main therapy) or adjuvant (add-on) platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ERLOTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| ERLOTINIB | TARCEVA | | | |

### GUIDELINES FOR USE

Our guideline named **ERLOTINIB (Tarceva)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread) OR locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)
B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)-approved test
C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

Commercial Effective: 07/01/20

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## ERYTHROPOIESIS STIMULATING AGENTS

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| DARBEPOETIN | ARANESP | | | | |
| EPOETIN ALFA | EPOGEN<br>PROCRIT | | | | |
| EPOETIN ALFA-EPBX | RETACRIT | | | | |
| METHOXY PEG-EPOETIN BETA | MIRCERA | | | | |

## GUIDELINES FOR USE

### INITIAL CRITERIA FOR PROCRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
   1. You have a hemoglobin level of less than 11g/dL
   2. Your hemoglobin level has decreased at least 2g/dL below your baseline level.

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   2. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have a hemoglobin level of less than 13g/dL

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR ARANESP (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin level has decreased at least 2g/dL below your baseline level

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried Procrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. You have a hemoglobin of less than 10g/dL

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR EPOGEN (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy,** approval also requires:
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 11g/dL **OR** your hemoglobin has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa,** approval also requires:
   1. You have tried Procrit
   2. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
   3. Your hemoglobin level is less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 13g/dL

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR RETACRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery

B. **If you have anemia associated with chronic kidney disease, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 11g/dL OR your hemoglobin has decreased at least 2g/dL below your baseline level

D. **If you have anemia related to zidovudine therapy, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 10g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. You have tried Procrit
   2. You have tried a lower ribavirin dose, unless there is a medical reason why you cannot (contraindication)
   3. You have a hemoglobin level of less than 10g/dL

F. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. You have tried Procrit
   2. You have a hemoglobin level of less than 13g/dL

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## ERYTHROPOIESIS STIMULATING AGENTS

### INITIAL CRITERIA FOR MIRCERA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for approval:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older, approval also requires**:
   1. You have tried Procrit
   2. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
C. **If you are between 5 and 17 years of age, approval also requires:**
   1. You are on hemodialysis
   2. You are changing from another erythropoiesis-stimulating agent (ESA; epoetin alfa, darbepoetin alfa) after the hemoglobin level has been stabilized with the ESA

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR PROCRIT

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are NOT on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR ARANESP

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
   2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR EPOGEN

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Epogen)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12 g/dL

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR RETACRIT

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Retacrit)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
   3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
   1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
   2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
   3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
   4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

D. **If you have anemia related to zidovudine therapy, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
   1. You have a hemoglobin level between 10g/dL and 12g/dL

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR MIRCERA

Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Mircera)** requires the following rule(s) be met for renewal:

A. You have anemia (low amount of healthy red blood cells) associated with chronic kidney disease
B. **If you are 18 years of age or older and are currently receiving dialysis treatment, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
    2. The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
C. **If you are 18 years of age or older and are NOT receiving dialysis treatment, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
    2. You have a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
D. **If you are between 5 and 17 years of age, renewal also requires:**
    1. You are currently receiving dialysis treatment
    2. You have ONE of the following:
        a. A hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
        b. A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

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Commercial Effective: 01/01/21

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

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**EVEROLIMUS**

| Generic | Brand | | | |
|---|---|---|---|---|
| EVEROLIMUS | AFINITOR | | | |
| EVEROLIMUS | AFINITOR DISPERZ | | | |

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

## GUIDELINES FOR USE

### AFINITOR DISPERZ

Our guideline named **EVEROLIMUS (Afinitor Disperz)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Subependymal giant cell astrocytoma (SEGA; a type of brain tumor) with tuberous sclerosis complex (TSC; genetic disorder with many non-cancer tumors)
   2. Tuberous sclerosis complex (TSC)-associated partial-onset seizures

B. **If you have subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC), approval also requires:**
   1. You are 1 year of age or older
   2. Your diagnosis requires therapeutic intervention but cannot be curatively resected (completely remove with surgery)

C. **If you have tuberous sclerosis complex (TSC)-associated partial-onset seizures, approval also requires:**
   1. You are 2 years of age or older
   2. The medication will be used as adjunctive (add-on) treatment

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## EVEROLIMUS

### GUIDELINES FOR USE (CONTINUED)

### AFINITOR

Our guideline named **EVEROLIMUS (Afinitor)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You have advanced renal cell carcinoma (type of kidney cancer) after failure of or contraindication to (medical reason why you cannot use) treatment with sunitinib (Sutent) or sorafenib (Nexavar) (which may also require prior authorization), AND you are 18 years of age or older
   2. You have subependymal giant cell astrocytoma (SEGA; a type of brain tumor) with tuberous sclerosis complex (TSC; genetic disorder with many non-cancer tumors) that requires therapeutic intervention but cannot be curatively resected (completely removed with surgery), AND you are 1 year of age or older
   3. You have progressive, neuroendocrine tumors (NET) with unresectable, locally advanced or metastatic disease, either neuroendocrine tumors of pancreatic origin (PNET) OR well-differentiated, non-functional neuroendocrine tumors of gastrointestinal (GI) or lung origin, AND you are 18 years of age or older
   4. You have renal angiomyolipoma (type of kidney tumor) and tuberous sclerosis complex (TSC) that does not require immediate surgery, AND you are 18 years of age or older
   5. You are a postmenopausal woman with advanced hormone receptor-positive, HER2 (human epidermal growth factor receptor 2: a gene/protein in breast cancer) - negative breast cancer (defined as IHC scores less than or equal to 3+ or FISH amplification ratio less than or equal to 2.0), AND the requested medication will be used in combination with Aromasin (exemestane) after failure of or contraindication (medical reason why you cannot use) to treatment with Femara (letrozole) or Arimidex (anastrozole).

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

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## FEDRATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| FEDRATINIB | INREBIC | | | |

### GUIDELINES FOR USE

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

Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for approval:
A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
B. You are 18 years of age or older
C. You previously had a trial of or contraindication (medical reason why you cannot use) to Jakafi (ruxolitinib)

### RENEWAL CRITERIA

Our guideline named **FEDRATINIB (Inrebic)** requires the following rule(s) be met for renewal:
A. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
B. You had symptom improvement by **ONE** of the following:
   1. You have a spleen volume reduction of 35% or greater from baseline after 6 months of therapy
   2. You have a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
   3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

Commercial Effective: 07/01/20

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

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## FENFLURAMINE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| FENFLURAMINE | FINTEPLA | | | | |

### GUIDELINES FOR USE

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

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)

### RENEWAL CRITERIA

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

Commercial Effective: 08/01/20

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

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## FENTANYL NASAL SPRAY

| Generic | Brand | | | |
|---|---|---|---|---|
| FENTANYL NASAL SPRAY | LAZANDA | | | |

### GUIDELINES FOR USE

Our guideline named **FENTANYL NASAL SPRAY (Lazanda)** requires the following rule(s) to be met for approval:

A. You have a diagnosis of cancer-related pain
B. You are currently taking a maintenance dose of a controlled-release pain medication (such as MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
E. You had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)

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Commercial Effective: 07/01/20

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

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## FENTANYL SUBLINGUAL SPRAY

| Generic | Brand | | | |
|---|---|---|---|---|
| FENTANYL SUBLINGUAL SPRAY | SUBSYS | | | |

## GUIDELINES FOR USE

Our guideline named **FENTANYL SUBLINGUAL SPRAY (Subsys)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. You had 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), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)
E. You had a trial of Abstral or Fentora, all of which may also require a prior authorization, 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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## FENTANYL TRANSDERMAL PATCH

| Generic | Brand | | | |
|---|---|---|---|---|
| FENTANYL | DURAGESIC | | | |

### GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSDERMAL PATCH (Duragesic)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is 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 (equal pain-relieving dose) of another opioid
B. The requested medication is not prescribed on an 'as needed' basis
C. Requests for dosing every 48 hours requires a trial of transdermal (absorbed through the skin) fentanyl patch dosed every 72 hours

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Commercial Effective: 07/01/20

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

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## FENTANYL TRANSMUCOSAL AGENTS

| Generic | Brand | | | |
|---|---|---|---|---|
| FENTANYL CITRATE | ACTIQ, ABSTRAL, FENTORA | | | |

## GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq, Fentora, Abstral)** requires the following rule(s) be met for approval:

A. You have cancer-related pain
B. You are currently using the requested medication 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)
C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## FLIBANSERIN

| Generic | Brand | | | |
|---|---|---|---|---|
| FLIBANSERIN | ADDYI | | | |

### GUIDELINES FOR USE

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

Our guideline named **FLIBANSERIN (Addyi)** requires the following rule(s) be met for approval:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder 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
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You previously had a trial of bupropion, unless there is a medical reason why you cannot (contraindication)
E. You are not currently using Vyleesi (bremelanotide)

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## FLIBANSERIN

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline for **FLIBANSERIN (Addyi)** requires the following rule(s) be met for renewal:

A. You have acquired, generalized hypoactive sexual desire disorder (HSDD; lack or absence of sexual desire). This is also referred to as female sexual interest/arousal disorder per DSM-5 (a diagnostic tool for mental disorders), as defined by **ALL** of the following criteria:
   1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
   2. Hypoactive sexual desire disorder 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
   3. Hypoactive sexual desire disorder symptom causes marked distress or interpersonal difficulty
B. You are a premenopausal female
C. You are 18 years of age or older
D. You are not currently using Vyleesi (bremelanotide)
E. You have demonstrated continued improvement in symptoms of hypoactive sexual desire disorder/female sexual interest and arousal disorder (such as increased sexual desire, lessened distress)

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Commercial Effective: 07/01/20

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

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## FLUOROURACIL 0.5% CREAM

| Generic | Brand | | | |
|---|---|---|---|---|
| FLUOROURACIL 0.5% | CARAC | | | |

### GUIDELINE FOR USE

Our guideline named **FLUOROURACIL 0.5% CREAM (Carac)** requires the following rule(s) be met for approval:

A. You have actinic or solar keratosis (rough, scaly patch on the skin caused by years of sun exposure)
B. You have previously tried at least **ONE** of the following:
   1. Generic topical (applied to skin) agents (such as imiquimod 5%, diclofenac 3%, fluorouracil 5%)
   2. Preferred topical (applied to skin) agents (such as Picato)

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Commercial Effective: 07/01/20

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

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## FOSTAMATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| FOSTAMATINIB | TAVALISSE | | | |

### GUIDELINES FOR USE

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

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for approval:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
D. You had a splenectomy (surgical removal of spleen) **OR** a previous trial of or contraindication to (medical reason why you cannot use) at least **TWO** of the following treatments:
    1. Corticosteroids
    2. IVIG (intravenous immunoglobulin)
    3. Rhogam
    4. Rituxan (rituximab)
    5. Thrombopoietin receptor agonist such as Promacta (eltrombopag), Nplate (romiplostim)

### RENEWAL CRITERIA

Our guideline named **FOSTAMATINIB (Tavalisse)** requires the following rule(s) be met for renewal:

A. You have chronic immune thrombocytopenia (cITP; Low levels of the blood cells that prevent bleeding)
B. You had clinically significant prevention of bleeds while on therapy
C. Your AST (aspartate transaminase) and ALT (alanine transaminase) levels (types of liver enzymes) have remained under 3 times the upper limits of normal per reference range
D. Your total bilirubin level has remained under 2 times the upper limits of normal per reference range
E. Your absolute neutrophil count (ANC; a measure of the number of neutrophils which are a type of white blood cell) has remained within normal limits per reference range
F. Your platelets have reached a level between 50 and 450 x 10(9)/L

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

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## FOSTEMSAVIR

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| FOSTEMSAVIR | RUKOBIA | | | | |

### GUIDELINES FOR USE

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

Commercial Effective: 08/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## GEFITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| GEFITINIB | IRESSA | | | |

## GUIDELINES FOR USE

Our guideline named **GEFITINIB (Iressa)** 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)
B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of permanent changes in your DNA that make up your gene) as detected by an FDA (Food and Drug Administration)-approved test

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## GILTERITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| GILTERITINIB FUMARATE | XOSPATA | | | |

**GUIDELINES FOR USE**

Our guideline named **GILTERITINIB (Xospata)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory acute myeloid leukemia (AML: type of white blood cell cancer)
B. You are 18 years of age or older
C. You have FMS-like tyrosine kinase 3 (type of gene) mutation (change in the DNA gene) as detected by a Food and Drug Administration-approved test

Commercial Effective: 07/01/20

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

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## GLASDEGIB

| Generic | Brand | | | |
|---|---|---|---|---|
| GLASDEGIB MALEATE | DAURISMO | | | |

### GUIDELINES FOR USE

Our guideline named **GLASDEGIB (Daurismo)** requires the following rule(s) be met for approval:

A. You have newly-diagnosed acute myeloid leukemia (AML: type of white blood cell cancer)
B. The requested medication will be used in combination with low-dose cytarabine
C. You are 75 years of age or older, **OR** you have comorbidities (having more than one disease) that prevents the use of intensive induction chemotherapy

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## GLYCEROL PHENYLBUTYRATE

| Generic | Brand | | | |
|---|---|---|---|---|
| GLYCEROL PHENYLBUTYRATE | RAVICTI | | | |

### GUIDELINES FOR USE

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

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for approval:

A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
B. Documentation of confirmation of urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
C. You are 2 months of age or older
D. Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
E. The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
F. The patient does **NOT** have a deficiency of N-acetylglutamate synthetase (type of enzyme) or acute hyperammonemia (short and sudden high ammonia levels)
G. You have previously tried Buphenyl (sodium phenylbutyrate), unless there is a medical reason why you cannot (contraindication)

### RENEWAL CRITERIA

Our guideline named **GLYCEROL PHENYLBUTYRATE (Ravicti)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
B. You had clinical benefit from baseline (such as normal fasting glutamine, low-normal fasting ammonia levels, or mental status clarity).

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## GLYCOPYRRONIUM TOPICAL

| Generic | Brand | | | |
|---|---|---|---|---|
| GLYCOPYRRONIUM 2.4% CLOTH | QBREXZA | | | |

## GUIDELINES FOR USE

Our guideline named **GLYCOPYRRONIUM TOPICAL (Qbrexza)** requires the following rule(s) be met for approval:

A. You have primary axillary hyperhidrosis (excessive underarm sweating)
B. You are 9 years of age or older
C. You had a trial of a prescription strength aluminum chloride product such as Drysol

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Commercial Effective: 10/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

| Generic | Brand | | | |
|---|---|---|---|---|
| LEUPROLIDE ACETATE | ELIGARD | | | |
| LEUPROLIDE ACETATE (GENERIC) | LEUPROLIDE ACETATE | | | |
| NAFARELIN ACETATE | SYNAREL | | | |

## GUIDELINES FOR USE

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

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)

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)

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

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

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## GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST

### INITIAL CRITERIA (CONTINUED)

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)

### RENEWAL CRITERIA

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

**STANDARD COMMERCIAL DRUG FORMULARY**
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## HYDROMORPHONE ER

| Generic | Brand | | | |
|---|---|---|---|---|
| HYDROMORPHONE HCL | EXALGO, HYDROMORPHONE ER | | | |

## GUIDELINES FOR USE

Our guideline named **HYDROMORPHONE ER (Exalgo)** requires the following rule(s) be met for approval:

A. You meet the definition of opioid tolerance. This is 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 (equal pain relieving dose) of another opioid
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

Commercial Effective: 07/01/20

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## IBRUTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| IBRUTINIB | IMBRUVICA | | | |

### GUIDELINES FOR USE

Our guideline named **IBRUTINIB (Imbruvica)** requires the following rule(s) be met for approval:

A. You have mantle cell lymphoma (type of white blood cell cancer), chronic lymphocytic leukemia (type of blood and bone marrow cancer), small lymphocytic lymphoma (type of white blood cell cancer), Waldenström's macroglobulinemia (type of cancer affecting two white cell types of B cells), marginal zone lymphoma (type of cancer of B-cells), or chronic graft versus host disease (donor bone marrow or stem cells attack the receiving person)
B. You are 18 years of age or older
C. Requests for Ibrutinib 140mg or 280mg tablets requires you had a trial of Ibrutinib 140mg capsules, unless there is a medical reason why you cannot (contraindication)
D. **If you have mantle cell lymphoma, approval also requires:**
   2. You have received at least one prior therapy for mantle cell lymphoma
E. **If you have marginal zone lymphoma, approval also requires:**
   1. You need systemic (treatment spreads through the blood) therapy
   2. You have received at least one prior anti-CD20-based therapy (such as Rituxan)
F. **If you have chronic graft versus host disease, approval also requires:**
   1. You have failed one or more lines of systemic therapy (treatment spread through the blood, such as corticosteroids)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## ICATIBANT

| Generic | Brand | | | |
|---|---|---|---|---|
| ICATIBANT | FIRAZYR | | | |

### GUIDELINES FOR USE

Our guideline named **ICATIBANT (Firazyr)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: an inherited condition of severe swelling attacks)
B. You are 18 years of age or older
C. Your diagnosis is confirmed via complement testing (blood test that measures the activity of a group of immune system proteins in the bloodstream)
D. The medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
E. The medication is prescribed by or given in consultation with an allergist/immunologist (doctor who specializes in allergies and immune disorders) or hematologist (blood doctor)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## IDELALISIB

| Generic | Brand | | | |
|---|---|---|---|---|
| IDELALISIB | ZYDELIG | | | |

### GUIDELINES FOR USE

Our guideline named **IDELALISIB (Zydelig)** requires you meet **ONE** of the following rules for approval:

A. You have relapsed chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer) and will use the requested medication with rituximab at the same time
B. You have relapsed follicular B-cell non-Hodgkin lymphoma (FL: type of immune system cancer) and you have received at least **TWO** prior systemic therapies (treatment that travels through the blood stream)
C. You have relapsed small lymphocytic lymphoma (SLL: type of immune system cancer) and you have received at least TWO prior systemic therapies (treatment that travels through the blood stream)

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Commercial Effective: 07/01/20

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## ILOPROST

| Generic | Brand | | | |
|---|---|---|---|---|
| ILOPROST | VENTAVIS | | | |

### GUIDELINES FOR USE

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

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symtpom)

### RENEWAL CRITERIA

Our guideline named **ILOPROST (Ventavis)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH; type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable in the 6-minute walk distance test AND your World Health Organization functional class has remained stable or improved (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

Commercial Effective: 07/01/20

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## INDOMETHACIN RECTAL

| Generic | Brand | | | |
|---|---|---|---|---|
| INDOMETHACIN | INDOCIN | | | |

### GUIDELINES FOR USE

Our guideline named **INDOMETHACIN RECTAL (Indocin)** requires that you meet ONE of the following rule(s) for approval:

A. You have dysphagia (difficulty swallowing), difficulty swallowing capsules, or have a feeding tube placed (such as a G-tube, J-tube)
B. You had a previous trial of at least two prescription strength oral NSAIDs (non-steroidal anti-inflammatory drugs such as ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

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## INHALED INSULIN

| Generic | Brand | | | |
|---|---|---|---|---|
| INSULIN REGULAR, HUMAN | AFREZZA | | | |

## GUIDELINES FOR USE

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

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for approval:

A. You have type 1 or type 2 diabetes
B. You are 18 years of age or older
C. You have a baseline spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume)
D. **If you have type 1 diabetes, approval also requires:**
   1. You are using a long-acting insulin with the requested medication and that you have tried a formulary rapid acting insulin: Humalog
E. **If you have type 2 diabetics, approval also requires:**
   1. You tried a formulary rapid acting insulin: Humalog
   2. Your prescriber has indicated that you are physically unable or unwilling to use injectable insulin

### RENEWAL CRITERIA

Our guideline named **INHALED INSULIN (Afrezza)** requires the following rule(s) be met for renewal:

A. You have type 1 or type 2 diabetes
B. You have documentation of follow up spirometry (test to measure how well your lungs work) to measure FEV1 (forced expiratory volume in one second) after 6 months of treatment and annually thereafter
C. Your FEV1 has NOT declined 20% or more from baseline
D. **If you have type 1 diabetes,** approval requires that you are using a long acting insulin at the same time with the requested medication

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## INOTERSEN

| Generic | Brand | | | |
|---|---|---|---|---|
| INOTERSEN SODIUM | TEGSEDI | | | |

### GUIDELINES FOR USE

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

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), hATTR specialist, or medical geneticist
D. You have stage 1 or 2 polyneuropathy
E. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
    1. Biopsy (surgical sample) of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR (Transthyretin) protein
    2. DNA genetic sequencing to confirm hATTR mutation

### RENEWAL CRITERIA

Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a disorder with build-up of a type of protein causing your body to not work properly) with polyneuropathy (widespread nerve pain/damage)
B. You have not progressed to stage 3 polyneuropathy (widespread nerve pain/damage) as shown by functional decline such as being wheelchair-bound or bedridden

**STANDARD COMMERCIAL DRUG FORMULARY**
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## INTERFERON ALFA-2B

| Generic | Brand | | | |
|---|---|---|---|---|
| INTERFERON ALFA-2B | INTRON A | | | |

**GUIDELINES FOR USE**

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

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires **ONE** of the following rule(s) be met for approval:

A. The requested medication is being used to treat one of the following:
   1. Chronic hepatitis C (type of liver inflammation)
   2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
   3. Condylomata acuminate (genital warts)
   4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
   5. Chronic hepatitis B (type of liver inflammation)
   6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
   7. Malignant melanoma (serious type of skin cancer)
   8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
   9. Follicular lymphoma (type of lymphatic system cancer)
   10. Angioblastoma (certain blood-vessel tumors of the brain)
   11. Carcinoid (cancer) tumor
   12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
   13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)
   14. Multiple myeloma (plasma cell cancer)
   15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
   16. Ovarian cancer
   17. Polycythemia vera (cancer where bone marrow makes too many red blood cells)
   18. Renal cell carcinoma (type of kidney cancer)
   19. Skin cancer, thrombocytosis (your body makes too many platelets)
   20. Thrombocytosis (high level of platelets (cells that helps blood clot and stop bleeding) in your blood)
   21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)

***(Initial denial text continued on next page)***

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## INTERFERON ALFA-2B

### INITIAL CRITERIA (CONTINUED)

B. **If you have chronic hepatitis C, approval also requires:**
   1. You are infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C
   2. Therapy is being supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist or a physician specializing in the treatment of hepatitis (such as a hepatologist)
   3. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of greater than or equal to 50 IU/mL
   4. The requested medication will be used with ribavirin or you have a medical reason why you cannot (contraindication)
   5. You had a previous trial of or contraindication to (medical reason why you cannot use) a peginterferon product

### RENEWAL CRITERIA

Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for renewal:

A. The request is for continuation of current therapy or renewal with Intron A therapy
B. **If you are being treated for chronic hepatitis C (type of liver inflammation), renewal also requires:**
   1. Therapy is being supervised by a gastroenterologist (a doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist or a physician specializing in the treatment of hepatitis (such as a hepatologist)
   2. You have a HCV (hepatitis C virus) RNA level (amount of virus in your blood) undetectable (less than 50 IU/mL) at 24 weeks

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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)

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## ISTRADEFYLLINE

| Generic | Brand | | | |
|---|---|---|---|---|
| ISTRADEFYLLINE | NOURIANZ | | | |

### GUIDELINES FOR USE

Our guideline named **ISTRADEFYLLINE (Nourianz)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. You are 18 years of age or older
C. You are experiencing 'OFF' episodes (times when medication wears off and you have movement problems)
D. Nourianz will be used along with levodopa/carbidopa
E. You had a previous trial of or contraindication to (medical reason why you cannot use) **TWO** Parkinson's agents from **TWO** different drug classes:
   1. Dopamine agonists (such as ropinirole, pramipexole, rotigotine)
   2. Monoamine oxidase-inhibitors (such as selegiline, rasagiline)
   3. Catechol-O-methyl transferase inhibitors (such as entacapone, tolcapone)

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Commercial Effective: 07/01/20

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## ITRACONAZOLE - TOLSURA

| Generic | Brand | | | |
|---|---|---|---|---|
| ITRACONAZOLE | TOLSURA | | | |

### GUIDELINES FOR USE

Our guideline named **ITRACONAZOLE (Tolsura)** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You have **ONE** of the following fungal infections:
   1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
   2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
   3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy
C. Therapy is prescribed by or given in consultation with an Infectious Disease Specialist
D. You had a previous trial of a generic itraconazole formulation
E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## IVOSIDENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| IVOSIDENIB | TIBSOVO | | | |

### GUIDELINES FOR USE

Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:

A. You have acute myeloid leukemia (AML: blood and bone marrow cancer with too many white blood cells)
B. **If you have relapsed or refractory acute myeloid leukemia (AML: type of blood and bone marrow cancer that returns after treatment), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You are 18 years of age or older
C. **If you have a new diagnosis of acute myeloid leukemia (AML: type of blood and bone marrow cancer), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You meet **ONE** of the following criteria:
      a. You are 75 years of age or older
      b. You are 18 years of age or older **AND** have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## IXAZOMIB

| Generic | Brand | | | |
|---|---|---|---|---|
| IXAZOMIB CITRATE | NINLARO | | | |

### GUIDELINES FOR USE

Our guideline named **IXAZOMIB (Ninlaro)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. The requested medication will be used in combination with lenalidomide and dexamethasone
C. You have received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| LACTIC ACID/ CITRIC ACID/ POTASSIUM BITARTRATE | PHEXXI | | | | |

### GUIDELINES FOR USE

Our guideline named **LACTIC ACID/CITRIC ACID/POTASSIUM BITARTRATE (Phexxi)** requires the following rule(s) be met for approval:

A. You are a female patient with reproductive potential using the requested medication for prevention of pregnancy
B. You are not using vaginal ring products (such as Annovera or Nuvaring) together with Phexxi
C. You had a previous trial of two contraceptive agents (such as an intrauterine device, hormonal implant, injection, patch, or oral products), unless there is a medical reason you cannot (contraindication)

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Commercial Effective: 10/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## LAPATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| LAPATINIB DITOSYLATE | TYKERB | | | |

## GUIDELINES FOR USE

Our guideline named **LAPATINIB (Tykerb)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer (breast cancer that has progressed or has spread to other parts of your body)
B. Your breast cancer is human epidermal growth factor receptor 2 (HER2: gene/protein in breast cancer) positive
C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. The requested medication will be used in combination with Xeloda (capecitabine)
   2. You have previously received treatment with Herceptin (trastuzumab), an anthracycline (such as daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (such as paclitaxel, docetaxel)
D. **If you have metastatic breast cancer, approval also requires:**
   1. Your tumor is hormone receptor-positive
   2. The requested medication will be used in combination with Femara (letrozole)
   3. You are a postmenopausal woman

Commercial Effective: 10/19/20

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

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## LAROTRECTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| LAROTRECTINIB | VITRAKVI | | | |

### GUIDELINES FOR USE

Our guideline named **LAROTRECTINIB (Vitrakvi)** requires the following rule(s) be met for approval:

A. You have a solid tumor (abnormal mass of tissue that usually does not contain cysts or liquid)
B. Your tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation (you have a type of enzyme that doesn't have a mutation)
C. Your tumor is metastatic (spreads to other parts of body) or surgical resection (removal) is likely to result in severe morbidity (illness)
D. There are no satisfactory alternative treatments, or your tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. You are a pediatric patient (less than 18 years of age)
    2. You are unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. You have other medical need for the oral solution

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
**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) bet 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)

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Commercial Effective: 04/01/20

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

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## LEFAMULIN

| Generic | Brand | | | |
|---|---|---|---|---|
| LEFAMULIN | XENLETA | | | |

## GUIDELINES FOR USE

Our guideline named **LEFAMULIN (Xenleta)** requires the following rule(s) be met for approval:

A. You have community-acquired bacterial pneumonia (type of lung infection)
B. You are 18 years of age or older
C. The infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
D. You meet **ONE** of the following criteria:
    1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
    2. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with a) resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** b) susceptibility to Xenleta
    3. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of at least **TWO** standard of care agents (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) for community-acquired bacterial pneumonia, 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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## LENALIDOMIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| LENALIDOMIDE | REVLIMID | | | |

### GUIDELINES FOR USE

Our guideline named **LENALIDOMIDE (Revlimid)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Multiple myeloma (plasma cell cancer)
   2. Anemia due to a myelodysplastic syndrome (cancer that affects blood cell production)
   3. Mantle cell lymphoma (type of white blood cell cancer)
   4. Follicular lymphoma (type of slow growing white blood cell cancer)
   5. Marginal zone lymphoma (a rare type of slow growing white blood cell cancer)

B. You are 18 years of age or older

C. **If you have anemia due to a myelodysplastic syndrome, approval also requires:**
   1. You have a deletion 5q (type of gene) abnormality

D. **If you have mantle cell lymphoma, approval also requires:**
   1. You have tried two prior therapies and the cancer returns or gets worse (relapses or progresses). One of the therapies tried must be Velcade (bortezomib) (Note: Velcade may be covered under the medical benefit and/or require prior authorization).

E. **If you have follicular lymphoma, approval also requires:**
   1. You have previously been treated for follicular lymphoma
   2. The requested medication is being taken in combination with a rituximab product (type of cancer drug)

F. **If you have marginal zone lymphoma, approval also requires:**
   1. You have previously been treated for marginal zone lymphoma
   2. The requested medication is being taken in combination with a rituximab product

Commercial Effective: 07/01/20

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

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## LENVATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| LENVATINIB MESYLATE | LENVIMA | | | |

### GUIDELINES FOR USE

Our guideline named **LENVATINIB (Lenvima)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Differentiated thyroid cancer (cancer cells look/act like normal thyroid cells)
   2. Advanced renal cell cancer (kidney cancer)
   3. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed by surgery)
   4. Advanced endometrial carcinoma (type of cancer that starts in the uterus)

B. **If you have differentiated thyroid cancer, approval also requires:**
   1. Your thyroid cancer is locally recurrent or metastatic (cancer that has spread to other parts of the body)
   2. Your thyroid cancer is progressive (getting worse)
   3. You have tried radioactive iodine therapy, unless there is medical reason why you cannot (contraindication)

C. **If you have advanced renal cell cancer, approval also requires:**
   1. Lenvima is used in combination with everolimus
   2. You have tried one prior anti-angiogenic therapy (treatment that stop tumors from growing their own blood vessels, such as Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])

D. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   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 have experienced disease progression following prior systemic therapy (disease has worsened after previous therapy)
   4. You are not a candidate for curative surgery or radiation

Commercial Effective: 07/01/20

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

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## LETERMOVIR PO

| Generic | Brand | | | |
|---|---|---|---|---|
| LETERMOVIR | PREVYMIS | | | |

### GUIDELINES FOR USE

Our guideline named **LETERMOVIR PO (Prevymis)** requires the following rule(s) be met for approval:

A. You are undergoing an allogeneic hematopoietic stem cell transplant (you have cells transplanted from a matching donor)
B. You are 18 years of age or older
C. You are CMV (Cytomegalovirus)-seropositive [R+]
D. Prevymis will be used for prophylaxis (prevention) of cytomegalovirus infection and disease
E. Prevymis will be started between Day 0 and Day 28 post-transplantation (before or after engraftment)
F. You are not receiving the medication beyond 100 days post-transplantation

Commercial Effective: 07/01/20

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

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## LEVODOPA

| Generic | Brand | | | |
|---|---|---|---|---|
| LEVODOPA | INBRIJA | | | |

### GUIDELINES FOR USE

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

Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
C. You are currently being treated with carbidopa/levodopa
D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist $A_{2A}$ (such as istradefylline)

### RENEWAL CRITERIA

Our guideline named **LEVODOPA INHALATION (Inbrija)** requires the following rule(s) be met for renewal approval:

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be 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.

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

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## LOFEXIDINE

| Generic | Brand | | | |
|---|---|---|---|---|
| LOFEXIDINE | LUCEMYRA | | | |

### GUIDELINES FOR USE

Our guideline name **LOFEXIDINE (Lucemyra)** requires the following rule(s) be met for approval:

A. Lucemyra is being used to lessen opioid withdrawal symptoms to help abrupt opioid discontinuation
B. You are 18 years of age or older
C. You are in a setting with close patient monitoring of Lucemyra (lofexidine) treatment for a maximum of 18 days
D. Treatment with Lucemyra is being administered as part of an opioid discontinuation plan that includes other withdrawal symptom management medications (such as stool softeners, sleep aids) and psychosocial support is in place to help prevent relapse

Commercial Effective: 07/01/20

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

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## LOMITAPIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| LOMITAPIDE | JUXTAPID | | | |

## GUIDELINES FOR USE

Our guideline named **LOMITAPIDE (Juxtapid)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol)
B. Your diagnosis of homozygous familial hypercholesterolemia (type of inherited high cholesterol) was determined by meeting **ONE** of the following criteria:
    1. Simon Broome diagnostic criteria
    2. Dutch Lipid Network criteria with a score of at least 8
    3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein) - cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (condition where fatty growth develops under the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents
C. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
D. You have an LDL (low density lipoprotein) - cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin (drug used for cholesterol) treatment
E. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors
F. **If you are statin tolerant, approval also requires:**
    1. You meet **ONE** of the following criteria:
        a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
        b. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
    2. You will continue statin (drug used for cholesterol) treatment in combination with Juxtapid

***(Criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

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

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## LOMITAPIDE

**GUIDELINES FOR USE (CONTINUED)**

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy (drug used for cholesterol) 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 such as creatine kinase elevation (a measurement of how much muscle damage you have) 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 (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.

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Commercial Effective: 07/01/20

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

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## LOMUSTINE

| Generic | Brand | | | |
|---|---|---|---|---|
| LOMUSTINE | GLEOSTINE | | | |

### GUIDELINES FOR USE

Our guideline named **LOMUSTINE (Gleostine)** requires the following rule(s) be met for approval:

A. You meet **ONE** of the following:
   1. You have Hodgkin's Lymphoma (type of immune system cancer)
   2. You have primary and metastatic brain tumors (tumor that has spread to other parts of body) **AND** you have previously received appropriate surgical and/or radiotherapeutic procedures

B. **If you have primary and metastatic brain tumors, approval also requires ONE of the following:**
   1. The requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine)
   2. You have had a previous trial of intravenous (IV) carmustine

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## LUMACAFTOR/IVACAFTOR

| Generic | Brand | | | |
|---|---|---|---|---|
| LUMACAFTOR/IVACAFTOR | ORKAMBI | | | |

### GUIDELINES FOR USE

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

Our guideline named **LUMACAFTOR-IVACAFTOR (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 **LUMACAFTOR-IVACAFTOR (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

**STANDARD COMMERCIAL DRUG FORMULARY**
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## LUSUTROMBOPAG

| Generic | Brand | | | |
|---|---|---|---|---|
| LUSUTROMBOPAG | MULPLETA | | | |

### GUIDELINES FOR USE

Our guideline named **LUSUTROMBOPAG (Mulpleta)** requires the following rule(s) be met for approval:

A. You have thrombocytopenia (low number of platelets in the blood)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist), gastroenterologist (digestive tract doctor), hepatologist (liver doctor), immunologist, or endocrinologist (hormone doctor)
D. You have chronic liver disease
E. You are scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
F. You have a platelet count of less than $50x10^9$ cells/L measured within the last 30 days
G. You are not receiving other thrombopoietin receptor agonist therapy (drugs that help make more blood platelets) such as avatrombopag, romiplostim, eltrombopag

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Commercial Effective: 07/01/20

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

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## MEBENDAZOLE

| Generic | Brand | | | |
|---|---|---|---|---|
| MEBENDAZOLE | EMVERM | | | |

### GUIDELINES FOR USE

Our guideline named **MEBENDAZOLE (Emverm)** requires the following rule(s) be met for approval:

A. Emverm is being used for the treatment of *Enterobius vermicularis* (pinworm), *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm)
B. You are 2 years of age or older
C. **If you have *enterobius vermicularis* (pinworm), approval also requires:**
   1. You previously had a trial of over-the-counter (OTC) pyrantel pamoate, unless there is a medical reason why you cannot (contraindication)
D. **If you have trichuris trichiura (whipworm) or ascaris lumbricoides (common roundworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication)
E. **If you have ancylostoma duodenale (common hookworm) or necator americanus (American hookworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication) OR you had a trial of over-the-counter (OTC) pyrantel pamoate

Commercial Effective: 10/01/20

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

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## MECAMYLAMINE HYDROCHLORIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| MECAMYLAMINE HCL | VECAMYL | | | |

### GUIDELINES FOR USE

Our guideline named **MECAMYLAMINE HYDROCHLORIDE (Vecamyl)** requires the following rule(s) be met for approval:

A. The requested medication will be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension
B. You have had a trial of at least three of the following, unless there is a medical reason why you cannot (contraindication): angiotensin converting enzyme inhibitor (ACE-I) 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.

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
**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)

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Commercial Effective: 04/01/20

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

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## MECHLORETHAMINE GEL

| Generic | Brand | | | |
|---|---|---|---|---|
| MECHLORETHAMINE HCL | VALCHLOR | | | |

### GUIDELINES FOR USE

Our guideline named **MECHLORETHAMINE GEL (Valchlor)** requires the following rule(s) be met for approval:

A. You have stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma (type of immune system cancer)
B. You had prior skin-directed therapy such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy

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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)
   3. Hypereosinophilic syndrome (HES) (a rare blood disorder)

B. **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)

C. **If you have eosinophilic granulomatosis with polyangiitis (EGPA), approval also requires:**
   **1.** You are 18 years of age or older

D. **If you have hypereosinophilic syndrome (HES), approval also requires:**
   1. You are 12 years of age or older
   2. You had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

**CONTINUED ON NEXT PAGE**

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

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## MEPOLIZUMAB

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

**NOTE:** For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA, Churg-Strauss syndrome) OR hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:

A. You have severe asthma with an eosinophilic phenotype
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 (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.)

