WELLFLEET

RX PLAN

Prior Authorization Guidelines

For Wellfleet Rx/ESI Only

(ID Card BIN: 003858)

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

Revised: 1/1/2025

WELLFLEET RX STUDENT FORMULARY

Guideline	Reviewed	Effective Date
CONTRACEPTIVES – CALIFORNIA SCHOOLS WITH RELIGIOUS EXEMPTIONS Edition 1	03/01/2024	03/01/2023

REQUIREMENTS:

Our guideline named CONTRACEPTIVES – CALIFORNIA SCHOOLS WITH RELIGIOUS EXEMPTIONS requires the following rule(s) be met for approval:

A. The patient is utilizing the requested product for a diagnosis other than contraception.

HYDROXYPROGESTERONE CAPROATE Edition 2			
Generic	Brand	Reviewed	Effective Date
HYDROXYPROGESTERONE CAPROATE	MAKENA	01/28/2024	6/1/2021
HYDROXYPROGESTERONE CAPROATE	HYDROXYPROGESTERONE CAPROATE (GENERIC FOR DELALUTIN)		

REQUIREMENTS:

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 biological female with a history of singleton spontaneous preterm birth
B. The patient does NOT have multiple gestations (twins, triplets, etc.)
C. The patient is at least 16 weeks pregnant but less than 37 weeks pregnant with a single gestation
D. The patient has 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 the patient is 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)

References:

1. Makena package insert. Waltham, MA. AMAG Pharmaceuticals, Inc. Revised February 2018. Accessed December 2022.
2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics. Prediction and Prevention of Spontaneous Preterm Birth: ACOG Practice Bulletin, Number 234. Obstet Gynecol. 2021;138(2):e65-e90. doi:10.1097/AOG.0000000000004479.

DIABETIC TEST STRIPS Edition 2			
Generic	Brand	Reviewed	Effective Date
BLOOD SUGAR DIAGNOSTIC	DIABETIC TEST STRIPS VARIOUS	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has tried ONE preferred blood glucose meter and test strips
B. The patient requires a non-preferred blood glucose test strip due to significant visual and/or cognitive impairment or similar disability
C. The patient requires a non-preferred blood glucose test strip because they are already using another manufacturer's companion insulin pump

Requests 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.

References:

1. Holt RIG, DeVries JH, Hess-Fischl A, et al. The Management of Type 1 Diabetes in Adults. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2021;44(11):2589-2625. doi:10.2337/dci21-0043.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TERIFLUNOMIDE Edition 2	AUBAGIO	1/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named TERIFLUNOMIDE (AUBAGIO) requires the following rules be met for approval:

A. The patient has a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
B. The patient is 18 years of age or older

References:

1. Aubagio package insert. Cambridge, MA. Genzyme Corporation. Revised April 2021. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

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INTERFERONS FOR MULTIPLE SCLEROSIS Edition 2			
Generic	Brand	Reviewed	Effective Date
INTERFERON BETA-1A	AVONEX, AVONEX PEN	01/28/2024	6/1/2021
INTERFERON BETA-1A /ALBUMIN	REBIF, REBIF REBIDOSE		
INTERFERON BETA-1B	BETASERON		
PEGINTERFERON BETA-1A	PLEGRIDY, PLEGRIDY PEN		

REQUIREMENTS:

The guideline named INTERFERONS FOR MULTIPLE SCLEROSIS requires the following rules(s) to be met for approval:

A. The patient has a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease
B. The patient is 18 years of age or older
C. The patient has trialed and failed either generic glatiramer or dimethyl fumarate.

References:
1. Avonex package insert. Cambridge, MA. Biogen Inc. Revised July 2023. Accessed December 2023.
2. Rebif package insert. Rockland, MA. EMD Serono, Inc. Revised July 2023. Accessed December 2023.
3. Betaseron package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised July 2023. Accessed December 2032.
4. Plegridy package insert. Cambridge, MA. Biogen Inc. Revised July 2023. Accessed December 2023.
5. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

Generic	Brand	Reviewed	Effective Date
ROPEGINTERFERON ALFA-2B-NJFT Edition 2	BESREMI	01/28/2024	01/28/2022

REQUIREMENTS:

Our guideline named ROPEGINTERFERON ALFA-2B-NJFT (Besremi) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested medication will be prescribed by or in consultation with an oncologist/hematologist
C. The patient has a diagnosis of polycythemia vera
D. The patient has tried, or has a documented medical contraindication, to hydroxyurea.

References:

1. Besremi package insert. Burlington, MA. PharmaEssentia Corporation. Revised November 2021. Accessed December 2023.
2. Tefferi A, Barbui T. Polycythemia vera and essential thrombocythemia: 2019 update on diagnosis, risk-stratification and management. Am J Hematol. 2019;94(1):133-143. doi:10.1002/ajh.25303.
3. Marchioli R, Finazzi G, Specchia G, et al. Cardiovascular events and intensity of treatment in polycythemia vera. N Engl J Med. 2013;368(1):22-33. doi:10.1056/NEJMoa1208500.

Generic	Brand	Reviewed	Effective Date
CORTICOTROPIN Edition 3	ACTHAR	01/28/2024	01/28/2024
CORTICOTROPIN	PURIFIED CORTROPHIN		

REQUIREMENTS:

Our guideline named CORTICOTROPIN (Acthar Gel, Purified Cortrophin Gel) requires the following rule(s) be met for approval:

A. The patient has infantile spasms
    a. The patient is less than 2 years of age
B. The patient has multiple sclerosis
    a. The patient is at least 18 years of age
    b. The requested product will be utilized to treat exacerbations of multiple sclerosis

For all other indications, consider the use of intravenous (IV) corticosteroids.

Other approved indications include:

1. Acute exacerbation of multiple sclerosis
2. Rheumatic disorders
    a. Psoriatic arthritis
    b. Rheumatoid arthritis
    c. Ankylosing spondylitis
3. Collagen diseases
    a. Systemic lupus erythematosus
    b. Systemic dermatomyositis
4. Dermatologic diseases
    a. Severe erythema multiforme
    b. Stevens-Johnson syndrome
5. Allergic disease
    a. Serum sickness
6. Ophthalmic disease
    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
    a. Symptomatic sarcoidosis

REQUIREMENTS: CORTICOTROPIN (CONTINUED)

8. Edematous state
    a. To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type, or that due to lupus erythematosus

References:
1. Acthar Gel package insert. Bedminster, NJ. Mallinckrodt ARD LLC. Revised October 2021. Accessed December 2023
2. Purified Cortrophin package insert. Baudette, MN. ANI Pharmaceuticals, Inc. Revised November 2021. Accessed December 2022.

Generic	Brand	Reviewed	Effective Date
CRIZANLIZUMAB-TMCA Edition 3	ADAKVEO	01/28/2024	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named CRIZANLIZUMAB-TMCA (Adakveo) requires the following rule(s) be met for approval:

A. The patient has sickle cell disease (type of red blood cell disorder)
B. The patient is at least 16 years old
C. The medication is prescribed by or given in consultation with a hematologist or a sickle cell disease specialist
D. The patient has previously tried hydroxyurea, unless there is a medical reason why they cannot
E. The patient has experienced at least 2 sickle cell-related vaso-occlusive crises (VOC) in the past 12 months. (A sickle cell-related VOC is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism, or splenic sequestration)
F. The patient will not be receiving Adakveo in combination with Oxbryta (voxelotor)
G. The patient will not be receiving concomitant chronic, prophylactic red-cell transfusion therapy
H. The patient will be receiving Adakveo concurrently with hydroxyurea, unless there is a medical reason why they cannot

RENEWAL CRITERIA
Our guideline named CRIZANLIZUMAB-TMCA (Adakveo) requires the following rule(s) be met for renewal:

A. The patient has sickle cell disease
B. The patient has experienced a reduction in the number of sickle cell-related vaso-occlusive crises (VOC) from pre-treatment baseline..
C. The patient is not receiving Adakveo in combination with Oxbryta (voxelotor)
D. The patient is not receiving concomitant chronic, prophylactic red-cell transfusion therapy.
E. The patient is receiving Adakveo concurrently with hydroxyurea, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

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REQUIREMENTS: CRIZANLIZUMAB-TMCA (CONTINUED)

References:

1. Adakveo package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised September 2022. Accessed December 2023.
2. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease:summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.
3. Ataga KI, Kutlar A, Kanter, J, et al. Crizanlizumab for the prevention of pain crises in sickle cell disease. N Engl J Med. 2017;376:429-39. DOI: 10.1056/NEJMoa1611770.

WELLFLEET RX STUDENT FORMULARY

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 2	Reviewed	Effective Date
Age Limit Exception Guidelines	01/28/2024	6/1/2021
Description Certain drugs may only be covered if you meet the minimum or maximum age limit and is intended to promote safe, appropriate use of medications. This guideline is only used when PA criteria is not available or does not address age exceptions.		

REQUIREMENTS:

All of the following must be met:

1. The drug must be proven to be safe for the member's age, AND
2. The drug must be proven to be effective for the member's condition and age.
    a. This must be demonstrated by at least TWO peer-reviewed articles

WELLFLEET RX STUDENT FORMULARY

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Edition 2	Reviewed	Effective Date
Guidelines for Drugs Without PA Criteria - FDA	01/28/2024	6/1/2021
Description This drug coverage policy applies only to drugs that do not have existing Prior Authorization criteria but requires Prior Authorization on the formulary.		

REQUIREMENTS:

1. Requested drug has been approved by the FDA, AND
2. Requested drug is not included in the Wellfleet Rx Plan Prior Authorization (PA) Guidelines, but requires PA on the formulary, AND
3. Patient is diagnosed with a condition that is consistent with an indication listed in the drug's FDA-approved prescribing information or package insert, AND
4. Patient meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
5. Requesting provider is of an appropriate specialty for prescribing the requested medication, if applicable

Generic	Brand	Reviewed	Effective Date
TESAMORELIN Edition 3	EGRIFTA	01/28/2024	01/28/2022

REQUIREMENTS:

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-infected patients who have lipodystrophy syndrome
B. The patient must be receiving treatment with an antiretroviral therapy (ART) regimen, which may include one or more of the following: protease inhibitor (PI) [e.g., saquinavir, ritonavir, indinavir, nelfinavir, lopinavir/ritonavir, atazanavir, fosamprenavir, tipranavir]; nucleoside reverse transcriptase inhibitor (NRTI) [e.g., zidovudine, didanosine, stavudine, lamivudine, abacavir, tenofovir, emtricitabine, lamivudine/zidovudine, abacavir/lamivudine/zidovudine, efavirenz/emtricitabine/tenofovir, emtricitabine/tenofovir]; non-nucleoside reverse transcriptase inhibitor (NNRTI) [e.g., efavirenz, nevirapine, etravirine, doravirine, delavirdine, rilpivirine]; an integrase strand transfer inhibitor (INSTI) [e.g., dolutegravir, raltegravir, cabotegravir, elvitegravir]; CD4 post-attachment inhibitor [e.g. ibalizumab]; a CCR5 antagonist [e.g., maraviroc]; gp120 attachment inhibitor [e.g., temsavir]; and/or a fusion inhibitor (FI) [e.g., enfuvirtide].

References:

1. Egrifta package insert. Montréal, Québec, Canada. Theratechnologies Inc. Revised July 2019. Accessed December 2023.
2. Lake JE, Stanley TL, Apovian CM, et al. Practical Review of Recognition and Management of Obesity and Lipohypertrophy in Human Immunodeficiency Virus Infection [published correction appears in Clin Infect Dis. 2017 Oct 15;65(8):1431-1433]. Clin Infect Dis. 2017;64(10):1422-1429. doi:10.1093/cid/cix178.
3. Ammassari A, Antinori A, Cozzi-Lepri A, et al. Relationship between HAART adherence and adipose tissue alterations. J Acquir Immune Defic Syndr. 2002;31 Suppl 3:S140-S144. doi:10.1097/00126334-200212153-00011.
4. United States Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/0 (Accessed on November 10, 2021).

Generic	Brand	Reviewed	Effective Date
VISMODEGIB Edition 2	ERIVEDGE	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline for VISMODEGIB (Erivedge) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    a. metastatic basal cell carcinoma
    b. locally advanced basal cell carcinoma that has returned after surgery or the patient is not a candidate for surgery or radiation.
B. Therapy will be prescribed by, or in consultation with, an oncologist

References:
1. Erivedge package insert. South San Francisco, CA. Genentech USA, Inc. Revised July 2020. Accessed December 2023.

WELLFLEET RX STUDENT FORMULARY

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 2	Reviewed	Effective Date
Excluded Formulary Drug Exception Guidelines	01/28/2024	6/1/2021

Description

In some cases, patients may be required to first try formulary drugs to treat a medical condition before they can utilize excluded drug options. The following exception guidelines are used only when drug-specific guidelines are not available or if the prescriber believes it is medically necessary for the patient to be on the excluded drug.

REQUIREMENTS:

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. The patient has 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 they 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. Requesting provider 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. Requesting provider 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 requested product is a Multi-Source Brand (Brand name product that the generic is currently available for), the patient has trialed and failed the generic alternative

D. 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, the requesting provider has provided medical justification supporting an inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products)

Generic	Brand	Reviewed	Effective Date
AFLIBERCEPT Edition 3	EYLEA	01/28/2024	1/28/2024

REQUIREMENTS:

Our guideline named AFLIBERCEPT (Eylea) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Neovascular (wet) age-related macular degeneration
    2. Macular edema following retinal vein occlusion
    3. Diabetic macular edema
    4. Diabetic retinopathy with diabetic macular edema
    5. Retinopathy of Prematurity
B. The medication is prescribed by or given in consultation with an ophthalmologist and/or retina specialist
C. The patient does not currently have an ocular/periocular infection or active intraocular inflammation

References:

1. Eylea package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised December 2023. Accessed December 2023.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024.
3. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025.
4. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(2):P288-P320. doi:10.1016/j.ophtha.2019.09.029.

Generic	Brand	Reviewed	Effective Date
VANDETANIB Edition 2	CAPRELSA	01/28/2024	1/28/2024

REQUIREMENTS:

Our guideline for VANDETANIB (Caprelsa) requires the following rule(s) be met for approval:

A. The patient has symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease
B. Therapy will be prescribed by, or in consultation with, an oncologist

References:
1. Caprelsa package insert. Cambridge, MA. Genzyme Corporation. Revised March 2022. Accessed December 2023.

WELLFLEET RX STUDENT FORMULARY

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 2	Reviewed	Effective Date
Compounded Drug Prior Authorization Guidelines	01/28/2024	6/1/2021

Description

Drug compounding is the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs and is performed by a licensed pharmacist, a licensed physician, or a person under the supervision of a licensed pharmacist. Compounded drugs are not FDA-approved.