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Commercial Effective: 10/12/20

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

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## MIDOSTAURIN

| Generic | Brand | | | |
|---|---|---|---|---|
| MIDOSTAURIN | RYDAPT | | | |

## GUIDELINES FOR USE

Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
   2. Aggressive systemic mastocytosis (ASM: condition with a build up of a type of white blood cell)
   3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
   4. Mast cell leukemia (MCL: type of white blood cell cancer)

B. **If you have newly diagnosed acute myeloid leukemia (AML), approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

Commercial Effective: 07/01/20

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

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## MIFEPRISTONE

| Generic | Brand | | | |
|---|---|---|---|---|
| MIFEPRISTONE | KORLYM | | | |

### GUIDELINES FOR USE

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

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for approval:

A. You have endogenous Cushing's syndrome (CS: condition that occurs after having high levels of cortisol hormone in the body for a long time)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. Your diagnosis has been confirmed by ONE of the following:
   1. 24-hour urine free cortisol test (at least 2 or more tests to confirm)
   2. Overnight 1mg dexamethasone test
   3. Late night salivary cortisol (at least 2 or more tests to confirm)
E. Your hypercortisolism (high levels of cortisol) is not a result of chronic glucocorticoids (class of drugs that consist of steroids)
F. You have type 2 diabetes mellitus (too much sugar in your blood) OR glucose intolerance (term for a group of conditions that result in elevated blood sugar)
G. You have failed surgical treatment for Cushing's syndrome OR you are not a candidate for surgery

### RENEWAL CRITERIA

Our guideline named **MIFEPRISTONE (Korlym)** requires the following rule(s) be met for renewal:

A. You have endogenous Cushing's syndrome (condition that occurs after having high levels of cortisol hormone in the body for a long time)
B. You continue to have improvement of glucose tolerance and/or stable glucose tolerance (such as reduced hemoglobin A1C [average amount of sugar in your blood over the last 2 to 3 months], improved fasting glucose)
C. You continue to tolerate Korlym
D. You are not a candidate for surgery or have failed surgery for Cushing's syndrome

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

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## MIGALASTAT

| Generic | Brand | | | |
|---|---|---|---|---|
| MIGALASTAT | GALAFOLD | | | |

## GUIDELINES FOR USE

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

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for approval:

A. You have confirmed Fabry disease (rare genetic disease)
B. You are 18 years of age or older
C. You have an amenable (responsive) galactosidase alpha gene (GLA) variant based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by clinical genetics professional as the cause of disease (pathogenic/likely pathogenic)
D. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
E. You are NOT concurrently using enzyme replacement therapy (Fabrazyme)
F. You are symptomatic OR have evidence of injury from GL-3 (a type of cell that builds up) to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR (measurement of how well your kidneys are working) for age, persistent albuminuria (buildup of a type of protein), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. You meet ONE of the following:
    1. If you are a female patient: Confirmation of Fabry disease (rare genetic disease) via genetic test documenting galactosidase alpha gene (GLA) mutation
    2. If you are a male patient: Confirmation of Fabry disease via enzyme assay (lab test) showing you have a low amount of alpha galactosidase A (a-Gal -A) OR genetic test documenting galactosidase alpha gene (GLA) mutation

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

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## MIGALASTAT

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **MIGALASTAT (Galafold)** requires the following rule(s) be met for renewal:

A. You have Fabry disease (rare genetic disease)
B. You have demonstrated improvement or maintenance/stabilization while on therapy in at least ONE of the following areas:
    1. Symptoms such as pain, hypohidrosis/anhidrosis (little to no sweat), exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas (condition with small, dark spots on the skin), abnormal cornea, tinnitus (ringing in the ears), or hearing loss
    2. Imaging such as brain/cardiac MRI (Magnetic resonance imaging), DEXA (Dual-energy X-ray absorptiometry: scan that measures bone density), or renal (kidney) ultrasound
    3. Laboratory or histological testing such as GL-3 (type of cell that builds up) in plasma/urine or renal biopsy

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Commercial Effective: 07/01/20

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

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## MIGLUSTAT

| Generic | Brand | | | |
|---|---|---|---|---|
| MIGLUSTAT | ZAVESCA | | | |

### GUIDELINES FOR USE

Our guideline named **MIGLUSTAT (Zavesca)** requires the following rule(s) be met for approval:

A. You have mild to moderate type 1 Gaucher disease (rare genetic disorder that affects organs and tissues)
B. You are 18 years of age or older
C. The requested medication will be used as monotherapy (used alone)
D. Enzyme replacement therapy is not a therapeutic option for this patient (due to allergy, hypersensitivity, or poor venous access)

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Commercial Effective: 07/01/20

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

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## MILTEFOSINE

| Generic | Brand | | | |
|---|---|---|---|---|
| MILTEFOSINE | IMPAVIDO | | | |

### GUIDELINES FOR USE

Our guideline for **MILTEFOSINE (Impavido)** requires the following rule(s) be met for approval:

A. You are 12 years of age or older
B. You have Leishmaniasis (type of parasite disease) with ONE of the following types of infection:
   1. Visceral leishmaniasis (affects your organs) caused by *Leishmania donovani*
   2. Cutaneous leishmaniasis (affects your skin layers) caused by ALL of the following:
      a. *Leishmania braziliensis*
      b. *Leishmania guyanensis*
      c. *Leishmania panamensis*
   3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by *Leishmania braziliensis*
C. Species identification must be confirmed via ONE of the following CDC (Center for Disease Control and Prevention) recommended tests:
   1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings
   2. Culture medium
   3. Polymerase chain reaction (lab method to make copies of genes)
   4. Serologic testing (testing your blood and body fluids such as rK39 Rapid Test)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## MINOCYCLINE HCL MICROSPHERES (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MINOCYCLINE HCL MICROSPHERES | ARESTIN | | | |

## GUIDELINES FOR USE

## INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have documentation of confirmed periodontitis (inflammation and infection of the gums)
B. You are age 18 years or older
C. The medication is prescribed by or given in consultation with an oral health care professional
D. You do not have a history of minocycline or tetracycline sensitivity or allergy
E. You do not have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. The requested medication will be administered by an oral health professional
G. The requested medication will be used as an adjunct (add-on therapy) 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
H. The requested medication is not being used for acutely abscessed periodontal pocket (not used for short-term and sudden infection with pus-filled pocket)
I. The medication is not being used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus
    2. Chemotherapy
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. The medication is not being used in the regeneration of alveolar bone (bone that has tooth sockets), either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

## RENEWAL CRITERIA

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:

A. You have documentation of periodontitis (inflammation and infection of the gums)
B. The medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planning

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

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## MIPOMERSEN SODIUM

| Generic | Brand | | | |
|---|---|---|---|---|
| MIPOMERSEN SODIUM | KYNAMRO | | | |

## GUIDELINES FOR USE

Our guideline named **MIPOMERSEN SODIUM (Kynamro)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia (type of inherited high cholesterol) which was determined by meeting **ONE** of the following criteria:
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of at least 8
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein)-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma (fatty growths underneath the skin) before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

C. The medication is prescribed by or recommended by a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management specialist)

D. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated drug treatment

E. You previously had a trial of Repatha (evolocumab) unless you do not have functional LDL (low density lipoprotein) receptors

**F. If you are statin tolerant, approval also requires:**
   1. You meet ONE of the following:
      i. You have 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**
      ii. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and you cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   2. You will continue statin treatment in combination with Kynamro

**G. If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication to (medical reason why you cannot use) 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 reaction
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measure of how much muscle damage you have) 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 (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

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

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Commercial Effective: 07/01/20

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

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## MOMETASONE SINUS IMPLANT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MOMETASONE FUROATE | SINUVA | | | |

### GUIDELINES FOR USE

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

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

### RENEWAL CRITERIA

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Commercial Effective: 10/01/20

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

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## NILOTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| NILOTINIB HCL | TASIGNA | | | |

## GUIDELINES FOR USE

Our guideline named **NILOTINIB (Tasigna)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML: a type of blood cell cancer) in chronic phase
   2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase

B. **If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (type of blood cell cancer) in chronic phase, approval also requires:**
   1. You are 1 year of age or older

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia (type of blood cell cancer) in chronic or accelerated phase, approval also requires:**
   1. You are 18 years of age or older
   2. You are resistant or intolerant to prior therapy including Gleevec (imatinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (a type gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

D. **If you have Philadelphia chromosome-positive chronic myeloid leukemia (a type of blood cell cancer) in chronic phase, approval also requires:**
   1. You are 1 to 17 years of age
   2. You are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You have a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis (type of gene testing) confirming that the following mutations (a permanent change in your DNA that make up your gene) are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

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

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## NIMODIPINE SOLUTION

| Generic | Brand | | | |
|---|---|---|---|---|
| NIMODIPINE | NYMALIZE | | | |

### GUIDELINES FOR USE

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

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Commercial Effective: 05/25/20

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

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**NIRAPARIB**

| Generic | Brand | | | |
|---|---|---|---|---|
| NIRAPARIB TOSYLATE | ZEJULA | | | |

**GUIDELINES FOR USE**

Our guideline named **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Recurrent (returning) epithelial ovarian cancer (cancer that forms on the surface of the ovary), fallopian tube cancer, or primary peritoneal cancer (type of abdominal cancer)
   2. Advanced ovarian, epithelial ovarian, fallopian tube, or primary peritoneal cancer

B. **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 complete or partial response to your most recent platinum-based chemotherapy
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*
   4. The requested medication will be used as monotherapy (used by itself for treatment)
   5. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (treatment)
   6. You have completed at least 2 or more lines of platinum-based chemotherapy

C. **If you have advanced ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have been treated with three or more prior chemotherapy regimens (treatments)
   3. Your cancer is associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:
      a. Deleterious (harmful) or suspected deleterious BRCA mutation (type of gene mutation)
      b. Genomic instability and have progressed more than six months after response to the last platinum-based chemotherapy
   4. You were selected for treatment based on an Food and Drug Administration-approved companion diagnostic test for Zejula

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. You are in complete or partial response to first-line platinum based-chemotherapy
   3. The requested medication will be used for maintenance treatment

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

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## OBETICHOLIC ACID

| Generic | Brand | | | |
|---|---|---|---|---|
| OBETICHOLIC ACID | OCALIVA | | | |

### GUIDELINES FOR USE

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

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following criteria:
   1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
   2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
   3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age and older
C. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor) or hepatologist (liver doctor)
D. You meet ONE of the following:
   1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
   2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
E. You do not have complete biliary obstruction (blockage of bile ducts)

### RENEWAL CRITERIA

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:

A. You have primary biliary cholangitis (type of liver disease)
B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) 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
C. You have not developed complete biliary obstruction (blockage of bile ducts)

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

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## OCTREOTIDE - ORAL

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| 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

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Commercial Effective: 09/07/20

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

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## OCTREOTIDE - SQ

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| OCTREOTIDE ACETATE | BYNFEZIA | | | | |

### GUIDELINES FOR USE

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

Our guideline named **OCTREOTIDE - SQ (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. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
   a. You are 18 years of age or older
   b. 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 severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:**
   a. You are 18 years of age or older

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas), approval also requires:**
   a. You are 18 years of age or older

### RENEWAL CRITERIA

Our guideline named **OCTREOTIDE - SQ (Bynfezia)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
   2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
   3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. You have had improvement or sustained remission of your symptoms

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

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## OMACETAXINE MEPESUCCINATE

| Generic | Brand | | | |
|---|---|---|---|---|
| OMACETAXINE MEPESUCCINATE | SYNRIBO | | | |

### GUIDELINES FOR USE

Our guideline named **OMACETAXINE (Synribo)** requires the following rule(s) be met for approval:

A. You have chronic myeloid leukemia (CML: type of blood cell cancer)
B. **If the request is for induction therapy, approval also requires:**
   1. You have previously tried or have a contraindication (a medical reason why you cannot) to two of the following therapies: Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig
   2. You have received less than 6 fills of Synribo
C. **If the request is NOT for induction therapy, approval also requires:**
   1. You have achieved a hematologic response (your blood tests show you have improvement), defined as an absolute neutrophil count [ANC] greater than or equal to 1.5 x 10(9)/L, AND platelets greater than or equal to 100 x 10(9)/L, AND no blood blasts; OR bone marrow blasts less than 5 percent)

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## OMADACYCLINE

| Generic | Brand | | | |
|---|---|---|---|---|
| OMADACYCLINE | NUZYRA | | | |

## GUIDELINES FOR USE

Our guideline named **OMADACYCLINE (Nuzyra)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Community-acquired bacterial pneumonia (CABP: type of lung infection)
   2. Acute (severe and sudden) bacterial skin or skin structure infection (ABSSSI)

B. **If you have community-acquired bacterial pneumonia, 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 isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

***(Criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

## OMADACYCLINE

### GUIDELINES FOR USE (CONTINUED)

C. **If you have acute bacterial skin or skin structure infection (ABSSSI), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *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*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of or contraindication to at least TWO standard of care agents for acute bacterial skin or skin structure infection (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, amoxicillin, nafcillin, ceftriaxone, cephalexin, cefazolin)

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

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## OMBITASVIR/PARITAPREVIR/RITONAVIR

| Generic | Brand | | | |
|---|---|---|---|---|
| OMBITASVIR/PARITAPREVIR/ RITONAVIR | TECHNIVIE | | | |

### GUIDELINES FOR USE

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR (Technivie)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 4 without cirrhosis (liver damage) or with compensated cirrhosis (you do not have symptoms related to liver damage; Child-Pugh A)
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. The requested medication will be used with ribavirin, unless you are treatment naïve without cirrhosis (you have never been previously treated and do not have liver damage) and you have an intolerance or contraindication to (medical reason why you cannot use) ribavirin
D. You are 18 years of age or older
E. You have previously failed a short trial of Harvoni or Epclusa or Mavyret. Reasons for failure may include adverse effect, intolerance to therapy, or contraindication to (medical reason why you cannot use) all 3 drugs (**NOTE:** If you completed a full course of therapy with Mavyret and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
F. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
G. You have evidence of current hepatitis C virus infection and chronic hepatitis C virus infection as documented by at least one detectable HCV RNA levels (amount of virus in your blood) within the past 6 months

**A total of 12 weeks of therapy will be approved.**

**The medication will NOT be approved for the following:**

A. You are using any of the following medications at the same time 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
B. You have moderate or severe liver impairment (Child Pugh B or Child Pugh C)
C. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)

D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
E. You have previously used (failed a full course of therapy) or are 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 (type of hepatitis C drug) including Harvoni (ledipasvir/sofosbuvir)
    3. Any HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)
    4. Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir) or Viekira XR

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## OSILODROSTAT

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| OSILODROSTAT | ISTURISA | | | | |

### GUIDELINES FOR USE

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

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for approval:

A. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
E. You previously had a trial of oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

### RENEWAL CRITERIA

Our guideline named **OSILODROSTAT (Isturisa)** requires the following rule(s) be met for renewal:

A. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
B. You continue to have improvement of Cushing's disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
C. You continue to tolerate treatment with Isturisa

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Commercial Effective: 10/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
**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:
      i. You are a postmenopausal female OR a male
      ii. You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      iii. Your disease has NOT worsened after previous 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:
      i. Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      ii. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancers by preventing the cancer cells from multiplying)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PANOBINOSTAT

| Generic | Brand | | | |
|---|---|---|---|---|
| PANOBINOSTAT | FARYDAK | | | |

### GUIDELINES FOR USE

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

Our guideline named **PANOBINOSTAT (Farydak)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (cancer that forms in a type of white blood cell)
B. You have been treated with at least 2 prior regimens including:
   1. Velcade (bortezomib)
   2. Immunomodulatory medication such as Thalomid, Revlimid, or Pomalyst. (These drugs adjust immune responses)
C. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone

### RENEWAL CRITERIA

Our guideline named **PANOBINOSTAT (Farydak)** requires the following rule(s) be met for renewal:

A. You have tolerated the first 8 weeks of therapy without experiencing any severe or medically significant toxicity

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PARATHYROID HORMONE

| Generic | Brand | | | |
|---|---|---|---|---|
| PARATHYROID HORMONE | NATPARA | | | |

## GUIDELINES FOR USE

Our guideline for **PARATHYROID HORMONE** requires the following rule(s) be met for approval:

A. You have hypocalcemia secondary to hypoparathyroidism (low blood calcium due to low levels of a type of hormone)
B. You have previously tried activated vitamin D (calcitriol) and calcium
C. Your hypoparathyroidism (low levels of a type of hormone) is not due to a calcium sensing receptor (CSR) mutation (changes in your DNA that make up your gene)
D. Your hypoparathyroidism is not considered acute post-surgical hypoparathyroidism (not sudden and severe due to surgery in past 30 days)
E. Therapy is prescribed by or given in consultation with an endocrinologist (hormone specialist)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PASIREOTIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| PASIREOTIDE | SIGNIFOR | | | |

### GUIDELINES FOR USE

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

Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for approval:

A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. You have undergone pituitary (a major hormone gland) surgery OR pituitary surgery is not an option
E. You have previously tried oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

### RENEWAL CRITERIA

Our guideline named **PASIREOTIDE (Signifor)** requires the following rule(s) be met for renewal:

A. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
B. You continue to have improvement of Cushing’s disease (such as clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of your disease)
C. You continue to tolerate treatment with Signifor

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Commercial Effective: 10/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PATIROMER

| Generic | Brand | | | |
|---|---|---|---|---|
| PATIROMER CALCIUM SORBITEX | VELTASSA | | | |

### GUIDELINES FOR USE

Our guideline named **PATIROMER (Veltassa)** requires the following rule(s) be met for approval:

A. You have hyperkalemia (high levels of potassium in blood)
B. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor) or cardiologist (heart doctor)
C. The requested medication is NOT being used as an emergency treatment for life-threatening hyperkalemia (high levels of potassium in blood)
D. You are NOT currently receiving dialysis
E. You have tried ONE of the following to lower the risks for hyperkalemia:
    1. Limit to taking no more than one of the following drugs at any given time:
        i. Angiotensin converting enzyme inhibitor (ACE-I such as lisinopril, benazepril)
        ii. Angiotensin receptor blocker (ARB such as valsartan, losartan)
    2. Lowering the dose of renin-angiotensin-aldosterone system (RAAS) inhibitors (such as ACE-I's, ARB's, aldosterone antagonists like spironolactone) has been considered
F. **If your estimated glomerular filtration rate (eGFR) is below 30 mL/min/1.73 m(2), approval also requires:**
    1. You have tried to treat hyperkalemia with loop diuretics such as bumetanide, ethacrynic acid, furosemide, torsemide
G. **If your estimated glomerular filtration rate (eGFR) is 30 mL/min/1.73 m(2) or above approval also requires:**
    1. You have tried to treat hyperkalemia with a loop diuretic such as bumetanide, ethacrynic acid, furosemide, torsemide, OR a thiazide diuretic such as chlorthalidone, hydrochlorothiazide, metolazone
H. You have previously tried Lokelma (sodium zirconium cyclosilicate)

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Commercial Effective: 07/01/20

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## PAZOPANIB

| Generic | Brand | | | |
|---|---|---|---|---|
| PAZOPANIB | VOTRIENT | | | |

## GUIDELINES FOR USE

Our guideline named **PAZOPANIB (Votrient)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   2. Advanced soft tissue sarcoma (STS: cancer that starts in soft tissues like muscle, tendons, fat, lymph vessels, blood vessels, and nerves)

B. **If you have advanced soft tissue sarcoma (STS), approval also requires:**
   1. You had a trial of chemotherapy (cancer treatment such as anthracycline treatment), unless there is a medical reason why you cannot (contraindication)
   2. You do NOT have adipocytic soft tissue sarcoma (type of cancer in fat cells) or gastrointestinal stromal tumors (GIST: type of cancer that starts in a type of cell in the digestive system)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

| Generic | Brand | | | |
|---|---|---|---|---|
| SILDENAFIL | REVATIO | | | |
| TADALAFIL | ADCIRCA, ALYQ | | | |

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

### GUIDELINES FOR USE

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

Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group I: a way to classify the severity of disease)
B. The medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documentation showing you have pulmonary arterial hypertension based on the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
E. You are NOT concurrently or intermittently taking oral erectile dysfunction agents (such as Cialis, Viagra) or any organic nitrates in any form
F. You are NOT concurrently taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas)
G. In addition to the above requirements, the following criteria apply to the specific agents listed:
    1. Request for REVATIO (Sildenafil) ORAL SUSPENSION requires that you are unable to swallow pills and you have tried crushed sildenafil tablets

**CONTINUED ON NEXT PAGE**

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

### RENEWAL CRITERIA

Our guideline named **PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (Revatio, Adcirca/Alyq)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO) Group 1 (a way to classify the severity of disease)
B. You meet ONE of the following criteria:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have a stable 6-minute walk distance test with a stable or improved World Health Organization functional class

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Commercial Effective: 07/01/20

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

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## PEANUT ALLERGEN POWDER-DNFP

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-DNFP | PALFORZIA | | | | |

## GUIDELINES FOR USE

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

Our guideline named **PEANUT ALLERGEN POWDER-DNFP (Palforzia)** requires the following rule(s) be met for approval:

A. You have a peanut allergy confirmed by ONE of the following:
   1. If you have undergone a purposeful food challenge: you have documentation of a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
   2. If you have NOT undergone a purposeful food challenge: you have documentation of a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
B. You are 4 to 17 years of age
C. Therapy is prescribed by given in consultation with an allergist/immunologist (allergy/immune system doctor)
D. You have a clinical history of allergic reaction to peanuts
E. The medication is to be used in conjunction with a peanut-avoidance diet
F. You are not currently on peanut-specific immunotherapy (such as Viaskin Peanut)

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

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## PEANUT ALLERGEN POWDER-DNFP

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

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. Therapy is prescribed by or given in consultation with an allergist/immunologist (allergy/immune system doctor)
C. Palforzia will be used together with a peanut-avoidance diet
D. You are not currently on peanut-specific immunotherapy (such as Viaskin Peanut)
E. You meet ONE of the following:
    1. You have a persistent peanut allergy (your peanut allergy has not gone away)
    2. If you have undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
    3. If you have NOT undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months

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

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## PEG-INTERFERON ALFA-2B

| Generic | Brand | | | |
|---|---|---|---|---|
| PEG-INTERFERON ALFA-2B | SYLATRON,<br>SYLATRON 4-PACK | | | |

### GUIDELINES FOR USE

Our guideline named **PEG-INTERFERON ALFA-2B (Sylatron)** requires the following rule(s) be met for approval:

A. You meet ONE of the following:
   1. You are currently taking Sylatron and have NOT received 5 years of treatment with Sylatron
   2. You have melanoma (skin cancer) with the presence of cancer cells in your lymph nodes (microscopic or gross nodal involvement), within 84 days of surgical removal of the cancer

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Commercial Effective: 10/01/20

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

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## PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

| Generic | Brand | | | |
|---|---|---|---|---|
| PEGINTERFERON ALFA-2A | PEGASYS, PEGASYS PROCLICK | | | |
| PEGINTERFERON ALFA-2B | PEGINTRON | | | |

### GUIDELINES FOR USE

Our guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 (type of liver inflammation caused by hepatitis C virus). Requests for Pegasys will also be approved for a diagnosis of chronic hepatitis B

B. **If you have chronic hepatitis B (type of liver inflammation caused by hepatitis B virus), approval also requires:**
   1. You are 3 years of age or older
   2. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specializing in disorders caused by viruses, bacteria, fungi and parasites), a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   3. You do not have cirrhosis (liver damage)
   4. You have tested positive for HBeAg (hepatitis B e-antigen)
   5. You have evidence of viral replication (the virus has multiplied in your body) with high serum ALT (high amount of a type of liver enzymes)

C. **If you have chronic hepatitis C (type of liver inflammation caused by hepatitis C virus), approval also requires:**
   1. You are between 3 and 11 years old
   2. The medication is prescribed by or given in a consultation with a gastroenterologist (digestive system doctor), infectious disease specialist (a doctor specializing in disorders caused by viruses, bacteria, fungi and parasites), or a doctor specializing in the treatment of hepatitis such as a hepatologist (liver doctor)
   3. You have other symptoms of hepatitis C (extrahepatic manifestations) such as cryoglobulinemia (abnormal proteins in the blood), rashes, and glomerulonephritis (inflammation in your kidneys) AND you have advanced fibrosis (scar tissue in the liver) that requires urgent treatment to lower your risks of getting worse or dying
   4. Peginterferon is being used with ribavirin, unless there is a medical reason why you cannot use ribavirin (contraindication)
   5. You have a detectable pretreatment HCV RNA level/viral load (amount of virus in your blood). The level varies by lab assay (test) but is a level typically greater than or equal to 25 IU/mL

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

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PEGVALIASE

| Generic | Brand | | | |
|---|---|---|---|---|
| PEGVALIASE-PQPZ | PALYNZIQ | | | |

### GUIDELINES FOR USE

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

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for approval:

A. You have phenylketonuria (PKU) (a type of birth defect that causes buildup of a chemical called phenylalanine)
B. You are 18 years of age or older
C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
D. You have previously tried Kuvan (sapropterin)
E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

### RENEWAL CRITERIA

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for renewal:

2. You have a diagnosis of phenylketonuria (PKU: type of birth defect that causes buildup of a chemical called phenylalanine)
3. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L

Commercial Effective: 12/12/20

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

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## PEMIGATINIB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| PEMIGATINIB | PEMAZYRE | | | | |

### GUIDELINES FOR USE

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 a Food and Drug Administration (FDA)-approved test

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Commercial Effective: 10/01/20

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

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## PENICILLAMINE

| Generic | Brand | | | |
|---|---|---|---|---|
| PENICILLAMINE | CUPRIMINE | | | |
| PENICILLAMINE | DEPEN | | | |
| PENICILLAMINE | D-PENAMINE | | | |

## GUIDELINES FOR USE

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

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for approval:

A. You have a known family history of Wilson's disease (a genetic disorder in which copper builds up in the body) or physical examination consistent with Wilson's disease, cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)

B. **If you have Wilson's disease, approval also requires:**
   1. The drug is prescribed by or given in consultation with a hepatologist (a liver doctor); and
   2. You have maintained a low copper diet (less than 2mg copper per day); and
   3. If you are requesting Cuprimine, you must have tried to Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)
   4. You meet ONE of the following:
      a. You have blood levels of the copper-protein ceruloplasmin less than 20mg/dL; or
      b. Your liver biopsy (sample cells taken from your liver) shows you have an abnormally high amount of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (rings around the iris of your eye); or
      c. Your diagnosis has been confirmed by genetic testing for ATP7B (type of gene) mutations

***(Initial criteria continued on next page)***

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## PENICILLAMINE

**INITIAL CRITERIA (CONTINUED)**

C. **If you have cystinuria, approval also requires:**
   1. You have nephrolithiasis (kidney stones) and one (1) or more of the following:
      a. Kidney stone analysis shows that there is cystine (an amino acid);
      b. Urine analysis shows there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria with positive tests results in the cyanide-nitroprusside screen (a test to determine the amount of cysteine in your body);
   2. You have a daily cystine output greater than 300mg per 24 hours after a urine cystine excretion testing
   3. You have failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following, unless there is a medical reason why you cannot (contraindicated):
      a. Increased fluid intake
      b. Modest reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   4. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor)
   5. For Cuprimine requests, you must have a previous trial of Depen (penicillamine) or D-Penamine (penicillamine) **AND** Thiola (tiopronin), unless there is a medical reason why you cannot (contraindication)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. The medication is prescribed by or given in consultation with a rheumatologist (joint disease doctor)
   2. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you must have tried Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)

E. **If you have an active prior authorization approval for Depen,** D-Penamine will be approved without meeting additional criteria during the period of Depen shortage.

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

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## PENICILLAMINE

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **PENICILLAMINE (Cuprimine, Depen, D-Penamine)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of Wilson's disease (a genetic disorder in which copper builds up in the body), cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)
B. **If you have Wilson's disease, approval also requires:**
    1. You have achieved free serum copper of less than 10 mcg/dL
C. **If you have cystinuria, approval also requires:**
    1. You have achieved cystine excretion of less than 200 mg/day
D. **If you have active rheumatoid arthritis, approval also requires:**
    1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
    2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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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

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Commercial Effective: 04/01/20

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

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## PEXIDARTINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| PEXIDARTINIB | TURALIO | | | |

### GUIDELINES FOR USE

Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:

A. You have symptomatic tenosynovial giant cell tumor (TGCT: type of non-cancerous growth in or around a joint causing tissue damage and reducing function)
B. TGCT is associated with severe morbidity (disease) or functional limitations
C. TGCT is NOT responsive to improvement with surgery
D. You are 18 years of age or older

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Commercial Effective: 07/01/20

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

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## PHENOXYBENZAMINE

| Generic | Brand | | | |
|---|---|---|---|---|
| PHENOXYBENZAMINE | DIBENZYLINE | | | |

### GUIDELINES FOR USE

Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:

A. You have pheochromocytoma (tumor in your adrenal gland)
B. The requested drug is used to treat pheochromocytoma before pheochromocytoma surgery to remove the tumor
C. The requested drug is prescribed by an endocrinologist (hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist/oncologist (cancer doctor)
D. You must have tried an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin), unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PIMAVANSERIN

| Generic | Brand | | | |
|---|---|---|---|---|
| PIMAVANSERIN | NUPLAZID | | | |

### GUIDELINES FOR USE

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

Our guideline named drug named **PIMAVANSERIN (Nuplazid)** requires you to meet the following rule(s) for approval:

A. You have a diagnosis of psychosis associated with Parkinson's disease (a mental disorder that causes you to have false beliefs or to hear or see things that are not really there and is related to a movement disorder)
B. You are at least 18 years old; and
C. The drug is prescribed by a doctor specializing in one of the following areas: neurology (brain doctor), geriatric medicine (specialty that focuses on health care of elderly people), or behavioral health (such as a psychiatrist).

### RENEWAL CRITERIA

Our guideline named **PIMAVANSERIN (Nuplazid)** requires that you have experienced an improvement in psychosis symptoms (mental issues such as false beliefs or hearing or seeing things that are not really there) from baseline during the past 12 months of therapy and you show a continued need for treatment.

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## PITOLISANT

| Generic | Brand | | | |
|---|---|---|---|---|
| PITOLISANT HCL | WAKIX | | | |

## GUIDELINES FOR USE

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

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for approval:

A. You have one of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
   2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. You have narcolepsy that is confirmed by **ONE** of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average 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 (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   2. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
   3. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   4. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have cataplexy with narcolepsy, approval also requires:**
   1. Wakix is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

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

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## PITOLISANT

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **PITOLISANT (Wakix)** requires the following rule(s) be met for renewal:

A. You have ONE of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
   2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. You meet ONE of the following:
   1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
   2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline

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Commercial Effective: 11/09/20

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

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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 COMMERCIAL DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## PREDNISONE DELAYED-RELEASE TABS

| Generic | Brand | | | |
|---|---|---|---|---|
| PREDNISONE | RAYOS | | | |

### GUIDELINES FOR USE

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

Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for approval:

A. The request is for a Food and Drug Administration-approved indication
B. You had a previous trial of **ONE** of the following, unless there is a medical reason why you cannot (contraindication): generic prednisone, prednisolone, or methylprednisolone
C. You have had a subclinical response (not a full response) or treatment failure of generic prednisone, prednisolone, or methylprednisolone

### RENEWAL CRITERIA

Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for renewal approval:

A. The request is for a Food and Drug Administration-approved indication
B. You have had a clinical benefit from using Rayos (such as improvement in inflammatory condition from baseline)
C. You cannot be tapered off (slowly lowering the dose to stop use) corticosteroid (Rayos)

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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)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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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

**CONTINUED ON NEXT PAGE**

**STANDARD COMMERCIAL DRUG FORMULARY**
**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)

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Commercial Effective: 04/01/20

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

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## REGORAFENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| REGORAFENIB | STIVARGA | | | |

### GUIDELINES FOR USE

Our guideline named **REGORAFENIB (Stivarga)** requires the following rule(s) be met for approval:

A. You have a diagnosis of metastatic colorectal cancer (colon cancer that has spread in the body), **OR** locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (type of growth in the digestive system tract, most commonly in the stomach or small intestine), OR hepatocellular carcinoma (type of liver cancer).

B. **If you have metastatic colorectal cancer (CRC), approval also requires:**
   1. If colorectal cancer is **wild type KRAS** (a type of unmutated gene), you must have tried an anti-EGFR therapy (treatment that stops a protein from helping cancer cells grow) such as Erbitux [cetuximab] or Vectibix [panitumumab], unless there is a medical reason why you cannot use these agents (contraindication).
   2. If colorectal cancer is **NOT wild type KRAS,** you must have tried **ALL** of the following preferred therapies unless there is a medical reason why you cannot (contraindication):
      a. An anti-VEGF therapy (group of medicines that reduce new blood vessel growth) such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept].
      b. A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine.

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had a trial with Gleevec (imatinib) and Sutent (sunitinib) unless there is a medical reason why you cannot use these agents (contraindication).

D. **If you have hepatocellular carcinoma (HCC), approval also requires:**
   1. You had a previous treatment with Nexavar (sorafenib).

These prior therapies may be covered under the medical benefit and/or may require prior authorization.

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Commercial Effective: 07/01/20

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

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## RILUZOLE SUSPENSION

| Generic | Brand | | | |
|---|---|---|---|---|
| RILUZOLE | TIGLUTIK | | | |

### GUIDELINES FOR USE

Our guideline named **RILUZOLE SUSPENSION (Tiglutik)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
B. You are 18 years of age or older
C. You have tried riluzole tablets
D. You are unable to take riluzole tablet formulation

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Commercial Effective: 07/01/20

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

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**RIPRETINIB**

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| RIPRETINIB | QINLOCK | | | | |

## GUIDELINES FOR USE

Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:

A. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
B. You are 18 years of age or older
C. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

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Commercial Effective: 10/01/20

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

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**RISDIPLAM**

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| 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

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

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## RUXOLITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| RUXOLITINIB PHOSPHATE | JAKAFI | | | |

## GUIDELINES FOR USE

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

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera
   3. Steroid -refractory acute graft-versus-host disease
B. **If you have intermediate or high-risk myelofibrosis, such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, approval also requires:**
   1. You are 18 years of age or older
C. **If you have polycythemia vera, approval also requires:**
   1. You are 18 years of age or older
   2. You had a trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)
D. **If you have steroid -refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older

## RENEWAL CRITERIA

Our guideline named **RUXOLITINIB (Jakafi)** requires the following rule(s) be met for renewal:

A. You have intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
B. You have experienced or maintained 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

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

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## SACROSIDASE

| Generic | Brand | | | |
|---|---|---|---|---|
| SACROSIDASE | SUCRAID | | | |

### GUIDELINES FOR USE

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:

A. You have a genetically determined sucrose deficiency (genetic disorder that will not allow your body to process a type of sugar), or congenital sucrase-isomaltase deficiency (CSID: disorder that affects your ability to digest certain sugars due to absent or low levels of two digestive enzymes).

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Commercial Effective: 01/11/21

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

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## SAPROPTERIN DIHYDROCHLORIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| SAPROPTERIN DIHYDROCHLORIDE | KUVAN | | | |

### GUIDELINES FOR USE

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

Our guideline named **SAPROPTERIN DIHYDROCHLORIDE (Kuvan)** requires the following rule(s) be met for approval:

A. You have hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You follow a phenylalanine-restricted diet

### RENEWAL CRITERIA

Our guideline named **SAPROPTERIN DIHYDROCHLORIDE (Kuvan)** requires the following rule(s) be met for renewal:

A. You hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You experienced at least a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride)
C. You continue to follow a phenylalanine-restricted diet

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Commercial Effective: 07/01/20

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

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## SARGRAMOSTIM

| Generic | Brand | | | |
|---|---|---|---|---|
| SARGRAMOSTIM | LEUKINE | | | |

### GUIDELINES FOR USE

Our guideline named **SARGRAMOSTIM (Leukine)** requires the following rule(s) be met for approval:

A. The requested medication is prescribed by or given in consultation with a hematologist (blood specialist) or oncologist (cancer/tumor doctor), **OR** you meet **ONE** of the following:
   1. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer) and are using the requested medication to shorten time to neutrophil (a type of white blood cell) recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND you are 55 years of age or older
   2. You are undergoing autologous transplantation (your own blood-forming stem cells are collected) and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (to collect blood sample and separate white blood cells in a lab test) AND you are 18 years of age or older
   3. You have non-Hodgkin's lymphoma (NHL: type of cancer), acute lymphoblastic leukemia (ALL: type of white blood cell cancer) or Hodgkin's lymphoma (type of cancer) and are using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation (to help your blood and bone marrow recover) AND you are 2 years of age or older
   4. The requested medication is being used for the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors (to help your blood and bone marrow recover after using a lab test to match you to the correct donors) AND you are 2 years of age or older
   5. The requested medication is being used for the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND you are 2 years of age or older
   6. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase your survival

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

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## SATRALIZUMAB-MWGE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| 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:
    a. Optic neuritis (inflammation that damages an eye nerve)
    b. Acute myelitis (sudden and severe inflammation of the spinal cord)
    c. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    d. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    e. 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
    f. 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

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

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**SECUKINUMAB**

| Generic | Brand | | | |
|---|---|---|---|---|
| SECUKINUMAB | COSENTYX | | | |

**GUIDELINES FOR USE**

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

Our guideline named **SECUKINUMAB (Cosentyx)** requires the following rule(s) be met for approval:

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 with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of spine pain that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age and older
   2. The requested 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 body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

C. **If you have psoriatic arthritis (PsA), 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 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 ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis (AS), 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 rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)

***(Initial criteria continued on next page)***

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

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## SECUKINUMAB

### INITIAL CRITERIA (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), 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 rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

### RENEWAL CRITERIA

Our guideline named **SECUKINUMAB (Cosentyx)** 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 with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)

B. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy.

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.

D. **If you have ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA), renewal also requires:**
   1. You have 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: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy.

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

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**SELEXIPAG**

| Generic | Brand | | | |
|---|---|---|---|---|
| SELEXIPAG | UPTRAVI | | | |

**GUIDELINES FOR USE**

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

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. The medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into right side of heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) of 25 mmHg or greater
    2. Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms (a way to classify how limited you are during physical activity)

**RENEWAL CRITERIA**

Our guideline named **SELEXIPAG (Uptravi)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance
    2. You have a stable 6-minute walk distance from baseline AND your World Health Organization (WHO) functional class (way to classify how limited you are during physical activity) has remained stable or improved

Commercial Effective: 07/01/20

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

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## SELPERCATINIB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| SELPERCATINIB | RETEVMO | | | | |

## GUIDELINES FOR USE

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 the entire 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

Commercial Effective: 10/01/20

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

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## SELUMETINIB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| SELUMETINIB | KOSELUGO | | | | |

### GUIDELINES FOR USE

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 to 17 years of age
C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

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Commercial Effective: 10/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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**SIMEPREVIR**

| Generic | Brand | | | |
|---|---|---|---|---|
| SIMEPREVIR | OLYSIO | | | |

## GUIDELINES FOR USE

Our guideline named **SIMEPREVIR (Olysio)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 1 (type of liver inflammation)
B. You are 18 years of age or older
C. You are currently supervised by a gastroenterologist (digestive system doctor), 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
D. You must have documentation of a recent hepatitis c virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the past 6 months
E. You will be using Olysio with Sovaldi taken at the same time
F. You have previously failed a short trial of Harvoni, Mavyret or Epclusa and stopped due to reasons such as adverse effect or intolerance early in therapy, unless there is a medical reason why you cannot (contraindication) take all 3 agents. The medication will not be approved for an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response)
G. You are treatment naïve (never previously treated) or treatment-experienced with prior treatment with peginterferon/ribavirin

**Olysio will not be approved for the following patients:**

A. You 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)
B. You have compensated cirrhosis (no symptoms related to liver damage) or decompensated cirrhosis (you have symptoms related to liver damage)
C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
D. You are using Olysio with ribavirin and peginterferon alfa

***(Denial text continued on next page)***

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## SIMEPREVIR

### GUIDELINES FOR USE (CONTINUED)

E. You are taking any of the following medications that are not recommended for concurrent use with Olysio:
   1. 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)
   2. Any cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost)
   3. Delavirdine, etravirine, nevirapine, or efavirenz
   4. Any HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

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Commercial Effective: 07/01/20

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

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## SIMVASTATIN ORAL SUSPENSION

| Generic | Brand | | | |
|---|---|---|---|---|
| SIMVASTATIN | FLOLIPID | | | |

## GUIDELINES FOR USE

Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:

A. You had a previous trial of simvastatin tablets, unless there is a medical reason why you cannot (contraindication)
B. Your prescriber provides documentation showing that you have dysphagia (general swallowing difficulties), difficulty swallowing tablets, or a feeding tube such as a G-tube or J-tube
C. Requests for zero dollar cost share also requires that you are between 40-75 years of age without a history of cardiovascular disease (relating to heart and blood vessels) and 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)

Commercial Effective: 07/01/20

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

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## SODIUM PHENYLBUTYRATE

| Generic | Brand | | | |
|---|---|---|---|---|
| SODIUM PHENYLBUTYRATE | BUPHENYL | | | |

### GUIDELINES FOR USE

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

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires the following rule(s) be met for approval:

A. You have urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. There is documentation confirming you have urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
C. Buphenyl will be used as adjunctive (add-on) therapy along with dietary protein restriction
D. Your condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone

### RENEWAL CRITERIA

Our guideline named **SODIUM PHENYLBUTYRATE (Buphenyl)** requires the following rule(s) be met for renewal:

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced clinical benefit from baseline (such as you are having normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity).

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
**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)

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Commercial Effective: 04/01/20

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

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**SOLRIAMFETOL**

| Generic | Brand | | | |
|---|---|---|---|---|
| SOLRIAMFETOL | SUNOSI | | | |

**GUIDELINES FOR USE**

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

Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for approval:

A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
    2. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
        i. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
        ii. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** one (1) early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** one (1) SOREMP (within about 15 minutes) on a sleep study (polysomnography) the night before the MSLT, with the sleep study ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
        iii. You have low orexin levels on a cerebrospinal fluid (CSF) assay (a test to determine the amount of a type of chemical for wakefulness in your brain)
    3. You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
    4. Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
    5. ou have tried one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)

**(*Initial criteria continued on the next page)***

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

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## SOLRIAMFETOL

### INITIAL CRITERIA (CONTINUED)

C. **If you have excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval also require:**
   1. Your diagnosis of OSA is confirmed by a sleep study (polysomnography), home sleep apnea testing devices, or hospital-based bedside monitoring
   2. You have had Excessive Daytime Sleepiness (EDS) for at least 3 months and your Epworth Sleepiness Scale (ESS) score is more than 10
   3. You have tried modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)
   4. You have been on a treatment for the obstructive causes of OSA, for at least one month since initiation, and you have been counseled on weight-loss intervention [if your BMI (Body Mass Index: a measure of body fat based on height and weight) is greater than 30]

### RENEWAL CRITERIA

Our guideline named **SOLRIAMFETOL (Sunosi)** requires the following rule(s) be met for renewal:

A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
B. You have sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

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Commercial Effective: 07/01/20

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

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## SONIDEGIB

| Generic | Brand | | | |
|---|---|---|---|---|
| SONIDEGIB | ODOMZO | | | |

### GUIDELINES FOR USE

Our guideline named **SONIDEGIB (Odomzo)** requires the following rule(s) be met for approval:

A. You have a locally advanced basal cell carcinoma (BCC: type of skin cancer).
B. This is a recurrence (disease returns) of basal cell carcinoma (BCC: type of skin cancer) after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
C. Baseline serum creatine kinase (CK: type of protein that helps determine muscle damage) and serum creatinine levels have been obtained before starting therapy
D. If you are a females of reproductive potential, you must verify your pregnancy status before starting therapy

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Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## SORAFENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| SORAFENIB TOSYLATE | NEXAVAR | | | |

## GUIDELINES FOR USE

Our guideline for **SORAFENIB (Nexavar)** requires that you have ONE of the following diagnoses for approval:

A. Advanced renal cell carcinoma (RCC: type of kidney cancer)
B. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery))
C. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned, spread , is getting worse and is not responding to a type of treatment)

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## STATIN ZERO COST SHARE OVERRIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| ROSUVASTATIN | CRESTOR, EZALLOR SPRINKLE | | | |
| PRAVASTATIN | PRAVACHOL | | | |
| SIMVASTATIN | ZOCOR | | | |
| ATORVASTATIN | LIPITOR | | | |
| LOVASTATIN, LOVASTATIN EXTENDED-RELEASE | ALTOPREV | | | |
| FLUVASTATIN, FLUVASTATIN EXTENDED-RELEASE | LESCOL, LESCOL XL | | | |
| PITAVASTATIN CALCIUM | LIVALO | | | |
| PITAVASTATIN MAGNESIUM | ZYPITAMAG | | | |

### GUIDELINES FOR USE

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)

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

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## STATIN ZERO COST SHARE OVERRIDE

**GUIDELINES FOR USE (CONTINUED)**

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:
   4. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   5. 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)
   6. 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)

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Commercial Effective: 06/08/20

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

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## STIRIPENTOL

| Generic | Brand | | | |
|---|---|---|---|---|
| STIRIPENTOL | DIACOMIT | | | |

### GUIDELINES FOR USE

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

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for approval:

A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
B. You are 2 years of age or older
C. You are currently being treated with clobazam (a type of seizure drug)
D. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
E. You had a trial of valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

### RENEWAL CRITERIA

Our guideline named **STIRIPENTOL (Diacomit)** requires the following rule(s) be met for renewal:

A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
B. You are currently being treated with clobazam (type of seizure drug)

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Commercial Effective: 07/01/20

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

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**SUNITINIB**

| Generic | Brand | | | |
|---|---|---|---|---|
| SUNITINIB MALATE | SUTENT | | | |

**GUIDELINES FOR USE**

Our guideline named **SUNITINIB (Sutent)** requires the following rule(s) be met for approval:

A. The requested medication is being used for one of the following:
1. Advanced renal cell carcinoma (RCC: type of kidney cancer)
2. Gastrointestinal stromal tumor (GIST: type of growth in the digestive system)
3. Unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET: type of pancreas cancer)
4. Adjuvant (add-on) treatment of renal cell carcinoma.

B. **If you have gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You had a previous trial of imatinib mesylate (Gleevec), unless there is a medical reason why you cannot (contraindication)

C. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:**
   1. Your tumor is progressive (getting worse) and well-differentiated

D. **If you have adjuvant treatment of renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You are at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy (surgical removal of kidney)

Commercial Effective: 07/01/20

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

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## TADALAFIL

| Generic | Brand | | | |
|---|---|---|---|---|
| TADALAFIL | CIALIS | | | |

### GUIDELINES FOR USE

Our guideline named **TADALAFIL (Cialis)** requires the following rule(s) be met for approval:

A. You have benign prostatic hyperplasia (BPH: your prostate is too big causing difficulty urinating) OR erectile dysfunction (difficulty getting/keeping an erection)
B. **If you have benign prostatic hyperplasia (BPH), approval also requires:**
   1. You previously tried at least two preferred formulary alternatives, including one medication from each of the following classes:
      a. 5-alpha-reductase inhibitors: (such as finasteride or dutasteride)
      b. Alpha blockers: (such as doxazosin, terazosin, tamsulosin, or alfuzosin)
C. **If you have erectile dysfunction, approval also requires**:
   1. You have previously tried generic sildenafil (Viagra)

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Commercial Effective: 09/07/20

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

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**TAFAMIDIS**

| Generic | Brand | | | |
|---|---|---|---|---|
| TAFAMIDIS MEGLUMINE | VYNDAQEL | | | |
| TAFAMIDIS | VYNDAMAX | | | |

## GUIDELINES FOR USE

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

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for approval:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein) which is confirmed by ONE of the following:
   1. Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mtcpyp/DPD (a type of test that shows your heart absorbs a chemical for imaging)( 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
   2. Biopsy of tissue of affected organ(s) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist
D. You have New York Heart Association (NYHA) class I, II or III heart failure (classification of heart failure symptoms)

## RENEWAL CRITERIA

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You have not progressed to (gotten worse to) New York Heart Association (NYHA) Class IV heart failure (classification of heart failure symptoms)

Commercial Effective: 07/01/20

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

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## TALAZOPARIB TOSYLATE

| Generic | Brand | | | |
|---|---|---|---|---|
| TALAZOPARIB TOSYLATE | TALZENNA | | | |

## GUIDELINES FOR USE

Our guideline named **TALAZOPARIB (Talzenna)** requires the following rule(s) be met for approval:

A. You have human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (disease that is advanced or has spread throughout the body and does not have a type of protein)
B. You are 18 years of age or older
C. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by an Food and Drug Administration-approved test
D. You have been treated with chemotherapy in the neoadjuvant (before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
E. **If you have hormone receptor (HR)-positive breast cancer, approval also requires:**
    1. You have previously had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

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Commercial Effective: 07/01/20

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

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## TAVABOROLE

| Generic | Brand | | | |
|---|---|---|---|---|
| TAVABOROLE | KERYDIN, TAVABOROLE | | | |

## GUIDELINES FOR USE

Our guideline named **TAVABOROLE (Kerydin)** requires the following rule(s) be met for approval:

A. You have onychomycosis of the toenails (toenail fungus infection)
B. You have complicating factors such as diabetes, peripheral vascular disease (narrowed blood vessels cause low blood flow), a suppressed immune system, or pain surrounding the nail or soft tissue
C. You have previously tried the following agents, unless there is a medical reason why you cannot (contraindication):
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

Commercial Effective: 11/09/20

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

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## TAZEMETOSTAT

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| TAZEMETOSTAT | TAZVERIK | | | | |

### GUIDELINES FOR USE

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

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Commercial Effective: 07/13/20

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

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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

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Commercial Effective: 07/01/20

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

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## TELOTRISTAT

| Generic | Brand | | | |
|---|---|---|---|---|
| TELOTRISTAT | XERMELO | | | |

### GUIDELINES FOR USE

Our guideline named **TELOTRISTAT (Xermelo)** requires the following rule(s) be met for approval:

A. You have carcinoid syndrome diarrhea (diarrhea caused by a type of tumor affecting nerves/hormones)
B. The medication will be used in combination with a somatostatin analog such as octreotide
C. You are 18 years of age or older
D. The medication is being prescribed by or given in consultation with an oncologist (cancer/tumor doctor) or gastroenterologist (digestive system doctor)
E. There is documentation showing that you have been receiving a stable dose of long-acting somatostatin analog therapy such as Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) for a minimum of 3 months – unless there is a medical reason why you cannot (contraindication)
F. You have diarrhea that is inadequately controlled as defined by the presence of at least four bowel movements per day

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Commercial Effective: 07/01/20

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

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## TEMOZOLOMIDE - PO

| Generic | Brand | | | |
|---|---|---|---|---|
| TEMOZOLOMIDE - PO | TEMODAR - PO | | | |

### GUIDELINES FOR USE

Our guideline named **TEMOZOLOMIDE (Temodar) - PO** requires you have one of the following diagnoses for approval:

A. Metastatic melanoma (type of skin cancer)
B. Anaplastic astrocytoma (type of brain tumor)
C. Glioblastoma multiforme (type of tumor affecting brain or spine)
D. Small cell lung cancer (SCLC)

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Commercial Effective: 07/01/20

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

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## TERIPARATIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| TERIPARATIDE | FORTEO | | | |

## GUIDELINES FOR USE

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)

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

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## TESAMORELIN

| Generic | Brand | | | |
|---|---|---|---|---|
| TESAMORELIN | EGRIFTA | | | |

### GUIDELINES FOR USE

Our guideline named **TESAMORELIN (Egrifta)** requires the following rule(s) be met for approval:

A. The medication is being used for the reduction of excess abdominal fat in HIV (human immunodeficiency virus)-infected patients who have lipodystrophy syndrome (abnormal distribution of fat in the body)
B. You must be receiving treatment with a protease inhibitor (PI), PI combination (saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, or tipranavir), a nucleoside reverse transcriptase inhibitor (NRTI), or an NRTI combination (zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, or abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir).

Commercial Effective: 07/01/20

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

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## TETRABENAZINE

| Generic | Brand | | | |
|---|---|---|---|---|
| TETRABENAZINE | XENAZINE | | | |

### GUIDELINES FOR USE

Our guideline named **TETRABENAZINE (Xenazine)** requires the following rule(s) be met for approval:

A. You have chorea (involuntary movements) associated with Huntington's disease (type of inherited disease that causes nerve cells in brain to break down over time)
B. The medication has been prescribed or given in consultation with a neurologist (nerve doctor)
C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
   1. You have been genotyped for CYP2D6 (type of enzyme) and you are identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

Commercial Effective: 07/01/20

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

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## THALIDOMIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| THALIDOMIDE | THALOMID | | | |

### GUIDELINES FOR USE

Our guideline named **THALIDOMIDE (Thalomid)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Multiple myeloma (plasma cell cancer)
   2. Erythema nodosum leprosum (ENL: type of inflammatory disease that causes skin lesions and nerve damage)
   3. Anemia due to myelodysplastic syndrome (group of disorders that disrupts red blood cell production) that has been previously treated
   4. Waldenström's Macroglobulinemia (type of cancer that affects immune system)

B. **If you have multiple myeloma, approval also requires:**
   1. Thalomid must be used in combination with dexamethasone or prednisone.

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Commercial Effective: 07/01/20

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

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## TOBRAMYCIN INHALED

| Generic | Brand | | | |
|---|---|---|---|---|
| TOBRAMYCIN | BETHKIS, TOBRAMYCIN | | | |
| TOBRAMYCIN IN 0.225% NACL | TOBI | | | |
| 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)

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.

Commercial Effective: 10/01/20

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

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## TOLVAPTAN

| Generic | Brand | | | |
|---|---|---|---|---|
| TOLVAPTAN | JYNARQUE | | | |

### GUIDELINES FOR USE

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

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

### RENEWAL CRITERIA

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)

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Commercial Effective: 06/08/20

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

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## TOREMIFENE

| Generic | Brand | | | |
|---|---|---|---|---|
| TOREMIFENE CITRATE | FARESTON | | | |

## GUIDELINES FOR USE

Our guideline named **TOREMIFENE (Fareston)** requires the following rule(s) be met for approval:

A. You have metastatic breast cancer (cancer has spread to other parts of body)
B. You are a postmenopausal female (already gone through menopause)
C. You have an estrogen-receptor positive or unknown tumor

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## TRAMETINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| TRAMETINIB DIMETHYL SULFOXIDE | MEKINIST | | | |

## GUIDELINES FOR USE

Our guideline named **TRAMETINIB DIMETHYL SULFOXIDE (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be removed by surgery or has spread)
   2. Metastatic non-small cell lung cancer (NSCLC: lung cancer that has spread in body)
   3. Melanoma (skin cancer)
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: thyroid cancer that has spread in body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer)

C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene) as detected by an Food and Drug Administration -approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
   1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires:**
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

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

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**TRIENTINE**

| Generic | Brand | | | |
|---|---|---|---|---|
| TRIENTINE | SYPRINE, CLOVIQUE | | | |

**GUIDELINES FOR USE**

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

Our guideline named **TRIENTINE (Syprine, Clovique)** requires the following rule(s) be met for approval:

A. You have a known family history of Wilson's disease (a genetic disorder that leads to copper accumulation in the organs) or physical examination consistent with Wilson's disease
B. You meet **ONE** of the following criteria:
    1. Your plasma copper-protein ceruloplasmin (amount of copper-carrying protein in your blood) in less than 20mg/dL
    2. You had a liver biopsy (sample) positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (brownish-yellow ring around the iris of the eye)
    3. Your diagnosis has been confirmed by genetic testing for ATP7B mutations (mutation in the Wilson disease protein)
C. You have maintained a reduced copper dietary intake (less than 2mg copper per day)
D. The medication is prescribed by or given in consultation with a hepatologist (a doctor who specialize in the liver, biliary tree, gallbladder, and the pancreas)
E. You have had a previous trial of or contraindication to (medical reason why you cannot take) Depen (penicillamine)

**RENEWAL CRITERIA**

Our guideline named **TRIENTINE (Syprine, Clovique)** requires the following rules be met for renewal:

A. You have Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
B. You have achieved a free serum copper (amount of copper in your blood) of less than 10 mcg/dL

Commercial Effective: 07/01/20

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

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## TRIFLURIDINE/TIPIRACIL

| Generic | Brand | | | |
|---|---|---|---|---|
| TRIFLURIDINE/TIPIRACIL | LONSURF | | | |

### GUIDELINES FOR USE

Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Metastatic (has spread in the body) colorectal cancer
   2. Metastatic gastric (stomach) or gastroesophageal junction adenocarcinoma (cancer of lower portion of the throat)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)
   2. If you are negative for the RAS (type of gene) mutation (you are RAS wild-type), you had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You had 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 (type of gene)/neu-targeted therapy

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
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## T: SLIM/MINIMED INSULIN PUMPS

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| SUBCUTANEOUS INSULIN PUMP | T:SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, MINIMED 670G, MINIMED 770G | | | | |

## GUIDELINES FOR USE

Our guideline named **T: SLIM/MINIMED INSULIN PUMPS** requires the following rule(s) be met for approval:

A. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
B. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and require frequent self-adjustments of your insulin dose for the past 6 months
D. You require glucose self-testing of at least 4 times per day on average in the previous 2 months
E. You have not received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
G. **If you are requesting the T: Slim X2 OR T: Slim X2 with Basal-IQ, approval also requires:**
    1. You are 6 years of age or older
H. **If you are requesting the T: Slim X2 with Control-IQ, approval also requires:**
    1. You are 6 years of age or older
I. **If you are requesting the MiniMed 670G, approval also requires:**
    1. You are 7 years of age or older
J. **If you are requesting the MiniMed 770G, approval also requires:**
    1. You are 2 years of age or older

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

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## TUCATINIB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| TUCATINIB | TUKYSA | | | | |

### GUIDELINES FOR USE

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 (specifically either trastuzumab or trastuzumab with pertuzumab)
D. The requested medication will be used in combination with trastuzumab and capecitabine

Commercial Effective: 10/01/20

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

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## URIDINE TRIACETATE

| Generic | Brand | | | |
|---|---|---|---|---|
| URIDINE TRIACETATE | XURIDEN | | | |

### GUIDELINES FOR USE

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

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) be met for approval:

A. You have hereditary orotic aciduria (HOA: genetic disease where you do not have a type of protein to make a chemical)
B. Your diagnosis is confirmed by ALL of the following:
   1. Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
   2. Elevated urinary orotic acid levels according to your age-specific reference range
C. Therapy is prescribed by or given in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)

### RENEWAL CRITERIA

Our guideline named **URIDINE TRIACETATE (Xuriden)** requires the following rule(s) to be met for renewal:

A. Your age dependent hematologic parameters (blood lab tests) have stabilized or improved from baseline while on treatment with Xuriden (uridine triacetate).

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Commercial Effective: 09/07/20

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

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## VALBENAZINE

| Generic | Brand | | | |
|---|---|---|---|---|
| VALBENAZINE | INGREZZA | | | |

### GUIDELINES FOR USE

Our guideline named **VALBENAZINE (Ingrezza)** requires the following rule(s) be met for approval:

A. You have moderate to severe tardive dyskinesia (involuntary movements, usually due to certain drugs) and it has been present for at least 3 months
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), movement disorder specialist, or psychiatrist (mental health doctor)
D. You have a history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

Commercial Effective: 07/01/20

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

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## VANDETANIB

| Generic | Brand | | | |
|---|---|---|---|---|
| VANDETANIB | CAPRELSA | | | |

### GUIDELINES FOR USE

Our guideline for **VANDETANIB (Caprelsa)** requires **ONE** of the following rule(s) be met for approval:

A. You are currently stable on the requested medication
B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery or has spread in body)

Commercial Effective: 07/01/20

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

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## VEMURAFENIB

| Generic | Brand | | | |
|---|---|---|---|---|
| VEMURAFENIB | ZELBORAF | | | |

## GUIDELINES FOR USE

Our guideline named **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:

A. You have unresectable or metastatic melanoma with a BRAF V600E mutation (you have skin cancer with a certain type of gene mutation and it cannot be removed with surgery or it has spread in the body) as detected by an Food and Drug Administration-approved test
B. You have Erdheim-Chester Disease with a BRAF V600 mutation (rare type of slow growing blood cancer that has a type of gene mutation)

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Commercial Effective: 07/01/20

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

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## VENETOCLAX

| Generic | Brand | | | |
|---|---|---|---|---|
| VENETOCLAX | VENCLEXTA | | | |

### GUIDELINES FOR USE

Our guideline named **VENETOCLAX (Venclexta)** requires that the following rules are met for approval:

A. You have **ONE** of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer), small lymphocytic lymphoma (SLL: type of immune system cancer)
   2. Newly-diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many undeveloped white blood cells)

B. **If you have chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
   1. You are 18 years of age or older

C. **If you have newly-diagnosed acute myeloid leukemia (AML), approval also requires:**
   1. You are 75 years of age or older, **OR** you are 18 years of age or older with comorbidities (additional diseases) that preclude (prevent) the use of intensive induction chemotherapy
   2. The requested medication will be used in combination with azacitidine or decitabine or low-dose cytarabine

Commercial Effective: 07/01/20

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

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## V-GO INSULIN DEVICES

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| SUB-Q INSULIN DEVICE, 20 UNIT | V-GO 20 | | | | |
| SUB-Q INSULIN DEVICE, 30 UNIT | V-GO 30 | | | | |
| SUB-Q INSULIN DEVICE, 40 UNIT | V-GO 40 | | | | |

### GUIDELINES FOR USE

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

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
C. You follow a maintenance program of at least 3 injections of insulin per day
D. You have worked with your doctor to adjust your insulin dose for the past 6 months and still have not met your glucose (blood sugar) goals
E. You do not require regular adjustments to your basal rate during a 24-hour time period
F. You require bolus insulin dosing in increments of 2 units per bolus
G. You do not require a total daily insulin dose of more than 76 units
H. You meet ONE of the following criteria while on a multiple daily insulin injection regimen:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
I. You previously had a trial of the Omnipod or Omnipod Dash (type of insulin device)

### RENEWAL CRITERIA

Our guideline named **V-GO INSULIN DEVICES** requires the following rule(s) be met for renewal:

A. You have shown a positive response to therapy AND are adherent to your doctor follow-up visits

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

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## VISMODEGIB

| Generic | Brand | | | |
|---|---|---|---|---|
| VISMODEGIB | ERIVEDGE | | | |

### GUIDELINES FOR USE

Our guideline for **VISMODEGIB (Erivedge)** requires **ONE** of the following rule(s) be met for approval:

A. You have metastatic basal cell carcinoma.
B. You have locally advanced basal cell carcinoma (type of skin cancers that have spread in the body or is advanced but has not spread) that has returned after surgery or you are not a candidate for surgery or radiation.

Commercial Effective: 07/01/20

**STANDARD COMMERCIAL DRUG FORMULARY**
**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)

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Commercial Effective: 04/01/20

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

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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

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Commercial Effective: 04/01/20

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

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## DIABETIC TEST STRIPS (MEDPERFORM)

| Generic | Brand | | | |
|---|---|---|---|---|
| BLOOD SUGAR DIAGNOSTIC<br>BLOOD SUGAR DIAGNOSTIC, DISC<br>BLOOD SUGAR DIAGNOSTIC, DRUM | DIABETIC TEST STRIPS VARIOUS | | | |

## GUIDELINES FOR USE

Our guideline named **DIABETIC TEST STRIPS** requires ONE of following rules be met for approval:

A. You have tried ONE preferred blood glucose (diabetic) meter and test strips. The preferred meters and test strips are FreeStyle and Precision by Abbott and may be limited to specific products. All other test strips are excluded from the formulary
B. You require an excluded blood glucose test strip due to significant visual and/or cognitive impairment (problem with memory and thinking)
C. You require an excluded blood glucose test strip because you use another manufacturer's companion insulin pump

Request for excluded test strips will not be approved if due to a need for data management software. Data management software is available for the formulary test strip products. Please contact Abbott for data management software and a connection cable for the meter.

| **Preferred Meters** (Retail Packaging) | **NDC Number** |
|---|---|
| FreeStyle Precision Neo Meter Kit | 57599-5175-01 |
| FreeStyle Lite Meter | 99073-0708-05 |
| FreeStyle Freedom Lite Meter | 99073-0709-14 |
| Precision Xtra Meter | 57599-8814-01 |
| FreeStyle InsuLinx Meter | 99073-0711-43 |

**CONTINUED ON NEXT PAGE**

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

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## DIABETIC TEST STRIPS (MEDPERFORM)

### GUIDELINES FOR USE (CONTINUED)

| Preferred Diabetic Test Strips | NDC Number |
|---|---|
| FreeStyle InsuLinx Test Strips- 50 ct | 99073-0712-31 |
| FreeStyle InsuLinx Test Strips-100 ct | 99073-0712-27 |
| FreeStyle Test Strips- 50 ct | 99073-0120-50 |
| FreeStyle Test Strips- 100 ct | 99073-0121-01 |
| FreeStyle Lite Test Strips- 50 ct | 99073-0708-22 |
| FreeStyle Lite Test Strips- 100 ct | 99073-0708-27 |
| Precision Xtra Test Strips- 50 ct | 57599-9728-04 |
| Precision Xtra Test Strips- 100 ct | 57599-9877-05 |
| Precision Xtra Beta Ketone Test Strips- 10 ct | 57599-0745-01 |
| FreeStyle Precision Neo Test Strips- 25 ct | 57599-1577-01 |
| FreeStyle Precision Neo Test Strips- 50 ct | 57599-1579-04 |

Commercial Effective: 06/01/20

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

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## FENTANYL TRANSMUCOSAL AGENTS (MEDPERFORM)

| Generic | Brand | | | |
|---|---|---|---|---|
| FENTANYL CITRATE | ACTIQ<br>ABSTRAL<br>FENTORA | | | |

## GUIDELINES FOR USE

Our guideline named **FENTANYL TRANSMUCOSAL AGENTS (Actiq)** requires the following rule(s) be met for approval:

A. You have cancer-related pain. Please note that Abstral and Fentora are excluded from the formulary
B. You are currently using the requested medication 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)
C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate IR, oxycodone/aspirin, oxycodone/acetaminophen, codeine/acetaminophen, hydromorphone, or meperidine), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)
D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

Commercial Effective: 07/01/20

**MEDPERFORM**
**PRIOR AUTHORIZATION GUIDELINES**

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## MILTEFOSINE (MEDPERFORM)

| Generic | Brand | | | |
|---|---|---|---|---|
| MILTEFOSINE | IMPAVIDO | | | |

## GUIDELINES FOR USE

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)

Commercial Effective: 07/01/16

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## ADO-TRASTUZUMAB EMTANSINE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ADO-TRASTUZUMAB EMTANSINE | KADCYLA | | | |

## GUIDELINES FOR USE

Our guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires the following rule(s) be met for approval:

A. You have metastatic breast cancer (cancer has spread to other parts of body) or early breast cancer
B. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (it has a protein that causes breast cancer cells to grow)
   2. You have previously received trastuzumab and a taxane (class of cancer medication), separately or in combination
   3. You have received prior therapy for metastatic disease (disease has spread) **OR** developed disease recurrence (disease returns) during or within six months of completing adjuvant (add-on) therapy
C. **If you have early breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (it has a protein that causes breast cancer cells to grow)
   2. You have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment (disease is still present after using certain types of cancer drugs)

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Commercial Effective: 05/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## AFLIBERCEPT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| AFLIBERCEPT | EYLEA | | | |

### GUIDELINES FOR USE

Our guideline named **AFLIBERCEPT (Eylea)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Neovascular (wet) age-related macular degeneration (eye disease that causes vision loss)
   2. Macular edema following retinal vein occlusion (blood vessel in the retina is blocked by blood clot)
   3. Diabetic macular edema (build up of fluid in the part of the retina)
   4. Diabetic retinopathy with diabetic macular edema (eye nerve damage due to diabetes)

B. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina (back part inside the eye) specialist

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Commercial Effective: 05/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**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 previously tried 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, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)

### 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: 01/01/21

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## ALGLUCOSIDASE ALFA

| Generic | Brand | | | |
|---|---|---|---|---|
| ALGLUCOSIDASE ALFA | LUMIZYME | | | |

### GUIDELINES FOR USE

Our guideline named **ALGLUCOSIDASE ALFA (Lumizyme)** requires that the following rules be met:

A. You have Pompe's disease (an inherited condition where complex sugar (glycogen) builds up in your body's cells because your body cannot make a type of enzyme called acid alpha-glucosidase) for approval

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Commercial Effective: 05/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## ASPARAGINASE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ASPARAGINASE (ERWINIA CHRYSAN) | ERWINAZE | | | |
| PEGASPARGASE | ONCASPAR | | | |

### GUIDELINES FOR USE

Our guideline named **ASPARAGINASE (Erwinaze, Oncaspar)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acute lymphoblastic leukemia (ALL: type of blood and bone marrow cancer)
B. The requested medication will be used as a part of a chemotherapeutic treatment plan with multiple drugs
C. **If you are requesting Oncaspar, approval also requires ONE of the following:**
   - Oncaspar will be used as a first-line therapy
   - You have hypersensitivity to native forms of L-asparaginase (you are allergic to natural forms of a type of enzyme/protein)
D. **If you are requesting Erwinaze, approval also requires:**
   1. You have developed a hypersensitivity to a E. Coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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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)
   6. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)

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)

***(Criteria continued on next page)***

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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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**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

H. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. The requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
   2. You have a BRAF V600 mutation (type of gene mutation)

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Commercial Effective: 09/07/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## AVELUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| AVELUMAB | BAVENCIO | | | |

### GUIDELINES FOR USE

Our guideline named **AVELUMAB (Bavencio)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
   2. Locally advanced or metastatic (disease that has spread) urothelial carcinoma (UC: type of urinary system cancer)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)

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, oxalipatin
      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

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Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## BELINOSTAT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BELINOSTAT | BELEODAQ | | | |

### GUIDELINES FOR USE

Our guideline named **BELINOSTAT (Beleodaq)** requires that the following rule be met for approval:

A. You have a diagnosis of relapsed or refractory (your condition has gotten worse after improving) peripheral T-cell lymphoma (PTCL; cancer that affects a type of immune system cells)
B. You are 18 years of age or older

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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:

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
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 (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.)

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BEVACIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BEVACIZUMAB | AVASTIN | | | |

### GUIDELINES FOR USE

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:
      a. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
      b. 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

***(Criteria continued on next page)***

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## 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)

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BEVACIZUMAB-AWWB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BEVACIZUMAB-AWWB | MVASI | | | |

## GUIDELINES FOR USE

Our guideline named **BEVACIZUMAB-AWWB (Mvasi)** 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. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)

B. **If you have metastatic colorectal cancer, approval also requires ONE of the following:**
   3. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
   4. 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:**
   3. 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**
   3. You are 18 years of age or older

E. **If you have metastatic renal cell carcinoma, approval also requires:**
   3. 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

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BEVACIZUMAB-BVZR (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BEVACIZUMAB-BVZR | ZIRABEV | | | |

## GUIDELINES FOR USE

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

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

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BLINATUMOMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BLINATUMOMAB | BLINCYTO | | | |

### GUIDELINES FOR USE

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

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)
   2. Minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)

B. **If you have minimal residual disease (MRD) - positive B-cell precursor acute lymphoblastic leukemia (ALL), approval also requires:**
   - You are in first or second complete remission (no symptoms or signs of *disease)*
   - You have minimal residual disease (small numbers cancer cells that remain in you after treatment) greater than or equal to 0.1%

### RENEWAL CRITERIA

Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   a. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)
   b. Minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)

B. **If you have relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), renewal also requires:**
   1. You have achieved complete remission (CR) (no symptoms or signs of *disease*) or CR with partial recovery of peripheral blood counts (CPh) after two cycles of induction (starter) treatment (cycle 1 and 2) with Blincyto
   2. You have NOT received allogeneic hematopoietic stem-cell transplant (stem cells from a genetically similar, but not identical, donor)

***(Renewal critera continued on next page)***

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**RENEWAL CRITERIA (CONTINUED)**

C. **If you have minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL), renewal also requires:**
   1. You have no detectable level of minimal residual disease (small numbers cancer cells that remain in you after treatment) g) within one cycle of Blincyto treatment
   2. You are relapse-free (your disease does not come back after being gone) which includes hematological (relating to blood) or extramedullary relapse, or secondary leukemia (cancer)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## BORTEZOMIB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BORTEZOMIB | VELCADE, BORTEZOMIB | | | |

## GUIDELINES FOR USE

Our guideline named **BORTEZOMIB (Velcade)** requires the following rule(s) be met for approval:

A. You have a diagnosis of multiple myeloma (plasma cell cancer) OR mantle cell lymphoma (white blood cell cancer)

B. **If you are requesting Bortezomib (manufactured by Fresenius Kabi), approval also requires:**
   1. You have previously received at least one therapy for mantle cell lymphoma (white blood cell cancer).

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## BRENTUXIMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BRENTUXIMAB VEDOTIN | ADCETRIS | | | |

## GUIDELINES FOR USE

Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
   1. Classical Hodgkin lymphoma (cancer with large, abnormal cells in immune system)
   2. Systemic anaplastic large cell lymphoma (type of non-Hodgkin lymphoma that affects immune system), or other CD30-expressing peripheral T-cell lymphomas (type of immune system cancer)
   3. Primary cutaneous anaplastic large cell lymphoma (cancer that present in the skin affecting immune system cells), or CD30-expressing mycosis fungoides (rare form of immune system cancer affecting the skin)
   4. Stage III or IV classical Hodgkin lymphoma (cHL)

B. You are 18 years of age or older

C. **If you have classical Hodgkin lymphoma, approval also requires ONE of the following:**
   1. You have failed autologous hematopoietic stem cell transplant (auto-HSCT; transplant cells are from your own body)
   2. You have failed at least two multi-agent chemotherapy regimens, which 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])
   3. You are considered high risk of relapse or disease progression (disease comes back or gets worse) after having auto-HSCT AND you have obtained complete/partial remission (little or no sign of cancer in your body), or stable disease to most recent pre-auto-HSCT salvage therapy

D. **If you have relapsed systemic anaplastic large cell lymphoma (ALCL), approval also requires:**
   1. You have failed at least one multi-agent chemotherapy regimen, which includes but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone]

E. **If you have 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 also requires:**
   1. You have not received previous treatment for sALCL or other CD30-expressing PTCL
   2. The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone

***(Denial text continued on next page)***

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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**GUIDELINES FOR USE (CONTINUED)**

F. **If you have primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), approval also requires:**
   1. You have received prior systemic therapy (therapy that spreads throughout the body in the blood)

G. **If you have Stage III or IV classical Hodgkin lymphoma (cHL), approval also requires:**
   1. The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
   2. You have not received previous treatment for Stage III or IV classical Hodgkin Lymphoma (cHL)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BUPRENORPHINE EXTENDED-RELEASE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BUPRENORPHINE EXTENDED-RELEASE | SUBLOCADE | | | |

## GUIDELINES FOR USE

Our guideline named **BUPRENORPHINE EXTENDED-RELEASE (Sublocade)** requires the following rule(s) be met for approval:

A. You have a diagnosis of moderate to severe opioid use disorder (mis-use of a type of pain medication)
B. You previously started treatment with a transmucosal (medication that enters body through a mucous layer like those in the mouth) buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BROLUCIZUMAB-DBLL (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BROLUCIZUMAB-DBLL | BEOVU | | | |

### GUIDELINES FOR USE

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for approval:

1. You have a diagnosis of neovascular (wet) age-related macular degeneration (AMD: abnormal blood vessels grow in the eye which bleed and leak fluid, causing blurry vision)
2. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor) or retina (area within the eye) specialist

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## BUPRENORPHINE IMPLANT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BUPRENORPHINE | PROBUPHINE | | | |

### GUIDELINES FOR USE

Our guideline named **BUPRENORPHINE IMPLANT (Probuphine)** requires the following rule(s) be met for approval:

A. You have NOT previously received ONE Probuphine treatment course in EACH arm (for a maximum of TWO 6-month treatment courses)
B. You have achieved and continued to have clinical stability on low to moderate doses of transmucosal buprenorphine (such as Subutex, Suboxone, Bunavail, or Zubsolv) defined as 8 mg per day or less of Subutex/Suboxone or a transmucosal buprenorphine equivalent for a minimum of 3 months without any need for additional dosing or adjustments
C. The requested medication is prescribed by a physician certified with the Probuphine REMS (Risk Evaluation and Mitigation Strategy) program to prescribe, insert, and remove Probuphine implants as confirmed by checking probuphinerems.com

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## BUROSUMAB-TWZA (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| BUROSUMAB-TWZA | CRYSVITA | | | |

## GUIDELINES FOR USE

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

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. 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)
   2. You are 6 months of age or older
   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. You will not be taking oral phosphate salt or active vitamin D analog supplementation with the requested medication
   5. You meet ONE of the following:
      a. You previously had a trial of or failure to phosphate/vitamin D analog therapy (such as calcitriol, paricalcitol)
      b. Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

***(Initial criteria continued on next page)***

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**PRIOR AUTHORIZATION GUIDELINES**

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## BUROSUMAB-TWZA (NSA)

### INITIAL CRITERIA (CONTINUED)

C. **If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO), approval also requires:**
   1. Your diagnosis is confirmed by the following:
      a. You have symptoms of tumor-induced osteomalacia (such as osteomalacia [softening of the bones], excessive fractures, muscle weakness, fatigue, bone pain)
   2. You are 2 years of age or older
   3. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformitis), or medical geneticist
   4. Your tumors cannot be curatively resected (surgically removed) or localized
   5. You have stopped oral phosphate and/or active vitamin D analogs (such as calcitriol, paricalcitol) at least 1 week prior to starting Crysvita
   6. You meet ONE of the following:
      - You previously had a trial of or failure to phosphate/vitamin D analog therapy
      - Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

### RENEWAL CRITERIA

Our guideline named **BUROSUMAB (Crysvita)** requires the following rules be met for renewal:

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), renewal also requires:**
   1. You have achieved normal blood phosphate levels as defined by the reference range for your age

C. **If you have Fibroblast growth factor 23 (FGF23) - related hypophosphatemia in tumor-induced osteomalacia, renewal also requires:**
   1. You have achieved normal fasting blood phosphate levels (around or above the lower end of the reference range for age and below 5 mg/dL)

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## CALASPARGASE PEGOL (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| CALASPARGASE PEGOL-MKNL | ASPARLAS | | | |

### GUIDELINES FOR USE

Our guideline named **CALASPARGASE PEGOL (Asparlas)** requires the following rule(s) be met for approval:

1. You have a diagnosis of acute lymphoblastic leukemia (type of blood and bone marrow cancer)
2. You are 1 month to 21 years of age
3. Asparlas will be used as a part of a chemotherapeutic treatment plan that contains multiple drugs

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## CARFILZOMIB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| CARFILZOMIB | KYPROLIS | | | |

### GUIDELINES FOR USE

Our guideline named **CARFILZOMIB (Kyprolis)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment)
B. You are 18 years of age or older
C. You meet **ONE** of the following criteria:
    1. You have previously received one to three lines of therapy AND will use Kyprolis in combination with ONE of the following regimens:
        a. lenalidomide and dexamethasone; OR
        b. dexamethasone; OR
        c. daratumumab and dexamethasone
    2. You have previously received one or more lines of multiple myeloma therapy and will be using Kyprolis alone

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Commercial Effective: 09/14/20

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## CERLIPONASE ALFA (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| CERLIPONASE ALFA | BRINEURA | | | |

### GUIDELINES FOR USE

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

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for approval:

A. You have a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2; group of severe diseases that affect the nervous system, including mental and movement skills), also known as tripeptidyl peptidase 1 (TPP1) deficiency
B. Your diagnosis is confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
C. You are ambulatory (able to walk) and experiencing symptoms such as instability, intermittent falls, requires assistance to walk, or can crawl only
D. You have a documented CLN2 Clinical Rating Scale Score (test to measure the severity of ceroid lipofuscinosis type 2) of 3 to 5, with a minimum score of 1 in each of the motor and language category
E. You are 3 years of age or older
F. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor) or pediatric ceroid lipofuscinosis type 2 specialist

### RENEWAL CRITERIA

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for renewal:

A. You have improved or maintained baseline motor function (such as ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (such as ambulation, walking or crawling) from baseline
B. You have a ceroid lipofuscinosis type 2 (CLN2) motor score of at least 1 (such as you are not bedridden or immobile)

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Commercial Effective: 07/01/20

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**CETUXIMAB (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| CETUXIMAB | ERBITUX | | | |

**GUIDELINES FOR USE**

Our guideline named **CETUXIMAB (Erbitux)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon/rectum cancer that has spread)
   2. Locally or regionally advanced squamous cell carcinoma (type of skin cancer) of the head and neck
   3. Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck
   4. Recurrent or metastatic squamous cell carcinoma of the head and neck.

B. **If you have metastatic colorectal cancer (mCRC), approval also requires:**
   1. Your cancer is KRAS wild-type (a type of gene with no mutation) as determined by an FDA (Food and Drug Administration)-approved test
   2. Your cancer is epidermal growth factor receptor (EGFR)-expressing as determined by an FDA-approved test
   3. You meet also ONE of the following:
      i. The requested medication is being used in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment
      ii. The requested medication is being used in combination with irinotecan and you are refractory (resistant) to irinotecan-based chemotherapy
      iii. The requested medication is being used as a single agent AND you have failed oxaliplatin-based and irinotecan-based chemotherapy unless you are intolerant to irinotecan

C. **If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used in combination with radiation therapy

D. **If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

***(Criteria continued on next page)***

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## CETUXIMAB (NSA)

**GUIDELINES FOR USE (CONTINUED)**

E. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used as a single agent
   2. You have previously failed platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

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Commercial Effective: 07/01/20

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## COPANLISIB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| COPANLISIB | ALIQOPA | | | |

### GUIDELINES FOR USE

Our guideline named **COPANLISIB (Aliqopa)** requires the following rule(s) be met for approval:

A. You have relapsed follicular lymphoma (FL: a type of blood cancer)
B. You are 18 years of age or older
C. You have received at least two prior systemic therapies (therapy that travels through the blood) for follicular lymphoma

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Commercial Effective: 07/01/20

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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]).