REQUIREMENTS:

1. Compounded drug is prescribed by a licensed healthcare provider, AND
2. Indication or diagnosis for the use of the requested compounded medication must be documented, AND
3. All ingredients that will be used in the compounded medication must be documented, AND
4. Active ingredient(s) is/are an FDA-approved prescription drug, AND
5. Patient meets ONE of the following:
    a. Clinical condition is NOT treatable with a commercially available drug product, AND
        i. The safety and effectiveness of this compound is supported by FDA approval, OR
        ii. The compound combination is supported by adequate medical and scientific evidence published in peer-reviewed journals (at least TWO articles) or standard reference compendia for the treatment of the clinical condition, OR
    b. Clinical condition is treatable with a commercially available drug product, AND
        i. The patient is unable to receive the commercially available manufactured form of the medication because the patient's medical condition causes difficulty in delivery of the uncompounded form, OR
        ii. The patient is allergic to an ingredient in the commercially available drug, AND
        iii. The safety and effectiveness of this compound supported by FDA approval, OR
        iv. The compound combination is supported by adequate medical and scientific evidence published in peer-reviewed journals (at least TWO articles), or standard reference compendia for the treatment of the clinical condition.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLATIRAMER ACETATE Edition 3	COPAXONE, GLATOPA	01/28/2024	1/28/2024

REQUIREMENTS:

The guideline named GLATIRAMER ACETATE (Copaxone) requires the following rule(s) to be met for approval:

A. The patient has a diagnosis of a relapsing form of multiple sclerosis.
B. The patient is at least 18 years of age
C. If the request is for Copaxone, the patient has a contraindication to Glatopa or currently available generic glatiramer products

References:

1. Copaxone package insert. Parsippany, NJ. Teva Neuroscience, Inc. Revised November 2023. Accessed December 2023.
2. Glatopa package insert. Princeton, NJ. Sandoz Inc. Revised November 2023. Accessed December 2023.
3. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

Generic	Brand	Reviewed	Effective Date
BUROSUMAB-TWZA Edition 2	CRYSVITA	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named BUROSUMAB (Crysvita) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. X-linked hypophosphatemia (XLH)
    2. Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO)
B. If the patient has X-linked hypophosphatemia (XLH), approval also requires:
    1. The diagnosis is confirmed by ONE of the following:
        i. Patient has XLH symptoms such as osteomalacia, excessive fractures, bowed legs, impaired growth and ONE of the following:
            a. If the patient is less than 18 years of age, their serum phosphate level is less than 3.2mg/dL with normal vitamin D levels
            b. If the patient is 18 years of age or older, their serum phosphate level is less than 2.5mg/dL with normal vitamin D levels
            c. The patient has more than normal amount of FGF23 protein on assay
            d. The patient has a family history of X-linked hypophosphatemia
        ii. The patient has a *PHEX* mutation (Phosphate-regulating neutral endopeptidase, X-linked) confirmed by genotyping
    2. The patient is 6 months of age or older
    3. Therapy is prescribed by or given in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist
    4. The patient will not be taking oral phosphate salt or active vitamin D analog supplementation with the requested medication
    5. The patient meets ONE of the following:
        i. They previously had a trial of or failure to phosphate/vitamin D analog therapy (such as calcitriol, paricalcitol)
        ii. Their disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for the patient compared to anticipated outcomes with Crysvita

(Criteria continued on next page)

REQUIREMENTS: BUROSUMAB-TWZA (CONTINUED)

C. If the patient has FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO), approval also requires:
    1. The diagnosis is confirmed by symptoms of tumor-induced osteomalacia
    2. The patient is 2 years of age or older
    3. Therapy is prescribed by or given in consultation with an endocrinologist, nephrologist, orthopedic surgeon, or medical geneticist
    4. The patient tumors cannot be curatively resected or localized
    5. The patient stopped oral phosphate and/or active vitamin D analogs (such as calcitriol, paricalcitol) at least 1 week prior to starting Crysvita
    6. The patient meets ONE of the following:
        i. They previously had a trial of or failure to phosphate/vitamin D analog therapy
        ii. Their disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for the patient compared to anticipated outcomes with Crysvita

RENEWAL CRITERIA

Our guideline named BUROSUMAB (Crysvita) requires the following rules be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. X-linked hypophosphatemia (XLH)
    2. Fibroblast growth factor 23 (FGF23) -related hypophosphatemia in tumor-induced osteomalacia (TIO)
B. If the patient has X-linked hypophosphatemia (XLH), renewal also requires:
    1. The patient has achieved normal blood phosphate levels as defined by the reference range for their age
C. If the patient has Fibroblast growth factor 23 (FGF23) - related hypophosphatemia in tumor- induced osteomalacia, renewal also requires:
    1. The patient has achieved normal fasting blood phosphate levels (around or above the lower end of the reference range for age and below 5 mg/dL)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: BUROSUMAB-TWZA (CONTINUED)

References:

1. Crysvita package insert. Novato, CA. Ultragenyx Pharmaceutical Inc. Revised June 2020. Accessed December 2023.
2. Carpenter TO, Imel EA, Holm IA, Jan de Beur SM, Insogna KL. A clinician's guide to X-linked hypophosphatemia [published correction appears in J Bone Miner Res. 2015 Feb;30(2):394]. J Bone Miner Res. 2011;26(7):1381-1388. doi:10.1002/jbmr.340.
3. Feng JQ, Clinkenbeard EL, Yuan B, White KE, Drezner MK. Osteocyte regulation of phosphate homeostasis and bone mineralization underlies the pathophysiology of the heritable disorders of rickets and osteomalacia. Bone. 2013;54(2):213-221. doi:10.1016/j.bone.2013.01.046.

Generic	Brand	Reviewed	Effective Date
VALBENAZINE Edition 3	INGREZZA	01/28/2024	1/28/2024

REQUIREMENTS:

Our guideline named VALBENAZINE (Ingrezza) requires the following rule(s) be met for approval:

A. The patient has moderate to severe tardive dyskinesia (involuntary movements, usually due to certain drugs) and it has been present for at least 3 months OR chorea associated with Huntington's Disease
B. The patient is 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
D. The patient has 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)

References:

1. Ingrezza package insert. San Diego, CA. Neurocrine Biosciences, Inc. Revised August 2023. Accessed December 2023
2. Bhidayasiri R, Jitkritsadakul O, Friedman JH, Fahn S. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. J Neurol Sci. 2018;389:67-75. doi:10.1016/j.jns.2018.02.010
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2013 Nov 26;81(22):1968]. Neurology. 2013;81(5):463-469. doi:10.1212/WNL.0b013e31829d86b6.

Generic	Brand	Reviewed	Effective Date
TOLVAPTAN Edition 2	JYNARQUE	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named TOLVAPTAN (Jynarque) requires the following rule(s) be met for approval:

A. The patient has autosomal dominant polycystic kidney disease (ADPKD)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a nephrologist
D. Diagnosis has been confirmed via CT or MRI imaging AND at least one of the following:
    1. The patient has a genotype that causes of autosomal dominant polycystic kidney disease OR
    2. The patient has a family history of confirmed polycystic kidney disease in one or both parents
E. The patient does not have End-Stage Renal Disease (ESRD), including no renal transplantation or dialysis
F. The patient is 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. The patient has autosomal dominant polycystic kidney disease (ADPKD)
B. The patient has NOT progressed to end stage renal disease (ESRD)

References:

1. Jynarque package insert. Rockville, MD. Otsuka America Pharmaceutical, Inc. Revised October 2020. Accessed December 2023.
2. Pei Y, Hwang YH, Conklin J, et al. Imaging-based diagnosis of autosomal dominant polycystic kidney disease. J Am Soc Nephrol. 2015;26(3):746-753. doi:10.1681/ASN.2014030297.
3. Chapman AB, Devuyst O, Eckardt KU, et al. Autosomal-dominant polycystic kidney disease (ADPKD): executive summary from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. Kidney Int. 2015;88(1):17-27. doi:10.1038/ki.2015.59.

Generic	Brand	Reviewed	Effective Date
SEBELIPASE ALFA Edition 2	KANUMA	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SEBELIPASE ALFA (Kanuma) requires the following rule(s) be met for approval:

A. The patient has lysosomal acid lipase (LAL) deficiency, as confirmed by the presence of clinical features such as hepatomegaly, elevated serum transaminases , dyslipidemia, or splenomegaly
B. The medication is prescribed by or given in consultation with an endocrinologist, hepatologist (liver specialist), gastroenterologist (digestive system doctor), medical geneticist, or lipidologist (cholesterol management specialist)
C. The patient meets ONE of the following:
    1. A blood test has indicated low or absent levels of lysosomal acid lipase enzyme activity
    2. A dried blood spot test has indicated low or absent lysosomal acid lipase enzyme activity
    3. A genetic test has indicated the bi-allelic presence of altered LIPA gene(s)

RENEWAL CRITERIA
Our guideline named SEBELIPASE ALFA (Kanuma) requires the following rule(s) be met for renewal:

A. The patient has lysosomal acid lipase (LAL) deficiency presenting after the first 6 months of life and not considered rapidly progressive
A. The patient has 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) 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

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: SEBELIPASE ALFA (CONTINUED)

References:

1. Kanuma package insert. Boston MA. Alexion Pharmaceuticals, Inc. Revised November 2021. Accessed December 2023.
2. Kohli R, Ratziu V, Fiel MI, Waldmann E, Wilson DP, Balwani M. Initial assessment and ongoing monitoring of lysosomal acid lipase deficiency in children and adults: Consensus recommendations from an international collaborative working group. Mol Genet Metab. 2020;129(2):59-66. doi:10.1016/j.ymgme.2019.11.004.
3. Burton BK, Balwani M, Feillet F, et al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. N Engl J Med 2015; 373:1010.
4. Jones SA, Rojas-Caro S, Quinn AG, et al. Survival in infants treated with sebelipase Alfa for lysosomal acid lipase deficiency: an open-label, multicenter, dose-escalation study. Orphanet J Rare Dis 2017; 12:25.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OFATUMUMAB Edition 2	KESIMPTA	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named OFATUMUMAB-SQ (Kesimpta) requires the following rule(s) be met for approval:

A. The patient has a relapsing form of multiple sclerosis (MS), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. The patient is 18 years of age or older
C. The patient has trialed and failed generic dimethyl fumarate or glatiramer

References:

1. Kesimpta package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2020. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

Generic	Brand	Reviewed	Effective Date
TOREMIFENE CITRATE Edition 2	FARESTON	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named TOREMIFENE (Fareston) requires the following rule(s) be met for approval:

A. The patient has metastatic breast cancer
B. The patient is a postmenopausal biological female
C. The patient has an estrogen-receptor positive or unknown tumor

References:
1. Fareston package insert. Bedminster, NJ. Kyowa Kirin Inc. Revised May 2017. Accessed December 2023.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EMAPALUMAB-LZSG Edition 2	GAMIFANT	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named EMAPALUMAB-LZSG (Gamifant) requires the following rule(s) be met for approval:

A. The patient has primary hemophagocytic lymphohistiocytosis (HLH)
B. The diagnosis is confirmed by ONE of the following:
    1. A genetic test identifying HLH-associated gene mutation such as PRF1 or UNC13D
    2. At least five of the following eight diagnostic criteria for HLH: fever; splenomegaly; cytopenias; hypertriglyceridemia and/or hypofibrinogenemia ; hemophagocytosis in bone marrow or spleen or lymph nodes, and no evidence of malignancy; low or absent natural killer-cell activity; ferritin level of at least 500 mcg/L; soluble CD25 level of at least 2,400 U/mL
C. The patient has refractory, recurrent, or progressive disease; OR 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 as dexamethasone
E. Therapy is prescribed by or given in consultation with an immunologist, hematologist, or oncologist

RENEWAL CRITERIA
Our guideline named EMAPALUMAB-LZSG (Gamifant) requires the following rule(s) be met for renewal:

A. The patient has primary hemophagocytic lymphohistiocytosis
B. The patient has not received successful hematopoietic stem cell transplantation
C. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease actibity measures and/or experienced improvement of symptoms

References:

1. Gamifant package insert. Waltham, MA. Sobi Inc. Revised November 2018. Accessed December 2023.
2. Yildiz H, Van Den Neste E, Defour JP, Danse E, Yombi JC. Adult haemophagocytic lymphohistiocytosis: a Review [published online ahead of print, 2020 Jan 14]. QJM. 2020;hcaa011. doi:10.1093/qjmed/hcaa011.
3. Jordan MB, Allen CE, Greenberg J, et al. Challenges in the diagnosis of hemophagocytic lymphohistiocytosis: Recommendations from the North American Consortium for Histiocytosis (NACHO). Pediatr Blood Cancer. 2019;66(11):e27929. doi:10.1002/pbc.27929.

ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE Edition 2			
Generic	Brand	Reviewed	Effective Date
IMIGLUCERASE	CEREZYME	01/28/2024	6/1/2021
TALIGLUCERASE ALFA	ELELYSO		
VELAGLUCERASE ALFA	VPRIV		

REQUIREMENTS:

ELELYSO

Our guideline named ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Elelyso) requires the following rule(s) be met for approval:

A. The patient has a confirmed diagnosis of type 1 Gaucher disease
B. The patient is 4 years of age or older
C. The patient previously had a trial of Vpriv or Cerezyme, unless there is a medical reason why they cannot

VPRIV

Our guideline named ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Vpriv) requires the following rule(s) be met for approval:

A. The patient has a confirmed diagnosis of type 1 Gaucher disease
B. The patient is 4 years of age or older

CEREZYME

Our guideline named ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE (Cerezyme) requires the following rule(s) be met for approval:

A. The patient has a confirmed diagnosis of type 1 Gaucher disease
B. The patient is 18 years of age or older

References:

1. Cerezyme package insert. Cambridge, MA. Genzyme Corporation. Revised April 2018. Accessed December 2023.
2. Elelyso package insert. New York, NY. Pfizer, Inc. Revised May 2023. Accessed December 2023.
3. Vpriv package insert. Lexington, MA. Shire Human Genetic Therapies, Inc. Revised December 2020. Accessed December 2023.
4. Biegstraaten M, Cox TM, Belmatoug N, et al. Management goals for type 1 Gaucher disease: An expert consensus document from the European working group on Gaucher disease. Blood Cells Mol Dis. 2018;68:203-208. doi:10.1016/j.bcmd.2016.10.008.
5. Wang RY, Bodamer OA, Watson MS, Wilcox WR; ACMG Work Group on Diagnostic Confirmation of Lysosomal Storage Diseases. Lysosomal storage diseases: diagnostic confirmation and management of presymptomatic individuals. Genet Med. 2011;13(5):457-484. doi:10.1097/GIM.0b013e318211a7e1.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GIVOSIRAN Edition 1	GIVLAARI	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GIVOSIRAN (Givlaari) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of 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. The patient is 18 years of age or older
C. The patient has genetic confirmation of AHP mutation as shown by an FDA (Food and Drug Administration)-approved test, OR high (beyond reference range) urinary or plasma porphobilinogen (PBG), or aminolevulinic acid (ALA)
D. The patient has 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 , hepatologist , hematologist, gastroenterologist , neurologist , dermatologist , or a healthcare provider experienced in managing acute hepatic porphyria
F. The provider has provided documentation of your weight

RENEWAL CRITERIA
Our guideline named GIVOSIRAN (Givlaari) requires the following rule(s) be met for renewal:

A. The patient has 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. The patient has achieved or maintained clinical benefit compared to baseline (such as lesshemin use, less AHP attacks, improvement of AHP symptoms, etc.)
C. The patient has not received a liver transplant
D. D. The provider has provided documentation of your weight

References:

1. Givlaari package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised February 2023. Accessed December 2023.
2. Balwani M, Wang B, Anderson KE, et al. Acute hepatic porphyrias: Recommendations for evaluation and long-term management. Hepatology. 2017;66(4):1314-1322. doi:10.1002/hep.29313.