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## DARATUMUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| DARATUMUMAB | DARZALEX | | | |

### GUIDELINES FOR USE

Our guideline named **DARATUMUMAB (Darzalex)** 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. You meet **ONE** of the following criteria:
   1. You have newly diagnosed multiple myeloma and are not eligible for autologous stem cell transplant (cells from your own body) and will receive daratumumab in combination with lenalidomide and dexamethasone
   2. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received at least one prior therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
   3. You are newly diagnosed with multiple myeloma, not eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone
   4. You are newly diagnosed with multiple myeloma, are eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, thalidomide and prednisone
   5. You have received at least one prior therapy **AND** will receive daratumumab in combination with bortezomib and dexamethasone
   6. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received one to three prior lines of therapy **AND** will receive daratumumab in combination with carfilzomib and dexamethasone
   7. You have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI: class of drug for myeloma cancer) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone
   8. 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)
   9. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent **AND** will receive daratumumab as monotherapy

**Note:** Proteasome inhibitors examples include: bortezomib, carfilzomib, or ixazomib and Immunomodulatory agent examples include: lenalidomide, pomalidomide, or thalidomide.

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## DARATUMUMAB-HYALURONIDASE-FIHJ (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| DARATUMUMAB-HYALURONIDASE-FIHJ | DARZALEX FASPRO | | | | |

## GUIDELINES FOR USE

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
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 multiple 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 (will not be used in combination with another drug)
   6. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent AND will receive daratumumab as monotherapy (will not be used in combination with another drug)

Note: Proteasome inhibitors include: bortezomib, carfilzomib, or ixazomib; immunomodulatory agents include: lenalidomide, pomalidomide, or thalidomide.

Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## DENOSUMAB-PROLIA (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| DENOSUMAB | PROLIA | | | |

## GUIDELINES FOR USE

Our guideline named **DENOSUMAB (Prolia)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak and brittle bones after menopause), osteoporosis in a male patient, glucocorticoid-induced osteoporosis (weak and brittle bones caused by steroids), bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer (using the medication to lower hormone levels for prostate cancer that has not spread to other parts of the body), or bone loss in women receiving adjuvant aromatase inhibitor therapy (type of breast cancer drug) for breast cancer.

B. **If you have postmenopausal osteoporosis, approval also requires ONE of the following:**
   1. You are at high risk for fracture defined as ONE of the following:
      a. History of osteoporotic (fragility, low trauma) fracture(s)
      b. 2 or more risk factors for fracture. Some risk factors are history of multiple recent low trauma fractures, bone marrow density T-score (measurement of bone density) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone analogs such as nafarelin
      c. No prior treatment for osteoporosis AND FRAX score (tool to measure your fracture risk) greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)
   3. You are unable to use oral therapy (for example, due to 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 your daily routine)

C. **If you have glucocorticoid-induced osteoporosis OR are a male with osteoporosis, approval also requires:**
   1. You are at high risk for fractures defined as ONE of the following:
      a. History of osteoporotic (fragility, low trauma) fracture(s)
      b. Two or more risk factors for fracture. Some risk factors are history of multiple recent low trauma fractures, bone marrow density T-score (measurement of bone density) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone analogs such as nafarelin
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)

***(Criteria continued on next page)***

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## DENOSUMAB-PROLIA (NSA)

**GUIDELINES FOR USE (CONTINUED)**

D. **If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer, OR you are a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:**
   1. You are at high risk for fracture. Some risk factors include history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of gonadotropin releasing hormone analogs such as nafarelin
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)

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Commercial Effective: 07/01/20

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## DENOSUMAB-XGEVA (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| DENOSUMAB | XGEVA | | | |

### GUIDELINES FOR USE

Our guideline named **DENOSUMAB (Xgeva)** requires you meet ONE of the following criteria:

A. You have multiple myeloma (plasma cell cancer) OR bone metastases from solid tumors (cancer has spread to bones from solid tumors) AND the requested medication is being used to prevent skeletal-related events (such as bone fractures or bone pain requiring radiation)
B. You have giant cell tumor of bone that is unresectable (tumor cannot be removed completely through surgery) or where surgical resection is likely to result in severe morbidity (illness)
C. You have hypercalcemia (higher than normal levels of calcium in blood) of malignancy that does not respond to bisphosphonate therapy (such as Fosamax, Actonel, or Boniva)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## DINUTUXIMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| DINUTUXIMAB | UNITUXIN | | | |

### GUIDELINES FOR USE

Our guideline named **DINUTUXIMAB (Unituxin)** requires the following rule(s) be met for approval:

A. You have high-risk neuroblastoma (a type of cancer that usually affects glands above the kidneys)
B. You are 17 years of age or younger
C. You have received an autologous (cells are from your own body) stem cell transplant
D. You had a partial response to chemotherapy given before you had an autologous stem cell transplant
E. You have not undergone 5 cycles of dinutuximab in the past
F. Dinutuximab will be used concurrently (at the same time) with isotretinoin and either Leukine or Proleukin

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## DURVALUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| DURVALUMAB | IMFINZI | | | |

### GUIDELINES FOR USE

Our guideline named **DURVALUMAB (Imfinzi)** requires the following rule(s) be met for approval:

A. You have locally advanced or metastatic urothelial carcinoma (urinary system cancer), unresectable (cannot be completely removed with surgery) Stage III non-small cell lung cancer (NSCLC), or extensive-stage small cell lung cancer (ES-SCLC)
B. You are 18 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 on or after treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. Your disease has worsened within 12 months of neoadjuvant or adjuvant treatment (additional treatment given before or during the main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
D. **If you have unresectable Stage III non-small cell lung cancer (NSCLC), approval also requires:**
    1. Your disease has not worsened after using concurrent platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (you used chemotherapy and radiation therapy at the same time)
E. **If you have extensive-stage small cell lung cancer (ES-SCLC), approval also requires:**
    1. The requested medication is being used as first line of therapy
    2. The requested medication will be used in combination with etoposide and either carboplatin or cisplatin

Commercial Effective: 05/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## ECALLANTIDE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ECALLANTIDE | KALBITOR | | | |

### GUIDELINES FOR USE

Our guideline named **ECALLANTIDE (Kalbitor)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (a type of genetic disorder where you have extreme swelling in various parts of the body)
B. You are 12 years of age or older
C. Your diagnosis is confirmed by complement testing (measures the amount of certain types of proteins in the blood)
D. The medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
E. The medication is prescribed by or given in consultation with an allergist/immunologist (allergy/immune system doctor) or hematologist (blood specialty doctor)
F. The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis (severe, possible life-threatening allergic reaction) and/or angioedema (extreme swelling/allergic reaction)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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**ECULIZUMAB (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| ECULIZUMAB | SOLIRIS | | | |

**GUIDELINES FOR USE**

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

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: life-threatening condition with red blood cells being destroyed)
   2. Atypical hemolytic uremic syndrome (aHUS: condition where blood clots form in small blood vessels of kidneys)
   3. Generalized myasthenia gravis (gMG: disease that causes skeletal muscle weakness)
   4. 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. 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. Therapy is prescribed by or in consultation with a neurologist (nerve doctor)
   3. Your diagnosis is confirmed by a positive anti-acetylcholine receptor antibody test
   4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
   5. You had a trial of corticosteroids, unless there is a medical reason why you cannot (contraindication)
   6. You meet ONE of the following:
      a. Failure of treatment with at least 2 immunosuppressive therapies (drugs that weaken
      b. your immune system such as azathioprine, cyclophosphamide, methotrexate)
      c. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (types of blood therapy)

***(Initial criteria continued on the next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## ECULIZUMAB (NSA)

### INITIAL CRITERIA (CONTINUED)

D. **If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   3. You have confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
      a. At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
      b. PNH granulocyte clone size greater than or equal to10%
   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 being destroyed) such as lactate dehydrogenase [LDH] level greater than or equal to 1.5 times the upper limit of normal, hemoglobinuria (type of blood protein is in urine) OR you have a history of major adverse vascular event from thromboembolism (blood clot)

E. **If you have neuromyelitis optica spectrum disorder (NMOSD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
   4. You have at least ONE of the following core clinical characteristics:
      a. Optic neuritis (inflammation that damages eye nerve)
      b. Acute myelitis (sudden and severe inflammation of the spinal cord)
      c. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
      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
   5. You will NOT use rituximab, inebilizumab, or satralizumab together with Soliris

**CONTINUED ON NEXT PAGE**

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## ECULIZUMAB (NSA)

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **ECULIZUMAB (Soliris)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: life-threatening condition with red blood cells being destroyed)
   2. Atypical hemolytic uremic syndrome (aHUS: condition where blood clots form in small blood vessels of kidneys)
   3. Generalized myasthenia gravis (gMG: disease that causes skeletal muscle weakness)
   4. 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. **If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:**
   1. You have had clinical benefit compared to baseline such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (type of enzyme) and hemoglobin levels

C. **If you have generalized myasthenia gravis, renewal also requires:**
   1. You have had 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, renewal also requires:**
   1. You have had a reduction in relapse frequency compared to baseline

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Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## EDARAVONE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| EDARAVONE | RADICAVA | | | |

### GUIDELINES FOR USE

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

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS; a disease that causes brain and spinal cord nerve cells to break down)
B. You are currently taking or have previously tried riluzole (Rilutek)
C. The medication is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system) or ALS specialist at an ALS Specialty Center or Care Clinic
D. You have the disease (from onset of symptoms) for less than 2 years
E. Your Normal Respiratory Function defined as a Forced Vital Capacity (FVC) is greater than 80%
F. You have mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (Amyotrophic Lateral Sclerosis Functional Rating Scale; for example, speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

### RENEWAL CRITERIA

Our guideline named **EDARAVONE (Radicava)** requires the following rule(s) be met for renewal:

A. You have amyotrophic lateral sclerosis (ALS; a disease that causes brain and spinal cord nerve cells to break down)
B. You have improved or maintained baseline functional ability or demonstrated a less-than-expected decline in functional ability from baseline as measured by functional assessments (such as Amyotrophic Lateral Sclerosis Functional Rating Scale)
C. You do not require invasive ventilation (such as inserting a breathing tube into your throat)
D. Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R (Amyotrophic Lateral Sclerosis Functional Rating Scale Revised)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## ELOSULFASE ALFA (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ELOSULFASE ALFA | VIMIZIM | | | |

### GUIDELINES FOR USE

Our guideline named **ELOSULFASE ALFA (Vimizim)** requires you have Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome - rare metabolic condition that mainly affects the skeleton).

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Commercial Effective: 07/01/20

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## ELOTUZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ELOTUZUMAB | EMPLICITI | | | |

### GUIDELINES FOR USE

Our guideline named **ELOTUZUMAB (Empliciti)** 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. You meet ONE of the following criteria:
   1. Empliciti is used in combination with lenalidomide and dexamethasone if you have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation
   2. Empliciti is used in combination with pomalidomide and dexamethasone if you have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib)

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## EMAPALUMAB-LZSG (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| EMAPALUMAB-LZSG | GAMIFANT | | | |

### GUIDELINES FOR USE

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

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for approval:

A. You have primary hemophagocytic lymphohistiocytosis (HLH; inherited condition where you have too much of certain types of immune cells, causing inflammation)
B. Your diagnosis is confirmed by ONE of the following:
   1. You have undergone a genetic test identifying HLH-associated gene mutation such as PRF1 (type of gene), UNC13D (type of gene)
   2. You have at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly (enlarged spleen); cytopenias (low number of a type of blood cell affecting at least 2 of 3 cell lineages); hypertriglyceridemia (type of high cholesterol) and/or hypofibrinogenemia (type of genetic disorder); hemophagocytosis (destruction of certain types of cells) 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
C. You have refractory, recurrent, or progressive disease (disease returns or does not respond to treatment and gets worse); **OR** you had a trial or intolerance to conventional hemophagocytic lymphohistiocytosis therapy (such as chemotherapy, steroids, immunotherapy)
D. The requested medication will be used at the same time with dexamethasone
E. Therapy is prescribed by or given in consultation with an immunologist (doctor who specializes in immune disorders), hematologist (blood doctor), or oncologist (cancer doctor)

### RENEWAL CRITERIA

Our guideline named **EMAPALUMAB-LZSG (Gamifant)** requires the following rule(s) be met for renewal:

A. You have hemophagocytic lymphohistiocytosis (inherited condition where you have too much of certain types of immune cells, causing inflammation)
B. You have not received successful hematopoietic stem cell transplantation
C. You have demonstrated improved immune system response from baseline as shown by any of the following: your fever has gone away, decreased splenomegaly (spleen size has gotten smaller), improvement in central nervous system symptoms such as altered mental status, improved complete blood count, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 (type of protein) levels

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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)

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Commercial Effective: 04/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| IMIGLUCERASE | CEREZYME | | | |
| TALIGLUCERASE ALFA | ELELYSO | | | |
| VELAGLUCERASE ALFA | VPRIV | | | |

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

### GUIDELINES FOR USE

### ELELYSO

Our guideline named **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Elelyso)** requires the following rule(s) be met for approval:

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 4 years of age or older

### VPRIV

Our guideline named **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Vpriv)** requires the following rule(s) be met for approval:

- You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
- You are 4 years of age or older
- You previously had a trial of Elelyso, unless there is a medical reason why you cannot (contraindication)

### CEREZYME

Our guideline named **ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Cerezyme)** requires the following rule(s) be met for approval:

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 18 years of age or older
C. You previously had a trial of Elelyso, unless there is a medical reason why you cannot (contraindication)

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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**ERIBULIN (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| ERIBULIN MESYLATE | HALAVEN | | | |

**GUIDELINES FOR USE**

Our guideline named **ERIBULIN (Halaven)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic (cancer has spread) breast cancer
   2. Unresectable or metastatic liposarcoma (cancer that starts in fat cells that has spread or cannot be completely removed by surgery)

B. **If you have metastatic breast cancer, approval also requires:**
   A. You had previous treatment with an anthracycline (class of medication for cancer such as daunorubicin, doxorubicin, etc)
   B. You had previous treatment with a taxane (such as paclitaxel and docetaxel)

C. **If you have unresectable or metastatic liposarcoma, approval also requires:**
   1. You had previous treatment with an anthracycline (class of medication for cancer such as daunorubicin, doxorubicin, etc)

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## ETELCALCETIDE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ETELCALCETIDE | PARSABIV | | | |

### GUIDELINES FOR USE

Our guideline named **ETELCALCETIDE (Parsabiv)** requires the following rule(s) be met for approval:

A. You have secondary hyperparathyroidism (too much parathyroid hormone due to low blood calcium levels)
B. You are 18 years of age or older
C. You have chronic kidney disease
D. You are on hemodialysis (a way of removing toxins from your blood)
E. You are NOT taking another calcimimetic agent (a drug that acts like calcium in the body
F. such as cinacalcet)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## FULVESTRANT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| FULVESTRANT | FASLODEX | | | |

## GUIDELINES FOR USE

Our guideline named **FULVESTRANT (Faslodex)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer
   2. HR-positive advanced breast cancer
   3. HR-positive, HER2-negative advanced or metastatic breast cancer (cancer that has spread)

B. **If you have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, approval also requires:**
   1. You are female and postmenopausal
   2. You have not previously been treated with endocrine (hormone) therapy
   3. The requested medication will be used as monotherapy (using a single drug to treat a condition)

C. **If you have hormone receptor (HR)-positive advanced breast cancer, approval also requires:**
   1. You are female and postmenopausal
   2. You have experienced disease progression (it has gotten worse) following endocrine (hormone) therapy
   3. The requested medication will be used as monotherapy (used alone)

D. **If you have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used concurrently (at the same time) with Ibrance (palbociclib) or Verzenio (abemaciclib) and you are a female that has experienced disease progression (it has gotten worse) after endocrine (hormone) therapy
   2. The requested medication will be used in combination with Kisqali (ribociclib) and you meet ALL of the following:
      a. You are a female and postmenopausal
      b. You have not received prior endocrine based therapy for metastatic breast cancer (such as letrozole, anastrozole, tamoxifen, exemestane) OR you have experienced disease progression on endocrine therapy

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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**
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## GIVOSIRAN (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| GIVOSIRAN | GIVLAARI | | | | |

### GUIDELINES FOR USE

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

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)
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

### RENEWAL CRITERIA

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

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TRIPTORELIN PAMOATE | TRIPTODUR, TRELSTAR | | | |
| HISTRELIN ACETATE | SUPPRELIN LA, VANTAS | | | |
| LEUPROLIDE ACETATE | LUPRON DEPOT–PED, LUPRON DEPOT, LUPANETA, FENSOLVI | | | |
| GOSERELIN ACETATE | ZOLADEX | | | |

**GUIDELINES FOR USE**

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

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

***(Initial criteria continued on next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

### INITIAL CRITERIA (CONTINUED)

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)

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

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

### INITIAL CRITERIA (CONTINUED)

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

### 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.

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 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

***(Renewal criteria continued on next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

**RENEWAL CRITERIA (CONTINUED)**

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

Commercial Effective: 05/25/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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**HYALURONATE (NSA)**

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| HYALURONATE SODIUM | EUFLEXXA, HYALGAN, GEL-ONE, GELSYN-3, ORTHOVISC, SUPARTZ FX, GENVISC 850, VISCO-3, TRIVISC, TRILURON, SODIUM HYALURONATE | | | | |
| HYALURONATE SODIUM, STABILIZED | MONOVISC, DUROLANE | | | | |
| HYALURONATE, MODIFIED, NON-CROSSLINK | HYMOVIS | | | | |
| HYLAN G-F 20 | SYNVISC, SYNVISC-ONE | | | | |

**GUIDELINES FOR USE**

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

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for approval:

A. You have osteoarthritis (cartilage between joints breaks down leading to pain, stiffness and swelling) of the knee
B. You are 21 years of age or older
C. You have failed a minimum of a 6-week trial of non-pharmacologic (non-drug) therapy such as education, exercise, use of insoles or braces, weight loss and physical therapy
D. You had a previous trial of intra-articular (injected within the joints) steroids

**RENEWAL CRITERIA**

Our guideline named **HYALURONATE (Euflexxa, Gel-One, Gelsyn-3, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synvisc, Synvisc-One, Genvisc 850, Visco-3, Trivisc, Durolane, Triluron, Sodium Hyaluronate)** requires the following rule(s) be met for renewal:

A. It has been at least 6 months since your last treatment on the same knee

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## HYDROXYPROGESTERONE CAPROATE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| HYDROXYPROGES-TERONE CAPROATE | MAKENA | | | |
| HYDROXYPROGES-TERONE CAPROATE | HYDROXY-PROGESTERONE CAPROATE (GENERIC FOR DELALUTIN) | | | |

## GUIDELINES FOR USE

Our guideline named **HYDROXYPROGESTERONE CAPROATE (Makena)** requires the following rule(s) be met for approval:

A. The medication will be used to lower the risk of preterm (early than normal 37 weeks) birth in a woman with a history of singleton spontaneous preterm birth
B. You do **NOT** have multiple gestations (twins, triplets, etc.)
C. You are at least 16 weeks pregnant but less than 37 weeks pregnant with a single gestation (embryo/fetus)
D. You have a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes

Our guideline named **HYDROXYPROGESTERONE CAPROATE (Generic Delalutin)** requires you are a non-pregnant female and are using the medication for **ONE** of the following:

A. For treatment of advanced adenocarcinoma of the uterine corpus (uterine cancer/tumor Stage III or IV)
B. For the management of primary/secondary amenorrhea (lack of normal menstruation) and abnormal uterine bleeding caused by hormonal imbalance with no organic pathology (no disease from body/organs), such as submucous fibroids or uterine cancer
C. As a test for endogenous (within the body) estrogen production
D. For the production of secretory endometrium and desquamation (shedding of the tissue lining of the uterus)

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## IBALIZUMAB-UIYK (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| IBALIZUMAB-UIYK | TROGARZO | | | | |

### GUIDELINES FOR USE

Our guideline named **IBALIZUMAB-UIYK (Trogarzo)** 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

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Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## INEBILIZUMAB-CDON (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| INEBILIZUMAB-CDON | UPLIZNA | | | | |

### GUIDELINES FOR USE

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

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** 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, satrilizumab, or eculizumab together with Uplizna

### RENEWAL CRITERIA

Our guideline named **INEBILIZUMAB-CDON (Uplizna)** 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 have shown clinical benefit (such as reduction in relapse frequency from baseline or a decrease in NMOSD-related hospitalizations) on therapy with Uplizna

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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**INFLIXIMAB (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| INFLIXIMAB | REMICADE | | | |

**GUIDELINES FOR USE**

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

Our guideline named **INFLIXIMAB (Remicade)** 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. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

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 or have a contraindication to (a medical reason why you cannot use) methotrexate
   4. You have previously tried at least 3 months of 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, Rinvoq, Xeljanz (immediate release/extended release)

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## INFLIXIMAB (NSA)

### INITIAL CRITERIA (CONTINUED)

C. **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 (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 drug), unless there is a medical reason why you cannot (contraindication), such as, methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), 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 have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also 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 body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   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
   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): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

***(Initial criteria continued on next page)***

**CONTINUED ON NEXT PAGE**

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## INFLIXIMAB (NSA)

### INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulatory (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira
      b. You are 18 years of age or older AND have previously tried BOTH of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age
      b. You are 18 years of age or older AND have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira,Stelara, Xeljanz (immediate release unless there is a medical reason why you cannot (contraindication)

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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## INFLIXIMAB (NSA)

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **INFLIXIMAB (Remicade)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), 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
   2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

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

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have 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

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## INFLIXIMAB-AXXQ (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| INFLIXIMAB-AXXQ | AVSOLA | | | | |

## GUIDELINES FOR USE

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

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** 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. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy 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 or have a contraindication to (a medical reason why you cannot use) methotrexate
   4. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug) such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   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, Rinvoq, Xeljanz immediate release/extended release

***(Initial criteria continued on next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## INFLIXIMAB-AXXQ (NSA)

### INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy 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) or dermatologist (skin doctor)
   3. You have previously tried 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 have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy 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 have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy 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 body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of the following standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   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): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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## INFLIXIMAB-AXXQ (NSA)

### INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulator (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]
      b. You are 18 years of age or older AND have previously tried BOTH of the following, preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless there is a medical reason why you cannot (contraindication)
   3. You meet ONE of the following:
      a. You are 6 to 17 years of age
      b. You are 18 years of age or older AND have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara, Xeljanz (immediate release/extended release

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## INFLIXIMAB-AXXQ (NSA)

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **INFLIXIMAB-AXXQ (Avsola)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), 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
   2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

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

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   1. You have 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

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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**INFLIXIMAB-DYYB (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| INFLIXIMAB-DYYB | INFLECTRA | | | |

**GUIDELINES FOR USE**

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

Our guideline named **INFLIXIMAB- DYYB (Inflectra)** 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. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   6. You are 18 years of age or older
   7. 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)
   8. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate
   9. You have previously tried at least 3 months of 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
   10. 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, Rinvoq, Xeljanz immediate release/extended release

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## INFLIXIMAB-DYYB (NSA)

### INITIAL CRITERIA (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   5. You are 18 years of age or older
   6. 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) or dermatologist (skin doctor)
   7. 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, leflunomide, hydroxychloroquine, or sulfasalazine
   8. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Stelara, Xeljanz (immediate release/extended release), Otezla

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   5. You are 18 years of age or older
   6. 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)
   7. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   8. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   6. You are 18 years of age or older
   7. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   8. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   9. You have previously tried at least ONE or more form of conventional therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   10. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Humira, Stelara, Tremfya, Skyrizi, Enbrel, Otezla

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## INFLIXIMAB-DYYB (NSA)

### INITIAL CRITERIA (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   4. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   5. You have previously tried at least ONE conventional therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   6. You meet ONE of the following:
      a. You are 6 to 17 years of age AND have previously tried the following preferred immunomodulatory (class of drug), unless there is a medical reason why you cannot (contraindication): Humira [**NOTE:** pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]
      b. You are 18 years of age or older AND have previously tried BOTH of the following, preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira and Stelara

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   4. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   5. You have previously tried at least ONE conventional therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   6. You meet ONE of the following:
      c. You are 6 to 17 years of age
      d. You are 18 years of age or older AND have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara, 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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## INFLIXIMAB-DYYB (NSA)

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **INFLIXIMAB- DYYB (Inflectra)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
   3. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   4. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   2. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
   2. You have 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

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
   2. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## INOTUZUMAB OZOGAMICIN (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| INOTUZUMAB OZOGAMICIN | BESPONSA | | | |

### GUIDELINES FOR USE

Our guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory B-cell pre-cursor acute lymphoblastic leukemia (ALL- type of blood and bone marrow cancer that affects white blood cells.)
B. You are 18 years of age or older
C. You have **NOT** received 6 cycles of Besponsa previously

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## IOBENGUANE IODINE 131 (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| IOBENGUANE I 131 | AZEDRA | | | |

## GUIDELINES FOR USE

Our guideline named **IOBENGUANE IODINE 131 (Azedra)** requires the following rule(s) be met for approval:

A. You have unresectable (cannot be removed completely through surgery), locally advanced or metastatic pheochromocytoma (type of tumor that releases hormones) or paraganglioma (type of tumors)
B. You are 12 years of age or older
C. You require systemic anticancer therapy (cancer treatment that travels in the blood throughout the entire body)
D. The tumors are iobenguane scan positive (type of test that detects a tumor)
E. You have **NOT** previously received 1 dosimetric dose (measurement of how much radiation dose is absorbed by the body) and 2 therapeutic doses of Azedra

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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)
   7. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (A tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs.)

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

***(Initial criteria continued on next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## IPILIMUMAB (NSA)

### INITIAL CRITEIRA (CONTINUED)

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)

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 expresses 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)

H. **If you have malignant pleural mesothelioma, approval also requires:**
   1. You are 18 years of age or older
   2. Yervoy will be used as first line treatment in combination with Opdivo (nivolumab)

### 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

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Commercial Effective: 10/19/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## IRINOTECAN LIPOSOMAL (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| IRINOTECAN LIPOSOMAL | ONIVYDE | | | |

### GUIDELINES FOR USE

Our guideline named **IRINOTECAN LIPOSOMAL (Onivyde)** requires the following rule(s) be met for approval:

A. You have metastatic adenocarcinoma of the pancreas (type of pancreas cancer that has spread)
B. You have experienced disease progression (disease has worsened) despite a trial of gemcitabine-based therapy (type of cancer drug)
C. Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## IXABEPILONE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| IXABEPILONE | IXEMPRA | | | |

### GUIDELINES FOR USE

Our guideline named **IXABEPILONE** requires the following rule(s) be met for approval:

A. You have metastatic (cancer that has spread to other parts of body) or locally advanced breast cancer
B. You meet **ONE** of the following:
1. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) **OR**
2. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), and a taxane (paclitaxel or docetaxel) **AND** the requested medication is being used in combination with Xeloda (capecitabine)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## LETERMOVIR IV (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| LETERMOVIR | PREVYMIS | | | |

### GUIDELINES FOR USE

Our guideline named **LETERMOVIR IV (Prevymis)** requires the following rule(s) be met for approval:

A. You are undergoing an allogeneic hematopoietic stem cell transplant (you have cells transplanted from a matching donor)
B. You are 18 years of age or older
C. You are CMV (Cytomegalovirus)-seropositive [R+]
D. Prevymis will be used for prophylaxis (prevention) of cytomegalovirus infection and disease
E. Prevymis will be started between Day 0 and Day 28 post-transplantation (before or after engraftment)
F. You are not receiving the medication beyond 100 days post-transplantation

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## LURBINECTEDIN (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| LURBINECTEDIN | ZEPZELCA | | | | |

### GUIDELINES FOR USE

Our guideline named **LURBINECTEDIN (Zepzelca)** requires the following rule(s) be met for approval:

A. You have metastatic small cell lung cancer (SCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You had disease progression (worsening) on or after platinum-based chemotherapy (such as carboplatin or cisplatin)

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Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**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 ONE of the following conditions:
   1. Beta thalassemia (blood disorder that reduces the production of hemoglobin) and you require regular red blood cell (RBC) transfusions
   2. Myelodysplastic syndromes (group of blood disorders caused when production of blood cells is disrupted) with ring sideroblasts (cells that contain rings of iron deposits) (MDS-RS)
   3. Myelodysplastic/myeloproliferative neoplasm (group of disorders in which the bone marrow makes too many white blood cells) with ring sideroblasts and thrombocytosis (excess of blood clotting cells (platelets)) (MDS/MPN-RS-T)
D. **If you have myelodysplastic syndromes with ring sideroblasts (MDS-RS) OR myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T), approval also requires:**
   1. You are failing an erythropoiesis (red blood cell production) stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks

Commercial Effective: 05/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## LUTETIUM LU 177 DOTATATE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| LUTETIUM LU 177 DOTATATE | LUTATHERA | | | |

### GUIDELINES FOR USE

Our guideline named **LUTETIUM LU 177 DOTATATE (Lutathera)** requires the following rule(s) be met for approval:

A. You have somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs: type of hormone cancer in digestive tract)
B. You are 18 years of age or older
C. You will be treated with a long-acting octreotide (type of hormone) as maintenance therapy together with the requested medication
D. You have been previously treated with a long acting somatostatin analog (such as octreotide or lanreotide) before the request of this medication
E. You have **NOT** previously received 4 doses of Lutathera

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED 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)
   3. Hypereosinophilic syndrome (HES) (a rare blood disorder)

B. **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)

C. **If you have eosinophilic granulomatosis with polyangiitis (EGPA), approval also requires:**
   1. You are 18 years of age or older

D. **If you have hypereosinophilic syndrome (HES), approval also requires:**
   1. You are 12 years of age or older
   2. You had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

**CONTINUED ON NEXT PAGE**

**STANDARD NON-SELF-ADMINISTERED 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 severe asthma with an eosinophilic phenotype
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 (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.)

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Commercial Effective: 10/12/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## MINOCYCLINE HCL MICROSPHERES (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MINOCYCLINE HCL MICROSPHERES | ARESTIN | | | |

### GUIDELINES FOR USE

### INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for approval:

A. You have documentation of confirmed periodontitis (inflammation and infection of the gums)
B. You are age 18 years or older
C. The medication is prescribed by or given in consultation with an oral health care professional
D. You do not have a history of minocycline or tetracycline sensitivity or allergy
E. You do not have a history of candidiasis (a type of fungal infection) or active oral candidiasis
F. The requested medication will be administered by an oral health professional
G. The requested medication will be used as an adjunct (add-on therapy) 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
H. The requested medication is not being used for acutely abscessed periodontal pocket (not used for short-term and sudden infection with pus-filled pocket)
I. The medication is not being used in an immunocompromised individual (your immune system is weakened), such as those immunocompromised by any of the following conditions:
    1. Uncontrolled diabetes mellitus
    2. Chemotherapy
    3. Radiation therapy
    4. HIV (human immunodeficiency virus) infection
J. The medication is not being used in the regeneration of alveolar bone (bone that has tooth sockets), either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

### RENEWAL CRITERIA

Our guideline named **MINOCYCLINE HCL MICROSPHERES (Arestin)** requires the following rule(s) be met for renewal:

A. You have documentation of periodontitis (inflammation and infection of the gums)
B. The medication will be used as an adjunct (add-on therapy) to scaling and root planing procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planning

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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**MITOMYCIN (NSA)**

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| MITOMYCIN | JELMYTO | | | | |

## GUIDELINES FOR USE

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

Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for approval:
A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an oncologist (doctor who specializes in cancer) or urologist (doctor who specializes in the urinary tract and male reproductive organs)

## RENEWAL CRITERIA

Our guideline named **MITOMYCIN (Jelmyto)** requires the following rule(s) be met for renewal:
A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
B. You were reassessed at no sooner than 3 months after initiation of Jelmyto
C. You showed complete response at the time of assessment

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Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## MITOXANTRONE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MITOXANTRONE HCL | NOVANTRONE | | | |

## GUIDELINES FOR USE

Our guideline named **MITOXANTRONE** requires ONE of following rules be met for approval:

A. The medication is prescribed by or given in consultation with an oncologist (tumor/cancer doctor)
B. You have ONE of the following:
   1. Pain related to advanced refractory prostate cancer
   2. Acute nonlymphocytic leukemia (type of white blood cell cancer)
   3. Secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis (disease where immune system attacks nerves)

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## MOGAMULIZUMAB-KPKC (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MOGAMULIZUMAB-KPKC | POTELIGEO | | | |

## GUIDELINES FOR USE

Our guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires the following rule(s) be met for approval:

A. You have Mycosis Fungoides or Sezary syndrome (types of blood cancers that affect the skin)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or not responsive to therapy)
D. You have tried and failed at least one prior systemic therapy (treatment that travels in the blood throughout the body)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## MOMETASONE SINUS IMPLANT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MOMETASONE FUROATE | SINUVA | | | |

### GUIDELINES FOR USE

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

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an otolaryngologist (ear, nose and throat doctor)
D. You previously had ethmoid sinus surgery (process to remove blockage in your sinuses)
E. You are a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms (symptoms return and do not respond to surgery) of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. You previously had a 90-day trial of ONE intranasal corticosteroid (such as fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. You have not received 4 implants (2 per nostril) in your lifetime

### RENEWAL CRITERIA

Our guideline named **MOMETASONE IMPLANT (Sinuva)** requires the following rule(s) be met for approval:

A. You have nasal polyps (small growths inside the nose)
B. You have ethmoid sinus polyps grade 1 or greater on any side
C. You do not have extensive ethmoid sinus polyp grade (grade 4 on at least one side) or extensive adhesions/synechiae (scar tissue) (grade 3 or 4)
D. You have not previously received 4 implants (2 per nostril) in your lifetime

Commercial Effective: 10/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## MOXETUMOMAB PASUDOTOX (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| MOXETUMOMAB PASUDOTOX-TDFK | LUMOXITI | | | |

## GUIDELINES FOR USE

Our guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires the following rule(s) be met for approval:

A. You have hairy cell leukemia (HCL: type of blood and bone marrow cancer)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or is not responsive to therapy)
D. You have received at least two prior systemic therapies, including treatment with a purine nucleoside analog (type of drug that treats certain blood cancers)
E. You have NOT previously received 6 cycles of Lumoxiti

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## NECITUMUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| NECITUMUMAB | PORTRAZZA | | | |

### GUIDELINES FOR USE

Our guideline named **NECITUMUMAB (Portrazza)** requires the following rule(s) be met for approval:

A. The medication will be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body) in combination with gemcitabine and cisplatin

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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 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 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

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## OBINUTUZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| OBINUTUZUMAB | GAZYVA | | | |

### GUIDELINES FOR USE

Our guideline named **OBINUTUZUMAB (Gazyva)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)
   2. Follicular lymphoma (FL: type of cancer with abnormal immune cells)
   3. Stage II bulky, III or IV follicular lymphoma

B. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You have not received previous treatment for chronic lymphocytic leukemia
   2. The requested medication will be used in combination with chlorambucil

C. **If you have follicular lymphoma, approval also requires:**
   1. You have relapsed after or are refractory to (your disease has returned or is resistant to) a regimen containing Rituxan (rituximab)
   2. The requested medication will be used in combination with bendamustine for the initial six cycles OR as monotherapy (the only drug used in treatment) thereafter

D. **If you have stage II bulky, III or IV follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received previous treatment for stage II bulky, III or IV follicular lymphoma
   3. The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] OR as monotherapy (the only drug used in treatment) thereafter

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## OCRELIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| OCRELIZUMAB | OCREVUS | | | |

## GUIDELINES FOR USE

Our guideline named **OCRELIZUMAB (Ocrevus)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Primary progressive multiple sclerosis (type of disease where body attacks its own nerves and it slowly gets worse)
   2. Relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)

B. **If you have primary progressive multiple sclerosis (PPMS), approval also requires:**
   1. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      a. You have previously tried any TWO agents 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, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)
      b. You show signs of severe disease requiring high-efficacy disease modifying therapy (DMT) such as high lesion (affected areas) volume and/or count, walking disability, or rapid decline

Commercial Effective: 01/01/21

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## OFATUMUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| OFATUMUMAB | ARZERRA | | | |

### GUIDELINES FOR USE

Our guideline named **OFATUMUMAB (Arzerra)** requires the following rule(s) be met for approval:

A. You have chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)
B. **If you have previously untreated chronic lymphocytic leukemia, approval also requires:**
   1. You have not received previous treatment for chronic lymphocytic leukemia
   2. Fludara (fludarabine)-based therapy is considered inappropriate for you
   3. The requested medication will be used in combination with chlorambucil
C. **If you have relapsed chronic lymphocytic leukemia (type of blood and bone marrow cancer that has returned), approval also requires:**
   1. The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide
D. **If you are requesting extended treatment of chronic lymphocytic leukemia, approval also requires:**
   1. You are in complete or partial response
   2. You have received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia
E. **If you have refractory chronic lymphocytic leukemia, approval also requires:**
   1. You are refractory (non-responsive) to Fludara (fludarabine) and Campath (alemtuzumab)

Commercial Effective: 09/14/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## OLARATUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| OLARATUMAB | LARTRUVO | | | |

### GUIDELINES FOR USE

Our guideline named **OLARATUMAB (Lartruvo)** requires the following rule(s) be met for approval:

A. You have soft tissue sarcoma (STS: type of cancer that starts in soft tissues like muscles/tendons)
B. The request is for continuation of Lartruvo therapy (you are currently on Lartruvo)
C. The requested medication will be used in combination with doxorubicin for the first 8 cycles
D. The histologic subtype of sarcoma (the type of tissue cancer such as undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen (a treatment plan that contains a specific type of cancer drug)
E. You are not responsive to curative treatment with radiotherapy or surgery

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## ONASEMNOGENE ABEPARVOVEC-XIOI (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ONASEMNOGENE ABEPARVOVEC-XIOI | ZOLGENSMA | | | |

## GUIDELINES FOR USE

Our guideline named **ONASEMNOGENE ABEPARVOVEC-XIOI (Zolgensma)** 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. You are less than 2 years of age
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. You have documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (SMN1: type of protein in spinal cord) mutations such as deletions and/or point mutations
E. You do NOT have anti-adeno-associated virus vector (anti-AAV9) antibody titers (amount of a type of immune system cells in blood) greater than 1:50 as determined by an enzyme linked immunosorbent assay (ELISA: type of lab test)
F. You do NOT have advanced spinal muscular atrophy (SMA) such as complete paralysis of the limbs or permanent ventilator dependence

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## PACLITAXEL PROTEIN-BOUND (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PACLITAXEL PROTEIN-BOUND | ABRAXANE | | | |

### GUIDELINES FOR USE

Our guideline named **PACLITAXEL (Abraxane)** 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. Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC: cancer that is in the advanced stage or that has spread to other parts of the body)
   3. Small Cell Lung Cancer (SCLC)
   4. Metastatic adenocarcinoma of the pancreas (pancreas cancer that has spread to other parts of the body)

B. **If you have metastatic breast cancer, approval also requires:**
   1. You have tried a chemotherapy regimen (cancer-treating medications) containing an anthracycline (cancer drug such as doxorubicin or epirubicin) or paclitaxel

C. **If you have metastatic adenocarcinoma of the pancreas, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## PALIVIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PALIVIZUMAB | SYNAGIS | | | |

## GUIDELINES FOR USE

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

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for approval:

A. You are less than 12 months old or less than 24 months at the start of respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season (mid-September to mid-May)

B. **If you are less than 12 months old, you must meet ONE of the following**:
   1. You have chronic lung disease of prematurity (a condition where you were born at less than 32 weeks and required more than 21% of additional oxygen for at least the first 28 days after birth)
   2. You are profoundly immunocompromised during RSV season (your body cannot fight off infections)
   3. You have received a solid-organ transplant during RSV season
   4. You have congenital (starting from birth) heart disease conditions at birth such as: acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) where you need medication to control chronic heart failure and will require heart surgical procedures; moderate to severe pulmonary hypertension (high blood pressure in the lungs); or cyanotic heart defect (low blood oxygen level) and the requested medication is prescribed by or given in consultation with a pediatric cardiologist (a heart doctor for children)
   5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that affects respiratory (lung/breathing) secretions
   6. You were born premature at less than 29 weeks (gestational age)
   7. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely

C. **If you are less than 24 months old, you must meet ONE of the following:**
   1. You are profoundly immunocompromised during RSV season (a condition where your body cannot fight off infections)
   2. You have chronic lung disease of prematurity and need medical support within 6 months before the start of the second respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season. Medical support includes oxygen, bronchodilator (drug that helps you breathe), diuretic (drug that makes you urinate), or chronic steroid therapy
   3. You have received a solid-organ transplant during RSV season

**CONTINUED ON NEXT PAGE**

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## PALIVIZUMAB (NSA)

### GUIDELINES FOR USE (CONTINUED)

### RENEWAL CRITERIA

Our guideline named **PALIVIZUMAB (Synagis)** requires the following rule(s) be met for renewal:

A. You are under 24 months old
B. You meet **ONE** of the following:
   1. You received cardiopulmonary bypass surgery (type of heart and lung surgery) during respiratory syncytial virus (RSV: type of lung and respiratory tract infection) prevention season (mid-September to mid-May)
   2. This request is for a second year of coverage and you have chronic lung disease of prematurity and need medical support during the 6 months before the start of the second RSV season. Medical support includes oxygen, bronchodilator (drug that helps you breathe), diuretic (drug that makes you urinate), or chronic steroid therapy

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Commercial Effective: 07/01/20

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## PANITUMUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PANITUMUMAB | VECTIBIX | | | |

## GUIDELINES FOR USE

Our guideline named **PANITUMUMAB (Vectibix)** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body) with wild-type RAS gene (a gene called RAS when it is found in its natural, unchanged form). Wild-type RAS is defined as wild-type in both the KRAS gene and NRAS gene, as determined by a Food and Drug Administration (FDA)-approved test for this use
B. You must meet ONE of the following:
    1. Vectibix will be used as monotherapy (the only drug used to treat your cancer) AND you have been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing cancer treatment (chemotherapy)
    2. Vectibix will be used in combination with FOLFOX (regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

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Commercial Effective: 07/01/20

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## PATISIRAN (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PATISIRAN | ONPATTRO | | | |

### GUIDELINES FOR USE

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

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for approval:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: rare genetic disorder described by abnormal build-up of protein in the body's organs and tissues) with polyneuropathy (nerve damage/pain all over your body)
B. You are 18 years of age or older
C. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by ONE of the following:
    1. Biopsy (surgical removal of a sample) of tissue/organ to confirm amyloid (abnormal protein that can build up in any tissue or organ) presence AND chemical typing to confirm the presence of TTR protein
    2. DNA genetic sequencing (lab test for genes) to confirm hereditary transthyretin-mediated amyloidosis (hATTR)
D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), or a physician at an amyloidosis treatment center (center that treats a certain type of genetic disease), or medical geneticist
E. You have Stage 1 or 2 polyneuropathy (nerve damage/pain all over your body)

### RENEWAL CRITERIA

Our guideline named **PATISIRAN (Onpattro)** requires the following rule(s) be met for renewal:

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: rare genetic disorder described by abnormal build-up of protein in the body's organs and tissues) with polyneuropathy (nerve damage/pain all over your body)
B. You have not progressed to stage 3 polyneuropathy as evidenced by functional decline such as being wheelchair-bound or bedridden

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Commercial Effective: 07/01/20

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## PEGAPTANIB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PEGAPTANIB SODIUM | MACUGEN | | | |

## GUIDELINES FOR USE

Our guideline named **PEGAPTANIB (Macugen)** requires the following rule(s) be met for approval:

1. You have neovascular (wet) age-related macular degeneration (a chronic eye disorder that causes blurred vision or a blind spot in your visual field)
2. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina specialist

Commercial Effective: 07/01/20

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## PEGLOTICASE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PEGLOTICASE | KRYSTEXXA | | | |

### GUIDELINES FOR USE

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

Our guideline named **PEGLOTICASE (Krystexxa)** requires the following rules be met for approval:

A. You have chronic gout that is refractory to conventional therapy (resistant to standard treatments)
B. You are 18 years of age or older
C. You have symptomatic gout as shown by **ONE** of the following:
   1. At least 3 or more gout flares in the previous 18 months
   2. History of at least 1 gout tophus (uric acid crystallizes in joints like hands/feet)
   3. Gouty arthritis (severe pain and inflammation in joints due to gout)
D. You had a baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications such as allopurinol, lesinurad
E. You do not have glucose-6-phosphate dehydrogenase (G6PD) deficiency (you are missing an enzyme that helps red blood cells work properly)
F. You will not be on urate-lowering therapy (such as xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) at the same time as using pegloticase
G. You have experienced failure, contraindication (medical reason why you cannot use), intolerance or inadequate response to previous therapy with a maximum tolerated dose for TWO conventional gout medications for at least 3 months (such as allopurinol, probenecid, lesinurad)

### RENEWAL CRITERIA

Our guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level below 6 mg/dL for renewal.

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Commercial Effective: 07/01/20

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## PEMETREXED (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PEMETREXED DISODIUM | ALIMTA | | | |

## GUIDELINES FOR USE

Our guideline named **PEMETREXED (Alimta)** the following rules be met for approval:

A. You have one of the following diagnoses:
   1. Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC)
   2. Metastatic, non-squamous, non-small cell lung cancer (NSCLC)
   3. Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC)
   4. Malignant pleural mesothelioma (cancer of the protective lining of the lung)

B. **If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:**
   1. The requested medication is being used in combination with cisplatin for initial treatment
   2. The requested medication is being used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy

C. **If you have metastatic, non-squamous, non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used for initial (starting) treatment
   2. The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
   3. You do NOT have EGFR (Epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations (types of gene mutations)

D. **If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used as a single agent
   2. You have received prior chemotherapy

E. **If you have malignant pleural mesothelioma (cancer of the protective lining of the lung), approval also requires:**
   1. The requested medication is being used in combination with cisplatin for initial (starting) treatment
   2. Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

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## 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)

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Commercial Effective: 07/01/20

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## POLATUZUMAB VEDOTIN (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| POLATUZUMAB VEDOTIN-PIIQ | POLIVY | | | |

### GUIDELINES FOR USE

Our guideline named **POLATUZUMAB VEDOTIN (Polivy)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (a type of cancer that affects your white blood cells and returns or resistant to treatment)
B. You are at least 18 years old
C. The requested drug will be used in combination with bendamustine and a rituximab product (type of cancer drug)
D. You have had at least two prior therapies.
E. You are not a candidate for autologous hematopoietic stem cell transplant (cells transferred from your own body)

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Commercial Effective: 07/01/20

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## PORFIMER (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PORFIMER SODIUM | PHOTOFRIN | | | |

## GUIDELINES FOR USE

Our guideline named **PORFIMER (Photofrin)** requires that the drug is being used for one of the following conditions:

A. The reduction of blockage and palliation of symptoms (treatment focused on relief from the symptoms and stress of a serious illness) in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or,
B. Treatment of microinvasive endobronchial non-small cell lung cancer (a type of lung cancer that involves airway blockage) where surgery and radiation therapy cannot be used; or
C. Helping to lessen your symptoms with completely obstructing or partially obstructing esophageal cancer, where in the opinion of your physician, you cannot be treated with Nd:YAG laser therapy (a high intensity laser that can be used to remove cancer) or,
D. The ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy (removal of precancerous cells of the esophagus and you did not have surgical treatment for esophageal cancer)

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Commercial Effective: 07/01/20

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## PRALATREXATE (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| PRALATREXATE | FOLOTYN | | | |

### GUIDELINES FOR USE

Our guideline named **PRALATREXATE (Folotyn)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (a type of white blood cell cancer that returns or does not fully respond to treatment).

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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 caner 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 rcolon 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)***

**CONTINUED ON NEXT PAGE**

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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)

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Commercial Effective: 07/01/20

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## RANIBIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| RANIBIZUMAB | LUCENTIS | | | |

## GUIDELINES FOR USE

Our guideline named **RANIBIZUMAB (Lucentis)** requires the following rule(s) be met for approval:

A. You have a diagnosis of neovascular (wet) age-related macular degeneration (abnormal blood vessels form in your eye causing vision loss), diabetic macular edema (buildup of fluid in the eye affecting vision), diabetic retinopathy (damage to blood vessels in the eye due to high blood sugar), macular edema following retinal vein occlusion (buildup of fluid in eye due to vein blockage), or myopic choroidal neovascularization (abnormal blood vessels grow in the back of the eye).
B. The medication is prescribed by an ophthalmologist (doctor who specializes in medical and surgical eye disease) or retina specialist.

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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.

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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, Rinvoq, 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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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**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

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Commercial Effective: 04/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**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, Rinvoq, 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.

***(Initial criteria continued on next page)***

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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

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Commercial Effective: 04/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## RITUXIMAB AND HYALURONIDASE HUMAN - SQ (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| RITUXIMAB/ HYALURONIDASE, HUMAN - SQ | RITUXAN HYCELA | | | |

## GUIDELINES FOR USE

Our guideline named **RITUXIMAB AND HYALURONIDASE HUMAN - SQ (Rituxan Hycela)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnosis:
   1. Follicular Lymphoma (FL: type of cancer that affects a type of white blood cells)
   2. Diffuse Large B-cell Lymphoma (DLBCL: cancer that affects specific immune system cells)
   3. Chronic Lymphocytic Leukemia (blood and bone marrow cancer) in adult patients who have received or will receive at least one full dose of a rituximab product by intravenous infusion (given into the veins) before starting requested medication

B. **If you have Follicular Lymphoma (FL), approval also requires ONE of the following:**
   1. The medication will be used as a single agent if you have relapsed or refractory Follicular Lymphoma (cancer that has returned or does not fully respond to treatment)
   2. The medication will be used in combination with first line chemotherapy if you have previously untreated Follicular Lymphoma
   3. The medication will be used as a single-agent for maintenance therapy if you have achieved a complete or partial response to rituximab in combination with chemotherapy
   4. The medication will be used as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy if you have non-progressing (does not get worse, including stable disease) Follicular Lymphoma

C. **If you have Diffuse Large B-cell Lymphoma (DLBCL) approval also requires ONE of the following:**
   1. 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)

D. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires ONE of the following:**
   1. The medication will be used in combination with fludarabine and cyclophosphamide (FC)

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## RITUXIMAB-PVVR (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| RITUXIMAB-PVVR | RUXIENCE | | | |

## GUIDELINES FOR USE

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)

B. **If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy 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. Therapy is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
   3. You are 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 using glucocorticoids (steroids such as methylprednisolone or prednisone) at the same time with the requested medication

Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## ROMIDEPSIN (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ROMIDEPSIN | ISTODAX | | | |

### GUIDELINES FOR USE

Our guideline named **ROMIDEPSIN (Istodax)** requires the following rule(s) be met for approval:

A. You have a diagnosis of cutaneous T-cell lymphoma or peripheral T-cell lymphoma (type of cancer that affects a certain type of immune system cells).
B. **If you have cutaneous T-cell lymphoma, approval also requires the following:**
   1. You had a trial of Zolinza (vorinostat), unless there is a medical reason why you cannot (contraindication) AND you are not able to tolerate oral medications.
   2. You have tried at least one form of systemic therapy (such as retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) AND you are able to tolerate oral medications.
C. **If you have peripheral T-cell lymphoma, approval also requires the following:**
   1. You have received at least one prior treatment.

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## ROMOSOZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ROMOSOZUMAB-AQQG | EVENITY | | | |

## GUIDELINES FOR USE

Our guideline named **ROMOSOZUMAB (Evenity)** requires the following rule(s) be met for approval:

A. You have postmenopausal osteoporosis (weak and brittle bones)
B. You have not received a total of 12 months or more of Evenity therapy.
C. You meet **ONE** of the following criteria:
   1. You are at high risk for fractures defined as **ONE** of the following:
      a. History of osteoporotic (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 (measurement of how high your risk for osteoporosis is) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.
      c. No prior treatment for osteoporosis **AND** FRAX score (test for your risk of fractures) greater than or equal to 20% for any major fracture **OR** greater than or equal to 3% for hip fracture
   2. You are unable to use oral therapy. Reasons include 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, intolerance to, or a contraindication to (medical reason why you cannot use) bisphosphonates such as Fosamax, Actonel, Boniva

Commercial Effective: 07/01/20

WELLFLEET
RX PLAN

# SACITUZUMAB

| Generic | Brand | Exception/Other |
|---|---|---|
| SACITUZUMAB GOVITECAN-HZIY | TRODELVY | |

## REQUIREMENTS

Our guideline named **SACITUZUMAB (Trodelvy)** requires the following rule(s) be met for approval:

A. You have unresectable locally advanced (the cancer has spread from where it started to nearby tissue or lymph nodes and cannot be surgically removed) OR 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 two or more previous systemic therapies (treatment that targets the entire body by traveling throughout your bloodstream), at least one of them for metastatic disease (disease that has spread to other parts of the body)

## RATIONALE

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

## REFERENCES


- Trodelvy [Prescribing Information]. Morris Plans, NJ: Immunomedics, Inc., April 2021.

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## SEBELIPASE ALFA (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| SEBELIPASE ALFA | KANUMA | | | |

### GUIDELINES FOR USE

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

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for approval:

A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol), as confirmed by the presence of clinical features such as hepatomegaly (enlarged liver), elevated serum transaminases (types of enzymes), dyslipidemia (abnormal levels of fats), splenomegaly (enlarge spleen)
B. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor), hepatologist (liver specialist), gastroenterologist (digestive system doctor), medical geneticist, or lipidologist (cholesterol management specialist)
C. You meet ONE of the following:
    1. A blood test indicating low or absent levels of lysosomal acid lipase enzyme activity
    2. A dried blood spot test indicating low or absent lysosomal acid lipase enzyme activity
    3. A genetic test indicating the bi-allelic presence of altered LIPA gene(s) (you have a change in a gene that provides instructions for producing an enzyme called lysosomal acid lipase)

### RENEWAL CRITERIA

Our guideline named **SEBELIPASE ALFA (Kanuma)** requires the following rule(s) be met for renewal:

A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol) presenting after the first 6 months of life and not considered rapidly progressive (getting worse)
B. You have documented improvement in ONE of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
    1. A relative reduction from baseline in any one of the following lipid levels (fat lab measurements such as LDL-c, Non-HDL-c, or triglycerides)
    2. Normalization of aspartate aminotransferase (AST: type of liver enzyme) based on age- and gender-specific normal ranges
    3. A decrease in liver fat content compared to baseline assessed by abdominal imaging such as multi-echo gradient echo [MEGE] MRI

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## SILTUXIMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| SILTUXIMAB | SYLVANT | | | |

## GUIDELINES FOR USE

Our guideline named **SILTUXIMAB (Sylvant)** requires the following rule(s) be met for approval:

A. You have multi-centric Castleman's disease (MCD: disease that affects the lymph nodes and related tissues)
B. You are negative for both human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## SUFENTANIL (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| SUFENTANIL CITRATE | DSUVIA | | | |

## GUIDELINES FOR USE

Our guideline named **SUFENTANIL (Dsuvia)** requires the following rule(s) be met for approval:

A. You have acute pain (sudden and severe pain)
B. You are 18 years of age or older
C. Your pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate. Alternative treatments that may be inadequate include non-opioid analgesic products or opioid combination products
D. Your 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

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## TAGRAXOFUSP-ERZS (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TAGRAXOFUSP-ERZS | ELZONRIS | | | |

## GUIDELINES FOR USE

Our guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires the following rule(s) be met for approval:

A. You have blastic plasmacytoid dendritic cell neoplasm (BPDCN: aggressive and rare disease of the bone marrow and blood that can affect multiple organs)
B. You are 2 years of age or older

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Commercial Effective: 07/01/20

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## TALIMOGENE LAHERPAREPVEC (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TALIMOGENE LAHERPAREPVEC | IMLYGIC | | | |

## GUIDELINES FOR USE

Our guideline for **TALIMOGENE LAHERPAREPVEC (Imlygic)** requires the following rule(s) be met for approval:

A. You have unresectable melanoma (type of skin cancer that cannot be removed with surgery)
B. Your melanoma lesions are recurrent after initial surgery (cancer returns after surgery)
C. You do not have a history of primary or acquired immunodeficient states (conditions that weaken your immune system), leukemia (type of white blood cell cancer), lymphoma (type of cancer affecting immune system), or Acquired Immunodeficiency Syndrome (AIDS)
D. You are not currently receiving immunosuppressive therapy (treatment that weakens your immune system)
E. You are 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
F. The request is for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions (injected into the skin layers) that are visible, palpable (can be felt), or detectable by ultrasound guidance

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## TEMOZOLOMIDE – IV (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TEMOZOLOMIDE - IV | TEMODAR - IV | | | |

## GUIDELINES FOR USE

Our guideline named **TEMOZOLOMIDE (Temodar) - IV** requires you have one of the following diagnoses for approval:

A. Metastatic melanoma (type of skin cancer)
B. Anaplastic astrocytoma (type of brain tumor)
C. Glioblastoma multiforme (type of tumor affecting brain or spine)
D. Small cell lung cancer (SCLC)

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Commercial Effective: 07/01/20

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## TEMSIROLIMUS (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TEMSIROLIMUS | TORISEL | | | |

### GUIDELINES FOR USE

Our guideline named **TEMSIROLIMUS (Torisel)** requires the following rule(s) be met for approval:

A. You have advanced renal cell carcinoma (RCC: type of kidney cancer).

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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)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## THYROTROPIN ALFA FOR INJECTION (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| THYROTROPIN ALFA FOR INJECTION | THYROGEN | | | |

## GUIDELINES FOR USE

Our guideline named **THYROTROPIN ALFA FOR INJECTION (Thyrogen)** requires that the requested product is being used as adjunctive (add-on) treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease (used to destroy thyroid tissue that is left over after using another treatment and you have no signs of the disease spreading in body)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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## TISAGENLECLEUCEL (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TISAGENLECLEUCEL | KYMRIAH | | | |

## GUIDELINES FOR USE

Our guideline named **TISAGENLECLEUCEL (Kymriah)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. B-cell precursor acute lymphoblastic leukemia (ALL: type of immune system cancer)
   2. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of immune system cancer that has returned or did not fully respond to previous treatment) not otherwise specified, high grade B-cell lymphoma (type of white blood cell cancer), or DLBCL arising from follicular lymphoma (FL: type of white blood cell cancer) such as transformed follicular lymphoma

B. Treatment is prescribed by a Kymriah-certified hematologist (blood specialist) or oncologist (tumor/ cancer doctor)

C. Kymriah will be administered at a treatment center that is certified to administer Kymriah

D. You have not had a previous trial of Kymriah

E. **If you have B-cell precursor acute lymphoblastic leukemia (ALL), approval also requires:**
   1. You are 25 years of age or younger
   2. You have **ONE** of the following criteria:
      a. You are in second or greater bone marrow relapse (disease returns)
      b. You are currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT: donor cells are from another person)
      c. You have not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (you have primary refractory disease)
      d. You have not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
      e. You have Philadelphia chromosome positive (Ph+; type of gene mutation) acute lymphoblastic leukemia and meets at least **ONE** of the following:
         i. You had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
         ii. You are unable to tolerate TKI therapy
         iii. You have a medical reason why you cannot take TKI therapy (contraindication)
      f. You are not eligible for allogeneic stem cell transplantation (SCT)

F. **If you have 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 also requires:**
   1. You are 18 years of age or older
   2. You meet **ALL** of the following criteria:

a. You are refractory (disease does not fully respond to treatment) or have had disease progression (gotten worse) after two or more lines of systemic therapy including rituximab and an anthracycline
b. You had disease progression or relapsed (disease worsens or returns) after autologous hematopoietic stem cell transplantation (ASCT) **OR** you are not eligible for ASCT

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

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## TRABECTEDIN (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TRABECTEDIN | YONDELIS | | | |

### GUIDELINES FOR USE

Our guideline named **TRABECTEDIN (Yondelis)** requires the following rule(s) be met for approval:

A. You have unresectable or metastatic liposarcoma or leiomyosarcoma (cancer of the fat cells or muscles that cannot be removed with surgery or has spread to other parts of body).
B. You have previously received therapy with an anthracycline-containing regimen such as doxorubicin.

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## TRASTUZUMAB-ANNS

| Generic | Brand | | | |
|---|---|---|---|---|
| TRASTUZUMAB-ANNS | KANJINTI | | | |

## GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-ANNS (Kanjinti)** 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 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. 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) therapy
   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

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)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or throat that has spread to other parts of the body), approval also requires:**
   1. You have HER2-positive tumor (you have a type of protein present in breast 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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## TRASTUZUMAB-DKST (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TRASTUZUMAB-DKST | OGIVRI | | | |

## GUIDELINES FOR USE

Our guideline named **TRASTUZUMAB-DKST (Ogivri)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Breast cancer
   2. Metastatic breast cancer (cancer has spread to other parts of the body)
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (type of 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) therapy
   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

C. **If you have metastatic breast cancer, approval also requires:**
   1. You have HER2-positive metastatic breast cancer (you have a 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)

D. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You have HER2-positive metastatic cancer (you have a type of protein and the cancer has spread to other parts of the body) 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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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:**
   3. You have HER2-positive tumor (type of protein present in breast cancer) as detected by a Food and Drug Administration-approved test
   4. 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)
   5. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

***(Criteria continued on next page)***

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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)

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Commercial Effective: 07/01/20

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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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

***(Criteria continued on next page)***

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**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)

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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:

E. 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)

F. **If you have breast cancer, approval also requires:**
   4. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   5. The request is for adjuvant (add-on) treatment
   6. 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
   7. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

G. **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

***(Criteria continued on next page)***

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## TRASTUZUMAB-PKRB (NSA)

### GUIDELINES FOR USE (CONTINUED)

H. **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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## TRASTUZUMAB-QYYP (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| TRASTUZUMAB-QYYP | TRAZIMERA | | | |

## GUIDELINES FOR USE

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. etastatic 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-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

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)

***(Criteria continued on next page)***

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## TRASTUZUMAB-QYYP (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)

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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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## 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

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## VORETIGENE NEPARVOVEC-RZYL (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| VORETIGENE NEPARVOVEC-RZYL | LUXTURNA | | | |

## GUIDELINES FOR USE

Our guideline named **VORETIGENE NEPARVOVEC-RZYL (Luxturna)** requires the following rule(s) be met for approval:

A. You have confirmed biallelic RPE65 mutation-associated retinal dystrophy (loss of vision in one or both eyes due to a gene mutation)
B. You are 3 years of age or older
C. Your diagnosis of biallelic RPE65 (type of gene) mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
D. The requested medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) or retinal specialist
E. You have a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
F. You have enough retinal cells as demonstrated by sufficient retinal thickness
G. You do **NOT** have pre-existing eye conditions that may lead to blindness independently of RPE65 (type of gene) -mutation associated retinal dystrophy. Pre-existing eye conditions may include leukemia (type of cancer) with Central Nervous System/optic nerve involvement, macular edema (fluid buildup in the eye) or cytomegalovirus retinitis (inflammation of the retina of the eye that can lead to blindness)
H. You have **NOT** previously received gene therapy (including Luxturna) for the treatment of vision loss
I. The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

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## ZIV-AFLIBERCEPT (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| ZIV-AFLIBERCEPT | ZALTRAP | | | |

### GUIDELINES FOR USE

Our guideline named **ZIV-AFLIBERCEPT** requires the following rule(s) be met for approval:

A. You have metastatic colorectal cancer (cancer has spread in body)
B. You previously had a trial of an oxaliplatin-containing regimen (such as FOLFOX)
C. You will be using the requested medication with fluorouracil, leucovorin, irinotecan (FOLFIRI) at the same time

Commercial Effective: 07/01/20

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## ANTIMIGRAINE AGENTS

| Generic | Brand | | | |
|---|---|---|---|---|
| ALMOTRIPTAN | AXERT | | | |
| ELETRIPTAN HBR | RELPAX | | | |
| FROVATRIPTAN SUCCINATE | FROVA | | | |
| NARATRIPTAN HCL | AMERGE | | | |
| RIZATRIPTAN BENZOATE | MAXALT, MAXALT MLT | | | |
| SUMATRIPTAN | IMITREX NASAL SPRAY | | | |
| SUMATRIPTAN SUCCINATE | ALSUMA, IMITREX, SUMAVEL DOSEPRO | | | |
| SUMATRIPTAN SUCC/NAPROXEN SOD | TREXIMET | | | |
| ZOLMITRIPTAN | ZOMIG, ZOMIG ZMT | | | |

### GUIDELINES FOR USE

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.

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Effective: 05/22/20

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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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 an 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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**PRIOR AUTHORIZATION GUIDELINES**

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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

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Effective: 10/16/20

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## PRIOR AUTHORIZATION GUIDELINES

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## BEMPEDOIC ACID AND EZETIMIBE

| Generic | Brand | | | |
|---|---|---|---|---|
| BEMPEDOIC ACID AND EZETIMIBE | NEXLIZET | | | |

### GUIDELINES FOR USE

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

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 an 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)

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**PRIOR AUTHORIZATION GUIDELINES**

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## 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

### RENEWAL CRITERIA

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

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Effective: 10/16/20

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RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## CINACALCET

| Generic | Brand | | | |
|---|---|---|---|---|
| CINACALCET | SENISPAR | | | |

### GUIDELINES FOR USE

The guideline named **CINACALCET (SENSIPAR)** requires that the patient is 18 years of age or older and has one of the following diagnoses. Additional guideline requirements may apply.

- Parathyroid carcinoma.
- Primary hyperparathyroidism and is unable to undergo parathyroidectomy.
- Secondary hyperparathyroidism
  - Has chronic kidney disease (CKD) and is on dialysis.
  - Has an intact parathyroid hormone (iPTH) level that was at least 2 times the upper limit of normal as defined by the laboratory reference values measured on TWO separate occasions.
  - Has tried and had an inadequate response to, intolerance to, or has a contraindication to one phosphate binder (e.g. PhosLo, Fosrenol, Renvela, Renagel, etc.) AND one vitamin D analog (e.g., calcitriol, doxercalciferol, paricalcitol, etc.)

**The medication will not be approved** if the patient has hypocalcemia (serum calcium less than the lower limit of the normal laboratory reference range).

**Renewal of therapy** requires the patient experience a reduction in serum calcium from baseline with cinacalcet (Sensipar) therapy.

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Effective: 05/01/19

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## CONTINUOUS GLUCOSE MONITORS

| Generic | Brand | | | |
|---|---|---|---|---|
| BLOOD-GLUCOSE METER, CONTINUOUS | DEXCOM, DEXCOM G4, DEXCOM G5, DEXCOM G6 | | | |
| BLOOD-GLUCOSE TRANSMITTER | DEXCOM G4, DEXCOM G5, DEXCOM G6 | | | |
| BLOOD-GLUCOSE SENSOR | DEXCOM G6, DEXCOM G5-G4 SENSOR | | | |
| FLASH GLUCOSE SCANNING READER | FREESTYLE LIBRE READER FREESTYLE LIBRE 2 READER | | | |
| FLASH GLUCOSE SENSOR | FREESTYLE LIBRE SENSOR FREESTYLE LIBRE 2 SENSOR | | | |

### GUIDELINES FOR USE

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

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Effective: 09/01/20

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## PRIOR AUTHORIZATION GUIDELINES

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## CONTOUR TEST STRIPS (INSULIN PUMP)

| Generic | Brand | | | |
|---|---|---|---|---|
| BLOOD SUGAR DIAGNOSTIC<br>BLOOD SUGAR DIAGNOSTIC, DISC<br>BLOOD SUGAR DIAGNOSTIC, DRUM | CONTOUR TEST STRIPS | | | |

### GUIDELINES FOR USE

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, Abbott (Freestyle and Precision Xtra), or Lifescan (One Touch).

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Effective: 05/01/20

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### CYCLOSPORINE OPHTHALMIC

| Generic | Brand | | | |
|---|---|---|---|---|
| CYCLOSPORINE OPHTHALMIC | RESTASIS | | | |
| CYCLOSPORINE OPHTHALMIC | CEQUA | | | |

### GUIDELINES FOR USE

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.

**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.
- 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.

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## DIROXIMEL FUMARATE

| Generic | Brand | | | |
|---|---|---|---|---|
| DIROXIMEL FUMARATE | VUMERITY | | | |

### GUIDELINES FOR USE

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, Extavia, Rebif, Plegridy

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Effective: 12/16/19

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## PRIOR AUTHORIZATION GUIDELINES

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## EMTRICITABINE/TENOFOVIR ALAFENAMIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| EMTRICITABINE-TENOFOVIR ALAFENAMIDE | DESCOVY | | | |

### GUIDELINES FOR USE

Our guideline named **EMTRICITABINE-TENOFOVIR ALAFENAMIDE (Descovy)** requires (Descovy) the following rules be met for approval (select only one of the following):

**HIV Infection**

A. You have a have a diagnosis of HIV infection
B. You are being prescribed other antiretroviral medications in addition to Descovy
C. You weigh greater than or equal to 25 kg
D. If you recently started HIV treatment, you must first use Truvada, or its generic equivalent, unless there is medical justification supporting why you cannot use that product

**PrEP**

A. You do NOT have a diagnosis of HIV and you have no signs or symptoms of active HIV infection
B. You are considered high risk for acquiring HIV infection
C. You weigh greater than or equal to 35 kg
D. You must first use Truvada, or its generic equivalent, unless there is medical justification supporting why you cannot use that product

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Effective: 01/08/21

## PRIOR AUTHORIZATION GUIDELINES

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## ENDOTHELIN RECEPTOR ANTAGONISTS

| Generic | Brand | | | |
|---|---|---|---|---|
| BOSENTAN | TRACLEER | | | |
| AMBRISENTAN | LETAIRIS | | | |
| MACITENTAN | OPSUMIT | | | |

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

### GUIDELINES FOR USE

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

### LETAIRIS

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)

### TRACLEER

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

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## ENDOTHELIN RECEPTOR ANTAGONISTS

### INITIAL CRITERIA (CONTINUED)

### OPSUMIT

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

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 Word 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).

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## EPTINEZUMAB-JJMR (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| EPTINEZUMAB-JJMR | VYEPTI | | | |

### GUIDELINES FOR USE

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

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

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

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## ERYTHROPOIESIS STIMULATING AGENTS

| Generic | Brand | | | |
|---|---|---|---|---|
| EPOETIN ALFA | PROCRIT | | | |
| EPOETIN ALFA-EPBX | RETACRIT | | | |

## GUIDELINES FOR USE

## INITIAL CRITERIA FOR PROCRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

**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

### INITIAL CRITERIA FOR RETACRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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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## PRIOR AUTHORIZATION GUIDELINES

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR PROCRIT

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 required 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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## PRIOR AUTHORIZATION GUIDELINES

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## ERYTHROPOIESIS STIMULATING AGENTS

### RENEWAL CRITERIA FOR RETACRIT

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 required 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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Effective: 02/14/20

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## EVOLOCUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| EVOLOCUMAB | REPATHA SYRINGE<br>REPATHA SURECLICK<br>REPATHA<br>PUSHTRONEX | | | |

### GUIDELINES FOR USE

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

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rule(s) be met for approval:

A. You have a diagnosis of established cardiovascular disease (health issues related to heart and blood vessels) 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 the aorta), carotid plaque with 50% or more stenosis (narrowing of blood vessel), **OR** primary hyperlipidemia (high cholesterol) such as heterozygous familial hypercholesterolemia (HeFH, type of inherited high cholesterol), **OR** homozygous familial hypercholesterolemia (HoFH, type of inherited high cholesterol)

B. The medication is prescribed by or recommended by a cardiologist (heart doctor), endocrinologist (hormone doctor) or lipidologist (cholesterol management doctor)

C. You have an LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL while on maximally tolerated statin treatment

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**PRIOR AUTHORIZATION GUIDELINES**

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**EVOLOCUMAB**

**INITIAL CRITERIA (CONTINUED)**

D. **If you are statin tolerant, approval also requires** you will continue statin treatment in combination with Repatha. You must also meet **ONE** of the following criteria:
   1. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for at least 8 weeks
   2. You have been taking a maximally tolerated dose of any statin for at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

E. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (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, 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

F. **If you have established cardiovascular disease, approval also requires you are** 18 years of age or older

G. **If you have primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), approval also requires:**
   1. You are 18 years of age or older
   2. The diagnosis is determined by Simon Broome diagnostic criteria (definite) **OR** Dutch Lipid Network criteria with a score of 6 or greater

H. **For patients with homozygous familial hypercholesterolemia (HoFH), the diagnosis must be determined by meeting ONE of the following criteria:**
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of 8 or greater
   3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein) - 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 (type of inherited high cholesterol) in both parents

**CONTINUED ON NEXT PAGE**

## PRIOR AUTHORIZATION GUIDELINES

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## EVOLOCUMAB

### RENEWAL CRITERIA

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rules be met for renewal:

A. You have a diagnosis of established cardiovascular disease (health issues related to heart and blood vessels), primary hyperlipidemia (high cholesterol such heterozygous familial hypercholesterolemia), or homozygous familial hypercholesterolemia (type of inherited high cholesterol)
B. You meet **ONE** of the following:
    1. You have continued to take a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) with the requested medication
    2. You have continued therapy with a maximally tolerated dose of any statin with the requested medication
    3. You have an absolute contraindication (medical reason why you cannot use) to statin therapy
    4. You have complete statin intolerance

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Effective: 10/16/20

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## PRIOR AUTHORIZATION GUIDELINES

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## FREMANEZUMAB-VFRM

| Generic | Brand | | | |
|---|---|---|---|---|
| FREMANEZUMAB-VFRM | AJOVY | | | |

### GUIDELINES FOR USE

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

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

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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Effective: 05/27/19

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## PRIOR AUTHORIZATION GUIDELINES

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## GLATIRAMER ACETATE

| Generic | Brand | | | |
|---|---|---|---|---|
| GLATIRAMER ACETATE | COPAXONE, GLATOPA | | | |

### GUIDELINES FOR USE

The guideline named **GLATIRAMER ACETATE (Copaxone)** requires a diagnosis of a relapsing form of multiple sclerosis.

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Effective: 01/01/18

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### GLECAPREVIR/PIBRENTASVIR

| Generic | Brand | | | |
|---|---|---|---|---|
| GLECAPREVIR/ PIBRENTASVIR | MAVYRET | | | |

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:
  - The patient is post liver transplant with no cirrhosis and is treatment naive or treatment experienced
  - The patient is post kidney transplant with no cirrhosis or compensated cirrhosis and is treatment naïve or treatment experienced
  - The patient is treatment naïve with no cirrhosis or with compensated cirrhosis
  - 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)
  - 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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Effective: 11/20/19

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## PRIOR AUTHORIZATION GUIDELINES

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## GRANULOCYTE COLONY-STIMULATING FACTORS

| Generic | Brand | | | |
|---|---|---|---|---|
| FILGRASTIM-AAFI | NIVESTYM | | | |
| FILGRASTIM-SNDZ | ZARXIO | | | |
| PEGFILGRASTIM | NEULASTA | | | |
| PEGFILGRASTIM-JMDB | FULPHILA | | | |
| PEGFILGRASTIM-BMEZ | ZIEXTENZO | 46183 | | ≠ UDENYCA |

### GUIDELINES FOR USE

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 Ziextenzo 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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Effective: 01/08/21

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## PRIOR AUTHORIZATION GUIDELINES

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## HYALURONATE

| Generic | Brand | | | |
|---|---|---|---|---|
| HYALURONATE SODIUM | EUFLEXXA, ORTHOVISC | | | |
| HYALURONATE SODIUM, STABILIZED | MONOVISC | | | |

### GUIDELINES FOR USE

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 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

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Effective: 08/16/19

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## PRIOR AUTHORIZATION GUIDELINES

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## INFLIXIMAB-ABDA

| Generic | Brand | | | |
|---|---|---|---|---|
| INFLIXIMAB-ABDA | RENFLEXIS | | | |

### GUIDELINES FOR USE

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

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).

**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**

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## 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

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## INFLIXIMAB-ABDA

### RENEWAL CRITERIA

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

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Effective: 05/27/19

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## PRIOR AUTHORIZATION GUIDELINES

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## LEDIPASVIR/SOFOSBUVIR

| Generic | Brand | | | |
|---|---|---|---|---|
| LEDIPASVIR/SOFOSBUVIR | HARVONI | | | |

### GUIDELINES FOR USE

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 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 the requested medication will be taken in combination 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

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## PRIOR AUTHORIZATION GUIDELINES

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## LEDIPASVIR/SOFOSBUVIR

**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

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Effective: 07/06/20

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## PRIOR AUTHORIZATION GUIDELINES

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## LIFITEGRAST

| Generic | Brand | | | |
|---|---|---|---|---|
| LIFITEGRAST | XIIDRA | | | |

### GUIDELINES FOR USE

The guideline named **LIFITEGRAST (XIIDRA)** requires that the patient has a diagnosis of suppressed tear production due to ocular inflammation. In addition, the patient must meet ALL the following criteria for approval:

- Patient is aged 17 years or older.
- The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
- The patient will not be using concurrently with Restasis.
- 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.

**For renewal of therapy,** the patient must have experienced an objective response to Xiidra therapy such as an increase in tear production or a decrease in dry eye symptoms.

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Effective: 01/08/21

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## PRIOR AUTHORIZATION GUIDELINES

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## METHYLNALTREXONE

| Generic | Brand | | | |
|---|---|---|---|---|
| METHYLNALTREXONE BROMIDE | RELISTOR | | | |

### GUIDELINES FOR USE

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

Effective: 10/02/20

WELLFLEET
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## PRIOR AUTHORIZATION GUIDELINES

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## MONOMETHYL FUMARATE

| Generic | Brand | | | |
|---|---|---|---|---|
| MONOMETHYL FUMARATE | BAFIERTAM | | | |

### GUIDELINES FOR USE

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
C. You have trialed and failed either generic glatiramer or dimethyl fumarate

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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Effective: 01/08/21

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## PRIOR AUTHORIZATION GUIDELINES

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### OMALIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| OMALIZUMAB | XOLAIR | | | |

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

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
- Patient 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:
  - 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

**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:
  - Asthma Control Test (ACT) score of less than 20
  - Asthma Control Questionnaire (ACQ) score of at least 1.5
  - Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1

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**PRIOR AUTHORIZATION GUIDELINES**

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## OMALIZUMAB (NSA)

### INITIAL CRITERIA (CONTINUED)

- 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

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

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## PRIOR AUTHORIZATION GUIDELINES

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## OCRELIZUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| OCRELIZUMAB | OCREVUS | | | |

### GUIDELINES FOR USE

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 (oral or injectable): Avonex, Gilenya, Plegridy, Rebif, Tecfidera, or glatiramer. Please note that other MS agents may also require prior authorization.

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Effective: 10/17/18

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## PRIOR AUTHORIZATION GUIDELINES

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### RIFAMYCIN

| Generic | Brand | | | |
|---|---|---|---|---|
| RIFAMYCIN | AEMCOLO | | | |

### GUIDELINES FOR USE

The guideline named **RIFAMYCIN (AEMCOLO)** requires a diagnosis of traveler's diarrhea (TD). The patient must also have a contraindication to **BOTH** azithromycin and ciprofloxacin. Aemcolo will not be approved if the patient has diarrhea complicated by fever or bloody stool.

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Effective: 05/01/19

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## PRIOR AUTHORIZATION GUIDELINES

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## RIFAXIMIN

| Generic | Brand | | | |
|---|---|---|---|---|
| RIFAXIMIN 200 MG<br>RIFAXIMIN 550 MG | XIFAXAN | | | |

### GUIDELINES FOR USE

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

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 currently on lactulose monotherapy
  - 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.

### RENEWAL CRITERIA

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).