Generic	Brand	Reviewed	Effective Date
ALGLUCOSIDASE ALFA Edition 2	LUMIZYME	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named ALGLUCOSIDASE ALFA (Lumizyme) requires that the following rules be met:

A. The patient has a diagnosis of 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)

References:

1. Lumizyme package insert. Cambridge, MA. Genzyme Corporation. Revised May 2023. Accessed December 2023.
2. Dornelles AD, Junges APP, Pereira TV, et al. A Systematic Review and Meta-Analysis of Enzyme Replacement Therapy in Late-Onset Pompe Disease. J Clin Med. 2021;10(21):4828. Published 2021 Oct 21. doi:10.3390/jcm10214828.
3. Cupler EJ, Berger KI, Leshner RT, et al. Consensus treatment recommendations for late-onset Pompe disease. Muscle Nerve. 2012;45(3):319-33.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LUTETIUM LU 177 DOTATATE Edition 2	LUTATHERA	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named LUTETIUM LU 177 DOTATATE (Lutathera) requires the following rule(s) be met for approval:

A. The patient has somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut tumors
B. The patient is 18 years of age or older
C. The patient will be treated with a long-acting octreotide (type of hormone) as maintenance therapy together with the requested medication
D. The patient has been previously treated with a long-acting somatostatin analog (such as octreotide or lanreotide) before the request of this medication
E. The patient has NOT previously received 4 doses of Lutathera

References:

1. Lutathera package insert. Millburn, NJ. Advanced Accelerator Applications USA, Inc. Revised March 2023. Accessed December 2023.

Generic	Brand	Reviewed	Effective Date
CLADRIBINE Edition 2	MAVENCLAD	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named CLADRIBINE (Mavenclad) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. The patient is 18 years of age or older
C. The patient has 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. The patient has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing- remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. The prescribing healthcare provider attests/ confirms that the patient has demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
C. The patient does not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
D. The patient has not received a total of two years or more of Mavenclad treatment, or it has been at least 2 years since their last course of therapy

References:
1. Mavenclad package insert. Rockland, MA. EMD Serono, Inc. Revised December 2023. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

Generic	Brand	Reviewed	Effective Date
MITOXANTRONE HCL Edition 2	NOVANTRONE	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named MITOXANTRONE requires the following rule(s) be met for approval:

A. The medication is prescribed by or given in consultation with an oncologist
B. The patient has ONE of the following diagnoses:
    1. Pain related to advanced refractory prostate cancer
    2. Acute nonlymphocytic leukemia
    3. Secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis

References:

1. Mitoxantrone hydrochloride package insert. Lake Forest, IL. Hospira Inc. Revised May 2018. Accessed December 2023.
2. Mitoxantrone hydrochloride package insert. Schaumburg, IL. APP Pharmaceuticals, LLC. Revised January 2008. Accessed December 2022.
3. Mitoxantrone hydrochloride package insert. Irvine, CA. Teva Parenteral Medicines, Inc. Revised October 2021. Accessed December 2022.
4. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PLERIXAFOR Edition 3	MOZOBIL	01/28/2024	1/28/2024

REQUIREMENTS:

Our guideline named PLERIXAFOR (Mozobil) requires you meet the following rule(s) for approval:

A. The patient has Non-Hodgkin's lymphoma or multiple myeloma
B. The medication is prescribed by or given in consultation with a hematologist or oncologist
C. The requested medication will be used in combination with filgrastim

References:

1. Mozobil package insert. Cambridge, MA. Genzyme Corporation. Revised September 2023. Accessed December 2023.

Generic	Brand	Reviewed	Effective Date
ALEMTUZUMAB Edition 2	LEMTRADA	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ALEMTUZUMAB (Lemtrada) requires the following rules be met for approval:

A. The patient has a relapsing form of multiple sclerosis, to include relapsing-remitting MS [RRMS] and active secondary progressive disease [SPMS], etc.
B. The patient is 18 years of age or older
C. The patient has previously tried TWO drugs that have been FDA-approved for the treatment of relapsing forms of multiple sclerosis
D. Administration of the requested product will be conducted in a care setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions, and patient will be monitored for at least 2 hours post-infusion

RENEWAL CRITERIA
Our guideline named ALEMTUZUMAB (Lemtrada) requires the following rules be met for renewal:

A. The patient has a relapsing form of multiple sclerosis, to include relapsing-remitting disease and active secondary progressive disease (advanced disease)
B. At least 12 months have passed since the patient received their most recent course of Lemtrada

References:
1. Lemtrada package insert. Cambridge, MA. Genzyme Corporation. Revised May 2022. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Comprehensive systematic review summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018 Apr 24;90(17):789-800.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MARALIXIBAT Edition 3	LIVMARLI	01/28/2024	01/28/2024

REQUIREMENTS:

Our guideline named MARALIXIBAT (Livmarli) requires the following rule(s) be met for approval:

A. The patient is 3 months of age or older
B. The requested product will be prescribed by or in consultation with a hepatologist or an Alagille syndrome specialist
C. The patient has a diagnosis of Alagille syndrome (ALGS)
A. The patient has a deletion or mutation of the JAG1 gene or NOTCH2 gene as detected by an FDA-approved test
D. The patient has severe cholestatic pruritus symptoms.
E. The patient's baseline assessment score for pruritus symptoms has been documented utilizing an established assessment instrument [e.g., CSS (clinician scratch scale), ISS (Itch Severity Scale), ItchRO[Obs] (Itch Reported Outcome Instrument), ItchyQoL (Itch-Related Quality of Life), NRS (numeric rating scale), QoL (quality of life), VAS (visual analog scale), VRS (verbal rating scale), etc.]

RENEWAL CRITERIA

Our guideline named MARALIXIBAT (Livmarli) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of Alagille syndrome (ALGS) and severe cholestatic pruritus symptoms.
B. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools

References:

1. Livmarli package insert. Foster City, CA. Mirum Pharmaceuticals, Inc. Revised March 2023. Accessed December 2023.
2. Ayoub MD, et al. Alagille syndrome: diagnostic challenges and advances in management. Diagnostics (Basel). 2020;10(11):907. Published November 6, 2020. doi:10.3390/diagnostics 10110907.
3. Kamath BM, et al. Systematic review: The epidemiology, natural history, and burden of Alagille syndrome. J Pediatr Gastroenterol Nutr. 2018; 67:148-156.doi: 10.1097/MPG.0000000000001958.

Generic	Brand	Reviewed	Effective Date
TRIFLURIDINE/TIPIRACIL Edition 2	LONSURF	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named TRIFLURIDINE/TIPIRACIL (Lonsurf) requires the following rule(s) be met for approval:

A. The patient has 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 the patient has metastatic colorectal cancer, approval also requires:
    1. They 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 they are negative for the RAS mutation (RAS wild-type), they have had a previous treatment with an anti-EGFR agent such as Erbitux(cetuximab) or Vectibix (panitumumab)
C. If the patient has metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:
    1. They 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

References:
1. Lonsurf package insert. Princeton, NJ. Taiho Oncology, Inc. Revised August 2023. Accessed December 2023.

BUPRENORPHINE IMPLANT			
Generic	Brand	Reviewed	Effective Date
BUPRENORPHINE Edition 2	PROBUPHINE	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named BUPRENORPHINE IMPLANT (Probuphine) requires the following rule(s) be met for approval:

A. The patient has NOT previously received ONE Probuphine treatment course in EACH arm (for a maximum of TWO 6-month treatment courses)
B. The patient has achieved and continues to have clinical stability on low to moderate doses of transmucosal buprenorphine (such as Subutex, Suboxone, Bunavail, or Zubsolv) defined as 8mg 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
D. The requested medication will be used as part of a complete treatment program, including counseling and psychosocial support.

References:

1. Probuphine package insert. South San Francisco, CA. Titan Pharmaceuticals, Inc. Revised June 2022. Accessed December 2023.
2. Drug Facts and Comparisons. Facts & Comparisons®eAnswers [database online]. St. Louis, MO: Wolters Kluwer Health, Inc. Available at: http://online.factsandcomparisons.com/. Updated periodically. Accessed April 2021.
3. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update [published correction appears in J Addict Med. 2020 May/Jun;14(3):267]. J Addict Med. 2020;14(2S Suppl 1):1-91.doi:10.1097/ADM.0000000000000633.
4. Substance Abuse and Mental Health Services Administration. (2021) Medications for opioid use disorder. Rockville, MD: Substance Abuse and Mental Health Services Administration. Treatment Improvement Protocol (TIP) series 63 publication no. PEP21-02-01-002.
5. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. 2016 Mar 18;65(1):1-49.
6. Utah Department of Health (2018). Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain. Salt Lake City, UT: Utah Department of Health.

Generic	Brand	Reviewed	Effective Date
LUSPATERCEPT-AAMT Edition 2	REBLOZYL	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named LUSPATERCEPT-AAMT (Reblozyl) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of anemia
B. Patient is 18 years of age or older
C. Patient has ONE of the following conditions:
    i. Beta thalassemia and requires regular red blood cell (RBC) transfusions
    ii. Myelodysplastic syndromes with ring sideroblasts (MDS-RS)
    iii. Myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
D. If the patient has a diagnosis of myelodysplastic syndromes with ring sideroblasts (MDS-RS) OR myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T), approval also requires:
    i. The patient is failing an erythropoiesis stimulating agent and requires 2 or more red blood cell (RBC) units over 8 weeks

References:
1. Reblozyl package insert. Summit, NJ. Celgene Corporation. Revised August 2023. Accessed December 2023.
2. Cappellini MD, Cohen A, Porter J, Taher A, Viprakasit V, eds. Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 3rd ed. Nicosia (CY): Thalassaemia International Federation; 2014.
3. Patnaik MM, Tefferi A. Refractory anemia with ring sideroblasts (RARS) and RARS with thrombocytosis: "2019 Update on Diagnosis, Risk-stratification, and Management". Am J Hematol. 2019;94(4):475-488. doi:10.1002/ajh.25397.
4. Fenaux P, Platzbecker U, Mufti GJ, et al. Luspatercept in Patients with Lower-Risk Myelodysplastic Syndromes. N Engl J Med 2020; 382:140.

TREPROSTINIL			
Generic	Brand	Reviewed	Effective Date
TREPROSTINIL SODIUM Edition 3	REMODULIN	01/28/2024	01/28/2022
TREPROSTINIL	TYVASO		
TREPROSTINIL	ORENITRAM		

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

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

REMODULIN

Our guideline named TREPROSTINIL (Remodulin) requires the following rule(s) be met for approval:

A. The patient has pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group I
B. The requested medication will be prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient has a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization 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, the patient must have NYHA-WHO Functional Class II, III, or IV symptoms
E. For new start requests, approval also requires ONE of the following:
    1. The patient has NYHA-WHO Functional Class III or IV symptoms
    2. The patient has NYHA-WHO Functional Class II symptoms AND had a previous trial of or a medical reason why you cannot use a phosphodiesterase-5 inhibitor (such as Adcirca [tadalafil] or Revatio [sildenafil]) or an endothelin receptor antagonist (such as Tracleer bosentan], Letairis [ambrisentan], Opsumit [macitentan])

(Criteria continued on next page)

REQUIREMENTS: TREPROSTINIL (CONTINUED)

TYVASO

Our guideline named TREPROSTINIL (Tyvaso) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group I
    2. Pulmonary hypertension (PH) World Health Organization (WHO) Group 3
B. If the patient has PAH (WHO Group 1), approval also requires:
    1. The requested medication will be prescribed by or given in consultation with a cardiologist or pulmonologist
    2. The patient has a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization 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. The patient has NYHA-WHO Functional Class III or IV symptoms
    4. Documentation of baseline 6-minute walk distance test
C. If the patient has PH (WHO Group 3), approval also requires:
    1. The patient's PAH must be associated with interstitial lung disease (PH-ILD)
    2. The requested medication will be prescribed by or given in consultation with a cardiologist or pulmonologist
    3. Documentation of baseline 6-minute walk distance test

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: TREPROSTINIL- ORENITRAM (CONTINUED)

ORENITRAM

Our guideline named TREPROSTINIL (Orenitram) requires the following rule(s) be met for approval:

A. The patient has pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group I
B. The requested medication will be prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient has a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization 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. The patient has NYHA-WHO Functional Class II, III or IV symptoms
E. Documentation of baseline 6-minute walk distance test
F. The patient does not have severe hepatic impairment
G. The patient meets ONE of the following:
    1. The request is for continuation of current Orenitram therapy
    2. The patient has 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])

RENEWAL CRITERIA

Our guideline named TREPROSTINIL (Remodulin, Tyvaso, Orenitram) requires the following rule(s) be met for renewal:

A. The patient pulmonary arterial hypertension World Health Organization (WHO) Group I OR pulmonary hypertension associated with interstitial lung disease WHO Group 3 (Orenitram ONLY).
B. The patient meets ONE of the following:
    1. They have shown improvement from baseline in the 6-minute walk distance test
    2. They have remained stable from baseline in the 6-minute walk distance test AND World Health Organization (WHO) functional class has improved or remained stable

(Criteria continued on next page)

REQUIREMENTS: TREPROSTINIL (CONTINUED)

References:

1. Remodulin package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised July 2021. Accessed December 2023.
2. Tyvaso package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised May 2022. Accessed December 2023.
3. Orenitram package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised November 2020. Accessed December 2023.
4. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. Chest. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.
5. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. Chest. 2014;146(2):449-475. doi:10.1378/chest.14-0793.
6. Badesch DB, Champion HC, Gomez-Sanchez MA, et al. Diagnosis and assessment of pulmonary arterial hypertension. J Am Coll Cardiol. 2009;54:S55-S66.
7. Rubin LJ; American College of Chest Physicians. Diagnosis and management of pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines. Chest. 2004;126(1 Suppl):7S-10S.
8. Prins KW, Duval S, Markowitz J, Pritzker M, Thenappan T. Chronic use of PAH-specific therapy in World Health Organization Group III Pulmonary Hypertension: a systematic review and meta-analysis. Pulm Circ. 2017;7(1):145-155. Published 2017 Mar 24. doi:10.1086/690017.

Generic	Brand	Reviewed	Effective Date
RITUXIMAB Edition 3	RITUXAN	01/28/2024	01/28/2022
RITUXIMAB-ARRX	RIABNI		
RITUXIMAB-ABBS	TRUXIMA		
RITUXIMAB-PVVR	RUXIENCE		
RITUXIMAB/HYALURONIDASE, HUMAN – SQ	RITUXAN HYCELA		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named RITUXIMAB (Rituxan, Riabni, Truxima, Ruxience, Rituxan Hycela) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA, excludes Rituxan Hycela and Riabni)
    2. Non-Hodgkin's Lymphoma
    3. Diffuse large B-cell lymphoma (DLBCL)
    4. Burkitt lymphoma (BL)
    5. Burkitt-like lymphoma (BLL)
    6. Mature B-cell acute leukemia (B-AL)
    7. Chronic Lymphocytic Leukemia (CLL)
    8. Wegener's Granulomatosis (WG)
    9. Microscopic Polyangiitis (MPA, excludes Rituxan Hycela)
    10. Moderate to severe Pemphigus Vulgaris (PV, excludes Rituxan Hycela and Riabni)

(Criteria continued on next page)

REQUIREMENTS: RITUXIMAB (CONTINUED)

B. If the patient has moderate to severe rheumatoid arthritis (RA), approval also requires:
    1. The patient is 18 years of age or older
    2. The request is for Rituxan, Riabni, Truxima, or Ruxience
    3. The medication will be prescribed by or given in consultation with a rheumatologist
    4. The patient is currently using methotrexate, unless there is a medical reason why they cannot
    5. The patient has previously tried at least ONE DMARD, unless there is a medical reason why they cannot, such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
    6. The patient has previously tried any TWO of the following preferred immunomodulators, unless there is a medical reason why you cannot: Enbrel, Humira, Rinvoq, Xeljanz (Immediate Release or Extended Release)
C. If the patient has Non-Hodgkin's Lymphoma (NHL), approval also requires:
    1. The patient is 18 years of age or older
    2. The medication will be prescribed by or given in consultation with an oncologist
D. If the patient has Chronic Lymphocytic Leukemia (CLL), approval also requires:
    1. The patient is 18 years of age or older
    2. The medication will be prescribed by or given in consultation with an oncologist
    3. The patient is currently using chemotherapy at the same time with the requested medication
E. If the patient has Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:
    1. The patient is 2 years of age or older
    2. The request is for Rituxan, Riabni, Truxima, or Ruxience
    3. The patient is currently on glucocorticoids along with the requested medication
F. If the patient has moderate to severe Pemphigus Vulgaris (PV), approval also requires:
    1. The patient is 18 years of age or older
    2. The request is for Rituxan, Riabni, Truxima, or Ruxience

(Criteria continued on next page)

REQUIREMENTS: RITUXIMAB (CONTINUED)

G. If the patient has diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL), approval also requires:
    1. The patient is 6 months of age or older
    2. The request is for Rituxan
    3. The medication is prescribed by or given in consultation with an oncologist
    4. The patients disease is previously untreated and advanced stage
    5. The patient will be using chemotherapy at the same time with the requested medication

RENEWAL CRITERIA

Our guideline named RITUXIMAB (Rituxan, Truxima, Ruxience) requires the following rule(s) be met for renewal:

A. The patient has moderate to severe rheumatoid arthritis (RA)
B. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy for renewal

References:

1. Rituxan package insert. South San Francisco, CA. Genentech, Inc. Revised December 2021. Accessed December 2023.
2. Riabni package insert. Thousand Oaks, CA. Amgen, Inc. Revised December 2020. Accessed December 2023.
3. Truxima package insert. North Wales, PA. Teva Pharmaceuticals USA, Inc. Revised May 2020. Accessed December 2023.
4. Ruxience package insert. New York, NY. Pfizer Inc. Revised November 2021. Accessed December 20223
5. Rituxan Hycela package insert. South San Francisco, CA. Genentech, Inc. Revised June 2021. Accessed December 2023.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.

Generic	Brand	Reviewed	Effective Date
OCRELIZUMAB Edition 2	OCREVUS	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named OCRELIZUMAB (Ocrevus) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Primary progressive multiple sclerosis (PPMS)
    2. Relapsing form of multiple sclerosis which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
B. The patient is at least 18 years of age
C. If the patient has a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, approval also requires:
    1. The patient meets ONE of the following:
        a. Has previously tried any TWO agents indicated for the treatment of multiple sclerosis (MS)
        b. Shows 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

References:
1. Ocrevus package insert. South San Francisco, CA. Genentech, Inc. Revised August 2023. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LETERMOVIR Edition 3	PREVYMIS	01/28/2024	1/28/2024

REQUIREMENTS:

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

A. The patient is undergoing an allogeneic hematopoietic stem cell transplant (HSCT) OR a kidney transplant
B.
C. The patient is 18 years of age or olderPrevymis will be used for prophylaxis of cytomegalovirus infection and disease

D. If the patient is undergoing HSCT, approval also requires:
    a. The patient is CMV (Cytomegalovirus)-seropositive [R+], as shown by an FDA-approved test
    b.
    Prevymis will be started between Day 0 and Day 28 post-transplantation and discontinued prior to 100 days post-transplantation
E. If the patient is undergoing a kidney transplant, approval also requires:
    a. The donor is CMV seropositive & recipient is CMV seronegative [D+/R-]
    b. Prevymis will be started between Day 0 and Day 7 post-transplantation and discontinued prior to 200 days post-transplantation

References:

1. Prevymis package insert. Whitehouse Station, NJ. Merck & Co.,Inc. Revised August 2023. Accessed December 2023.
2. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective [published correction appears in Biol Blood Marrow Transplant. 2010 Feb;16(2):294. Boeckh, Michael A [corrected to Boeckh, Michael J]]. Biol Blood Marrow Transplant. 2009;15(10):1143-1238. doi:10.1016/j.bbmt.2009.06.019.

WELLFLEET RX STUDENT FORMULARY

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 2	Reviewed	Effective Date
Step Therapy (ST) Exception Guidelines	01/28/2024	6/1/2021

Description

In some cases, patients may be required to first try certain preferred formulary drugs to treat a medical condition before they can move up a “step” to non-preferred drug options. The following exception guidelines are used only when drug-specific step therapy guidelines are not available or if the prescriber believes it is medically necessary for the patient to be on the non-preferred drug.

REQUIREMENTS:

1. A patient may use a non-preferred drug option without first trying the preferred agent if ONE of the following conditions are met:
    a. The prescription drug(s) required under the step-therapy protocol is contraindicated under the drug manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medical condition, including a comorbid condition, is likely to do any of the following:
        i. Cause an adverse reaction to the covered individual;
        ii. Decrease the ability of the covered individual to achieve or maintain reasonable functional ability in performing daily activities; or
        iii. Cause physical or mental harm to the covered individual;
    b. The prescription drug(s) required under the step-therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person (such as the covered person's adherence to, or compliance with, the covered person's individual plan of care) and any of the following:
        i. The known characteristics of the prescription drug regimen as described in peer- reviewed literature or in the manufacturer's prescribing information for the drug; or
        ii. The health care provider's medical judgment based on clinical practice guidelines or peer-reviewed journals; or
        iii. The covered person's documented experience with the prescription drug regimen;
    c. The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step-therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and the prescription drug was discontinued by the covered person's health care provider due to lack of effectiveness; or

(Criteria continued on next page)

REQUIREMENTS: STEP THERAPY EXCEPTION (CONTINUED)

d. The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care provider for the medical condition under consideration while under the covered person's current or previous health benefit plan.

BUPRENORPHINE EXTENDED-RELEASE			
Generic	Brand	Reviewed	Effective Date
BUPRENORPHINE EXTENDED-RELEASE Edition 2	SUBLOCADE	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named BUPRENORPHINE EXTENDED-RELEASE (Sublocade) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of moderate to severe opioid use disorder
B. The patient previously started treatment with a transmucosal buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days
C. The patient will be undergoing a complete treatment program that includes counseling and psychosocial support
D. The patient and provider have discussed the availability and administration of Narcan (naloxone)

References:

1. Sublocade package insert. North Chesterfield, VA. Indivior Inc. Revised December 2023. Accessed December 2023.
2. Drug Facts and Comparisons. Facts & Comparisons®eAnswers [database online]. St. Louis, MO: Wolters Kluwer Health, Inc. Available at: http://online.factsandcomparisons.com/. Updated periodically. Accessed April 2021.
3. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update [published correction appears in J Addict Med. 2020 May/Jun;14(3):267]. J Addict Med. 2020;14(2S Suppl 1):1-91.doi:10.1097/ADM.0000000000000633.
4. Substance Abuse and Mental Health Services Administration. (2021) Medications for opioid use disorder. Rockville, MD: Substance Abuse and Mental Health Services Administration. Treatment Improvement Protocol (TIP) series 63 publication no. PEP21-02-01-002.
5. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. 2016 Mar 18;65(1):1-49.
6. Utah Department of Health (2018). Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain. Salt Lake City, UT: Utah Department of Health.

Generic	Brand	Reviewed	Effective Date
PALIVIZUMAB Edition 3	SYNAGIS	01/28/2024	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PALIVIZUMAB (Synagis) requires the following rule(s) be met for approval:

A. The patient is less than 24 months at the start of respiratory syncytial virus (RSV) season (mid-September to mid-May)
B. The request is for a maximum of 5 doses, providing 6 months of prophylactic therapy given for RSV season. Note: Requests made mid-season will only be approved for the number of doses required to cover through RSV season (mid-September to mid-May)
C. If the patient is LESS THAN 12 months old at the start of the RSV season, they must meet ONE of the following:
    1. They were born premature at less than 29 weeks (gestational age)
    2. They have chronic lung disease (CLD) of prematurity AND they were born at less than 32 weeks AND required more than 21% of additional oxygen for at least the first 28 days after birth
    3. The patient is profoundly immunocompromised during RSV season with ONE of the following:
        a. Severe combined immunodeficiency (SCID)
        b. Acquired immunodeficiency syndrome (AIDS)
        c. Chemotherapy recipient
        d. Solid organ or stem cell transplant
    4. The patient is receiving a heart transplant during RSV season
    5. The patient has congenital abnormalities of the lung airways or a neuromuscular disorder that impairs their ability to clear respiratory secretions
    6. The patient has cystic fibrosis (CF) with clinical evidence of ONE of the following
        a. Chronic lung disease
        b. Nutritional compromise

(Criteria continued on next page)

REQUIREMENTS: PALIVIZUMAB (CONTINUED)

7. They have ONE of the following hemodynamically significant heart conditions at birth:
    a. Acyanotic heart disease with ONE of the following:
        1. They need medication to control chronic heart failure and will require heart surgical procedures
        2. They have moderate to severe pulmonary hypertension
    b. Cyanotic heart defect and the requested medication will be prescribed by or given in consultation with a pediatric cardiologist
8. They are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely

D. If the patient is at least 12 months old AND less than 24 months old at the start of the RSV season, they must meet ONE of following:
    1. They are profoundly immunocompromised during RSV season with ONE of the following:
        a. Severe combined immunodeficiency (SCID)
        b. Acquired immunodeficiency syndrome (AIDS)
        c. Chemotherapy recipient
        d. Solid organ or stem cell transplant
    2. They have chronic lung disease of prematurity AND they were born at less than 32 weeks AND required more than 21% of additional oxygen for at least the first 28 days after birth AND needed medical support within 6 months before the start of the second respiratory syncytial virus (RSV) season. Medical support must include ONE of the following:
        a. Supplemental oxygen
        b. Diuretic (drug that makes you urinate)
        c. Chronic systemic corticosteroid therapy
    3. They are receiving a heart transplant during RSV season
    4. They have cystic fibrosis and at least ONE of the following:
        a. Previous hospitalization for pulmonary exacerbation in the first year of life
        b. Abnormalities on chest radiography, or chest computed tomography that persist when stable
        c. Weight for length is less than the 10th percentile.

(Criteria continued on next page)

REQUIREMENTS: PALIVIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named PALIVIZUMAB (Synagis) requires the following rule(s) be met for renewal:

A. The patient is under 24 months old
B. The patient will undergo a surgery requiring cardiopulmonary bypass during respiratory syncytial virus (RSV) season (mid-September to mid-May)
C. The patient has previously been approved for 5 doses of prophylactic therapy given for the current RSV season and this request is for 1 additional dose to be given post-operatively OR at the conclusion of extracorporeal membrane oxygenation (ECMO)

References:

1. Synagis package insert. Gaithersburg, MD. MedImmune, LLC. Revised May 2017. Accessed December 2023.
2. American Academy of Pediatrics, Committee on Infectious Diseases. Policy statement: Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics. 2014;134(2):415-420. Reaffirmed February 2019. doi:10.1542/peds.2014-1665.
3. American Academy of Pediatrics Committee on Infectious Diseases; American Academy of Pediatrics Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection [published correction appears in Pediatrics. 2014 Dec;134(6):1221]. Pediatrics. 2014;134(2):415-420. doi:10.1542/peds.2014-1665.
4. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality - United States, 2014-2017. MMWR Morb Mortal Wkly Rep. 2018;67(2):71-76. Published 2018 Jan 19. doi:10.15585/mmwr.mm6702a4.
5. Centers for Health Control and Prevention. Increased Interseasonal Respiratory Syncytial Virus (RSV) Activity in Parts of the Southern United States. CDC Health Advisory. Published June 10, 2021. Accessed November 16, 2021. Available at: https://emergency.cdc.gov/han/2021/han00443.asp.
6. American Academy of Pediatrics. Interim guidance for use of palivizumab prophylaxis to prevent hospitalization from severe respiratory syncytial virus infection during the current atypical interseasonal RSV spread. Published September 23, 2021. Accessed November 16, 2021. Available at: https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/ .

Generic	Brand	Reviewed	Effective Date
ASCIMINIB Edition 2	SCEMBLIX	01/28/2024	01/28/2022

REQUIREMENTS:

Our guideline named ASCIMINIB (Scemblix) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested medication will be prescribed by or in consultation with an oncologist or hematologist
C. The patient has a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)
D. The disease is in chronic phase (CP)
E. The patient meets ONE of the following criteria:
    1. They have been previously treated with two or more tyrosine kinase inhibitors
    2. They have a T315I mutation as detected by an FDA (Food and Drug Administration)-approved test

References:

1. Scemblix package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised November 2023. Accessed December 2023.
2. Deininger MW, Shah NP, Altman JK, et al. Chronic Myeloid Leukemia, Version 2.2021, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2020;18(10):1385-1415. Published 2020 Oct 1. doi:10.6004/jnccn.2020.0047.

Generic	Brand	Reviewed	Effective Date
AFAMELANOTIDE Edition 2	SCENESSE	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named AFAMELANOTIDE (Scenesse) requires the following rule(s) be met for approval:

A. The patient has erythropoietic protoporphyria as shown by an FDA-approved test
B. The patient is 18 years of age or older
C. The patient has a history of phototoxic reactions on the skin
D. The requested medication will be used to increase pain free light exposure

References:
1. Scenesse package insert. West Menlo Park, CA. Clinuvel, Inc. Revised October 2019. December 2023.
2. National Institute of Health. Genetic and Rare Disease Information Center. Erythropoietic Protoporphyria. Accessed 12/12/2022. Available at: https://rarediseases.info.nih.gov/diseases/4527/erythropoieticprotoporphyria.