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## PRIOR AUTHORIZATION GUIDELINES

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## SODIUM ZIRCONIUM CYCLOSILICATE

| Generic | Brand | | | |
|---|---|---|---|---|
| SODIUM ZIRCONIUM CYCLOSILICATE | LOKELMA | | | |

### GUIDELINES FOR USE

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

Effective: 07/01/19

## PRIOR AUTHORIZATION GUIDELINES

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## SOMATROPIN

| Generic | Brand | | | |
|---|---|---|---|---|
| SOMATROPIN | GENOTROPIN | | | |
| SOMATROPIN | NORDITROPIN FLEXPRO | | | |
| SOMATROPIN | SEROSTIM | | | |
| SOMATROPIN | ZORBTIVE | | | |

**GUIDELINES FOR USE**

**NOTE: Please use the criteria for the specific drug requested.**

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

**SEROSTIM**

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)
- 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:
  - Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
  - Diarrhea
  - Inadequate energy (caloric) intake
  - Malignancies
  - Opportunistic infections

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**PRIOR AUTHORIZATION GUIDELINES**

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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

**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:
  - 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)

**ZORBTIVE**

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

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**PRIOR AUTHORIZATION GUIDELINES**

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## SOMATROPIN

### INITIAL CRITERIA (CONTINUED)

### GENOTROPIN/NORDITROPIN

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)
- The patient meets at least **ONE** of the following criteria for short stature:
  - Patient's height is greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender
  - Height velocity less than the 25$^{th}$ percentile for age
  - 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)
- The patient's height is 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

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**PRIOR AUTHORIZATION GUIDELINES**

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## SOMATROPIN

### INITIAL CRITERIA - GENOTROPIN/NORDITROPIN (CONTINUED)

**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
- The patient's height is 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

### RENEWAL CRITERIA

**SEROSTIM**

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:
  - ≥ 10% increase in weight or BCM from baseline (**NOTE**: current and baseline weight must be documented including dates of measurement)
- The patient must be on HIV anti-retroviral therapy

**ZORBTIVE**

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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**PRIOR AUTHORIZATION GUIDELINES**

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## SOMATROPIN

### RENEWAL CRITERIA (CONTINUED)

### GENOTROPIN/NORDITROPIN

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

## PRIOR AUTHORIZATION GUIDELINES

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### TESTOSTERONE

| Generic | Brand | | | |
|---|---|---|---|---|
| TESTOSTERONE | ANDRODERM, ANDROGEL, AXIRON, STRIANT, TESTIM, VOGELXO | | | |
| TESTOSTERONE CYPIONATE | DEPO-TESTOSTERONE | | | |
| TESTOSTERONE ENANTHATE | DELATESTRYL, TESTOSTERONE ENANTHATE | | | |

### GUIDELINES FOR USE

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

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 also 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 (e.g., AndroGel 1%, AndroGel 1.62%, Axiron, Depo-Testosterone, intramuscular testosterone enanthate [Delatestryl])

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## PRIOR AUTHORIZATION GUIDELINES

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## TESTOSTERONE

### RENEWAL CRITERIA

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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Effective: 12/16/19

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## PRIOR AUTHORIZATION GUIDELINES

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## VEDOLIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| VEDOLIZUMAB | ENTYVIO | | | |

### GUIDELINES FOR USE

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

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

The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis for renewal.

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Effective: 04/01/20

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**PRIOR AUTHORIZATION GUIDELINES**

**AMINO ACID BASED AND ENTERAL FORMULAS**

| Generic | STC Description |
|---|---|
| | PARENTERAL AMINO ACID SOLUTIONS AND COMBINATIONS |
| | PROTEIN REPLACEMENT |
| | NUTRITIONAL THERAPY, MED COND SPECIAL FORMULATION |

## GUIDELINES FOR USE

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-medicated 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.

## 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

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**PRIOR AUTHORIZATION GUIDELINES**

**SAXENDA**

| Generic | Brand |
|---|---|
| LIRAGLUTIDE | SAXENDA |

**GUIDELINES FOR USE**

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

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/$m^2$ or greater **OR**
  - BMI of 27 kg/$m^2$ 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

**RENEWAL CRITERIA**

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.

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## PRIOR AUTHORIZATION GUIDELINES

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## AMINO ACID BASED AND ENTERAL FORMULAS

| Generic | Brand | | | |
|---|---|---|---|---|
| ENTERAL FORMULAS | VARIOUS | | | |
| INFANT FORMULAS | VARIOUS | | | |

## GUIDELINES FOR USE

The guideline named **AMINO ACID BASED AND ENTERAL FORMULAS** requires a diagnosis of malabsorption of food caused by one of the following: Crohn's disease; ulcerative colitis; gastroesophageal reflux (GERD); gastrointestinal motility; chronic intestinal pseudo-obstruction; phenylketonuria (PKU); eosinophilic gastrointestinal disorders; inherited diseases of amino acids and organic acids; multiple severe food allergies; branded-chain ketonuria; galactosemia; homocystinuria; immunoglobulin E and non-immunoglobulin E mediated allergies to multiple food proteins; severe food protein-induced enterocolitis syndrome; eosinophilic disorders, as evidenced by the results of the biopsy; and impaired absorption of nutrients caused by the disorders affecting the absorptive surface, functional length, and motility of the gastrointestinal tract.

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Effective: 07/17/20

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## PRIOR AUTHORIZATION GUIDELINES

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## ELUXADOLINE

| Generic | Brand | | | |
|---|---|---|---|---|
| ELUXADOLINE | VIBERZI | | | |

### GUIDELINES FOR USE

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

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)

### RENEWAL CRITERIA

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:

- The patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
- 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)

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Effective: 11/15/19

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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### IMMUNE GLOBULIN

| Generic | Brand | | | |
|---|---|---|---|---|
| IMMUNE GLOBULIN | BIVIGAM, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA | | | |
| IMMUNE GLOB, GAM CAPRYLATE | GAMUNEX-C, GAMMAKED | | | |
| IMMUNE GLOBULIN / MALTOSE | OCTAGAM | | | |
| IGG/HYALURONIDASE, RECOMBINANT | HYQVIA | | | |
| IMMUN GLOB G(IGG)/GLY/IGA OV50 | CUVITRU | | | |
| IMMUN GLOB G(IGG)-IFAS/GLYCINE | PANZYGA | | | |
| IMMUN GLOB G(IGG)-HIPP/MALTOSE | CUTAQUIG | | | |
| IMMUNE GLOBULIN (HUMAN)-KLHW | XEMBIFY | | | |

**This drug must be reviewed by a pharmacist.**

**GUIDELINES FOR USE**

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:
- Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
- Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
- Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
- Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)
- Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
- 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)
- Guillain-Barre Syndrome (immune system attacks the nerves)

- Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
- Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
- Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation) related to a solid organ transplant
- Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)-infected child
- Reduction of secondary infections in pediatric HIV infections
- Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
- Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
- Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
- IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
- Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
- Neonatal sepsis (blood infection in infants)
- Rotaviral enterocolitis (severe diarrhea among infants and young children)
- Toxic shock syndrome (life-threatening complication of certain bacterial infections)
- Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
- Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
- 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
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
- Pediatric acute-onset neuropsychiatric syndrome (PANS)

B. **For Gamastan S-D, approval requires:**
- 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:**
- 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) 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:**

**PRIOR AUTHORIZATION GUIDELINES**

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- You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

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Effective: 05/22/20

WELLFLEET
RX PLAN

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

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**ESKETAMINE (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| ESKETAMINE | SPRAVATO | | | |

**GUIDELINES FOR USE**

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

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Treatment-resistant depression (TRD: no improvement in depression symptoms after treatment within a certain amount of time)
   2. Major depressive disorder (MDD: clinical depression or low mood)

B. **If you have treatment-resistant depression (TRD), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used in combination with an oral antidepressant
   3. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
   4. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
   5. You do NOT have active substance abuse
   6. 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)

C. **If you have major depressive disorder (MDD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
   3. You have acute suicidal ideation or behavior (thoughts of killing yourself)
   4. The requested medication will be used in combination with an oral antidepressant
   5. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
   6. You do NOT have active substance abuse



Revised: 12/17/2020

**ESKETAMINE (NSA)**

**GUIDELINES FOR USE (CONTINUED)**

**RENEWAL CRITERIA**

Our guideline named **ESKETAMINE (Spravato)** requires the following rule(s) be met for renewal:

A. You have treatment-resistant depression (TRD: no improvement in depression symptoms after treatment within a certain amount of time) OR major depressive disorder (MDD: clinical depression or low mood)
B. You have demonstrated clinical benefit (improvement in depression) compared to baseline

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Commercial Effective: 01/01/21



Revised: 12/17/2020

WELLFLEET
RX PLAN

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

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**ETEPLIRSEN (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| ETEPLIRSEN | EXONDYS 51 | | | |

**GUIDELINES FOR USE**

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

Our guideline named **ETEPLIRSEN (Exondys-51)** 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 documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 51 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

**RENEWAL CRITERIA**

Our guideline named **ETEPLIRSEN (Exondys-51)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## PRIOR AUTHORIZATION GUIDELINES

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## FINGOLIMOD

| Generic | Brand | | | |
|---|---|---|---|---|
| FINGOLIMOD | GILENYA | | | |

### GUIDELINES FOR USE

The guideline named **FINGOLIMOD (Gilenya)** requires a diagnosis of a 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 of either generic glatiramer or dimethyl fumarate. 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)

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Effective: 01/01/21

Revised: 10/06/2020

WELLFLEET
RX PLAN

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

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**GALCANEZUMAB-GNLM**

| Generic | Brand | | | |
|---|---|---|---|---|
| GALCANEZUMAB-GNLM | EMGALITY | | | |

**GUIDELINES FOR USE**

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

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:

A. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
D. **If you have episodic cluster headaches, approval also requires:**
   1. You are 18 years of age or older

**CONTINUED ON NEXT PAGE**



Revised: 12/17/2020

**GALCANEZUMAB-GNLM**

**GUIDELINES FOR USE (CONTINUED)**

**RENEWAL CRITERIA**

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
B. **If you have migraines, renewal also requires ONE of the following:**
    1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
    2. You have experienced a reduction in migraine severity with Emgality therapy
    3. You have experienced a reduction in migraine duration with Emgality therapy
C. **If you have episodic cluster headaches, renewal also requires:**
    1. You had improvement in episodic cluster headache frequency as compared to baseline

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Commercial Effective: 01/01/21



Revised: 12/17/2020

WELLFLEET
RX PLAN

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

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## GOLODIRSEN (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| GOLODIRSEN | VYONDYS-53 | | | | |

## GUIDELINES FOR USE

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

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 documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in 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)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

## RENEWAL CRITERIA

Our guideline named **GOLODIRSEN (Vyondys-53)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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

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**IMATINIB**

| Generic | Brand | | | |
|---|---|---|---|---|
| IMATINIB MESYLATE | GLEEVEC, IMATINIB MESYLATE | | | |

## GUIDELINES FOR USE

Our guideline named **IMATINIB (Gleevec)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia positive chronic myeloid leukemia (type of blood cell cancer that begins in bone marrow with an abnormal gene) in chronic phase
   2. Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
   3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer that has returned or did not respond to treatment)
   4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   5. Myelodysplastic/myeloproliferative disease (a group of diseases where the bone marrow makes too many white blood cells) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
   6. Aggressive systemic mastocytosis (a type of cell accumulates in internal tissues and organs) without D816V c-Kit mutation or with c-Kit mutational status unknown
   7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (type of inflammatory cancer)
   8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (type of rare skin tumor that cannot be completely removed by surgery or returns/ spreads)
   9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (tumor in stomach/intestines that spreads or cannot be removed by surgery) with a Kit (CD117) positive
   10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor

B. **If you are newly diagnosed with Philadelphia positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)



Revised: 12/17/2020

**IMATINIB**

**GUIDELINES FOR USE (CONTINUED)**

C. **If you have Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

D. **If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of age or older

A. **If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. The requested medication will be used in combination with chemotherapy

B. **If you have myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, approval also requires:**
   1. You are 18 years of age or older

C. **If you have aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, approval also requires:**
   1. You are 18 years of age or older

D. **If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:**
   1. You are 18 years of age or older

E. **If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:**
   1. You are 18 years of age or older

F. **If the request is for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You are 18 years of age or older

G. **If you have gastrointestinal stromal tumor, approval also requires:**
   1. For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 (type of gene) mutation (a permanent change in your DNA that make up your gene)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## INTERFERONS FOR MULTIPLE SCLEROSIS

| Generic | Brand | | | |
|---|---|---|---|---|
| INTERFERON BETA-1A | AVONEX,<br>AVONEX PEN | | | |
| INTERFERON BETA-1A /ALBUMIN | AVONEX ADMINISTRATION PACK,<br>REBIF,<br>REBIF REBIDOSE | | | |
| INTERFERON BETA-1B | BETASERON | | | |
| PEGINTERFERON BETA-1A | PLEGRIDY,<br>PLEGRIDY PEN | | | |

## GUIDELINES FOR USE

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 in patients 18 years of age or older disease AND meet the following criteria:

- The patient is 18 years of age or older
- The patient has trialed and failed either generic glatiramer or dimethyl fumarate.

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Effective: 01/01/21

Revised: 10/06/2020

WELLFLEET
RX PLAN

**STANDARD COMMERCIAL DRUG FORMULARY**
**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 have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You are 4 months of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert
D. You are NOT homozygous (have 2 copies of the same gene) for the F508del mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
E. If you are between 4 months and less than 6 years of age, **Ivacaftor packets** will be approved. Documentation of your weight is required
F. You have documentation of ONE of the following mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene:

| | | | | |
|---|---|---|---|---|
| *711+3A→G* | *F311del* | *I148T* | *R75Q* | *S589N* |
| *2789+5G→A* | *F311L* | *I175V* | *R117C* | *S737F* |
| *3272-26A→G* | *F508C* | *I807M* | *R117G* | *S945L* |
| *3849+10kbC→T* | *F508C; S1251N* | *I1027T* | *R117H* | *S977F* |
| *A120T* | *F1052V* | *I1139V* | *R117L* | *S1159F* |
| *A234D* | *F1074L* | *K1060T* | *R117P* | *S1159P* |
| *A349V* | *G178E* | *L206W* | *R170H* | *S1251N* |
| *A455E* | *G178R* | *L320V* | *R347H* | *S1255P* |
| *A1067T* | *G194R* | *L967S* | *R347L* | *T338I* |
| *D110E* | *G314E* | *L997F* | *R352Q* | *T1053I* |
| *D110H* | *G551D* | *L1480P* | *R553Q* | *V232D* |
| *D192G* | *G551S* | *M152V* | *R668C* | *V562I* |
| *D579G* | *G576A* | *M952I* | *R792G* | *V754M* |
| *D924N* | *G970D* | *M952T* | *R933G* | *V1293G* |
| *D1152H* | *G1069R* | *P67L* | *R1070Q* | *W1282R* |
| *D1270N* | *G1244E* | *Q237E* | *R1070W* | *Y1014C* |
| *E56K* | *G1249R* | *Q237H* | *R1162L* | *Y1032C* |
| *E193K* | *G1349D* | *Q359R* | *R1283M* | |
| *E822K* | *H939R* | *Q1291R* | *S549N* | |
| *E831X* | *H1375P* | *R74W* | *S549R* | |



Revised: 12/17/2020

WELLFLEET
RX PLAN

**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)

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Commercial Effective: 02/01/21



Revised: 12/17/2020

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

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## BELANTAMAB MAFODOTIN-BLMF (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| BELANTAMAB MAFODOTIN-BLMF | BLENREP | | | | |

## GUIDELINES FOR USE

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)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

WELLFLEET
RX PLAN

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

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## BREXUCABTAGENE AUTOLEUCEL (NSA)

| Generic | Brand | | | | Exception/Other |
|---|---|---|---|---|---|
| BREXUCABTAGENE AUTOLEUCEL | TECARTUS | | | | |

## GUIDELINES FOR USE

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

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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# BUDESONIDE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| BUDESONIDE | ORTIKOS | | | | |

## GUIDELINES FOR USE

Our guideline named **BUDESONIDE (Ortikos)** requires the following rule(s) be met for approval:

A. You have mild to moderate Crohn's Disease (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
   2. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product
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)
   3. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## C1 ESTERASE INHIBITOR

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| C1 ESTERASE INHIBITOR | BERINERT, CINRYZE HAEGARDA | | | | |
| C1 ESTERASE INHIBITOR, RECOMBINANT | RUCONEST | | | | |

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

### GUIDELINES FOR USE

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

### CINRYZE

Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. You are 6 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Cinryze together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, danazol, berotralstat)

### HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. You are 6 years of age or older

***(Initial HAEGARDA criteria continued on the next page)***



Revised: 12/17/2020

## C1 ESTERASE INHIBITOR

### INITIAL CRITERIA - HAEGARDA (CONTINUED)

D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Haegarda together with an alternative preventive agent for HAE (such as Takhzyro, Cinryze, danazol, berotralstat)

### BERINERT

Our guideline named **C1 ESTERASE INHIBITOR (Berinert)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

### RUCONEST

Our guideline named **C1 ESTERASE INHIBITOR (Ruconest)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

**CONTINUED ON NEXT PAGE**

# C1 ESTERASE INHIBITOR

## GUIDELINES FOR USE (CONTINUED)

## RENEWAL CRITERIA

**NOTE: For requests of Berinert or Ruconest, please refer to the initial criteria section.**

### CINRYZE

Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

### HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in HAE attacks

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## CANNABIDIOL

| Generic | Brand | | | |
|---|---|---|---|---|
| CANNABIDIOL | EPIDIOLEX | | | |

## GUIDELINES FOR USE

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

Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
   2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
   3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

B. **If you have seizures associated with Dravet syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried clobazam AND valproic acid derivative, unless there is a medical reason why you cannot (contraindication)

C. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried TWO of the following, unless there is a medical reason why you cannot (contraindication): clobazam, valproic acid derivative, topiramate, lamotrigine

D. **If you have seizures associated with tuberous sclerosis complex, approval also requires:**
   1. You are 1 year of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. You have previously tried TWO anti-epileptic medications (drugs to treat seizures) such as clobazam, valproic acid derivative, topiramate, lamotrigine, unless there is a medical reason why you cannot (contraindication)

## RENEWAL CRITERIA

Our guideline named **CANNABIDIOL (Epidiolex)** requires the following rule to be met for renewal:

A. You have ONE of the following diagnoses:



Revised: 12/17/2020

1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

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Commercial Effective: 01/01/21

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## PRIOR AUTHORIZATION GUIDELINES

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## CLADRIBINE

| Generic | Brand | | HICL | GCN | Exception/Other |
|---|---|---|---|---|---|
| CLADRIBINE | MAVENCLAD | | | | |

### GUIDELINES FOR USE

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

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:

A. You have a diagnosis of a relapsing form of multiple sclerosis (disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. You are 18 years of age or older
C. You have had a trial and failure of generic glatiramer or dimethyl fumarate

### RENEWAL CRITERIA

Our guideline named **CLADRIBINE (Mavenclad)** requires the following rule(s) be met for approval:

A. You have a diagnosis of a relapsing form of multiple sclerosis (disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. Your physician attests/ confirms that you have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
D. You have not received a total of two years of Mavenclad treatment

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Effective: 01/01/21

Revised: 10/06/2020

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## DECITABINE/CEDAZURIDINE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| DECITABINE/ CEDAZURIDINE | INQOVI | | | | |

## GUIDELINES FOR USE

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

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## PRIOR AUTHORIZATION GUIDELINES

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## DIMETHYL FUMARATE

| Generic | Brand | | | |
|---|---|---|---|---|
| DIMETHYL FUMARATE | TECFIDERA | | | |

### GUIDELINES FOR USE

Our guideline named **DIMETHYL FUMARATE (Tecfidera)** 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), which includes 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
C. You have trialed and failed generic glatiramer

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Effective: 01/01/21

Revised: 10/06/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## ELAGOLIX/ESTRADIOL/NORETHINDRONE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| ELAGOLIX AND ESTRADIOL AND NORETHINDRONE | ORIAHNN | | | | |

### GUIDELINES FOR USE

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

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHINDRONE (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 18 years of age or older
C. You are a premenopausal woman
D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
E. You have not received a total of 24 months cumulative treatment with Oriahnn

### RENEWAL CRITERIA

Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You had improvement of heavy menstrual bleeding on therapy
C. You have not received a total of 24 months cumulative treatment with Oriahnn

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR | TRIKAFTA | | | | |

## GUIDELINES FOR USE

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

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (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. Therapy is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert
D. You meet ONE of the following:
   1. 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
   2. Documentation that you have at least one of the following mutations in the CFTR gene:

| | | | | | |
|---|---|---|---|---|---|
| *3141del9* | *E822K* | *G1069R* | *L967S* | *R117L* | *S912L* |
| *546insCTA* | *F191V* | *G1244E* | *L997F* | *R117P* | *S945L* |
| *A46D* | *F311del* | *G1249R* | *L1077P* | *R170H* | *S977F* |
| *A120T* | *F311L* | *G1349D* | *L1324P* | *R258G* | *S1159F* |
| *A234D* | *F508C* | *H139R* | *L1335P* | *R334L* | *S1159P* |
| *A349V* | *F508C; S1251N* | *H199Y* | *L1480P* | *R334Q* | *S1251N* |
| *A455E* | *F508del* | *H939R* | *M152V* | *R347H* | *S1255P* |
| *A554E* | *F575Y* | *H1054D* | *M265R* | *R347L* | *T338I* |
| *A1006E* | *F1016S* | *H1085P* | *M952I* | *R347P* | *T1036N* |
| *A1067T* | *F1052V* | *H1085R* | *M952T* | *R352Q* | *T1053I* |
| *D110E* | *F1074L* | *H1375P* | *M1101K* | *R352W* | *V201M* |
| *D110H* | *F1099L* | *I148T* | *P5L* | *R553Q* | *V232D* |
| *D192G* | *G27R* | *I175V* | *P67L* | *R668C* | *V456A* |
| *D443Y* | *G85E* | *I336K* | *P205S* | *R751L* | *V456F* |
| *D443Y; G576A; R668C* | *G126D* | *I502T* | *P574H* | *R792G* | *V562I* |
| *D579G* | *G178E* | *I601F* | *Q98R* | *R933G* | *V754M* |



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| | | | | | |
|---|---|---|---|---|---|
| *D614G* | *G178R* | *I618T* | *Q237E* | *R1066H* | *V1153E* |
| *D836Y* | *G194R* | *I807M* | *Q237H* | *R1070Q* | *V1240G* |
| *D924N* | *G194V* | *I980K* | *Q359R* | *R1070W* | *V1293G* |
| *D979V* | *G314E* | *I1027T* | *Q1291R* | *R1162L* | *W361R* |
| *D1152H* | *G463V* | *I1139V* | *R31L* | *R1283M* | *W1098C* |
| *D1270N* | *G480C* | *I1269N* | *R74Q* | *R1283S* | *W1282R* |
| *E56K* | *G551D* | *I1366N* | *R74W* | *S13F* | *Y109N* |
| *E60K* | *G551S* | *K1060T* | *R74W; D1270N* | *S341P* | *Y161D* |
| *E92K* | *G576A* | *L15P* | *R74W; V201M* | *S364P* | *Y161S* |
| *E116K* | *G576A; R668C* | *L165S* | *R74W; V201M; D1270N* | *S492F* | *Y563N* |
| *E193K* | *G622D* | *L206W* | *R75Q* | *S549N* | *Y1014C* |
| *E403D* | *G628R* | *L320V* | *R117C* | *S549R* | *Y1032C* |
| *E474K* | *G970D* | *L346P* | *R117G* | *S589N* | |
| *E588V* | *G1061R* | *L453S* | *R117H* | *S737F* | |

**RENEWAL CRITERIA**

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (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)

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Commercial Effective: 02/01/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**EPOPROSTENOL IV (NSA)**

| Generic | Brand | Exception/Other |
|---|---|---|
| EPOPROSTENOL SODIUM (GLYCINE) | FLOLAN, EPOPROSTENOL SODIUM | |
| EPOPROSTENOL SODIUM (ARGININE) | VELETRI, EPOPROSTENOL SODIUM | |

## GUIDELINES FOR USE

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

Our guideline named **EPOPROSTENOL (Flolan, Veletri)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

## RENEWAL CRITERIA

Our guideline named **EPOPROSTENOL (Flolan, Veletri)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable in the 6-minute walk distance test AND your World Health Organization functional class has remained stable or improved (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

## RATIONALE

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

## REFERENCES


- Flolan [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; November 2019.

- Veletri [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc; January 2021.

Commercial Effective: 02/05/21

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

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# ERENUMAB-AOOE

| Generic | Brand | | | |
|---|---|---|---|---|
| ERENUMAB-AOOE | AIMOVIG | | | |

## GUIDELINES FOR USE

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

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Aimovig is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

## RENEWAL CRITERIA

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:

A. Aimovig is being prescribed for preventive treatment of migraines.
B. You meet **ONE** of the following criteria:
   1. You have experienced less migraines or headache attacks by at least 2 days per month with Aimovig therapy
   2. You have experienced a lessening in migraine severity with Aimovig therapy
   3. You have experienced a lessening in migraine duration with Aimovig therapy

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## TAFASITAMAB-CXIX (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| TAFASITAMAB-CXIX | MONJUVI | | | | |

## GUIDELINES FOR USE

Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of white blood cancer that has returned or did not respond to previous treatment)
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)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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

## TEPOTINIB (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| TEPOTINIB HCL | TEPMETKO | |

## GUIDELINES FOR USE

Our guideline named **TEPOTINIB (Tepmetko)** requires the following rule(s) be met for approval:

A. You have metastatic non-small cell lung cancer (NSCLC)
B. You are 18 years of age or older
C. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

## RATIONALE

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

## REFERENCES


- Tepmetko [Prescribing Information]. Rockland, MA: EMD Serono, Inc.; February 2021.


Commercial Effective: 02/12/21

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## PRIOR AUTHORIZATION GUIDELINES

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## TERIFLUNOMIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| TERIFLUNOMIDE | AUBAGIO | | | |

Our guideline named **TERIFLUNOMIDE (Aubagio)** requires the following rule(s) be met for approval:

A. You have a diagnosis of a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have had a trial and failure of generic glatiramer or dimethyl fumarate

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Effective: 01/01/21

Revised: 10/06/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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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 have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
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:

| | | | | | |
|---|---|---|---|---|---|
| 546insCTA | E92K | G576A | L346P | R117G | S589N |
| 711+3A→G | E116K | G576A; R668C | L967S | R117H | S737F |
| 2789+5G→A | E193K | G622D | L997F | R117L | S912L |
| 3272-26A→G | E403D | G970D | L1324P | R117P | S945L |
| 3849+10kbC→T | E588V | G1069R | L1335P | R170H | S977F |
| A120T | E822K | G1244E | L1480P | R258G | S1159F |
| A234D | E831X | G1249R | M152V | R334L | S1159P |
| A349V | F191V | G1349D | M265R | R334Q | S1251N |
| A455E | F311del | H939R | M952I | R347H | S1255P |
| A554E | F311L | H1054D | M952T | R347L | T338I |
| A1006E | F508C | H1375P | P5L | R347P | T1036N |
| A1067T | F508C; S1251N | I148T | P67L | R352Q | T1053I |
| D110E | F508del | I175V | P205S | R352W | V201M |
| D110H | F575Y | I336K | Q98R | R553Q | V232D |
| D192G | F1016S | I601F | Q237E | R668C | V562I |



Revised: 12/17/2020

| | | | | | |
|---|---|---|---|---|---|
| D443Y | F1052V | I618T | Q237H | R751L | V754M |
| D443Y; G576A; R668C | F1074L | I807M | Q359R | R792G | V1153E |
| D579G | F1099L | I980K | Q1291R | R933G | V1240G |
| D614G | G126D | I1027T | R31L | R1066H | V1293G |
| D836Y | G178E | I1139V | R74Q | R1070Q | W1282R |
| D924N | G178R | I1269N | R74W | R1070W | Y109N |
| D979V | G194R | I1366N | R74W; D1270N | R1162L | Y161S |
| D1152H | G194V | K1060T | R74W; V201M | R1283M | Y1014C |
| D1270N | G314E | L15P | R74W; V201M; D1270N | R1283S | Y1032C |
| E56K | G551D | L206W | R75Q | S549N | |
| E60K | G551S | L320V | R117C | S549R | |

**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)

A. 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)

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Commercial Effective: 02/01/21

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**STANDARD COMMERCIAL DRUG FORMULARY**
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# TRIHEPTANOIN

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| TRIHEPTANOIN | DOJOLVI | | | | |

## GUIDELINES FOR USE

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

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for approval:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. Your diagnosis is confirmed by documentation of at least TWO of the following:
   1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
   2. Low enzyme activity in cultured fibroblasts
   3. One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
D. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive tract doctor) or physician specialist in medical genetics/inherited metabolic disorders
E. You have previously tried commercial MCT oil (a medical food product) unless there is a medical reason you are unable to (contraindication)

## RENEWAL CRITERIA

Our guideline named **TRIHEPTANOIN (Dojolvi)** requires the following rule(s) be met for renewal:

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. You had a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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# UBROGEPANT

| Generic | Brand | | | |
|---|---|---|---|---|
| UBROGEPANT | UBRELVY | | | |

## GUIDELINES FOR USE

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

Our guideline named **UBROGEPANT (Ubrelvy)** 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 have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

## RENEWAL CRITERIA

Our guideline named **UBROGEPANT (Ubrelvy)** 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

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Commercial Effective: 01/01/21



Revised: 12/17/2020

WELLFLEET RX PLAN

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

**VERICIGUAT**

| Generic | Brand | Exception/Other |
|---|---|---|
| VERICIGUAT | VERQUVO | |

## GUIDELINES FOR USE

## INITIAL CRITERIA

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for approval:

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You are 18 years of age or older
D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Farxiga, Xigduo XR, Jardiance, Synjardy
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

## RENEWAL CRITERIA

Our guideline named **VERICIGUAT (Verquvo)** requires the following rule(s) be met for renewal:

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

## RATIONALE

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

## REFERENCES


- Verquvo [Prescribing Information]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2021.


Commercial Effective: 02/05/21

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MedImpact

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

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**VILTOLARSEN (NSA)**

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| VILTOLARSEN | VILTEPSO | | | | |

## GUIDELINES FOR USE

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

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 documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in 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)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)

## RENEWAL CRITERIA

Our guideline named **VILTOLARSEN (Viltepso)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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

# VOCLOSPORIN

| Generic | Brand | Exception/Other |
|---|---|---|
| VOCLOSPORIN | LUPKYNIS | |

## GUIDELINES FOR USE

## INITIAL CRITERIA

Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for approval:

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (doctor who specializes in the kidney)
D. The requested medication will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids)

## RENEWAL CRITERIA

Our guideline named **VOCLOSPORIN (Lupkynis)** requires the following rule(s) be met for renewal:

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

## RATIONALE

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

## REFERENCES


- Lupkynis [Prescribing Information]. Victoria, BC: Aurinia Pharmaceuticals Inc.; January 2021.


Commercial Effective: 02/05/21

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

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# LANADELUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| LANADELUMAB-FLYO | TAKHZYRO | | | |

## GUIDELINES FOR USE

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

Our guideline named **LANADELUMAB (Takhzyro)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Takhzyro together with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

## RENEWAL CRITERIA

Our guideline named **LANADELUMAB (Takhzyro)** requires the following rule(s) be met for renewal:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. You have experienced improvement (reductions in attack frequency or attack severity) compared to baseline in hereditary angioedema attacks

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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# LASMIDITAN

| Generic | Brand | Exception/Other |
|---|---|---|
| LASMIDITAN SUCCINATE | REYVOW | |

## GUIDELINES FOR USE

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

Our guideline named **LASMIDITAN (Reyvow)** 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 have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

## RENEWAL CRITERIA

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

## 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: 12/12/20
Created: 02/20
Client Approval: 12/20
P&T Approval: 01/20

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## LEVAMLODIPINE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| 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
C. You have tried and failed BOTH of the following unless there is a medical reason you are unable to (contraindication):
    1. TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine, nifedipine)
    2. TWO other antihypertensive agents from any of the following classes:
        a. Thiazides (such as hydrochlorothiazide, chlorothiazide)
        b. Angiotensin-converting enzyme inhibitors (such as lisinopril, enalapril)
        c. Angiotensin II receptor blockers (such as losartan, irbesartan)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## METOCLOPRAMIDE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| METOCLOPRAMIDE | GIMOTI | | | | |

## GUIDELINES FOR USE

Our guideline named **METOCLOPRAMIDE (Gimoti)** requires the following rule(s) be met for approval:

A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (disorder that causes delayed emptying of food from the stomach)
B. You are 18 years of age or older
C. You have previously tried or have a contraindication (medical reason why you cannot take) to metoclopramide ODT (orally disintegrating tablet)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## PRIOR AUTHORIZATION GUIDELINES

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## NATALIZUMAB (NSA)

| Generic | Brand | | | |
|---|---|---|---|---|
| NATALIZUMAB | TYSABRI | | | |

## GUIDELINES FOR USE

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

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 have previously tried **both** generic glatiramer and dimethyl fumarate

**CONTINUED ON NEXT PAGE**

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**PRIOR AUTHORIZATION GUIDELINES**

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# NATALIZUMAB (NSA)

## RENEWAL CRITERIA

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)

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Effective: 01/01/21

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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. Therapy 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

***(Initial criteria continued on next page)***

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Revised: 12/17/2020

**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. Therapy 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. Therapy 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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## 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

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Commercial Effective: 01/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

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**NITISINONE**

| Generic | Brand | | | |
|---|---|---|---|---|
| NITISINONE | ORFADIN, NITYR | | | |

**GUIDELINES FOR USE**

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

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for approval:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10 mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have previously tried generic nitisinone capsules unless there is a medical reason why you cannot (contraindication)

**RENEWAL CRITERIA**

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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## OPICAPONE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| OPICAPONE | ONGENTYS | | | | |

## GUIDELINES FOR USE

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)
    4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**OSIMERTINIB**

| Generic | Brand | | | |
|---|---|---|---|---|
| OSIMERTINIB MESYLATE | TAGRISSO | | | |

**GUIDELINES FOR USE**

Our guideline named **OSIMERTINIB (Tagrisso)** requires the following rule(s) be met for approval:

A. You have non-small cell lung cancer (type of lung cancer)
B. You are 18 years of age or older
C. **If you have metastatic non-small cell lung cancer (lung cancer that has spread throughout the body), approval also requires you meet ONE of the following:**
    1. You are positive for an epidermal growth factor receptor (EGFR) T790M (type of gene) mutation as confirmed by an FDA (Food and Drug Administration)-approved test AND meet all of the following:
        a. You have progressed (your condition has worsened) while on or after EGFR tyrosine kinase-inhibitor therapy. Examples of EGFR tyrosine kinase-inhibitor therapy include Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
        b. You are not currently receiving therapy with an EGFR tyrosine kinase-inhibitor such as Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
    2. You are positive for epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (types of genes) mutations as confirmed by an FDA-approved test AND you have not received prior systemic treatment (therapy that travels through the blood) for metastatic non-small cell lung cancer
D. **If you have non-small cell lung cancer, approval also requires ALL of the following:**
    1. The requested medication is being used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor)
    2. You are positive for an epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (type of genes) mutations as confirmed by an FDA-approved test

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Commercial Effective: 02/01/21



Revised: 12/17/2020

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## PRIOR AUTHORIZATION GUIDELINES

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## OZANIMOD

| Generic | Brand | | | |
|---|---|---|---|---|
| OZANIMOD | ZEPOSIA | | | |

## GUIDELINES FOR USE

Our guideline named **OZANIMIOD (Zeposia)** requires the following rule(s) be met for approval:

A. 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)
B. You are 18 years of age or older
C. You had a previous trial of either generic glatiramer or dimethyl fumarate

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Effective: 01/01/21

Revised: 10/06/2020

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**PEMBROLIZUMAB (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| PEMBROLIZUMAB | KEYTRUDA | | | |

## GUIDELINES FOR USE

Our guideline named **PEMBROLIZUMAB (Keytruda)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   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)



Revised: 12/17/2020

21. Locally recurrent unresectable or metastatic Triple-Negative Breast Cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)

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:
      a. You have stage III non-small cell lung cancer AND are not a candidate for surgical resection (removal) or definitive chemoradiation
      b. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

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:

   a. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (gene mutations)
   b. 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)
   c. 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:
      a. The medication will be given in combination with platinum and fluorouracil (FU)
      b. 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 2 or more prior lines of therapy

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)

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)



Revised: 12/17/2020

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 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

X. **If you have locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC), approval also requires:**
   1. The medication is used in combination with chemotherapy
   2. 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

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## PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| PERTUZUMAB-TRASTUZUMAB-HY-ZZXF | PHESGO | | | | |

## GUIDELINES FOR USE

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. Your breast cancer is HER2-positive
   2. 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. Your breast cancer is HER2-positive
   2. 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. Your breast cancer is HER2-positive
   2. You have not previously received anti-HER2 therapy or chemotherapy for metastatic disease
   3. The requested medication is being used in combination with docetaxel

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**PIRFENIDONE**

| Generic | Brand | | | |
|---|---|---|---|---|
| PIRFENIDONE | ESBRIET | | | |

## GUIDELINES FOR USE

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

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:

A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (an inflammatory disease that affects multiple organs in the body, but mostly the lungs and lymph glands), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (condition that weakens your immune system), viral hepatitis (liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

## RENEWAL CRITERIA

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:

A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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# PONATINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| PONATINIB HCL | ICLUSIG | | | |

## GUIDELINES FOR USE

Our guideline for the drug named **PONATINIB (Iclusig)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Chronic Phase (CP) Chronic Myeloid Leukemia (CML: type of blood-cell cancer that begins in the bone marrow)
   2. Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   3. T315I-positive (a genetic mutation) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow) OR T315I-positive (a genetic mutation) Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)

B. **If you have Chronic Phase (CP) Chronic Myeloid Leukemia (CML), approval also requires:**
   1. You are 18 years of older
   2. You are resistant or not able to safely use at least two prioir kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib)

C. **If you have Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of older
   2. No other kinase inhibitors treatment, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib), can be used for your disease

D. **If you have T315I-positive chronic myeloid leukemia (CML), OR T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of older

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Commercial Effective: 02/01/21



Revised: 12/17/2020

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**PRALSETINIB**

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| PRALSETINIB | GAVRETO | | | | |

**GUIDELINES FOR USE**

Our guideline named **PRALSETINIB (Gavreto)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (MTC: thyroid cancer that started in the center of the thyroid and has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor that has been detected by an Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) mutant tumor
   3. You need systemic therapy (medicine that goes into the entire body)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor
   3. You need systemic therapy (medicine that goes into the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is appropriate)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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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 ODT)** 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 ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

**RENEWAL CRITERIA**

Our guideline named **RIMEGEPANT (Nurtec ODT)** 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

Commercial Effective: 01/01/21



Revised: 12/17/2020

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**SELINEXOR**

| Generic | Brand | | | |
|---|---|---|---|---|
| SELINEXOR | XPOVIO | | | |

## GUIDELINES FOR USE

Our guideline named **SELINEXOR (Xpovio)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Multiple myeloma (MM: cancer of a type of white blood cells called plasma cells)
   2. 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)
   3. 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 multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone
   2. You have received at least one therapy before Xpovio

D. **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)

E. **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)

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Commercial Effective: 01/18/21



Revised: 12/17/2020

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## PRIOR AUTHORIZATION GUIDELINES

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## SIPONIMOD

| Generic | Brand | | | |
|---|---|---|---|---|
| SIPONIMOD | MAYZENT | | | |

### GUIDELINES FOR USE

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

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:

A. You have a diagnosis of relapsing forms of multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have trialed and failed either generic glatiramer or dimethyl fumarate
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

### RENEWAL CRITERIA

Our guideline named **SIPONIMOD (Mayzent)** requires the following rule(s) be met for approval:

A. You have a diagnosis of relapsing forms of secondary progressive multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. Your physician attests (confirms) you have demonstrated a clinical benefit compared to pre-treatment baseline
C. You do not have lymphopenia (low levels of a type of white blood cell)
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

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Effective: 01/01/21

Revised: 10/06/2020

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

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## SODIUM/CALCIUM/MAG/POT OXYBATE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| SODIUM, CALCIUM, MAG, POT OXYBATE | XYWAV | | | | |

## GUIDELINES FOR USE

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

Our guideline named **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Cataplexy in narcolepsy (sudden and uncontrollable muscle weakness or paralysis associated with a sleep disorder)
   2. Excessive daytime sleepiness (EDS) in narcolepsy (sleep disorder)

B. **If you have cataplexy in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have tried TWO of the following: venlafaxine, fluoxetine, or tricyclic anti-depressants (such as amitriptyline, clomipramine, imipramine)

C. **If you have excessive daytime sleepiness (EDS) in narcolepsy, approval also requires:**
   1. You are 7 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   3. You have EDS persisting for 3 or more months and an Epworth Sleepiness Scale (tool to measure your sleepiness) score of more than 10
   4. Your diagnosis of narcolepsy is confirmed by ONE of the following:
      a. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods
      b. A Multiple Sleep Latency Test (MSLT) showing both an average 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 (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
      c. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)



Revised: 12/17/2020

5. You had a trial of ONE amphetamine derivative (such as amphetamine sulfate, methylphenidate, etc.) AND modafinil, armodafinil, solriamfetol or pitolisant - unless there is a medical reason why you cannot (contraindication)

This medication will not be approved for patients currently being treated with sedative hypnotic agents (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, or Belsomra (suvorexant)).