Generic	Brand	Reviewed	Effective Date
ECULIZUMAB Edition 2	SOLIRIS	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ECULIZUMAB (Soliris) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Paroxysmal nocturnal hemoglobinuria (PNH)
    2. Atypical hemolytic uremic syndrome (aHUS)
        i. Soliris is NOT being used for hemolytic uremic syndrome related to Shiga toxin E.coli
    3. Generalized myasthenia gravis (gMG)
    4. Neuromyelitis optica spectrum disorder (NMOSD)
B. If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:
    1. The patient is 18 years of age or older
    2. Therapy is prescribed by or given in consultation with a hematologist
    3. Diagnosis of PNH has been confirmed as demonstrated by ALL of the following via flow cytometry:
        i. At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
        ii. PNH granulocyte clone size greater than or equal to10%
    4. The patient meets at least ONE of the following:
        i. Transitioning from alternative complement inhibitor therapy (such as Ultomiris)
        ii. Documentation of evidence of intravascular hemolysis, such as lactate dehydrogenase [LDH] level greater than or equal to 1.5 times the upper limit of normal, hemoglobinuria, OR the patient has a history of major adverse vascular event from thromboembolism
C. If the patient has generalized myasthenia gravis (gMG), approval also requires:
    1. The patient is 18 years of age or older
    2. Therapy is prescribed by or in consultation with a neurologist
    3. The patient's diagnosis is confirmed by a positive anti-acetylcholine receptor antibody test
    4. The patient has Myasthenia Gravis Foundation of America class II, III, or IV
    5. The patient has had a trial of corticosteroids, unless there is a medical reason why they cannot
    6. The patient meets at least ONE of the following:
        i. Failure of treatment with at least 2 immunosuppressive therapies (such as azathioprine, cyclophosphamide, methotrexate)
        ii. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange

(Criteria continued on next page)

REQUIREMENTS: ECULIZUMAB (CONTINUED)

D. If the patient has neuromyelitis optica spectrum disorder (NMOSD), approval also requires:
    1. The patient is 18 years of age or older
    2. Therapy is prescribed by or given in consultation with a neurologist
    3. The diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4: type of protein) antibodies
    4. The patient has at least ONE of the following core clinical characteristics:
        i. Optic neuritis (inflammation that damages eye nerve)
        ii. Acute myelitis (sudden and severe inflammation of the spinal cord)
        iii. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
        iv. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
        v. Symptomatic narcolepsy (sudden sleepiness) or acute diencephalic clinical syndrome (tumor in a part of brain) with NMOSD-typical diencephalic MRI lesions (affected areas)
        vi. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
    5. The patient will NOT concomitantly use rituximab, inebilizumab, or satralizumab with Soliris

RENEWAL CRITERIA

Our guideline named ECULIZUMAB (Soliris) requires the following rule(s) be met for renewal:

A. The patient has one of the following diagnoses:
    1. Paroxysmal nocturnal hemoglobinuria (PNH)
    2. Atypical hemolytic uremic syndrome (aHUS)
    3. Generalized myasthenia gravis (gMG)
    4. Neuromyelitis optica spectrum disorder (NMOSD)

B. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms while on Soliris therapy

References:

1. Soliris package insert. Boston, MA. Alexion Pharmaceuticals, Inc. Revised November 2020. Accessed December 2023.
2. Borowitz MJ, Craig FE, Digiuseppe JA, et al. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Cytometry B Clin Cytom. 2010;78(4):211-230. doi:10.1002/cyto.b.20525.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790.
4. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015;85(2):177-189. doi:10.1212/WNL.0000000000001729.
5. Loirat C, Fakhouri F, Ariceta G, et al. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. Pediatr Nephrol. 2016;31(1):15-39. doi:10.1007/s00467-015-3076-8.
6. Trebst C, Jarius S, Berthele A, et al. Update on the diagnosis and treatment of neuromyelitis optica: recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol. 2014;261(1):1-16. doi:10.1007/s00415-013-7169-7.
7. Jaretzki A 3rd, Barohn RJ, Ernstoff RM, et al. Myasthenia gravis: recommendations for clinical research standards. Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America. Ann Thorac Surg. 2000;70(1):327-334. doi:10.1016/s0003-4975(00)01595-2.

Generic	Brand	Reviewed	Effective Date
NUSINERSEN Edition 2	SPINRAZA	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named NUSINERSEN (Spinraza) requires the following rule(s) be met for approval:

A. The patient has Spinal muscular atrophy (SMA)
B. The 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)
C. The requested medication is prescribed by or given in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. If the patient is pre-symptomatic, approval also requires:
    1. There is documentation showing the patient has up to three copies of survival motor neuron 2 (*SMN2: type of protein in spinal cord*) based on screening done when they were a newborn
E. If the patient is symptomatic, approval also requires:
    1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
    2. There is documentation showing they had a baseline motor function assessment by a neuromuscular specialist or SMA specialist
    3. If they previously received gene therapy, they had less than expected clinical benefit

(Criteria continued on next page)

REQUIREMENTS- NUSINERSEN (CONTINUED)

RENEWAL CRITERIA

Our guideline named NUSINERSEN (Spinraza) requires the following rule(s) be met for renewal:

A. The patient has spinal muscular atrophy (SMA)
B. The patient meets ONE of the following:
    1. The patient has 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. The patient has improved, maintained, or demonstrated less than expected decline in other muscle function such, as pulmonary function

References:

1. Spinraza package insert. Cambridge, MA. Biogen. Revised February 2023. Accessed December 2023.
2. Committee Opinion No. 691: Carrier Screening for Genetic Conditions. Obstet Gynecol. 2017;129(3):e41-e55. doi:10.1097/AOG.0000000000001952.
3. Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. J Neuromuscul Dis. 2018;5(2):145-158. doi:10.3233/JND-180304.

Generic	Brand	Reviewed	Effective Date
THALIDOMIDE Edition 3	THALOMID	01/28/2024	01/28/2022

REQUIREMENTS:

Our guideline named THALIDOMIDE (Thalomid) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. Multiple myeloma
    2. Erythema nodosum leprosum (ENL)
B. If the patient has multiple myeloma, approval also requires:
    1. Thalomid must be used in combination with dexamethasone or prednisone.

References:
1. Thalomid package insert. Summit, NJ. Celgene Corporation. Revised March 2023. Accessed December 2023.
2. Kumar SK, Callander NS, Adekola K, et al. Multiple Myeloma, Version 3.2021, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2020;18(12):1685-1717. Published 2020 Dec 2. doi:10.6004/jnccn.2020.0057.

Generic	Brand	Reviewed	Effective Date
IBALIZUMAB-UIYK Edition 2	TROGARZO	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named IBALIZUMAB-UIYK (Trogarzo) requires the following rule(s) be met for approval:

A. The patient has human immunodeficiency virus type 1 (HIV-1) infection
B. The patient has multidrug-resistant HIV-1 infection, as evidenced by a trial of at least ONE medication from each of the following classes: Nucleoside Reverse Transcriptase Inhibitor, Non-Nucleoside Reverse Transcriptase Inhibitor, Protease Inhibitor
C. The patient is 18 years of age or older
D. The requested medication will be used in combination with at least ONE other antiretroviral
E. The patient is failing their current antiretroviral therapy

References:
1. Trogarzo package insert. Montréal, Québec Canada. Theratechnologies Inc. Revised December 2023. Accessed December 2023.

T: SLIM/MINIMED INSULIN PUMPS Edition 2			
Generic	Brand	Reviewed	Effective Date
SUBCUTANEOUS INSULIN PUMP	T: SLIM X2, T: SLIM X2 CONTROL-IQ, T: SLIM X2 WITH BASAL-IQ, MINIMED 530G, MINIMED 670G, MINIMED 770G	01/28/2024	6/1/2021

REQUIREMENTS:

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. The patient has completed a comprehensive diabetes education program within the previous 24 months
C. The patient utilizes a maintenance program of at least 3 injections of insulin per day and requires frequent self-adjustments of the insulin dose over the past 6 months AND they meet one of the following:
D. The patient requires glucose self-testing of at least 4 times per day on average in the previous 2 months AND they meet one of the following:
    1. They have a glycosylated hemoglobin level greater than 7 percent
    2. The patient has a history of recurring hypoglycemia
    3. The patient has wide fluctuations in blood sugar before mealtime
    4. The patient has experienced 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. The patient has a history of severe glycemic excursions (sudden spikes in blood sugar levels)
E. The patient has not received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
F. If you are requesting the T: Slim X2, T: Slim X2 with Basal-IQ, OR T: Slim X2 with Control-IQ, approval also requires:
    1. The patient is 6 years of age or older
G. If you are requesting the MiniMed 530G, approval also requires:
    1. The patient is 16 years of age or older
H. If you are requesting the MiniMed 670G, approval also requires:
    1. The patient is 7 years of age or older

(Criteria continued on next page)

REQUIREMENTS- T: SLIM/MINIMED INSULIN PUMPS (CONTINUED)

I. If you are requesting the MiniMed 770G, approval also requires:
    1. The patient is 2 years of age or older

References:

1. Medtronic, Inc. MiniMed 670G system. Summary of Safety and Effectiveness Data. Premarket Approval Application No. P160017. Rockville, MD: U.S. Food and Drug Administration; September 28, 2016. Accessed December 2023
2. Medtronic, Inc. MiniMed 770G system. Summary of Safety and Effectiveness Data. Premarket Approval Application No. P160017. Rockville, MD: U.S. Food and Drug Administration; August 31, 2020. Accessed December 2023.
3. Tandem Diabetes Care, Inc. T:slim X2 Insulin Pump With Basal-IQ Technology system. Summary of Safety and Effectiveness Data. Premarket Approval Application No. P180008. Rockville, MD: U.S. Food and Drug Administration; December 19, 2019. Accessed November 2023
4. Tandem Diabetes Care, Inc. T:slim X2 Insulin Pump With Dexcom G5 Mobile CGM System. Summary of Safety and Effectiveness Data. Premarket Approval Application No. P140015. Rockville, MD: U.S. Food and Drug Administration; December 19, 2019. Accessed November 2023.
5. Grunberger G, Abelseth JM, Bailey TS, et al. Consensus Statement by the American Association of Clinical Endocrinologists/American College of Endocrinology insulin pump management task force. Endocr Pract. 2014;20(5):463-489. doi:10.4158/EP14145.PS.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TUCATINIB Edition 3	TUKYSA	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named TUCATINIB (Tukysa) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of one of the following:
    a. advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer
    b. RAS wild-type HER2-positive unresectable or metastatic colorectal cancer
B. The patient is 18 years of age or older
C. If the patient has a diagnosis of breast cancer:
    a. The patient has previously received one or more anti-HER2-based treatment for metastatic disease (specifically either trastuzumab or trastuzumab with pertuzumab)
    b. The requested medication will be used in combination with trastuzumab and capecitabine
D. If the patient has a diagnosis of colorectal cancer:
    a. The patient has previously received fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy
    b. The requested medication will be used in combination with trastuzumab

References:

1. Tukysa package insert. Bothell, WA. Seattle Genetics, Inc. Revised January 2023. Accessed December 2022.

Generic	Brand	Reviewed	Effective Date
AVACOPAN Edition 2	TAVNEOS	01/28/2024	01/28/2022

REQUIREMENTS:

Our guideline named AVACOPAN (Tavneos) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested product will be prescribed by or in consultation with a rheumatologist
C. The patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)- associated vasculitis (i.e., granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA])
D. The patient has tested positive for either anti-PR3 or anti-MPO antibodies
E. The patient's baseline assessment score for disease activity has been documented utilizing an established assessment instrument [e.g., Birmingham Vasculitis Activity Score (BVAS), BVAS for Wegener granulomatosis (BVAS/WG), BVAS 2003, Physician Global Assessment (PGA), Disease Extent Index (DEI), Five Factor Score (FFS), etc.]
F. The patient is currently receiving a standard course of immunosuppressive therapy with ONE of the following regimens:
    1. cyclophosphamide followed by either azathioprine or mycophenolate mofetil
    2. rituximab

RENEWAL CRITERIA

Our guideline named AVACOPAN (Tavneos) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (i.e., granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA])
B. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools
C. The patient is currently receiving a standard course of immunosuppressive therapy with ONE of the following regimens:
    1. cyclophosphamide followed by either azathioprine or mycophenolate mofetil
    2. rituximab

References:

1. Tavneos package insert. Cincinnati, OH. ChemoCentryx, Inc. Revised July 2022. Accessed December 2023.
2. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Rheumatol. 2021;73(8):1366-1383. doi:10.1002/art.41773.

Generic	Brand	Reviewed	Effective Date
DIMETHYL FUMARATE Edition 2	TECFIDERA	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named DIMETHYL FUMARATE (Tecfidera) requires the following rules be met for approval:

A. The patient has a relapsing form of multiple sclerosis (MS), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. The patient is 18 years of age or older
C. The patient has trialed and failed generic glatiramer, or has a contraindication to it

References:

1. Tecfidera package insert. Cambridge, MA. Biogen Inc. Revised December 2023. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEMOZOLOMIDE Edition 3	TEMODAR	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named TEMOZOLOMIDE (Temodar) requires the following rule(s) to be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Anaplastic astrocytoma
    2. Glioblastoma multiforme

References:

1. Temodar package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised September 2023. Accessed December 2023..
2. Ettinger DS, Wood DE, Aisner DL, et al. NCCN Guidelines Insights: Non-Small Cell Lung Cancer, Version 2.2021. J Natl Compr Canc Netw. 2021;19(3):254-266. Published 2021 Mar 2. doi:10.6004/jnccn.2021.0013.
3. Swetter SM, Thompson JA, Albertini MR, et al. NCCN Guidelines® Insights: Melanoma: Cutaneous, Version 2.2021. J Natl Compr Canc Netw. 2021;19(4):364-376. Published 2021 Apr 1. doi:10.6004/jnccn.2021.0018.

V-GO INSULIN DEVICES Edition 2			
Generic	Brand	Reviewed	Effective Date
SUB-Q INSULIN DEVICE, 20 UNIT	V-GO 20	01/28/2023	6/1/2021
SUB-Q INSULIN DEVICE, 30 UNIT	V-GO 30		
SUB-Q INSULIN DEVICE, 40 UNIT	V-GO 40		

REQUIREMENTS:

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. The patient is 18 years of age or older
B. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
C. The patient follows a maintenance program of at least 3 injections of insulin per day
D. The patient/provider have worked to adjust the insulin dose for the past 6 months and still have not met their glucose (blood sugar) goals
E. The patient does not require regular adjustments to your basal rate during a 24-hour time period
F. The patient requires bolus insulin dosing in increments of 2 units per bolus
G. The patient does not require a total daily insulin dose of more than 76 units
H. The patient meets ONE of the following criteria while on a multiple daily insulin injection regimen:
    1. 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. A history of recurring hypoglycemia (low blood sugar)
    3. Wide fluctuations in blood sugar before mealtime
    4. Experiences 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. A history of severe glycemic excursions (sudden spikes in blood sugar levels)
I. The patient has previously had a trial of the Omnipod or Omnipod Dash (type of insulin device)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS- V-GO INSULIN DEVICES (CONTINUED)

RENEWAL CRITERIA

Our guideline named V-GO INSULIN DEVICES requires the following rule(s) be met for renewal:

A. The patient has shown a positive response to therapy AND are adherent to follow-up visits

References:

1. Valeritas, LLC. V-Go Disposable Insulin Delivery Device Model # V-GO 20, V-GO 30, V-GO40. 510(k) summary, No. K100504. Rockville, MD: U.S. Food and Drug Administration; December 1, 2010. Accessed December 2023.
2. Lajara R, Davidson JA, Nikkel C, Morris TL. Clinical and cost effectiveness of insulin delivery with V-Go disposable insulin delivery device versus multiple daily injections in patients with type 2 diabetes inadequately controlled on basal insulin. Endocrine Practice 2016 June;22(6):726-735.
3. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American association of clinical endocrinologists and american college of endocrinology - clinical practice guidelines for developing a diabetes mellitus comprehensive care plan - 2015. Endocr Pract. 2015;21 Suppl 1(Suppl 1):1-87. doi:10.4158/EP15672.G.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELOSULFASE ALFA Edition 3	VIMIZIM	01/28/2024	1/28/24

REQUIREMENTS:

Our guideline named ELOSULFASE ALFA (Vimizim) requires the following to be met:

A. The patient has a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA).
B. The patient is at least 5 years of age or older
C. Therapy will be administered in a healthcare setting suited to manage anaphylactic and hypersensitivity reactions

References:

1. Vimizim package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised December 2019. Accessed December 2023.
2. Hendriksz CJ, Berger KI, Giugliani R, et al. International guidelines for the management and treatment of Morquio A syndrome. Am J Med Genet A. 2015;167A(1):11-25. doi:10.1002/ajmg.a.36833.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VOSORITIDE Edition 3	VOXZOGO	01/28/2024	1/28/2024

REQUIREMENTS:

Our guideline named VOSORITIDE (Voxzogo) requires the following rule(s) be met for approval:

A. The requested product will be prescribed by or in consultation with a pediatric endocrinologist
B. The patient has a diagnosis of achondroplasia confirmed by genetic testing
C. The patient's bone growth plates (epiphyses) are open, as confirmed by radiograph of the wrist and hand

RENEWAL CRITERIA

Our guideline named VOSORITIDE (Voxzogo) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of achondroplasia confirmed by genetic testing (detected mutation in the FGFR3 gene)
B. The patient's bone growth plates (epiphyses) are open, as confirmed by radiograph of the wrist and hand
C. The patient has shown a response to therapy as indicated by improvement in annualized growth velocity

References:

1. Voxzogo package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised October 2023. Accessed December 2023.
2. White KK, Bompadre V, Goldberg MJ, et al. Best practices in peri-operative management of patients with skeletal dysplasias. Am J Med Genet A. 2017;173(10):2584-2595. doi:10.1002/ajmg.a.38357.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DIROXIMEL FUMARATE Edition 2	VUMERITY	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named DIROXIMEL FUMARATE (Vumerity) requires the following rules be met for approval:

A. The patient has a diagnosis of relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
B. The patient is 18 years of age or older
C. 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

References:

1. Vumerity package insert. Cambridge, MA. Biogen Inc. Revised December 2023. Accessed December 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BELZUTIFAN Edition 3	WELIREG	01/28/2024	01/28/2024

REQUIREMENTS:

Our guideline named BELZUTIFAN (Welireg) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested medication will be prescribed by or in consultation with an oncologist or hematologist
C. The patient has a diagnosis of von Hippel-Lindau (VHL) disease OR Advanced Renal Cell Carcinoma (RCC)
D. If the patient has a diagnosis of VHL, approval also requires:
    1. The patient requires therapy for at least ONE of the following associated diagnoses not requiring immediate surgery:
        i. Renal cell carcinoma (RCC)
        ii. Central nervous system (CNS) hemangioblastomas
        iii. Pancreatic neuroendocrine tumors (pNET)
E. If the patient has a diagnosis of RCC, approval also requires:
    1. The patient has had a previous trial of a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI)

References:

1. Welireg package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised December 2023. Accessed December 2023.

Generic	Brand	Reviewed	Effective Date
INEBILIZUMAB-CDON Edition 2	UPLIZNA	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named INEBILIZUMAB-CDON (Uplizna) requires the following rule(s) be met for approval:

A. The patient has neuromyelitis optica spectrum disorder (NMOSD)
B. The patient is 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist
D. The diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
E. The patient has 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. The patient will NOT concomitantly use rituximab, satrilizumab, or eculizumab with Uplizna

RENEWAL CRITERIA
Our guideline named INEBILIZUMAB-CDON (Uplizna) requires the following rule(s) be met for renewal:

A. The patient has neuromyelitis optica spectrum disorder (NMOSD)
B. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms while on Uplizna therapy

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: INEBILIZUMAB-CDON (CONTINUED)

References:

1. Uplinza package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised July 2021. Accessed November 2023.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015;85(2):177-189. doi:10.1212/WNL.0000000000001729.
3. Trebst C, Jarius S, Berthele A, et al. Update on the diagnosis and treatment of neuromyelitis optica: recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol. 2014;261(1):1-16. doi:10.1007/s00415-013-7169-7.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VENETOCLAX Edition 2	VENCLEXTA	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named VENETOCLAX (Venclexta) requires that the following rules are met for approval:

A. The patient has ONE of the following diagnoses:
    1. Chronic lymphocytic leukemia (CLL)
    2. Small lymphocytic lymphoma (SLL)
    3. Newly-diagnosed acute myeloid leukemia (AML)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If the patient has chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:
    1. They are 18 years of age or older
D. If The patient has newly-diagnosed acute myeloid leukemia (AML), approval also requires:
    1. They are 75 years of age or older, OR they are 18 years of age or older with comorbidities that prevent the use of intensive induction chemotherapy
    2. The requested medication will be used in combination with azacitidine or decitabine or low-dose cytarabine

References:
1. Venclexta package insert. North Chicago, IL. AbbVie Inc. Revised June 2022. Accessed December 2023.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ABEMACICLIB Edition 3	VERZENIO	01/28/2024	01/28/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Advanced or metastatic breast cancer that is hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2)
    2. Early breast cancer that is hormone receptor-positive (HR+) and human epidermal growth factor receptor 2-negative (HER2)
B. If the patient has advanced or metastatic breast cancer, approval also requires that they meet ONE of the following:
    1. If the medication will be used in combination with fulvestrant, approval also requires:
        i. The patient is 18 years of age or older
        ii. The disease has gotten worse after using endocrine therapy
        iii. The disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy
    2. If the medication will be used as monotherapy, approval also requires:
        i. The patient is 18 years of age or older
        ii. The disease has gotten worse after using both endocrine therapy and chemotherapy in the metastatic setting
        iii. The disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy
    3. If the medication will be used in combination with an aromatase inhibitor (e.g., Anastrozole, letrozole), approval also requires:
        i. The patient is a biological female and postmenopausal or is a biological male
        ii. The patient has 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. The disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy

(Criteria continued on next page)

CRITERIA CONTINUED- ABEMACICLIB

C. If the patient has early breast cancer, approval also requires:
    1. The patient is 18 years of age or older
    2. The medication will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor [e.g., letrozole, anastrozole, or exemestane]) as adjuvant treatment
    3. The disease is lymph node positive and at high risk of recurrence
    4. The patient has a Ki-67 score of 20% or greater as determined by a Food and Drug Administration (FDA)-approved test
    5. The disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy

References:
1. Verzenio package insert. Indianapolis, IL. Eli Lilly and Company. Revised October 2021. Accessed December 2023.
2. Shien T, Iwata H. Adjuvant and neoadjuvant therapy for breast cancer. *Jpn J Clin Oncol*. 2020;50(3):225-229. doi:10.1093/jjco/hyz213.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VEMURAFENIB Edition 3	ZELBORAF	01/28/2024	01/28/2022

REQUIREMENTS:

Our guideline named VEMURAFENIB (Zelboraf) requires ONE of the following rules be met for approval:

A. The patient has unresectable or metastatic melanoma with a BRAF V600E mutation as detected by an Food and Drug Administration-approved test
B. The patient has Erdheim-Chester Disease with a BRAF V600 mutation

References:

1. Zelboraf package insert. South San Francisco, CA. Genentech USA, Inc. Revised May 2020. Accessed December 2023.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ONASEMNOGENE ABEPARVOVEC-XIOI Edition 2	ZOLGENSMA	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named ONASEMNOGENE ABEPARVOVEC-XIOI (Zolgensma) requires the following rule(s) be met for approval:

A. The patient has spinal muscular atrophy (SMA)
B. The patient is less than 2 years of age
C. The requested medication is prescribed by or given in consultation with a neuromuscular specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. The patient has documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (SMN1) mutations such as deletions and/or point mutations
E. The patient does NOT have anti-adeno-associated virus vector (anti-AAV9) antibody titers greater than 1:50 as determined by an enzyme linked immunosorbent assay (ELISA)
F. The patient does NOT have advanced spinal muscular atrophy (SMA) such as complete paralysis of the limbs or permanent ventilator dependence

References:

1. Zolgensma package insert. Bannockburn, IL. Novartis Gene Therapies, Inc. Revised October 2021. Accessed December 2023.
2. Committee Opinion No. 691: Carrier Screening for Genetic Conditions. Obstet Gynecol. 2017;129(3):e41-e55. doi:10.1097/AOG.0000000000001952.
3. Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. J Neuromuscul Dis. 2018;5(2):145-158. doi:10.3233/JND-180304.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TETRABENAZINE Edition 2	XENAZINE	01/28/2024	6/1/2021

REQUIREMENTS:

Our guideline named TETRABENAZINE (Xenazine) requires the following rule(s) be met for approval:

A. The patient has chorea (involuntary movements) associated with Huntington's disease
B. The medication has been prescribed or given in consultation with a neurologist
C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
    1. The patient has been genotyped for CYP2D6 (type of enzyme) and has been identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

References:

1. Xenazine package insert. Deerfield, IL. Lundbeck. Revised September 2017. Accessed December 2023.
2. Armstrong MJ, Miyasaki JM; American Academy of Neurology. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. Neurology. 2012;79(6):597-603. doi:10.1212/WNL.0b013e318263c443.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
URIDINE TRIACETATE Edition 2	XURIDEN	01/28/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named URIDINE TRIACETATE (Xuriden) requires the following rule(s) be met for approval:

A. The patient has hereditary orotic aciduria (HOA)
B. The patient 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

RENEWAL CRITERIA
Our guideline named URIDINE TRIACETATE (Xuriden) requires the following rule(s) to be met for renewal:

A. The patients age dependent hematologic parameters (blood lab tests) have stabilized or improved from baseline while on treatment with Xuriden (uridine triacetate).

References:
1. Xuriden package insert. Rockville, MD. Wellstat Therapeutics Corporation. Revised December 2019. Accessed December 2023.
2. Hereditary Orotic Aciduria. Genetic and Rare Diseases Information Center. Updated 2018. Available at: https://https://rarediseases.org/rare-diseases/hereditary-orotic-aciduria/. Accessed November 2021.

Generic	Brand	Reviewed	Effective Date
RIOCIGUAT Edition 2	ADEMPAS	4/29/2024	6/1/2021

REQUIREMENTS: (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

INITIAL CRITERIA
Our guideline named RIOCIGUAT (Adempas) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. For biological females ONLY: The patient is confirmed to be not pregnant; if the patient continues to be of reproductive potential, this confirmation will be done monthly. The patient must also be enrolled in the Adempas Risk Evaluation and Mitigation Strategy (REMS) program.
C. The patient has a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension World Health Organization Group 4 (CTEPH) or a diagnosis of pulmonary arterial hypertension World Health Organization Group 1 (PAH)
D. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
E. If the patient has pulmonary arterial hypertension, approval also requires:
    1. The patient has a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization 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. The patient has NYHA-WHO Functional Class II to IV symptoms
    3. The patient is 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)
F. If the patient has chronic thromboembolic pulmonary hypertension, approval also requires:
    1. The patient has persistent or recurrent disease after surgical treatment OR they are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
    2. The patient has NYHA-WHO Functional Class II to IV symptoms
    3. The patient is 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)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: RIOCIGUAT (CONTINUED)

RENEWAL CRITERIA

Our guideline named RIOCIGUAT (Adempas) requires the following rule(s) be met for renewal:

A. The patient has one of the following diagnoses:
    1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (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. The patient has shown improvement from baseline in the 6-minute walk distance OR has a stable 6- minute walk distance with a stable or improved World Health Organization (WHO) functional class.

References:

1. Adempas package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised September 2021. Accessed March 2024.
2. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. Chest. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.
3. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults: CHEST guideline and expert panel report. Chest. 2014;146(2):449-475. doi:10.1378/chest.14-0793.
4. Badesch DB, Champion HC, Gomez-Sanchez MA, et al. Diagnosis and assessment of pulmonary arterial hypertension. J Am Coll Cardiol. 2009;54:S55-S66.
5. Rubin LJ; American College of Chest Physicians. Diagnosis and management of pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines. Chest. 2004;126(1 Suppl):7S-10S.
6. Prins KW, Duval S, Markowitz J, Pritzker M, Thenappan T. Chronic use of PAH-specific therapy in World Health Organization Group III Pulmonary Hypertension: a systematic review and meta-analysis. Pulm Circ. 2017;7(1):145-155. Published 2017 Mar 24. doi:10.1086/690017.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NADOFARAGENE FIRADENOVEC-VNCG Edition 1	ADSTILADRIN	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named NADOFARAGENE FIRADENOVEC-VNCG (Adstiladrin) requires the following rule(s) be met for approval:

A. Diagnosis of high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-Muscle Invasive Bladder Cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors, and
B. The patient is 18 years of age or older, and
C. The patient is BCG-unresponsive
D. Therapy will be prescribed by, or in consultation with, an oncologist

References:

1. Kim HS, Seo HK. Emerging treatments for bacillus Calmette-Guérin-unresponsive non-muscle-invasive bladder cancer. Investig Clin Urol. 2021 Jul;62(4):361-377. doi: 10.4111/icu.20200602. Epub 2021 May 27. PMID: 34085791; PMCID: PMC8246016.
2. Lebacle C, Loriot Y, Irani J. BCG-unresponsive high-grade non-muscle invasive bladder cancer: what does the practicing urologist need to know? World J Urol. 2021 Nov;39(11):4037-4046. doi: 10.1007/s00345-021-03666-w. Epub 2021 Mar 27. PMID: 33772322; PMCID: PMC7997797.
3. Adstiladrin™ suspension for intravesical use [prescribing information]. Denmark: Ferring Pharmaceuticals; December 2022.

Generic	Brand	Reviewed	Effective Date
RIFAMYCIN Edition 2	AEMCOLO	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named RIFAMYCIN (AEMCOLO) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age.
B. The patient has a diagnosis of traveler's diarrhea (TD) caused by non-invasive strains of E. coli.
C. The patient has a contraindication to BOTH azithromycin and ciprofloxacin.
D. The patient does NOT have diarrhea complicated by fever or bloody stool.

References:
1. Aemcolo package insert. Lainate, Milan, Italy. Cosmo S.p.A. Revised November 2018. Accessed March 2024.
2. Riddle MS, Connor BA, Beeching NJ, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. J Travel Med. 2017;24(suppl_1):S57-S74. doi:10.1093/jtm/tax026.

AMINO ACID BASED AND ENTERAL FORMULAS Edition 2			
Generic	Brand	Reviewed	Effective Date
ENTERAL FORMULAS	VARIOUS	4/29/2024	6/1/2021
INFANT FORMULAS	VARIOUS		

REQUIREMENTS:

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.

References:
1. Becker P, Carney LN, Corkins MR, et al. Consensus statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition). Nutr Clin Pract. 2015;30(1):147-161. doi:10.1177/0884533614557642
2. Pironi L, Arends J, Bozzetti F, et al. ESPEN guidelines on chronic intestinal failure in adults [published correction appears in Clin Nutr. 2017 Apr;36(2):619]. Clin Nutr. 2016;35(2):247-307. doi:10.1016/j.clnu.2021.07.002.