**RENEWAL CRITERIA**

Our guideline named **SODIUM OXYBATE (Xyrem)** requires the following rule(s) be met for renewal approval:

A. You have narcolepsy (uncontrollable daytime sleepiness)
B. You meet **ONE** of the following:
   1. You have demonstrated improvement in cataplexy symptoms (sudden and uncontrollable muscle weakness) compared to baseline
   2. You have maintained an improvement in Epworth Sleepiness Scale (tool to measure sleepiness) scores by at least 25% compared to baseline

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Commercial Effective: 01/01/21

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## SOFOSBUVIR/VELPATASVIR

| Generic | Brand | | | |
|---|---|---|---|---|
| SOFOSBUVIR/VELPATASVIR | EPCLUSA | | | |

## GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6
B. You are 6 years of age or older OR weigh at least 17 kg
C. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), 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
D. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires:**
    1. The requested medication will be used with ribavirin
F. **If you do not have cirrhosis (liver damage) OR you have compensated cirrhosis (a condition where liver is extensively scarred, but you do not have symptoms of liver damage), approval also requires ONE of the following:**
    1. You are treatment naive (never previously treated)
    2. You are treatment experienced (have previously been treated) with peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio, Incivek or Victrelis with peginterferon/ribavirin)
    3. You have genotype 1b or genotype 2 infection AND you are treatment experienced with a Sovaldi (sofosbuvir)-containing regimen that does not include an NS5A inhibitor (type of hepatitis drug) such as Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio

**Epclusa will not be approved in the following condition(s):**

- You are using any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
- You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

Commercial Effective: 02/01/21



Revised: 12/17/2020

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# APALUTAMIDE

| Generic | Brand | | | |
|---|---|---|---|---|
| APALUTAMIDE | ERLEADA | | | |

## GUIDELINES FOR USE

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

C. **If you have a non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] levels)

## RENEWAL CRITERIA

Our guideline named **APALUTAMIDE (Erleada)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
   B. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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**STANDARD COMMERCIAL DRUG FORMULARY**
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## AZACITIDINE

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| AZACITIDINE | ONUREG | | | | |

### GUIDELINES FOR USE

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)

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Commercial Effective: 01/01/21



Revised: 12/17/2020

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

# AMANTADINE EXTENDED RELEASE

| Generic | Brand | Exception/Other |
|---|---|---|
| AMANTADINE EXTENDED RELEASE | GOCOVRI | |
| AMANTADINE HCL | OSMOLEX ER | |

## GUIDELINES FOR USE

### GOCOVRI

Our guideline named **AMANTADINE EXTENDED RELEASE (Gocovri)** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (nervous system disorder that affects movement)
B. **If you have dyskinesia (abnormal involuntary movements), approval also requires:**
   1. You are receiving levodopa-based therapy
   2. You have previously tried generic amantadine capsules, tablets, or solution
C. **If you are experiencing 'off' episodes (when the medication stops working), approval also requires:**
   1. You are also receiving levodopa-carbidopa therapy

### OSMOLEX ER

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

## 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.; January 2021.
- Osmolex ER [Prescribing Information]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC. October 2019.

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

# AMANTADINE EXTENDED RELEASE

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 09/17
Client Approval: 02/21
P&T Approval: 04/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**BOTULINUM NEUROTOXIN (NSA)**

| Generic | Brand | Exception/Other |
|---|---|---|
| ONABOTULINUM TOXIN A | BOTOX | FDB: BRAND ≠ BOTOX COSMETIC |
| ABOBOTULINUM TOXIN A | DYSPORT | |
| 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. You are using the requested medication for ONE of the following non-cosmetic (not for appearance) conditions:
   1. Overactive bladder (OAB: problem with the bladder function that causes the sudden need to urinate)
   2. Urinary incontinence (uncontrolled leakage of urine)
   3. Neurogenic detrusor overactivity (NDO: nerve related bladder dysfunction)
   4. Prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer)
   5. Spasticity (stiffness or tightness of your muscles)
   6. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   7. Severe axillary hyperhidrosis (excessive underarm sweating)
   8. Blepharospasm (involuntary forcible closure of the eyelid); or treatment of strabismus (cross-eyed)

B. **If you have overactive bladder (OAB), approval also requires:**
   1. You are 18 years of age or older.
   2. You previously tried an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why you cannot (contraindication)

C. **If you have 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 such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why you cannot

D. **If you have neurogenic detrusor overactivity (NDO), approval also requires:**
   1. You are 5 years of age or older

2. You did not have an adequate response or are not able to take anticholinergic medications

E. **If you have 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.

F. **If you have cervical dystonia and severe axillary hyperhidrosis, approval also requires:**
   1. You are 18 years of age or older.

G. **If you have spasticity, approval also requires:**
   1. You are 2 years of age or older.

H. **If you have blepharospasm and strabismus, approval also requires:**
   1. You are 12 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).

## 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 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).

## MYOBLOC

Our guideline named **BOTULINUM NEUROTOXIN (Myobloc)** requires the following rule(s) be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
   1. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   2. 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).

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

## XEOMIN

Our guideline named **BOTULINUM NEUROTOXIN (Xeomin)** requires the following rules be met for approval:

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
   1. Chronic sialorrhea (drooling or excessive salivation)
   2. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   3. Blepharospasm (involuntary forcible closure of the eyelid)
   4. Upper limb spasticity (stiffness or tightness of your muscles)

B. **If you have cervical dystonia or blepharospasm, approval also requires:**
   1. You are 18 years of age or older

C. **If you have chronic sialorrhea, approval also requires:**
   1. You are 2 years of age or older

D. **If you have upper 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)

**NOTE:** This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

## RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for the specified drugs in this guideline.

## REFERENCES


- Botox [Prescribing Information]. Irvine, CA: Allergan; February 2021.
- Dysport [Prescribing Information]. Basking Ridge, NJ Ispen: Biopharmaceuticals, Inc.; July 2020.
- Myobloc [Prescribing Information] South San Francisco, CA: Solstice Neurosciences, Inc.; August 2019.
- Xeomin [Prescribing Information]. Greensboro, NC: Merz Pharmaceuticals, LLC; December 2020.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 03/08/21
Created: 01/10
Client Approval: 02/21
P&T Approval: 04/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# LISOCABTAGENE MARALEUCEL (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| LISOCABTAGENE MARALEUCEL | BREYANZI | |

## GUIDELINES FOR USE

Our guideline named **LISOCABTAGENE MARALEUCEL (Breyanzi)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory large B-cell lymphoma (type of immune system cancer that has returned or is not responding to treatment, including diffuse large B-cell lymphoma [DLBCL] not otherwise specified [including DLBCL arising from indolent lymphoma], high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B)
B. You are 18 years of age or older
C. You have previously received 2 or more lines of systemic therapy (treatment that travels throughout the body)

## RATIONALE

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

## REFERENCES


- Breyanzi [Prescribing Information]. Bothell, WA Juno Therapeutics Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A Created: 02/21
Commercial Effective: 02/19/21 Client Approval: P&T Approval: 04/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# CEMIPLIMAB-RWLC (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| CEMIPLIMAB-RWLC | LIBTAYO | |

## GUIDELINES FOR USE

Our guideline named **CEMIPLIMAB-RWLC (Libtayo)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC: type of skin cancer that has spread or has highly developed)
   2. Metastatic or locally advanced basal cell carcinoma (BCC: type of skin cancer that has spread or has highly developed)

B. **If you have metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC), approval also requires:**
   1. You are not a candidate for curative surgery or curative radiation

C. **If you have metastatic or locally advanced basal cell carcinoma (BCC), approval also requires:**
   1. You have previously been treated with a hedgehog pathway inhibitor (such as Erivedge, Odomzo) or a hedgehog pathway inhibitor is not appropriate for you

## 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.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 03/08/21
Created: 11/18
Client Approval: 02/21
P&T Approval: 04/21

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RX PLAN

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

# OPIOID NAIVE FILL LIMIT

| Generic | Brand | Exception/Other |
|---|---|---|
| N/A | N/A | N/A |

## GUIDELINES FOR USE

Our guideline named **OPIOID NAIVE FILL LIMIT** allows an approval of the requested drug when it exceeds the fill limit for an initially opioid-naïve patient (those who have not used opioid drugs within the past 60 days) when ONE of the following conditions is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms that the additional fill of the requested opioid analgesic (pain-relieving) medication is intended and clinically appropriate for you

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 to address prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

In addition, the goal is to align with the opioid restrictions from the SUPPORT Act. The SUPPORT Act is an acronym for the Congress HR 6 - *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act.* The rule identified six requirements that each State and Managed Care Entity must have in place by October 1, 2019. CMS defined the SUPPORT Act requirements as minimum Drug Utilization Review (DUR) standards for MMCPs and they are listed below:

- Safety edits, as specified by the states, for subsequent opioid fills and maximum daily morphine milligram equivalent that exceed state-defined limitations
- Automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines or antipsychotics
- Monitoring antipsychotic prescribing for children
- Process that identifies potential fraud or abuse by enrolled individuals and pharmacies
- Report to the Secretary annually on state DUR activities
- Have in place managed care contracts that include these provisions

CMS noted that minimum standards may be expanded by the states or CMS in future rule making.

## REFERENCES


- SUPPORT for Patients and Communities Act, H.R. 6, Section 1004, 115th Congress. (2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6 . [Accessed 7/30/19]
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for

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

Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 08/19
Client Approval: 02/21
P&T Approval: 04/21

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RX PLAN

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

# UMBRALISIB

| Generic | Brand | Exception/Other |
|---|---|---|
| UMBRALISIB TOSYLATE | UKONIQ | |

## GUIDELINES FOR USE

Our guideline named **UMBRALISIB (Ukoniq)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory marginal zone lymphoma or follicular lymphoma (types of immune system cancer that have returned or are not responding to treatment)
B. You are 18 years of age or older
C. **If you have marginal zone lymphoma**, approval also requires:
   1. You have received at least one prior anti-CD20-based regimen (type of cancer treatment)
D. **If you have follicular lymphoma**, approval also requires:
   1. You have received at least three prior lines of systemic therapy (treatment that travels throughout the body)

## RATIONALE

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

## REFERENCES


- Ukoniq [Prescribing Information]. Edison, NJ: TG Therapeutics, Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A Created: 02/21
Commercial Effective: 02/19/21 Client Approval: P&T Approval: 01/21

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

# CABOZANTINIB S-MALATE

| Generic | Brand | Exception/Other |
|---|---|---|
| CABOZANTINIB S-MALATE | COMETRIQ, CABOMETYX | |

## GUIDELINES FOR USE

### COMETRIQ

Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:

A. You have progressive, metastatic medullary thyroid cancer (type of thyroid cancer that has spread)

### CABOMETYX

Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced renal cell carcinoma (type of kidney cancer)
   2. Hepatocellular carcinoma (type of liver cancer)

B. **If Cabometyx will be used in combination with Opdivo, approval also requires:**
   1. You have advanced renal cell carcinoma (type of kidney cancer)
   2. You have not received prior treatment for advanced renal cell carcinoma

C. **If you have hepatocellular carcinoma (type of kidney cancer), approval also requires:**
   3. You have 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.; February 2020.
- Cabometyx [Prescribing Information]. South San Francisco, CA: Exelixis, Inc.; January 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 01/13
Client Approval: 02/21
P&T Approval: 04/21

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

# DROXIDOPA

| Generic | Brand | Exception/Other |
|---|---|---|
| DROXIDOPA | NORTHERA, DROXIDOPA | |

## GUIDELINES FOR USE

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

Our guideline named **DROXIDOPA (Northera)** requires the following rules be met for approval:

A. You have neurogenic orthostatic hypotension (a type of low blood pressure)
B. You are 18 years of age or older
C. You have 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 (you are missing a type of enzyme), or non-diabetic autonomic neuropathy (nerve pain/damage)
D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
E. The medication is prescribed or given in consultation with a neurologist (nerve doctor) or cardiologist (heart doctor)
F. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
G. You have 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
H. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'

## RENEWAL CRITERIA

Our guideline named **DROXIDOPA (Northera)** requires the following rule(s) be met for renewal:

A. You have neurogenic orthostatic hypotension (NOH)
B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

## RATIONALE

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

## REFERENCES


- Northera [Prescribing Information]. Deerfield, IL: Lundbeck Pharmaceuticals LLC; July 2019.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

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**PRIOR AUTHORIZATION GUIDELINES**

Part D Effective: N/A
Commercial Effective: 07/01/20
Created: 9/14
Client Approval: 04/20
P&T Approval: 11/14

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RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**NIVOLUMAB (NSA)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| NIVOLUMAB | OPDIVO | 41654 | | GPI-10 (2135304100) | |

## GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient will be using Opdivo as a single agent **OR** in combination with Yervoy (ipilimumab)
   - No concurrent therapy with Tafinlar (dabrafenib), Mekinist (trametinib), Cotellic (cobimetinib), or Zelboraf (vemurafenib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #2.

2. Does the patient have a diagnosis of melanoma with lymph node involvement or metastatic disease and meet **ALL** of the following criteria?
   - The patient has undergone complete resection
   - The requested medication will be used as an adjuvant treatment

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #3.

3. 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 express PD-L1 (≥1%) as determined by an FDA-approved test
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - The requested medication will be used as first-line treatment in combination with Yervoy (ipilimumab)

   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**

**NIVOLUMAB (NSA)**

**GUIDELINES FOR USE (CONTINUED)**

4. Does the patient have a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The tumor does NOT have EGFR or ALK genomic tumor aberrations
   - The requested medication will be used as first-line treatment in combination with Yervoy (ipilimumab) AND 2 cycles of platinum-doublet chemotherapy

   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 non-small cell lung cancer (NSCLC) and meet **ALL** of the following criteria?
   - The patient has disease progression while on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)
   - For patients who have an ALK mutation, there must also be disease progression despite also trying an FDA-approved ALK-directed therapy (e.g., crizotinib, ceritinib)
   - For patients who have an EGFR mutation, there must also be disease progression despite also trying an FDA-approved EGFR-directed therapy (e.g., erlotinib, gefitinib, afatinib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #6.

6. Does the patient have a diagnosis of unresectable malignant pleural mesothelioma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as first-line treatment in combination with Yervoy (ipilimumab)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #7.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**NIVOLUMAB (NSA)**

**GUIDELINES FOR USE (CONTINUED)**

7. Does the patient have a diagnosis of advanced renal cell carcinoma (RCC) and meet **ONE** of the following criteria?
   - Opdivo will be used in combination with Yervoy (ipilimumab) and meet **ALL** of the following:
     - The patient has intermediate or poor risk disease
     - The patient has not received prior treatment for advanced renal cell carcinoma (first-line treatment)
   - Opdivo will be used in combination with Cabometyx (cabozantinib) and meet the following:
     - The patient has not received prior treatment for advanced renal cell carcinoma (first-line treatment)
   - Opdivo will be used as a single agent and meet the following:
     - The patient has previously received **ONE** prior anti-angiogenic therapy such as Sutent (sunitinib), Votrient (pazopanib), Cabometyx (cabozantinib), Inlyta (axitinib), Nexavar (sorafenib)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #8.

8. Does the patient have a diagnosis of classical Hodgkin lymphoma (cHL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's disease has relapsed or progressed after **ONE** of the following:
     - Autologous hematopoietic stem cell transplantation (HSCT) and Adcetris (brentuximab vedotin)
     - 3 or more lines of systemic therapy that includes autologous HSCT

   If yes, **approve for 12 months by HICL or GPI-10**.
   If no, continue to #9.

9. Does the patient have a diagnosis of recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) **AND** meet the following criterion?
   - The patient has disease progression on or after treatment with a platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin)

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #10.

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**NIVOLUMAB (NSA)**

**GUIDELINES FOR USE (CONTINUED)**

10. 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 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)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #11.

11. Does the patient have a diagnosis of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) and meet **ALL** the following criteria?
    - The patient is 12 years of age or older
    - The patient will be using Opdivo as a single agent OR in combination with Yervoy (ipilimumab)
    - The patient has disease progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #12.

12. Does the patient have a diagnosis of hepatocellular carcinoma (HCC) **AND** meet the following criterion?
    - The patient will be using Opdivo as a single agent **OR** in combination with Yervoy (ipilimumab)
    - The patient has been previously treated with Nexavar (sorafenib)

    If yes, **approve for 12 months by HICL or GPI-10.**
    If no, continue to #13.

13. Does the patient have a diagnosis of unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) **AND** meet the following criterion?
    - The patient has received prior fluoropyrimidine and platinum-based chemotherapy

    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**

**NIVOLUMAB (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 **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. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (A tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs.)
   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

***(Denial text continued on next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**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 meet ONE of the following:
      a. **For metastatic NSCLC:** the requested medication will be used in combination with Yervoy (ipilimumab) AND your tumor expresses 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 malignant pleural mesothelioma, approval also requires:**
   1. You are 18 years of age or older
   2. Opdivo will be used as first line treatment in combination with Yervoy (ipilimumab)

G. **If you have advanced renal cell carcinoma (RCC), approval also requires ONE of the following:**
   1. 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
   2. Opdivo will be used in combination with Cabometyx (cabozantinib) AND meet the following:
      a. You have not received prior treatment for advanced renal cell carcinoma
   3. 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)

***(Denial text continued on next page)***

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**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)

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 Opdivo.

**REFERENCES**

- Opdivo [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; January 2021.


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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**NIVOLUMAB (NSA)**

| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 05/15
Client Approval: 02/21
P&T Approval: 04/21

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RX PLAN

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

# EVINACUMAB-DGNB (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| EVINACUMAB-DGNB | EVKEEZA | |

## GUIDELINES FOR USE

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia
B. You are 12 years of age or older
C. Evkeeza will be used as an adjunct (add-on) to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (such as statins, PCSK9 inhibitors, ezetimibe, lomitapide, lipoprotein apheresis)

## RATIONALE

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

## REFERENCES


- Evkeeza [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 02/26/21
Created: 02/21
Client Approval:
P&T Approval: 04/21

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RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

## TRILACICLIB (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| TRILACICLIB DIHYDROCHLORIDE | COSELA | |

## GUIDELINES FOR USE

Our guideline named **TRILACICLIB (Cosela)** requires the following rule(s) be met for approval:

A. You have extensive-stage small cell lung cancer
B. You are 18 years of age or older
C. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression (decreased bone marrow activity causing fewer red blood cells, white blood cells, and platelets)
D. Cosela will be given prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

## RATIONALE

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

## REFERENCES


- Cosela [Prescribing Information]. Durham, NC: G1 Therapeutics, Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 02/26/21
Created: 02/21
Client Approval:
P&T Approval: 04/21

WELLFLEET
RX PLAN

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

# NERATINIB

| Generic | Brand | Exception/Other |
|---|---|---|
| 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 requested medication will be used as a single agent for extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
   4. 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

## RATIONALE

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

## REFERENCES


- Nerlynx [Prescribing Information]. Los Angeles, CA: Puma Biotechnology; July 2020.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 07/17
Client Approval: 02/21
P&T Approval: 04/20

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RX PLAN

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

# OPIOID-NAIVE DAY SUPPLY LIMITATION

| Generic | Brand | Exception/other |
|---|---|---|
| N/A | N/A | N/A |

## GUIDELINES FOR USE

Our guideline named **OPIOID-NAIVE DAY SUPPLY LIMITATION** allows approval of the requested drug for a longer day supply when you are opioid-naïve and meet at least **ONE** of the following conditions:

A. You have active cancer
B. You are enrolled in hospice
C. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of blood disorder)
F. You are NOT opioid naïve (you have been consistently using opioid pain medications)
G. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary

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:
“Beginning in 2019, we expect all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days’ supply…”. *CMS 2019 Call Letter, page 237*

Prior authorization will be required for opioid prescriptions with a longer day supply for opioid naive patients. 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 residents of a long-term care facility.

In addition, if the patient is determined to NOT be opioid naive during the coverage determination process, they are exempt from this safety edit. This exemption is based on the following guidance:
“If during the coverage determination process, it becomes known that the patient is not opioid naive, he or she should be excluded from the opioid naive edit.” *CMS Additional Guidance memo from October 23, 2018, page 8.*

Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. This guideline also allows an override when there is attestation from the prescriber that the prescribed dose of opioids with the requested day supply is intended and medically necessary.

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

## 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]
- The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21

Created: 02/19
Client Approval: 02/21

P&T Approval: 04/21

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RX PLAN

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

# OPIOID CUMULATIVE DOSING OVERRIDE

| Generic | Brand | Exception/other |
|---|---|---|
| N/A | N/A | N/A |

## GUIDELINES FOR USE

A claim for a pain medication will be denied when there are two or more providers prescribing opioid agents for a patient who is receiving a high quantity of these agents. Our guideline named **OPIOID CUMULATIVE DOSING OVERRIDE** will allow you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
   1. You have active cancer
   2. You are receiving palliative care (treatment for comfort from symptoms) or end-of life care
   3. You are enrolled in a hospice
   4. You are a resident of a long-term care facility or intermediate care for intellectually disabled
   5. You have sickle cell disease (type of blood disorder)

B. Your prescriber is aware that there is more than one provider prescribing opiates for you, and you meet **TWO** of the following:
   1. You have documentation showing your current level of opioid use is necessary and required for your level of pain management needed
   2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
   3. You have a pain contract in place
   4. You do not have a history of substance abuse or addiction
   5. Your provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record.

This safety edit allows for an override for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine milligram equivalent (MME)) or hard-stop threshold (200 mg morphine milligram equivalent (MME)). Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

## 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.
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 milligram equivalent (MME). MedImpact's standard hard opioid edit threshold is set at ≥ 200 mg MME. This requirement should not apply to patients with active cancer, hospice patients, those receiving palliative or end of life care, residents of a long term facility or patients approved by case management or retrospective DUR Programming. Following CMS guidance, patients with a diagnosis of sickle cell disease are also exempt from this restriction based on acute attacks and painful complications associated with the disease. Additional payment determination is required for patients identified as hospice. Soft-thresholds

may also be overriden by the pharmacy via DUR PPS codes or as part of coverage determination process and by certain PPS codes. Hard-thresholds are 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-MME days' criterion as it would not prevent beneficiaries from reaching high opioid doses.

## 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]
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- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed 8/11/16].
- 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 1/2/17].
- CMS Department of Health and Human Services Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit Memo. July 7, 2017.
- The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
- Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A Created: 09/16

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

Commercial Effective: 03/01/21 Client Approval: 02/21 P&T Approval: 04/21

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RX PLAN

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

# OPIOID-BENZODIAZEPINE CONCURRENT USE

| Generic | Brand | Exception/Other |
|---|---|---|
| N/A | N/A | N/A |

## GUIDELINES FOR USE

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms (attests) 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 or intermediate care for intellectually disabled
- 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

## 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].

- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21

Created: 10/17
Client Approval: 02/21

P&T Approval: 04/21

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

# OPIOID-BUPRENORPHINE CONCURRENT USE

| Generic | Brand | Exception/Other |
|---|---|---|
| N/A | N/A | N/A |

## GUIDELINES FOR USE

Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine-containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

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 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].
- CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 2/1/21].


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A Created: 12/18

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

Commercial Effective: 03/01/21 Client Approval: 02/21 P&T Approval: 04/21

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RX PLAN

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

# OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE

| Generic | Brand | Exception/Other |
|---|---|---|
| N/A | N/A | N/A |

## GUIDELINES FOR USE

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you

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 mitigate the risk of the overdose from dangerous combinations of CNS depressants while preserving patient access to drug regimens if deemed medically necessary.
The Opioid-Benzodiazepine-Soma Concurrent Use at POS edit will identify and deny concurrent use of opioids, benzodiazepines, and carisoprodol when there is an overlap in day supply (for at least one drug from each 'class'). This edit will reject the claim that creates the three-drug overlap.
The edit will have internal reject codes REJ- 433- 1204, and the following parameters:

1. Triple drug overlap = 1 day
2. Prescriber threshold = 1 prescriber
3. Exceptions =
   a) Cancer diagnosis (edit will lookback for presence of claims related to these diseases in the past 180 days to automatically exclude from the edit)
   b) Hospice or palliative care (edit will look for hospice attribute on claims to automatically exclude from the edit)
   c) Long Term Care residence (edit will look for patient residence code to automatically exclude from the edit)

Please note that sickle cell disease will not be included in the exception criteria. Although opioids and benzodiazepines can be used in managing pain crises, treatment guidelines do not mention skeletal muscle relaxants such as carisoprodol as a typical treatment modality.

| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 07/19
Client Approval: 02/21
P&T Approval: 04/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# PERTUZUMAB (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| PERTUZUMAB | PERJETA | |

## GUIDELINES FOR USE

Our guideline named **PERTUZUMAB (Perjeta)** 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 body parts)
   2. Locally advanced, inflammatory, or early stage breast cancer (breast cancer defined as either greater than 2 cm in diameter or node positive)
   3. Early breast cancer at high risk of recurrence (returning)

B. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (higher than normal levels of a protein called human epidermal growth factor receptor 2)
   2. You have not received prior therapy with an anti-HER2 agent (drug that works against a protein called human epidermal growth factor receptor 2) or chemotherapy for metastatic disease (cancer treatment for disease that has spread to other parts of the body)
   3. The requested medication will be used in combination with trastuzumab and docetaxel

C. **If you have locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), approval also requires:**
   1. Your breast cancer is HER2-positive (higher than normal levels of a protein called human epidermal growth factor receptor 2)
   2. The requested medication will be used in the neoadjuvant setting (given before surgery)
   3. The requested medication will be used in combination with trastuzumab and chemotherapy (cancer drug treatment such as paclitaxel, carboplatin, or cyclophosphamide) as part of a complete drug regimen for early breast cancer

D. **If you have early breast cancer at a high risk of recurrence, approval also requires:**
   1. Your breast cancer is HER2-positive (higher than normal levels of a protein called human epidermal growth factor receptor 2)
   2. The requested medication will be used in the adjuvant setting (given as add-on treatment)
   3. The requested medication will be used in combination with trastuzumab and chemotherapy (cancer drug treatment such as paclitaxel, carboplatin, or cyclophosphamide)

## RATIONALE

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

## REFERENCES


- Perjeta [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; October 2020.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

Part D Effective: N/A
Commercial Effective: 03/08/21
Created: 08/12
Client Approval: 02/21
P&T Approval: 01/18

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# ROMIPLOSTIM (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| ROMIPLOSTIM | NPLATE | |

## GUIDELINES FOR USE

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

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding)
   2. Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS: you have been acutely exposed to myelosuppressive doses of radiation)

B. **If you have immune thrombocytopenia (ITP), approval also requires:**
   1. You are 1 year of age or older
   2. You have previously tried or have a contraindication to (medical reason why you cannot use) corticosteroids or immunoglobulins, OR you had an insufficient response to a splenectomy (surgical removal of spleen)
   3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
   4. **If you are between 1 and 17 years old, approval also requires:**
      a. You had immune thrombocytopenia (ITP) for at least 6 months

## RENEWAL CRITERIA

**NOTE:** For the diagnoses of Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS), please refer to the Initial Criteria section.

Our guideline named **ROMIPLOSTIM (Nplate)** requires the following rule(s) be met for renewal:

A. You have immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding)
B. You had a clinical response, as defined by an increase in platelet count to at least 50 X 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.; January 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Created: 10/08
Commercial Effective: 03/01/21
Client Approval: 02/21
P&T Approval: 04/21

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

# URSODIOL

| Generic | Brand | Exception/Other |
|---|---|---|
| URSODIOL | RELTONE | |

## GUIDELINES FOR USE

Our guideline named **URSODIOL (Reltone)** requires the following rule(s) be met for approval:

A. You have radiolucent (barely visible on x-ray), noncalcified gallbladder stones (hardened deposits formed in gallbladder that do not contain calcium)
B. Your gallbladder stones are less than 20 mm in diameter
C. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, **OR** you refuse surgery
D. You have tried generic ursodiol or are unable to take generic ursodiol formulations

## RATIONALE

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

## REFERENCES


- Ursodiol 200 mg & 400 mg Capsules [Prescribing Information]. Irvine, CA: Nexgen Pharma, Inc.; May 2020.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/01/21
Created: 02/21
Client Approval: 02/21
P&T Approval: 01/21

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## PRIOR AUTHORIZATION GUIDELINES

**ALIROCUMAB**

| Generic | Brand | Exception/Other |
|---|---|---|
| ALIROCUMAB | PRALUENT PEN, PRALUENT SYRINGE | |

**GUIDELINES FOR USE**

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

Our guideline named **ALIROCUMAB (Praluent)** 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. Primary hyperlipidemia (high cholesterol such as 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 have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL

E. **If you are statin tolerant, approval also requires:**
   1. You will continue statin treatment in combination with Praluent
   2. You meet ONE of the following:
      i. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
      ii. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

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**PRIOR AUTHORIZATION GUIDELINES**

**ALIROCUMAB**

**INITIAL CRITERIA (CONTINUED)**

F. **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

G. **If you have primary hyperlipidemia (such as heterozygous familial hypercholesterolemia [HeFH]), approval also requires the diagnosis is determined by meeting ONE of the following:**
   1. Simon Broome diagnostic criteria (definite)
   2. Dutch Lipid Network criteria with a score of at least 6

**RENEWAL CRITERIA**

Our guideline named **ALIROCUMAB (Praluent)** 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)
   2. Primary hyperlipidemia (high cholesterol such as heterozygous familial hypercholesterolemia [HeFH]: type of inherited high cholesterol)

B. You also meet ONE of the following:
   1. You have continued to take a high intensity statin atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with the requested medication
   2. You have continued therapy with a maximally tolerated dose of any statin along with the requested medication
   3. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   4. You have complete statin intolerance

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**RATIONALE**

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

**REFERENCE**


- Praluent [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; September 2019.


Effective 10-1-20

WELLFLEET
RX PLAN

# PRIOR AUTHORIZATION GUIDELINES

## GRANULOCYTE COLONY-STIMULATING FACTORS

| Generic | Brand | Exception/Other |
|---|---|---|
| PEGFILGRASTIM-CBQV | UDENYCA | |

### GUIDELINES FOR USE

The guideline named **PEGFILGRASTIM-CBQV** requires that the following be met:

A. The requested medication is prescribed by or recommended by a hematologist (blood doctor) or oncologist (cancer/tumor doctor)
B. You have a nonmyeloid malignancy (cancer not affecting bone marrow) and are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (drugs that affect bone marrow and cause low levels of a type of white blood cell) 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.


Effective 4-1-20

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

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## AMIFAMPRIDINE

| Generic | Brand | | | |
|---|---|---|---|---|
| AMIFAMPRIDINE | FIRDAPSE | | | |

### GUIDELINES FOR USE

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

Our guideline named **AMIFAMPRIDINE (Firdapse)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor) or hematologist-oncologist (blood-cancer doctor)
D. Diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (types of lab tests) antibody testing **AND** clinical triad (3 symptoms) of muscle weakness, autonomic dysfunction, and decreased tendon reflexes
E. **If you are requesting Firdapse, approval also requires:**
    1. You are 18 years of age or older
F. **If you are requesting Ruzurgi, approval also requires:**
    1. Documentation of your weight

### RENEWAL CRITERIA

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (LEMS - a type of muscle disorder)
B. You have experienced improvement or stabilization in muscle weakness compared to baseline

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Commercial Effective: 05/01/20



Revised: 2/24/2021

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**RIBOCICLIB**

| Generic | Brand | | | |
|---|---|---|---|---|
| RIBOCICLIB SUCCINATE | KISQALI | | | |
| RIBOCICLIB SUCCINATE/ LETROZOLE | KISQALI FEMARA CO-PACK | | | |

**GUIDELINES FOR USE**

Our guideline named **RIBOCICLIB (Kisqali, Kisqali/Femara co-pack)** requires the following rule(s) be met for approval:

A. You have advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (cancer that has spread throughout the body and has a type of hormone with no gene mutation).
B. **For Kisqali-Femara Co-Pack, approval also requires:**
   a. You are female
   b. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   c. You have **NOT** experienced disease progression (worsening of disease) after previously using CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
   d. You meet **ONE** of the following:
      i. You are pre/perimenopausal
      ii. You are post-menopausal and had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)
C. **For Kisqali, approval also requires ONE of the following:**
   1. Kisqali will be used in combination with an aromatase inhibitor and you meet all of the following:
      a. You are female
      b. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      c. You have **NOT** experienced disease progression (worsening of disease) following prior CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
      d. You meet ONE of the following:
         i. You are pre/perimenopausal
         ii. You are post-menopausal and had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

***(Criteria continued on next page)***



Revised: 2/24/2021

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Revised: 2/24/2021

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## RIBOCICLIB

### GUIDELINES FOR USE (CONTINUED)

2. Kisqali will be used in combination with Faslodex (fulvestrant) and you meet all of the following:
   a. You are female and post-menopausal
   b. You have **NOT** experienced disease progression (worsening of disease) following prior CDK (cyclin-dependent kinase) inhibitor therapy (type of treatment that prevents cancer cells from multiplying)
   c. You meet **ONE** of the following:
      i. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      ii. You have experienced disease progression on endocrine therapy **AND** had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

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Commercial Effective: 07/01/20



Revised: 2/24/2021

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## SODIUM OXYBATE

| Generic | Brand | | | |
|---|---|---|---|---|
| SODIUM OXYBATE | XYREM | | | |

### GUIDELINES FOR USE

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

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:**

- 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 manufacturer
- The patient has tried **TWO** of the following: venlafaxine, fluoxetine, or a tricyclic antidepressant (e.g., amitriptyline, clomipramine, imipramine)
- 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.**
- 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:**

- 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 manufacturer
- 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)
- Modafinil in doses up to 400 mg daily, OR armodafinil in doses up to 250 mg daily, has been ineffective, not tolerated, or contraindicated

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# SODIUM OXYBATE

## INITIAL CRITERIA (CONTINUED)

- At least one generic stimulant (e.g., methylphenidate, dextroamphetamine, or amphetamine) has been ineffective, not tolerated, or contraindicated
- 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.**
  - 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
  - Alternately, low CSF orexin/hypocretin levels per assay
- 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.**
- 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

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.**

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Effective: 03/01/21

Revised: 02/01/2021

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## USTEKINUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| USTEKINUMAB | STELARA | | | |

### GUIDELINES FOR USE

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

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, **OR** 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 also 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 6 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

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# USTEKINUMAB

**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

## RENEWAL CRITERIA

The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of psoriatic arthritis without co-existent plaque psoriasis, **OR** 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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Effective: 03/01/21

Revised: 02/01/2021

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## ADALIMUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| ADALIMUMAB | HUMIRA | | | |

### GUIDELINES FOR USE

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

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:

**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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

**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

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## ADALIMUMAB

### INITIAL CRITERIA (CONTINUED)

**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 of 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

**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

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# ADALIMUMAB

## INITIAL CRITERIA (CONTINUED)

**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

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 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

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**ADALIMUMAB**

**RENEWAL CRITERIA (CONTINUED)**

**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

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Effective: 01/08/21

Revised: 02/01/2021

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## BARICITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| BARICITINIB | OLUMIANT | | | |

### GUIDELINES FOR USE

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

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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- 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, 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

The guideline named **BARICITINIB (Olumiant)** requires a diagnosis of moderate to severe rheumatoid 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.

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Effective: 01/08/21

Revised: 02/01/2021

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## ANAKINRA

| Generic | Brand | | | |
|---|---|---|---|---|
| ANAKINRA | KINERET | | | |

### GUIDELINES FOR USE

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

The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis, Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS), or Deficiency of Interleukin-1 Receptor Antagonist (DIRA). 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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- 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, 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

The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis, Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS), or Deficiency of Interleukin-1 Receptor Antagonist (DIRA) 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

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Effective: 03/01/21

Revised: 02/01/2021

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## ETANERCEPT

| Generic | Brand | | | |
|---|---|---|---|---|
| ETANERCEPT | ENBREL | | | |

### GUIDELINES FOR USE

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

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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

**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

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## PRIOR AUTHORIZATION GUIDELINES

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# ETANERCEPT

## INITIAL CRITERIA (CONTINUED)

**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

## RENEWAL CRITERIA

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.

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## APREMILAST

| Generic | Brand | | | |
|---|---|---|---|---|
| APREMILAST | OTEZLA | | | |

### GUIDELINES FOR USE

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

The guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

A. 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. 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), 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 had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

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

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**PRIOR AUTHORIZATION GUIDELINES**

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# APREMILAST

## INITIAL CRITERIA (CONTINUED)

D. **For the diagnosis of oral ulcers associated with Behcet'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)
   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

The 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.

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## PRIOR AUTHORIZATION GUIDELINES

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## GOLIMUMAB - IV (NSA)

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| GOLIMUMAB - IV | SIMPONI ARIA - IV | | | | |

### GUIDELINES FOR USE

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

The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or polyarticular juvenile idiopathic arthritis. 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:
  - 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

**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 2 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

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## PRIOR AUTHORIZATION GUIDELINES

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## GOLIMUMAB - IV (NSA)

**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

**For the diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), approval requires:**

- 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.

## RENEWAL CRITERIA

**NOTE:** For the diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), please refer to the initial criteria section.

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

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Effective: 03/01/21

Revised: 02/01/2021

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## GUSELKUMAB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| 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

### 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

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Effective: 01/08/21

Revised: 02/01/2021

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## RISANKIZUMAB-RZAA

| Generic | Brand | | | |
|---|---|---|---|---|
| RISANKIZUMAB-RZAA | SKYRIZI | | | |

### GUIDELINES FOR USE

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

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

### RENEWAL CRITERIA

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

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Effective: 03/13/20

Revised: 02/01/2021

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## SARILUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| SARILUMAB | KEVZARA | | | |

### GUIDELINES FOR USE

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

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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- Patient is 18 years of age or older
- Previous trial of **TWO** formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR

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

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.

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Effective: 01/08/21

Revised: 02/01/2021

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## TILDRAKIZUMAB-ASMN

| Generic | Brand | | | |
|---|---|---|---|---|
| TILDRAKIZUMAB-ASMN | ILUMYA | | | |

### GUIDELINES FOR USE

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

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

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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## TOCILIZUMAB – IV

| Generic | Brand | | | |
|---|---|---|---|---|
| TOCILIZUMAB - IV | ACTEMRA - IV | | | |

### GUIDELINES FOR USE

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

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:
  - 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

**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 **ONE** of the formulary preferred immunomodulators: Humira or Enbrel

**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

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**PRIOR AUTHORIZATION GUIDELINES**

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# TOCILIZUMAB – IV

## INITIAL CRITERIA (CONTINUED)

**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.

## RENEWAL CRITERIA

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.

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Effective: 01/01/21

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## PRIOR AUTHORIZATION GUIDELINES

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## TOCILIZUMAB - SQ

| Generic | Brand | | | |
|---|---|---|---|---|
| TOCILIZUMAB - SQ | ACTEMRA - SQ | | | |

### GUIDELINES FOR USE

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

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 is 18 years of age or older
- The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- The patient had a previous trial of the following preferred immunomodulator: Humira

**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 **ONE** of the formulary preferred immunomodulators: Humira or Enbrel

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## PRIOR AUTHORIZATION GUIDELINES

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# TOCILIZUMAB - SQ

## INITIAL CRITERIA (CONTINUED)

**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.

## RENEWAL CRITERIA

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

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## PRIOR AUTHORIZATION GUIDELINES

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## UPADACITINIB

| Generic | Brand | | | | |
|---|---|---|---|---|---|
| UPADACITINIB | RINVOQ | | | | |

### GUIDELINES FOR USE

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

The guideline named **UPADACITINIB (Rinvoq)** requires a diagnosis of moderate to severe rheumatoid arthritis. 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 rheumatologist
- The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

### RENEWAL CRITERIA

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

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Effective: 01/08/21

Revised: 02/01/2021

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

# ELBASVIR/GRAZOPREVIR

| Generic | Brand | Exception/Other |
|---|---|---|
| ELBASVIR/ GRAZOPREVIR | ZEPATIER | |

## GUIDELINES FOR USE

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have hepatitis C (type of liver inflammation caused by a virus)
B. You have genotype 1 or genotype 4 hepatitis C
C. You are 18 years of age or older
D. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. You have documentation of HCV (hepatitis C virus) infection that shows at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. You have previously tried Epclusa or Harvoni unless you have a contraindication (medical reason why you cannot try) to both. Patients with previous failure of a full treatment of Epclusa or Harvoni will not be approved
G. If you have genotype 1a infection, we require testing for baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)
H. Ribavirin use is required if you meet ANY of the following:
    1. You have genotype 1a or 1b infection and were previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (such as Victrelis, Incivek, Olysio) plus peginterferon/ribavirin
    2. You have genotype 1a infection, are treatment naïve, and have baseline NS5A polymorphisms
    3. You have genotype 1a infection, were previously treated, and have baseline NS5A polymorphisms (variations of a type of protein)
    4. You have genotype 4 infection and were previously treated
I. 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)

**Zepatier will not be approved if you meet any of the following:**

A. You are using any of the following interacting medications at the same time while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
B. You are taking Sovaldi (sofosbuvir) with Zepatier

C. You have moderate or severe liver impairment (Child-Pugh B or C)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

## RATIONALE

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

## REFERENCES

- Zepatier [Prescribing Information]. Kenilworth, NJ: Merck; December 2019.

Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# BELIMUMAB – SQ

| Generic | Brand | Exception/Other |
|---|---|---|
| BELIMUMAB | BENLYSTA | |

## GUIDELINES FOR USE

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

Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Autoantibody-positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. **If you have active lupus nephritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (kidney doctor)
   3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

## RENEWAL CRITERIA

Our guideline named **BELIMUMAB - SQ (Benlysta)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Autoantibody-positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), renewal also requires:**
   1. You have had clinical improvement while on Benlysta

C. **If you have active lupus nephritis, renewal also requires:**

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

1. You have had clinical improvement in renal response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

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**RATIONALE**

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

**REFERENCES**


- Benlysta [Prescribing Information]. Rockville, Maryland: Human Genome Sciences, Inc.; December 2020.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# FOSDENOPTERIN (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| FOSDENOPTERIN HYDROBROMIDE | NULIBRY | |

## GUIDELINES FOR USE

Our guideline named **FOSDENOPTERIN (Nulibry)** requires the following rule(s) be met for approval:

A. You have molybdenum cofactor deficiency (MoCD) Type A (rare condition characterized by brain dysfunction)

## RATIONALE

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

## REFERENCES


- Nulibry [Prescribing Information]. Boston, MA: Origin Biosciences, Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 03/12/21
Created: 03/21
Client Approval:
P&T Approval: 04/21

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## PRIOR AUTHORIZATION GUIDELINES

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## EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA

| Generic | Brand | | | |
|---|---|---|---|---|
| EXCLUDED DRUGS | | | | |

## GUIDELINES FOR USE

The guideline named **EXCLUDED FORMULARY DRUG EXCEPTION CRITERIA** 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 have met at least ONE of the following criteria:
   1. You have trialed and failed THREE formulary alternatives with the same route of administration and active ingredients (if available); if the same route of administration and/or active ingredients is not available, then you have trialed and failed THREE formulary alternatives, one of which must be in the same class (or as many up to three if fewer than three alternatives are commercially available)
   2. Your doctor has provided documentation of contraindications or clinically significant adverse effects to ALL preferred agents with the same therapeutic class or preferred drugs that are recognized as standards of care for the treatment of the member's diagnosis
   3. Your doctor has provided documentation which details the absolute clinical need for the immediate use of the excluded drug product without trial and failure of preferred therapeutic alternatives

C. If the request is for a combination product or for a product that is an alternative dosage form or strength to an existing commercially available product, your doctor has provided medical justification supporting your inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products)

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Effective: 04/01/21

Revised: 02/01/2021

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**BELIMUMAB (NSA)**

| Generic | Brand | Exception/Other |
|---|---|---|
| BELIMUMAB | BENLYSTA | |

## GUIDELINES FOR USE

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

Our guideline named **BELIMUMAB IV (Benlysta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Autoantibody-positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), approval also requires:**
   1. You are 5 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   3. You are currently using corticosteroids, antimalarials (drug that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. **If you have active lupus nephritis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (kidney doctor)
   3. You are receiving standard treatment (such as steroids, antimalarials, nonsteroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

## RENEWAL CRITERIA

Our guideline named **BELIMUMAB IV (Benlysta)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Autoantibody-positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
   2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), renewal also requires:**
   1. You have had clinical improvement while on Benlysta

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**PRIOR AUTHORIZATION GUIDELINES**

**BELIMUMAB (NSA)**

**RENEWAL CRITERIA (CONTINUED)**

C. **If you have active lupus nephritis, renewal also requires:**
   1. You have had clinical improvement in renal response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

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

**REFERENCES**

- Benlysta [Prescribing Information]. Rockville, MD. Human Genome Sciences, Inc.; December 2020.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# CANAKINUMAB (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| CANAKINUMAB/PF | ILARIS | |

## GUIDELINES FOR USE

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

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. 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)
   2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic disorders that have recurrent fever episodes and inflammation)
   4. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   5. Systemic Juvenile Idiopathic Arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **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 (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)

C. **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 (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You had a previous trial of 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)

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**PRIOR AUTHORIZATION GUIDELINES**

**CANAKINUMAB (NSA)**

## INITIAL CRITERIA (CONTINUED)

D. **If you have Adult-Onset Still's Disease (AOSD), approval also requires:**
   1. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) dermatologist (skin doctor), or immunologist (immune system doctor)
   2. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

**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

**NOTE**: For the diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), or Familial Mediterranean Fever (FMF), please refer to the Initial Criteria section.

Our guideline named **CANAKINUMAB (Ilaris)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. 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)
   2. Systemic Juvenile Idiopathic Arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   3. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD), renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

## 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.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

## CASIMERSEN (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| CASIMERSEN | AMONDYS-45 | |

### GUIDELINES FOR USE

Our guideline named **CASIMERSEN (Amondys-45)** 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 in the DMD gene that is responsive to exon 45 skipping (a process that allows a protein to still function with sections of faulty genetic code)

### RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Amondys-45.

### REFERENCES


- Amondys-45 [Prescribing Information]. Cambridge, MA: Sarepta Therapeutics, Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 03/12/21
Created: 03/21
Client Approval:
P&T Approval: 04/21

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## 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. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

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:**
   1. You have previously tried generic Zytiga (abiraterone acetate) 250 mg unless there is a medical reason why you cannot take it (contraindication)

E. **If you have metastatic castration-sensitive prostate cancer, approval also requires:**
   1. You have trialed and failed or have a contraindication to generic Zytiga (abiraterone) 250 mg.

### 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)

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## PRIOR AUTHORIZATION GUIDELINES

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Effective: 03/26/21

Revised: 02/01/2021

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

# DAROLUTAMIDE

| Generic | Brand | Exception/Other |
|---|---|---|
| DAROLUTAMIDE | NUBEQA | |

## GUIDELINES FOR USE

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

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)
B. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)
C. You meet ONE of the following:
    1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
    2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
    3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

## RENEWAL CRITERIA

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:

A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)
B.

## 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.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# HYDROCORTISONE

| Generic | Brand | Exception/Other |
|---|---|---|
| HYDROCORTISONE | ALKINDI SPRINKLE | |

## GUIDELINES FOR USE

Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:

A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
B. You are less than 18 years of age
C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

## RATIONALE

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

## REFERENCES


- Alkindi Sprinkle [Prescribing Information]. Baden-Wuerttemberg, Germany: Eton Pharmaceuticals, Inc.; October 2020.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# LONAFARNIB

| Generic | Brand | Exception/Other |
|---|---|---|
| LONAFARNIB | ZOKINVY | |

## GUIDELINES FOR USE

Our guideline named **LONAFARNIB (Zokinvy)** requires the following rule(s) be met for approval:

A. You have Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies (rare genetic disorders that cause premature aging in children)
B. You are 1 year of age or older
C. You have a body surface area (BSA) of 0.39 meters squared or more
D. **If you have processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:**
    1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
    2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

## RATIONALE

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

## REFERENCES


- Zokinvy [Prescribing Information]. Palo Alto, CA: Eiger BioPharmaceuticals, Inc.; November 2020.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# LOTEPREDNOL

| Generic | Brand | Exception/Other |
|---|---|---|
| LOTEPREDNOL ETABONATE | EYSUVIS | |

## GUIDELINES FOR USE

Our guideline named **LOTEPREDNOL (Eysuvis)** requires the following rule(s) be met for approval:

A. You have dry eye disease
B. You previously tried one generic loteprednol ophthalmic product **AND** one non-loteprednol ophthalmic (eye) corticosteroid (such as fluorometholone, dexamethasone, prednisolone) unless there is a medical reason why you cannot (contraindication)

## RATIONALE

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

## REFERENCES


- Eysuvis [Prescribing Information]. Watertown, MA: Kala Pharmaceuticals, Inc.; October 2020.


Commercial Effective: 04/01/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
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**LUMASIRAN (NSA)**

| Generic | Brand | Exception/Other |
|---|---|---|
| LUMASIRAN SODIUM | OXLUMO | |

## GUIDELINES FOR USE

Our guideline named **LUMASIRAN (Oxlumo)** requires the following rule(s) be met for approval:

A. You have primary hyperoxaluria type 1 (PH1: a rare disorder in which buildup of a substance called oxalate is deposited in the kidneys and urinary tract)

## RATIONALE

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

## REFERENCES


- Oxlumo [Prescribing Information]. Cambridge, MA: Alynlam Pharmaceuticals, Inc.; November 2020.


Commercial Effective: 04/01/21

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**PRIOR AUTHORIZATION GUIDELINES**

# RELUGOLIX

| Generic | Brand | Exception/Other |
|---|---|---|
| RELUGOLIX | ORGOVYX | |

## GUIDELINES FOR USE

Our guideline named **RELUGOLIX (Orgovyx)** requires the following rule(s) be met for approval:
A. You have advanced prostate cancer
B. You are 18 years of age or older

## RATIONALE

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

## REFERENCES


- Orgovyx [Prescribing Information]. Brisbane, CA: Myovant Sciences, Inc.; December 2020.


Commercial Effective: 04/01/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# MARGETUXIMAB-CMKB (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| MARGETUXIMAB-CMKB | MARGENZA | |

## GUIDELINES FOR USE

Our guideline named **MARGETUXIMAB-CMKB (Margenza)** requires the following rule(s) be met for approval:

A. You have metastatic HER2 (human epidermal growth factor receptor 2)-positive breast cancer (cancer has spread to other parts of the body)
B. Margenza will be used in combination with chemotherapy (such as Xeloda, Halaven, gemcitabine, Navelbine)
C. You have received two or more prior anti-HER2 regimens (such as Herceptin, Perjeta), at least one of which was for metastatic disease

## RATIONALE

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

## REFERENCES


- Margenza [Prescribing Information]. Rockville, MD: MacroGenics, Inc.; December 2020.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 03/12/21
Created: 03/21
Client Approval:
P&T Approval: 04/21

WELLFLEET
RX PLAN

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

# MELPHALAN FLUFENAMIDE (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| MELPHALAN FLUFENAMIDE HCL | PEPAXTO | |

## GUIDELINES FOR USE

Our guideline named **MELPHALAN FLUFENAMIDE (Pepaxto)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not responsive to treatment)
B. You are 18 years of age or older
C. Pepaxto will be used in combination with dexamethasone
D. You have received at least four prior lines of therapy
E. Your disease is refractory to at least one proteasome inhibitor (such as Velcade, Kyprolis), one immunomodulatory agent (such as Revlimid, Pomalyst), AND one CD38-directed monoclonal antibody (such as Darzalex)

## RATIONALE

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

## REFERENCES


- Pepaxto [Prescribing Information]. Waltham, MA: Oncopeptides Inc.; February 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A Created: 03/21
Commercial Effective: 03/12/21 Client Approval: P&T Approval: 04/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# NAXITAMAB-GQGK (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| NAXITAMAB-GQGK | DANYELZA | |

## GUIDELINES FOR USE

Our guideline named **NAXITAMAB-GQGK (Danyelza)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory high-risk neuroblastoma (cancer that starts in early nerve cells that has returned or no longer responds to treatment) in the bone or bone marrow
B. You are 1 year of age or older
C. The requested medication will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)
D. You have demonstrated a partial response, minor response, or stable disease to prior therapy

## RATIONALE

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

## REFERENCES


- Danyelza [Prescribing Information]. New York, NY: Y-mAbs Therapeutics, Inc.; November 2020.


Commercial Effective: 04/01/21

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## 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.*

## OFATUMUMAB-SQ

| Generic | Brand | | | |
|---|---|---|---|---|
| OFATUMUMAB | KESIMPTA | | | |

### GUIDELINES FOR USE

Our guideline named **OFATUMUMAB-SQ (Kesimpta)** 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), which includes 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
C. You have previously trialed and failed generic dimethyl fumarate or glatiramer

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Effective: 03/26/21

Revised: 02/01/2021

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

# OLAPARIB

| Generic | Brand | Exception/Other |
|---|---|---|
| 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: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment )

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

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 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 (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, 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

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 worsened following prior treatment with enzalutamide or abiraterone
4. You meet ONE of the following:
   a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
   b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
   c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

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**RATIONALE**

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

**REFERENCES**

- Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. May 2020.

Commercial Effective: 04/01/21

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

**OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR**

| Generic | Brand | Exception/Other |
|---|---|---|
| OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR | VIEKIRA PAK | |
| OMBITASVIR/ PARITAPREVIR/ RITONAVIR/ DASABUVIR | VIEKIRA XR | |

## GUIDELINES FOR USE

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 or Harvoni unless you have a medical reason why you cannot use (contraindication) BOTH drugs. Reasons for failure include adverse effect early in therapy, intolerance to therapy (**NOTE:** If you completed a full course of therapy with Epclusa or Harvoni 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

**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, methylergonovine, 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.

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**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.


Commercial Effective: 04/01/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**RAVULIZUMAB-CWVZ (NSA)**

| Generic | Brand | Exception/Other |
|---|---|---|
| RAVULIZUMAB-CWVZ | ULTOMIRIS | |

## GUIDELINES FOR USE

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

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely)
   2. Atypical hemolytic uremic syndrome (aHUS: a rare disorder that causes abnormal blood clots to form in small vessels in the kidneys)

B. **If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
   1. You are 18 years of age or older
   2. There is documentation of your current weight
   3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   4. You have confirmed paroxysmal nocturnal hemoglobinuria as supported by **ALL** of the following via flow cytometry (type of measurement of physical and chemical qualities of cells):
      a. At least 2 different GPI-protein deficiencies (you're missing a certain type of protein such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes, granulocytes)
      b. Paroxysmal nocturnal hemoglobinuria granulocyte clone size of 10% or greater
   5. You meet **ONE** of the following:
      a. You are transitioning from alternative complement inhibitor therapy (such as Soliris)
      b. You have evidence of intravascular hemolysis (blood cells break down within your blood stream) such as lactate dehydrogenase level of at least 1.5 times the upper limit of normal or hemoglobinuria (urine has substance called hemoglobin)
      c. You have history of major adverse vascular event from thromboembolism (blood clot)

C. **If you have atypical hemolytic uremic syndrome, approval also requires:**
   1. You are one month of age or older
   2. There is documentation of your current weight

## RENEWAL CRITERIA

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely) or atypical hemolytic uremic syndrome

B. **If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:**

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

1. You have shown clinical benefit (such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (an enzyme) and hemoglobin levels) compared to baseline (before you started treatment)
2. There is documentation of your current weight

C. **If you have atypical hemolytic uremic syndrome, renewal also requires:**
1. There is documentation of your current weight

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**RATIONALE**
For further information, please refer to the Prescribing Information and/or Drug Review for Ultomiris.

**REFERENCES**

- Ultomiris [Prescribing Information]. Boston, MA: Alexion Pharmaceuticals, Inc.; October 2020.


Commercial Effective: 04/01/21

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

# TRAMADOL

| Generic | Brand | Exception/Other |
|---|---|---|
| TRAMADOL HCL | QDOLO | |

## GUIDELINES FOR USE

Our guideline named **TRAMADOL (Qdolo)** requires the following rule(s) be met for approval:

A. The request is for the management of pain severe enough to require an opioid analgesic (type of pain medication) for which alternative treatments are inadequate
B. You are 18 years of age or older
C. You previously tried generic tramadol or a generic tramadol with acetaminophen product unless there is a medical reason why you cannot (contraindication)
D. You are unable to take oral solid formulations of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

## RATIONALE

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

## REFERENCES


- Qdolo [Prescribing Information]. Athens, GA: Athena Bioscience, LLC; September 2020.


Commercial Effective: 04/01/21

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

# RIOCIGUAT

| Generic | Brand | Exception/Other |
|---|---|---|
| RIOCIGUAT | ADEMPAS | |

## GUIDELINES FOR USE

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

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

## RENEWAL CRITERIA

Our guideline named **RIOCIGUAT (Adempas)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
   1. 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
   2. 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.

## RATIONALE

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

## REFERENCES


- Adempas [Prescribing Information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.


Commercial Effective: 04/01/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**RITUXIMAB-ARRX (NSA)**

| Generic | Brand | Exception/Other |
|---|---|---|
| RITUXIMAB-ARRX | RIABNI | |

## GUIDELINES FOR USE

Our guideline named **RITUXIMAB-ARRX (Riabni)** 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. Granulomatosis with polyangiitis (GPA or Wegener's granulomatosis: a condition that causes inflammation of the blood vessels)
   4. Microscopic polyangiitis (MPA: blood vessel inflammation, which can damage organ systems)

B. You are 18 years of age or older

C. **If you have non-Hodgkin's lymphoma (NHL), approval also requires:**
   1. Therapy is prescribed by or in consultation with an oncologist (cancer/tumor doctor)

D. **If you have chronic lymphocytic leukemia (CLL), approval also requires:**
   1. The requested medication will be used in combination with fludarabine and cyclophosphamide (FC)
   2. Therapy is prescribed by or in consultation with an oncologist (cancer/tumor doctor)

E. **If you have granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), approval also requires:**
   1. The requested medication will be used with glucocorticoids (steroids such as methylprednisolone or prednisone)

## RATIONALE

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

## REFERENCES


- Riabni [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; December 2020.


Commercial Effective: 04/01/21

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

| Generic | Brand | Exception/Other |
|---|---|---|
| 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
   4. You meet ONE of the following:
      a. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

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

# RUCAPARIB

## RATIONALE

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

## REFERENCES


- Rubraca [Prescribing Information]. Boulder, CO: Clovis Oncology, Inc.; May 2020.


Commercial Effective: 04/01/21

WELLFLEET
RX PLAN

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

# SETMELANOTIDE

| Generic | Brand | Exception/Other |
|---|---|---|
| SETMELANOTIDE ACETATE | IMCIVREE | |

## GUIDELINES FOR USE

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

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:

A. The request is for chronic weight loss management
B. You are 6 years of age or older
C. Your obesity is confirmed by ONE of the following deficiencies:
   1. Proopiomelanocortin (POMC: type of gene)
   2. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
   3. Leptin receptor (LEPR: type of gene)
D. Confirmed genetic testing shows variants (changes) in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic (causing disease), likely pathogenic, or of uncertain significance (VUS)

## RENEWAL CRITERIA

Our guideline named **SETMELANOTIDE (Imcivree)** requires the following rule(s) be met for approval:

A. You have lost at least 5% of your baseline body weight or 5% of your baseline body mass index (BMI: a measure of body fat based on your height and weight)

## RATIONALE

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

## REFERENCES


- Imcivree [Prescribing Information]. Boston, MA: Rhythm Pharmaceuticals, Inc.; November 2020.


Commercial Effective: 04/01/21

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

# SOFOSBUVIR

| Generic | Brand | Exception/Other |
|---|---|---|
| SOFOSBUVIR | SOVALDI | |

## GUIDELINES FOR USE

Our guideline named **SOFOSBUVIR (Sovaldi)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (long term type of liver inflammation)
B. You are 18 years of age or older with genotype 1 or 3, **OR** you are 3 to 17 years old with genotype 2 or 3
C. You are currently supervised by a gastroenterologist (digestive system doctor), 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
D. There is evidence showing you have current and chronic hepatitis c virus infection documented by one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
    2. You will be using Sovaldi with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
    3. You had a short trial of a preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (medical reason why you cannot use) to therapy with the preferred formulary agent(s) as specified below. An individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved
        a. If you have genotype 1 infection, you had a short trial of Epclusa or Harvoni or you have a contraindication to BOTH agents
        b. If you have genotype 3 infection, you had a short trial of Epclusa or you have a contraindication to this agent
F. **If you are a pediatric patient (under age 18) approval also requires:**
    1. The request must meet the Food and Drug Administration (FDA)-approved indication [treatment naive (never previously treated) or treatment experienced patient with compensated cirrhosis (no symptoms related to liver damage) (Child-Pugh A) or without cirrhosis (liver scarring)]
    2. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)

**The medication will not be approved for the following:**

A. You have severe renal (kidney) impairment (Glomerular filtration rate less than 30 mL/min/1.73m2), end stage renal disease and/or those requiring dialysis
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (additional diseases)
C. You are an adult with compensated cirrhosis (no symptoms related to liver damage)

D. You are using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
E. You are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
F. You are an adult who is taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin

**For requests for Sovaldi/Olysio regimen for genotype 1, the following must also be met:**
A. You are 18 years of age or older
B. You do not have cirrhosis (liver scarring)
C. You have not previously failed a full course of therapy with 1) any hepatitis c virus protease inhibitor (type of Hep C drug such as Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir) **OR** 2) a regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
D. You will not be using the requested medication together with any of the following medications as they are contraindicated (there is a medical reason why you cannot use the drug) or not recommended by the manufacturer:
    1. 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)
    2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
    3. A cobicistat-containing medication such as Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost
    4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

**For patients using Sovaldi with Daklinza, the following must also be met:**
A. You are 18 years of age or older
B. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
C. You will not be using the requested medication together with any of the following medications because they are contraindicated (medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
D. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (you have symptoms related to liver damage) or you are post-liver transplant

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

## REFERENCES
- Sovaldi [Prescribing Information]. Foster City, CA: Gilead Sciences; March 2020.

- 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.

Commercial Effective: 04/01/21

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## TASIMELTEON

| Generic | Brand | | | |
|---|---|---|---|---|
| TASIMELTEON | HETLIOZ | | | |

### GUIDELINES FOR USE

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

The guideline named **TASIMELTEON (HETLIOZ)** requires a diagnosis of Non-24 Hour Sleep Wake Disorder (N24HSWD) or Smith-Magenis Syndrome. In addition, ALL the following criteria must be met:

**For Non-24 Hour Sleep Wake Disorder:**

- 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 ALL of the following:
  - A history of insomnia, excessive daytime sleepiness, or both, that alternates with time periods of being asymptomatic, as the individual rotates between alignment and misalignment with the environmental light-dark schedule
  - Symptoms must be present for at least three months
  - Daily sleep logs and/or actigraphy for at least 14 days (though preferably longer) demonstrate a gradual daily drift (typically later) in rest-activity patterns
  - The symptoms are not better explained by another current sleep, medical, neurologic, mental, or substance abuse disorder; or medication use
- The patient has had a trial of melatonin with inadequate results.

**For Smith-Magenis Syndrome:**

- The patient had a trial and failure of maximally-tolerated melatonin therapy

### RENEWAL CRITERIA

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.

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Effective: 03/26/21

Revised: 02/01/2021

WELLFLEET
RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**

**PRIOR AUTHORIZATION GUIDELINES**

**ABATACEPT - IV (NSA)**

| Generic | Brand | | | |
|---|---|---|---|---|
| ABATACEPT/MALTOSE | ORENCIA - IV | | | |

**GUIDELINES FOR USE**

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

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 had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- 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/XR

**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, Xeljanz/XR, or Actemra SC

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WELLFLEET
RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**

**PRIOR AUTHORIZATION GUIDELINES**

# ABATACEPT - IV (NSA)

## INITIAL CRITERIA (CONTINUED)

**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, Stelara, Otezla, Tremfya, 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

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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WELLFLEET
RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**

**PRIOR AUTHORIZATION GUIDELINES**

**ABATACEPT - SQ**

| Generic | Brand | | | |
|---|---|---|---|---|
| ABATACEPT - SQ | ORENCIA - SQ, ORENCIA CLICKJECT - SQ | | | |

**GUIDELINES FOR USE**

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

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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- 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, Rinvoq, or Xeljanz.

**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, Xeljanz/XR, or Actemra SC.

**CONTINUED ON NEXT PAGE**

WELLFLEET
RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**

**PRIOR AUTHORIZATION GUIDELINES**

# ABATACEPT - SQ

**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, Stelara, Otezla, Tremfya, 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

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

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Effective: 04/23/21

Revised: 02/01/2021

WELLFLEET
RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**AGALSIDASE BETA (NSA)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| AGALSIDASE BETA | FABRAZYME | 24861 | | GPI-10 (3090361010) | |

## GUIDELINES FOR USE

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for approval:

A. You have Fabry disease (inherited disorder that causes buildup of a type of fat)
B. You are 2 years of age or older
C. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist physician in genetics or inherited metabolic disorders
D. You are NOT concurrently using an alpha-galactosidase A (a-Gal A- a type of protein) pharmacological chaperone (a molecule that helps correct other bad proteins) such as Galafold (migalastat)
E. You are symptomatic OR have evidence of injury from GL-3 (Globotriaosylceramide – a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury would include decreased Glomerular filtration rate (GFR- a test to see how well kidneys function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI

## RENEWAL CRITERIA

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of Fabry disease (inherited disorder that causes buildup of a type of fat)
B. You have demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regard to at least ONE of the following:
    1. Symptoms which includes pain, hypohidrosis/anhidrosis (less sweating or no sweating), exercise intolerance, GI (gastrointestinal) symptoms, angiokeratomas (dark red/purple raised spots), abnormal cornea, tinnitus (ringing in the ears)/hearing loss
    2. Imaging such as brain/cardiac MRI (Magnetic resonance imaging), DEXA (test to measure bone density), renal (kidney) ultrasound
    3. Laboratory or histological (viewed by microscope) testing such as GL-3 (Globotriaosylceramide - a type of fat) 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; March 2021.

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

Commercial Effective: 04/10/21

WELLFLEET RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**AXICABTAGENE CILOLEUCEL (NSA)**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| AXICABTAGENE CILOLEUCEL | YESCARTA | 44577 | | GPI-10 (2165101010) | |

**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, continue to #5.

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.

4. Does the patient meet **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 or GPI-10.**
   If no, do not approve.
   **DENIAL TEXT:** See the denial text at the end of the guideline.

**CONTINUED ON NEXT PAGE**

WELLFLEET RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**AXICABTAGENE CILOLEUCEL (NSA)**

**GUIDELINES FOR USE (CONTINUED)**

5. Does the patient have a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND** meet the following criteria?
   - The patient is 18 years of age or older
   - The patient has received two or more lines of systemic therapy

   If yes, **approve 1 fill 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 **AXICABTAGENE CILOLEUCEL (Yescarta)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Diffuse large B-cell lymphoma not otherwise specified (DLBCL: type of white blood cell cancer)
      2. Primary mediastinal large B-cell lymphoma
      3. High grade B-cell lymphoma (such as double-hit or triple-hit lymphoma)
      4. Diffuse large B-cell lymphoma arising from follicular lymphoma [such as transformed follicular lymphoma (TFL)]
      5. Relapsed or refractory (disease worsens after improving or no longer responds to treatment) follicular lymphoma (FL: type of cancer that affects your white blood cells)
   B. You are 18 years of age or older
   C. **If you have diffused large B-cell lymphoma, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or diffuse large B-cell lymphoma arising from follicular lymphoma, approval also requires:**
      1. Therapy is prescribed by a Yescarta-certified hematologist (blood doctor) or oncologist (cancer doctor)
      2. Yescarta will be administered at a treatment center that is certified to administer Yescarta
      3. You have not previously tried Yescarta
      4. Your disease has worsened or relapsed (worsens after improving) after stem cell transplantation (SCT) OR after two or more lines of systemic therapy (treatment that spreads through the bloodstream)
   D. **If you have relapsed or refractory follicular lymphoma (FL), approval also requires:**
      1. You have received two or more lines of systemic therapy

   ***(Denial text continued on next page)***

**CONTINUED ON NEXT PAGE**

WELLFLEET RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**AXICABTAGENE CILOLEUCEL (NSA)**

**GUIDELINES FOR USE (CONTINUED)**

E. **Yescarta will not be approved for ANY of the following indications:**
   1. Primary Central Nervous System Lymphoma (PCNSL: disease where cancer cells form in the lymph tissue of the brain/spinal cord)
   2. Mantle Cell Lymphoma (MCL: type of cancer that affects your white blood cells)
   3. Burkitt's lymphoma (type of cancer that affects your white blood cells)

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 Yescarta.

**REFERENCES**

- Yescarta [Prescribing Information]. Santa Monica, CA: Kite Pharma, Inc.; March 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Part D Effective: N/A
Commercial Effective: 04/10/21
Created: 10/17
Client Approval: 03/21
P&T Approval: 04/21

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## BRODALUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| BRODALUMAB | SILIQ | | | |

### GUIDELINES FOR USE

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

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, Enbrel, 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

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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Effective: 04/23/21

Revised: 02/01/2021

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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## CERTOLIZUMAB PEGOL

| Generic | Brand | | | |
|---|---|---|---|---|
| CERTOLIZUMAB PEGOL | CIMZIA | | | |

### GUIDELINES FOR USE

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

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, non-radiographic axial spondyloarthritis, 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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, 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 **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, 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
  - The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz, Otezla, or Tremfya.

**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, or Cosentyx

## CERTOLIZUMAB PEGOL

### INITIAL CRITERIA (CONTINUED)

Revised: 02/01/2021

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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**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 **TWO** of the formulary preferred immunomodulators: Humira and Stelara

**For patients with non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:**

- The patient is 18 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 an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
- The patient meets ONE of the following objective signs of inflammation:
  - C-reactive protein (CRP) levels above the upper limit of normal
  - Sacroiliitis on magnetic resonance imaging (MRI)
- The patient is pregnant, breastfeeding, or trying to become pregnant

**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, Enbrel, Otezla, 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.

## CERTOLIZUMAB PEGOL

**RENEWAL CRITERIA**

Revised: 02/01/2021

WELLFLEET
RX PLAN

## PRIOR AUTHORIZATION GUIDELINES

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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, non-radiographic axial spondyloarthritis, 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 non-radiographic axial spondyloarthritis (nr-axSpA), 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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Effective: 04/23/21

Revised: 02/01/2021

WELLFLEET
RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# DAUNORUBICIN/CYTARABINE LIPOSOME (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| DAUNORUBICIN/ CYTARABINE LIPOSOME | VYXEOS | |

## GUIDELINES FOR USE

Our guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires the following rule(s) be met for approval:

A. You have a new diagnosis of therapy-related acute myeloid leukemia (type of white blood cell cancer) OR acute myeloid leukemia with myelodysplasia-related changes (type of blood and bone marrow cancer that affects production of blood cells)
B. You are 1 year of age or older

## RATIONALE

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

## REFERENCES


- Vyxeos [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc. March 2021.


Commercial Effective: 05/01/21

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## PRIOR AUTHORIZATION GUIDELINES

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## GOLIMUMAB - SQ

| Generic | Brand | | | |
|---|---|---|---|---|
| GOLIMUMAB - SQ | SIMPONI - SQ | | | |

### GUIDELINES FOR USE

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

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 patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
- 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, 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, Stelara, Otezla, Tremfya, or Xeljanz.

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## PRIOR AUTHORIZATION GUIDELINES

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## GOLIMUMAB - SQ

### INITIAL CRITERIA (CONTINUED)

**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, or 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 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 the formulary preferred immunomodulator: 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

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

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**PRIOR AUTHORIZATION GUIDELINES**

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## GOLIMUMAB - SQ

### RENEWAL CRITERIA (CONTINUED)

**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

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Effective: 04/23/21

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**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

## IDECABTAGENE VICLEUCE (NSA) (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| IDECABTAGENE VICLEUCEL | ABECMA | |

### GUIDELINES FOR USE

Our guideline named **IDECABTAGENE VICLEUCEL (Abecma)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not responsive to treatment)
B. You are 18 years of age or older
C. You have received four or more prior lines of therapy, including an immunomodulatory agent (such as Revlimid, Pomalyst), a proteasome inhibitor (such as Velcade, Kyprolis), and an anti-CD38 monoclonal antibody (such as Darzalex)

### RATIONALE

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

### REFERENCES


- Abecma [Prescribing Information]. Summit, NJ: Celgene Corporation; March 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | No | Yes |

Commercial Effective: 04/09/21

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RX PLAN

**STANDARD NON-SELF-ADMINISTERED DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

# ISATUXIMAB-IRFC (NSA)

| Generic | Brand | Exception/Other |
|---|---|---|
| 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 (type of white blood cell cancer) OR relapsed or refractory multiple myeloma (type of white blood cell cancer that has returned or no longer responds to treatment)
B. You are 18 years of age or older
C. **If you have multiple myeloma, approval also requires:**
    1. The requested medication will be used in combination with pomalidomide and dexamethasone
    2. You have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor (such as ixazomib, carfilzomib)
D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
    1. The requested medication will be used in combination with carfilzomib and dexamethasone
    2. You have received 1 to 3 prior lines of therapy

## RATIONALE

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

## REFERENCES


- Sarclisa [Prescribing Information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC, March 2021.


Commercial Effective: 05/01/21

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## PRIOR AUTHORIZATION GUIDELINES

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## IXEKIZUMAB

| Generic | Brand | | | |
|---|---|---|---|---|
| IXEKIZUMAB | TALTZ | | | |

### GUIDELINES FOR USE

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

The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA). 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
- The patient meets one of the following:
  - You are 6 to 17 years of age **AND** have previously tried **BOTH** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel **AND** Stelara
  - You are 18 years of age or older **AND** have previously tried any **THREE** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Cosentyx, Enbrel, Humira, Otezla, Stelara, Tremfya, Skyrizi

**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, Otezla, Tremfya, 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

**PRIOR AUTHORIZATION GUIDELINES**

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- The patient has had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Cosentyx, Enbrel, or Humira

**INITIAL CRITERIA (CONTINUED)**

**For the diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:**

- You are 18 years of age or older
- Therapy 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)
- You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
- You have ONE of the following signs of inflammation:
  - C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
  - Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
- The patient had a trial of or contraindication to the formulary preferred immunomodulators: Cosentyx AND Cimzia

**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**

The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA), or ankylosing spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA) 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) or non-radiographic axial spondyloarthritis (nr-axSpA), 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

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## PRIOR AUTHORIZATION GUIDELINES

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Effective: 04/23/21

Revised: 02/01/2021

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

**LORLATINIB**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| LORLATINIB | LORBRENA | 45448 | | GPI-10 (2153055600) | |

## GUIDELINES FOR USE

Our guideline named **LORLATINIB (Lorbrena)** 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. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme) - positive which is shown by an FDA (Federal and Drug Administration) approved test

## 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.; March 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Commercial Effective: 04/10/21

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

# TIVOZANIB (INTERIM)

| Generic | Brand | Exception/Other |
|---|---|---|
| TIVOZANIB HCL | FOTIVDA | |

## GUIDELINES FOR USE

Our guideline named **TIVOZANIB (Fotivda)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory advanced renal cell carcinoma (type of kidney cancer that returns or has not responded to treatment)
B. You are 18 years of age or older
C. You previously had two or more prior systemic therapies

## RATIONALE

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

## REFERENCES


- Fotivda [Prescribing Information]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Commercial Effective: 04/02/21

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## PRIOR AUTHORIZATION GUIDELINES

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## TOFACITINIB

| Generic | Brand | | | |
|---|---|---|---|---|
| TOFACITINIB CITRATE | XELJANZ, XELJANZ XR | | | |

**GUIDELINES FOR USE**

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

The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ulcerative colitis, or polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints). 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 had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

**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

***(Denial text continued on next page)***

**CONTINUED ON NEXT PAGE**

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**PRIOR AUTHORIZATION GUIDELINES**

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# TOFACITINIB

## INITIAL CRITERIA (CONTINUED)

**If you have polyarticular course juvenile idiopathic arthritis (pcJIA), approval also requires:**

- You are 2 years of age or older
- Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
- You have previously tried 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)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERTUNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a differentmedication or get us more information if it will allow us to approve this request.

## RENEWAL CRITERIA

Our guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract
   4. Polyarticular course juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)

B. **If you have moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), 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

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

# TREPROSTINIL

| Generic | Brand | Exception/Other |
|---|---|---|
| TREPROSTINIL SODIUM | REMODULIN | |
| TREPROSTINIL | TYVASO | |
| TREPROSTINIL | ORENITRAM | |

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

## GUIDELINES FOR USE

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

### REMODULIN

Our guideline named **TREPROSTINIL (Remodulin)** requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. **For continuation of current therapy**, you must have NYHA-WHO Functional Class II, III, or IV symptoms (a way to classify how limited you are during physical activity)
E. **For new start requests**, approval also requires **ONE** of the following:
    1. You have NYHA-WHO Functional Class III or IV symptoms
    2. You have NYHA-WHO Functional Class II symptoms **AND** had a previous trial of or a medical reason why you cannot use (contraindication to) a phosphodiesterase-5 inhibitor (such as Adcirca or Revatio) or an endothelin receptor antagonist (such as Tracleer, Letairis, Opsumit)

### TYVASO

Our guideline named **TREPROSTINIL (Tyvaso)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)

2. Pulmonary hypertension (PH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 3 (type of classification of the disease)

B. **If you have PAH (WHO Group 1), approval also requires:**
   1. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
   2. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the 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
   3. You have NYHA-WHO Functional Class III or IV symptoms (a way to classify how limited you are during physical activity)

C. **If you have PH (WHO Group 3), approval also requires:**
   1. Your PAH must be associated with interstitial lung disease (PH-ILD; scarring and inflammation of the tissues in the lungs which makes it difficult to breath)

**ORENITRAM**

Our guideline named **TREPROSTINIL (Orenitram**) requires the following rule(s) be met for approval:

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)

B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)

C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
   1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than 3 Wood units

D. You have NYHA-WHO Functional Class II, III or IV symptoms (a way to classify how limited you are during physical activity)

E. You do not have severe hepatic (liver) impairment

F. You meet **ONE** of the following:
   1. Your request is for continuation of current Orenitram therapy
   2. You have tried a preferred formulary phosphodiesterase-5 inhibitor (such as sildenafil [Revatio] or tadalafil [Adcirca]) **OR** an endothelin receptor antagonist (such as Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

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

## RENEWAL CRITERIA

**NOTE:** For the diagnosis of pulmonary hypertension (PH) (WHO Group 3), please refer to the Initial Criteria section.

Our guideline named **TREPROSTINIL (Remodulin, Tyvaso, Orenitram)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. You meet **ONE** of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable from baseline in the 6-minute walk distance test **AND** your World Health Organization (WHO) functional class (a way to classify how limited you are during physical activity) has improved or remained stable

## RATIONALE

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

## REFERENCES


- Remodulin [Prescribing Information]. Research Triangle Park, NC; United Therapeutics. July 2018.
- Tyvaso [Prescribing Information]. Research Triangle Park, NC United Therapeutics. March 2021.
- Orenitram [Prescribing Information]. Research Triangle Park, NC United Therapeutics. October 2017.


Commercial Effective: 05/01/21

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## PRIOR AUTHORIZATION GUIDELINES

## OPIOID GUIDELINES - PENNSYLVANIA

| Generic | Brand | HICL | GCN | Exception/other |
|---|---|---|---|---|
| OPIOIDS | OPIOIDS | | | |

**Note: As of November 13, 2020, this applies to KU048 and KU052.**

### GUIDELINES FOR USE

The guideline named **OPIOID GUIDELINES - PENNSYLVANIA** requires the following rule(s) be met for approval:

A. You have a diagnosis of active cancer or sickle cell disease, are enrolled in hospice or palliative care, or your prescriber is a pain management specialist
B. Your physician has indicated that the requested high days supply duration is medically necessary

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### RATIONALE

To align with opioid restrictions required by Pennsylvania for fully insured plans and to prevent overutilization of opioids and increase safety.

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

Pennsylvania Opioid Disaster Declaration, Signed January 10th, 2018

Effective: 11/13/20