Generic	Brand	Reviewed	Effective Date
CASIMERSEN Edition 3	AMONDYS-45	4/29/2024	04/29/2021

REQUIREMENTS:

Our guideline named CASIMERSEN (Amondys-45) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. The patient has 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)
C. Therapy is prescribed by or given in consultation with a neurologist specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. The patient is ambulatory (able to move and walk)
E. The patient is currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why they cannot, such as a drug allergy or previous severe adverse reaction
F. Requested medication is not concurrently prescribed with other exon-skipping therapies (e.g.,Exondys 51, Vyondys 53, Viltepso)

RENEWAL CRITERIA

Our guideline named CASIMERSEN (Amondys-45) requires the following rule(s) be met for renewal:

A. The patient has maintained or demonstrated less than expected decline in ambulatory ability based on muscle function assessments (such as the 6-minute walk test) OR
B. The patient has maintained or demonstrated less than expected decline in other muscle function (such as pulmonary or cardiac function)

References:

1. Amondys 45 package insert. Cambridge, MA. Sarepta Therapeutics, Inc. Revised March 2023. Accessed March 2024.
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267. doi:10.1016/S1474-4422(18)30024-3.
3. Rivera SR, Jhamb SK, Abdel-Hamid HZ, et al. Medical management of muscle weakness in Duchenne muscular dystrophy. PLoS One. 2020;15(10):e0240687. Published 2020 Oct 19. doi:10.1371/journal.pone.0240687.

TESTOSTERONE Edition 3			
Generic	Brand	Reviewed	Effective Date
TESTOSTERONE GEL	ANDROGEL, STRIANT, TESTIM, VOGELXO	4/29/2024	04/29/2022
TESTOSTERONE PATCH	ANDRODERM		
TESTOSTERONE PELLET IMPLANT	TESTOPEL		
TESTOSTERONE SOLUTION	AXIRON		
TESTOSTERONE CYPIONATE	DEPO-TESTOSTERONE		
TESTOSTERONE ENANTHATE	DELATESTRYL		
TESTOSTERONE UNDECANOATE	JATENZO, KYZATREX, TLANDO		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named TESTOSTERONE requires you to have ONE of the following diagnoses for approval:

A. Primary hypogonadism or hypogonatotropic hypogonadism (secondary hypogonadism)
B. Delayed puberty in biological males
C. Gender dysphoria
D. Metastatic breast cancer
E. AIDS/HIV-associated wasting syndrome

In addition, the following criteria must be met:

For a diagnosis of metastatic breast cancer, approval requires:

A. Prescribed by or in consultation with an oncologist
B. Patient is biologically female
C. Patient has failed first-line treatment used for metastatic breast cancer
D. Request is for intramuscular testosterone (testosterone cypionate [Depo-Testosterone], testosterone enanthate [Delatestryl])

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: TESTOSTERONE (CONTINUED)

For a diagnosis of delayed puberty in biological males, approval requires:

A. Prescribed by or in consultation with an endocrinologist
B. Diagnosis of delayed puberty is not secondary to a pathological disorder
C. Patient is a biological male 14 years of age or older
D. Request is for intramuscular testosterone (testosterone cypionate [Depo-Testosterone], testosterone enanthate [Delatestryl])

For biological male patients with a diagnosis of primary hypogonadism or hypogonatotropic hypogonadism (secondary hypogonadism), approval requires:

A. 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
B. The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels:
C. 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
D. Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)

For biological male patients with a diagnosis of AIDS/HIV-associated wasting syndrome, approval requires:

A. Unexplained involuntary weight loss (greater than 10% baseline body weight) with obvious wasting or body mass index less than 18.5 kg/m^2
A. All other causes of weight loss have been ruled out

For requests of Androderm patch, Striant, Testim, or Vogelxo approval requires:

A. Trial of or contraindication to a generic lower cost agent (e.g., AndroGel 1%, AndroGel 1.62%, Axiron, intramuscular testosterone cypionate [Depo-Testosterone], intramuscular testosterone enanthate [Delatestryl])

RENEWAL CRITERIA

The guideline named TESTOSTERONE requires you to have ONE of the following diagnoses for renewal:

A. Primary hypogonadism or hypogonatotropic hypogonadism (secondary hypogonadism)
B. Delayed puberty in biological males
C. Gender dysphoria
D. Metastatic female breast cancer
E. AIDS/HIV-associated wasting syndrome

In addition, the following criteria must be met:

(Criteria continued on next page)

REQUIREMENTS: TESTOSTERONE (CONTINUED)

For male patients with a diagnosis of primary hypogonadism or hypogonatotropic hypogonadism (secondary hypogonadism), approval requires:

A. Physician attestation of improved symptoms compared to baseline and tolerance to treatment
B. Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline

For a male patient with a diagnosis of delayed puberty, only the following will be approved:

A. Intramuscular testosterone (testosterone cypionate [Depo-Testosterone], testosterone enanthate [Delatestryl])

For a female patient with a diagnosis of metastatic breast cancer, only the following will be approved:

A. Intramuscular testosterone (testosterone cypionate [Depo-Testosterone], testosterone enanthate [Delatestryl])

For biological male patients with a diagnosis of AIDS/HIV-associated wasting syndrome, approval requires:

A. Documentation of clinical response (e.g. improvement in weight, lean body mass)

References:

1. Androderm package insert. Madison, NJ. Allergan USA, Inc. Revised May 2020. Accessed March 2024.
2. Androgel package insert. North Chicago, IL. Abbvie Inc. Revised February 2019. Accessed March 2024.
3. Axiron package insert. Indianapolis, IN. Lilly USA, LLC. Revised July 2017. Accessed March 2024.
4. Testim package insert. Malvern, PA. Endo Pharmaceuticals, Inc. Revised August 2021. Accessed March 2024.
5. Vogelxo package insert. Maple Grove, MN. Upsher-Smith Laboratories. Revised April 2020. Accessed March 2024.
6. Depo-testosterone package insert. New York, NY. Pfizer, Inc. Revised August 2018. Accessed March 2024.
7. Delatestryl package insert. Malvern, PA. Endo Pharmaceuticals, Inc. Revised October 2016. Accessed March 2024.
8. Striant package insert. Malvern, PA. Actient Pharmaceuticals LLC. Revised October 2016. Accessed March 2024.
9. Testopel package insert. Malvern, PA. Endo Pharmaceuticals Inc. Revised August 2018. Accessed March 2024.
10. World Professional Association for Transgender Health. (2022). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [8th Version]. https://www.tandfonline.com/doi/pdf.
11. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658.
12. Unger CA. Hormone therapy for transgender patients. Transl Androl Urol. 2016;5(6):877-884. doi:10.21037/tau.2016.09.04.
13. Boni C, Pagano M, Panebianco M, et al. Therapeutic activity of testosterone in metastatic breast cancer. Anticancer Res. 2014;34(3):1287-1290.
14. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. J Urol. 2018;200(2):423-432. doi:10.1016/j.juro.2018.03.115.
15. Wanke C, Kotler D; HIV Wasting Collaborative Consensus Committee. Collaborative recommendations: the approach to diagnosis and treatment of HIV wasting. J Acquir Immune Defic Syndr. 2004;37 Suppl 5:S284-S288. doi:10.1097/01.qai.0000144384.55091.0f.
16. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744. doi:10.1210/jc.2018-00229.

IMMUNE GLOBULIN Edition 2			
Generic	Brand	Reviewed	Effective Date
IMMUNE GLOBULIN	BIVIGAM, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	4/29/2024	6/1/2021
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.

REQUIREMENTS:

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 the patient to have ONE of the following diagnoses:

1. Primary Immunodeficiency Disease
2. Idiopathic Thrombocytopenic Purpura
3. Chronic Inflammatory Demyelinating Polyneuropathy
4. Dermatomyositis: For Octagam ONLY

(Criteria continued on next page)

REQUIREMENTS: IMMUNE GLOBULIN (CONTINUED)

5. Multifocal Motor Neuropathy
6. Kawasaki Syndrome
7. B-cell Chronic Lymphocytic Leukemia with Autoimmune Hemolytic Anemia, Immune Thrombocytopenic Purpura OR Pure Red Cell Blood Aplasia
8. Guillain-Barre Syndrome
9. Myasthenia Gravis
10. Autoimmune Graves' Ophthalmopathy
11. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant
12. Prevention of bacterial infection in an HIV-infected child
13. Reduction of secondary infections in pediatric HIV infections
14. Dermatomyositis or polymyositis
15. Autoimmune uveitis
16. Lambert-Eaton myasthenic syndrome
17. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy
18. Stiff-man syndrome
19. Neonatal sepsis
20. Rotaviral enterocolitis
21. Toxic shock syndrome
22. Enteroviral meningoencephalitis
23. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome
24. Autoimmune Mucocutaneous Blistering Disease such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita
25. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
26. Pediatric acute-onset neuropsychiatric syndrome (PANS)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: IMMUNE GLOBULIN (CONTINUED)

For Gamastan S-D, approval requires:

1. The patient is using the requested drug for prophylaxis or passive immunization of hepatitis A, measles, varicella, or rubella

For Hizentra, approval requires:

1. The medication is only for subcutaneous use
2. The patient has a diagnosis of primary immunodeficiency disease OR chronic Inflammatory Demyelinating Polyneuropathy

For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:

1. The medication is only for subcutaneous use
2. You have a diagnosis of primary immunodeficiency disease

For Gammagard Liquid, Gamunex-C, or Gammaked for subcutaneous use, approval requires:

1. You have a diagnosis of primary immunodeficiency disease

References:

1. Bivigam package insert. Boca Raton, FL. Biotest Pharmaceuticals Corporation, Revised June 2013. Accessed March 2024.
2. Flebogamma DIF package insert. Los Angeles, CA. Grifols Biologicals, Inc. Revised October 2018. Accessed March 2024.
3. GamaSTAN S/D package insert. Research Triangle Park, NC. Grifolis Therapeutics, Inc. Revised February 2013. Accessed March 2024.
4. Gammagard S/D package insert. Westlake Village, CA. Baxalta US Inc. Revised June 2014. Accessed March 2024.
5. Gammaplex package insert. Durham, NC. BPL Inc. Revised July 2015. Accessed March 2024.
6. Privigen package insertn. Kankakee, IL. CSL Behring, LLC. Revised September 2017. Accessed March 2024.
7. Gammagard Liquid package insert. Westlake Village, CA. Baxalta US Inc. Revised June 2012. Accessed March 2024.
8. Hizentra package insert. Kankakee, IL. CSL Behring LLC. Revised April 2021. Accessed March 2024.
9. Gamunex-C package insert. Research Triangle Park, NC. Grifols Therapeutics, Inc. Revised December 2015. Accessed March 2024.
10. Gammaked package insert. Research Triangle Park, NC. Grifols Therapeutics Inc. Revised June 2018. Accessed March 2024.
11. Octagam package insert. Hoboken, NJ. Octapharma USA, Inc.Revised June 2021. Accessed March 2024.
12. HyQvia package insert. Westlake Village, CA. Baxalta US Inc. Revised September 2014. Accessed March 2024.
13. Cuvitru package insert. Westlake Village, CA. Baxalta US, Inc. Revised September 2021. Accessed March 2024.
14. Panzyga package insert. Hoboken, NJ. Octapharma. Revised January 2021. Accessed March 2024.
15. Cutaquig package insert. Hoboken, NJ. Octapharma USA, Inc. Revised October 2021. Accessed March 2024.
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WELLFLEET RX STUDENT FORMULARY

BOTULINUM NEUROTOXIN Edition 2			
Generic	Brand	Reviewed	Effective Date
ONABOTULINUM TOXIN A	BOTOX	4/29/2024	6/1/2021
ABOBOTULINUM TOXIN A	DYSPORT		
RIMABOTULINUM TOXIN B	MYOBLOC		
INCOBOTULINUM TOXIN A	XEOMIN		

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

REQUIREMENTS:

BOTOX

Our guideline named BOTULINUM NEUROTOXIN (Botox) requires the following rule(s) be met for approval:

A. The patient will be using the requested medication for ONE of the following non-cosmetic (not for appearance) conditions:
    1. Overactive bladder (OAB)
    2. Urinary incontinence
    3. Neurogenic detrusor overactivity (NDO)
    4. Prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer)
    5. Spasticity
    6. Cervical dystonia
    7. Severe axillary hyperhidrosis
    8. Blepharospasm
    9. Strabismus

B. If the patient has overactive bladder (OAB), approval also requires:
    1. The patient is 18 years of age or older.
    2. The patient has symptoms of urge urinary incontinence, urgency, AND frequency
    3. The patient has previously tried at least ONE anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why they cannot

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WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: BOTOX (CONTINUED)

C. If the patient has urinary incontinence, approval also requires:
    1. The patient is 18 years of age or older.
    2. The patient has detrusor overactivity associated with a neurologic condition such as: spinal cord injury (SCI) or multiple sclerosis (MS).
    3. The patient has previously tried at least ONE anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why they cannot
D. If the patient has neurogenic detrusor overactivity (NDO), approval also requires:
    1. The patient is 5 years of age or older
    2. The patient has previously tried at least ONE anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why they cannot
E. If the patient has chronic migraine headaches approval also requires:
    1. The patient is 18 years of age or older.
    2. The patient experiences at least 15 days per month with a headache, which lasts 4 hours a day or longer.
    3. The patient previously tried any TWO (2) of the following migraine prevention treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol.
F. If the patient has cervical dystonia approval also requires:
    1. The patient is 18 years of age or older.
G. If the patient has severe axillary hyperhidrosis, approval also requires:
    1. The patient is 18 years of age or older.
    2. The condition is inadequately controlled utilizing topical agents, such as aluminum chloride hexahydrate antiperspirant (Drysol), if appropriate
H. If the patient has spasticity , approval also requires:
    1. The patient is 2 years of age or older.
I. If the patient has blepharospasm and strabismus, approval also requires:
    1. The patient is 12 years of age or older.

NOTE: This medication will not be approved for the prophylaxis of episodic migraines (less than 14 days per month with headache). This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

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WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: BOTULINUM NEUROTOXIN (CONTINUED)

DYSPORT
Our guideline named BOTULINUM NEUROTOXIN (Dysport) requires the patient to have ONE of the following non-cosmetic (not for appearance) diagnoses and meet the associated rule(s) for approval:

A. The patient has cervical dystonia; also called spasmodic torticollis AND they are 18 years of age or older
B. The patient has spasticity AND they 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. The patient has ONE of the following non-cosmetic (not for appearance) conditions:
    1. Cervical dystonia
    2. Chronic sialorrhea
B. The patient is 18 years of age or older

NOTE: This medication will not be approved for the improvement of appearance of glabellar lines in the face (for example, wrinkles).

XEOMIN
Our guideline named BOTULINUM NEUROTOXIN (Xeomin) requires the following rules be met for approval:

A. The patient has ONE of the following non-cosmetic (not for appearance) conditions:
    1. Chronic sialorrhea
    2. Cervical dystonia
    3. Blepharospasm
    4. Upper limb spasticity
B. If you have cervical dystonia or blepharospasm, approval also requires:
    1. The patient is 18 years of age or older
C. If you have chronic sialorrhea, approval also requires:
    1. The patient is 2 years of age or older
D. If you have upper limb spasticity, approval also requires ONE of the following:
    1. The patient is 18 years of age or older
    2. The patient is 2 to 17 years of age and does not have spasticity caused by cerebral palsy

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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WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: BOTULINUM NEUROTOXIN (CONTINUED)

References:

1. Botox package insert. Madison, NJ. Allergan USA, Inc. Revised August 2023. Accessed March 2024.
2. Dysport package insert. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. Revised September 2023. Accessed March 2023.
3. Myobloc package insert. Rockville, MD. Solstice Neurosciences, LLC. Revised March 2021. Accessed March 2024.
4. Xeomin package insert. Raleigh, NC. Merz Pharmaceuticals, LLC. Revised September 2023. Accessed March 2024.
5. Lightner DJ, Gomelsky A, Souter L et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. J Urol 2019; 202: 55.
6. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society [published correction appears in Neurology. 2013 Feb 26;80(9):871]. Neurology. 2012;78(17):1337-1345. doi:10.1212/WNL.0b013e3182535d20.
7. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(19):1818-1826. doi:10.1212/WNL.0000000000002560.
8. Arora G, Kassir M, Patil A, et al. Treatment of Axillary hyperhidrosis. J Cosmet Dermatol. 2022;21(1):62-70. doi:10.1111/jocd.14378
9. Seppi K, Ray Chaudhuri K, Coelho M, et al. Update on treatments for nonmotor symptoms of Parkinson's disease-an evidence-based medicine review [published correction appears in Mov Disord. 2019 May;34(5):765]. Mov Disord. 2019;34(2):180-198. doi:10.1002/mds.27602.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
UBLITUXIMAB-XIIY Edition 1	BRIUMVI	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named UBLITUXIMAB-XIIY (Briumvi) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. The patient has a diagnosis of a relapsing form of multiple sclerosis
C. The patient has had a previous trial of generic dimethyl fumarate or glatiramer

References:

1. Briumvi™ intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; December 2022.
2. Steinman L, Fox E, Hartung HP, et al, for the ULTIMATE I and ULTIMATE II investigators. Ublituximab versus teriflunomide in relapsing multiple sclerosis. *N Engl J Med*. 2022;387(8):704-714.
3. Fox E, Lovett-Racke AE, Formley M, et al. A phase 2 multicenter study of ublituximab, a novel glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis. *Mult Scler*. 2021;27:420-429.
4. McGinley MP, Goldschmidt CH, Rae-Grant A. Diagnosis and treatment of multiple sclerosis: a review. *JAMA*. 2021;325(8):765-779.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ODEVIXIBAT Edition 3	BYLVAY	04/29/2024	04/29/2022

REQUIREMENTS:

Our guideline named ODEVIXIBAT (Bylvay) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of ONE of the following:
    a. Progressive familial intrahepatic cholestasis (PFIC) Type 1 or 2
    b. Alagille Syndrome
B. The patient has performed a baseline assessment for pruritus symptoms and this has been documented utilizing an established assessment instrument [e.g., CSS (clinician scratch scale), ISS (Itch Severity Scale), ItchRO[Obs] (Itch Reported Outcome Instrument), ItchyQoL (Itch- Related Quality of Life), NRS (numeric rating scale), QoL (quality of life), VAS (visual analog scale), VRS (verbal rating scale), etc.]
C. The requested medication will be prescribed by or in consultation with a hepatologist
D. The patient has a severe cholestatic pruritus (itching due to reduction or stoppage of bile flow) symptoms.

For a diagnosis of Progressive familial intrahepatic cholestasis, approval also requires:

A. The patient is 3 months of age or older

For a diagnosis of Alagille Syndrome, approval also requires:

A. The patient is 12 months of age or older

RENEWAL CRITERIA

Our guideline named ODEVIXIBAT (Bylvay) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) or Alagille Syndrome and severe cholestatic pruritus symptoms.
B. The patient has experienced or maintained pruritus symptom improvement from baseline utilizing an established assessment instrument [e.g., CSS (clinician scratch scale), ISS (Itch Severity Scale), ItchRO[Obs] (Itch Reported Outcome Instrument), ItchyQoL (Itch-Related Quality of Life), NRS (numeric rating scale), QoL (quality of life), VAS (visual analog scale), VRS (verbal rating scale), etc.]

References:

1. Bylvay package insert. Boston, MA. Albireo Pharma, Inc. Revised June 2023. Accessed March 2024.
2. Flamm SL, Yang YX, Singh S, Falck-Ytter YT; AGA Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Guidelines for the Diagnosis and Management of Acute Liver Failure. Gastroenterology. 2017;152(3):644-647.
3. Jansen PL, Müller MM. Progressive familial intrahepatic cholestasis types 1, 2, and 3. Gut. 1998;42(6):766-767.
4. Davit-Spraul A, Gonzales E, Baussan C, Jacquemin E. Progressive familial intrahepatic cholestasis. Orphanet J Rare Dis. 2009;4:1. Published 2009 Jan 8.

CONTOUR TEST STRIPS (INSULIN PUMP) Edition 2			
Generic	Brand	Reviewed	Effective Date
BLOOD SUGAR DIAGNOSTIC BLOOD SUGAR DIAGNOSTIC, DISC BLOOD SUGAR DIAGNOSTIC, DRUM	CONTOUR TEST STRIPS	4/29/2024	6/1/2021

REQUIREMENTS:

The guideline named CONTOUR TEST STRIPS requires that this product is only covered for patients who have a companion insulin pump.

References:
1. Garber AJ, Handelsman Y, Grunberger G, et al. CONSENSUS STATEMENT BY THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY ON THE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM - 2020 EXECUTIVE SUMMARY. Endocr Pract. 2020;26(1):107-139. doi:10.4158/CS-2019-0472.
2. Professional Practice Committee: Standards of Medical Care in Diabetes—2021. Diabetes Care 1 January 2021; 44 (Supplement_1): S3. https://doi.org/10.2337/dc21-Sppc.

WELLFLEET RX STUDENT FORMULARY

TRILACICLIB			
Generic	Brand	Reviewed	Effective Date
TRILACICLIB DIHYDROCHLORIDE Edition 2	COSELA	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named TRILACICLIB (Cosela) requires the following rule(s) be met for approval:

A. The patient has extensive-stage small cell lung cancer
B. The patient is 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

References:

1. Cosela package insert. Durham, NC. G1 Therapeutics, Inc. Revised August 2023. Accessed March 2024.

Generic	Brand	Reviewed	Effective Date
TRIHEPTANOIN Edition 2	DOJOLVI	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named TRIHEPTANOIN (Dojolvi) requires the following rule(s) be met for approval:

A. The patient has a long-chain fatty acid oxidation disorder (LC-FAOD)
B. The patient's 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. The patient is symptomatic for LC-FAOD (for example, rhabdomyolysis or cardiomyopathy)
D. Therapy is prescribed by or given in consultation with a gastroenterologist or physician specialist in medical genetics/inherited metabolic disorders
E. The patient has previously tried commercial MCT oil (a medical food product) unless there is a medical reason they are unable to

RENEWAL CRITERIA
Our guideline named TRIHEPTANOIN (Dojolvi) requires the following rule(s) be met for renewal:

A. The patient has a long-chain fatty acid oxidation disorder (LC-FAOD)
B. The patient has had a positive clinical response or stabilization of clinical status compared to baseline since starting Dojolvi

References:
1. Dojolvi package insert. Novato, CA. Ultragenyx Pharmaceutical Inc. Revised October 2023. Accessed March 2024.
2. Yamada K and Taketani T. Management and diagnosis of mitochondrial fatty acid oxidation disorders: focus on very-long-chain acyl-CoA dehydrogenase deficiency. Journal of Human Genetics 2019; 64:73-85.

Generic	Brand	Reviewed	Effective Date
CANNABIDIOL Edition 3	EPIDIOLEX	4/29/2024	4/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named CANNABIDIOL (Epidiolex) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Seizures associated with Dravet syndrome
    2. Seizures associated Lennox-Gastaut syndrome
    3. Seizures associated tuberous sclerosis complex
B. The patient is 1 year of age or older
C. Therapy is prescribed by or given in consultation with a neurologist
D. If the patient has seizures associated with Dravet syndrome, approval also requires:
    1. They have previously tried clobazam AND valproic acid derivative, unless there is a medical reason why they cannot
E. If the patient has seizures associated with Lennox-Gastaut syndrome, approval also requires:
    1. They have previously tried TWO of the following, unless there is a medical reason why they cannot: clobazam, valproic acid derivative, topiramate, or lamotrigine
F. If the patient has seizures associated with tuberous sclerosis complex, approval also requires:
    1. They have previously tried TWO anti-epileptic medications, such as clobazam, valproic acid derivative, topiramate, or lamotrigine, unless there is a medical reason why they cannot

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REQUIREMENTS: CANNABIDIOL (CONTINUED)

RENEWAL CRITERIA

Our guideline named CANNABIDIOL (Epidiolex) requires the following rule to be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Seizures associated with Dravet syndrome
    2. Seizures associated Lennox-Gastaut syndrome
    3. Seizures associated tuberous sclerosis complex
B. They have experienced positive response to therapy, as evidenced by clinical improvement from baseline

References:

1. Epidiolex package insert. Carlsbad, CA. Greenwich Biosciences, Inc. Revised February 2022. Accessed March 2024.
2. Chin RF, Mingorance A, Ruban-Fell B, et al. Treatment Guidelines for Rare, Early-Onset, Treatment-Resistant Epileptic Conditions: A Literature Review on Dravet Syndrome, Lennox-Gastaut Syndrome and CDKL5 Deficiency Disorder. Front Neurol. 2021;12:734612. Published 2021 Oct 25. doi:10.3389/fneur.2021.734612.
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the American Epilepsy Society and the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Epilepsy Curr. 2018;18(4):269-278. doi:10.5698/1535-7597.18.4.269.
4. Schubert-Bast S, Strzelczyk A. Review of the treatment options for epilepsy in tuberous sclerosis complex: towards precision medicine. Ther Adv Neurol Disord. 2021;14:17562864211031100. Published 2021 Jul 17. doi:10.1177/17562864211031100.

Generic	Brand	Reviewed	Effective Date
PIRFENIDONE Edition 2	ESBRIET	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PIRFENIDONE (Esbriet) requires the following rule(s) be met for approval:

A. The patient has idiopathic pulmonary fibrosis (IPF)
B. The patient is 18 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist
D. The patient does NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer
E. The patient has a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
F. The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
G. The patient does NOT currently smoke cigarettes
H. If the request is for the brand, the patient has tried & failed the generic formulation or has a medical reason as to why they cannot take it

RENEWAL CRITERIA
Our guideline named PIRFENIDONE (Esbriet) requires the following rule(s) be met for renewal:

A. The patient has idiopathic pulmonary fibrosis (IPF)
B. The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline.
C. The patient does NOT currently smoke cigarettes

References:
1. Esbriet package insert. South San Francisco, CA. Genentech, Inc. Revised February 2023. Accessed March 2024.
2. Clinical Practice Guideline. Am J Respir Crit Care Med. 2018;198(5):e44-e68. doi:10.1164/rccm.201807-1255ST.
3. Morrow LE, Hilleman D, Malesker MA. Management of patients with fibrosing interstitial lung diseases. Am J Health Syst Pharm. 2022;79(3):129-139. doi:10.1093/ajhp/zxab375.

HYALURONATE Edition 2			
Generic	Brand	Reviewed	Effective Date
HYALURONATE SODIUM	EUFLEXXA, ORTHOVISC	4/29/2024	6/1/2021
HYALURONATE SODIUM, STABILIZED	MONOVISC		

REQUIREMENTS:
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 Orthovisc:

A. The patient is at least 21 years of age
B. 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
C. 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:

A. At least 6 months since the last treatment has been received

References:
1. Euflexxa package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised July 2016. Accessed March 2024.
2. Orthovisc package insert. Raynham, MA. DePuy Mitek. Revised July 2016. Accessed March 2024.
3. Monovisc package insert. Bedford, MA. Anika Therapeutics, Inc. Revised March 2014. Accessed March 2024.
4. Synvisc package insert. Ridgefield, NJ. Genzyme Biosurgery. Revised September 2014. Accessed March 2024.
5. Synvisc One package insert. Ridgefield, NJ. Genzyme Biosurgery. Revised September 2014. Accessed March 2024.
6. Hyalgan package insert. Parsippany, NJ. Fidia Pharma USA, Inc. Revised May 2014. Accessed March 2024.
7. Supartz package insert. Tokyo, Japan. Seigaku Corporation. Revised February 2001. Accessed March 2024.
8. Gel-One package insert. Warsaw, IN. Zimmer. Revised May 2011. Accessed March 2024.
9. Hymovis package insert. Parsippany, NJ. Fidia Pharma USA, Inc. Revised October 2015. Accessed March 2024.
10. Gelsyn-3 package insert. Durham, NC. Bioventus LLC. Revised December 2017. Accessed March 2024.
11. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (NonArthroplasty) Evidence-Based Clinical Practice Guideline. https://www.aaos.org/oak3cpg Published 08/31/2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FENFLURAMINE Edition 3	FINTEPLA	4/29/2024	4/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named FENFLURAMINE (Fintepla) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Seizures associated with Dravet syndrome
    2. Seizures associated with Lennox-Gastaut syndrome
B. The patient is 2 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist
D. If the patient has seizures associated with Dravet syndrome, approval also requires:
    1. They had a previous trial of clobazam AND valproic acid derivatives, unless there is a medical reason why they cannot
E. If the patient has seizures associated with Lennox-Gastaut syndrome, approval also requires:
    1. They have previously tried TWO of the following, unless there is a medical reason why you cannot: clobazam, valproic acid derivative, topiramate, lamotrigine

RENEWAL CRITERIA
Our guideline named FENFLURAMINE (Fintepla) requires the following rule(s) be met for approval:

A. The patient has seizures associated with Dravet syndrome or Lennox-Gastaut syndrome
B. The patient has shown continued clinical benefit while on therapy

References:

1. Fintepla package insert. Emeryville CA. Zogenix Inc. Revised December 2023. Accessed March 2024.
2. Chin RF, Mingorance A, Ruban-Fell B, et al. Treatment Guidelines for Rare, Early-Onset, Treatment-Resistant Epileptic Conditions: A Literature Review on Dravet Syndrome, Lennox-Gastaut Syndrome and CDKL5 Deficiency Disorder. Front Neurol. 2021;12:734612. Published 2021 Oct 25. doi:10.3389/fneur.2021.734612.
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the American Epilepsy Society and the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Epilepsy Curr. 2018;18(4):269-278. doi:10.5698/1535-7597.18.4.269.

EPOPROSTENOL IV Edition 3			
Generic	Brand	Reviewed	Effective Date
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN	4/29/2024	4/29/2022
EPOPROSTENOL SODIUM (ARGININE)	VELETRI		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named EPOPROSTENOL (Flolan, Veletri) requires the following rule(s) be met for approval:

A. The patient has pulmonary arterial hypertension
B. Therapy is prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient is 18 years of age or older
D. There is documentation confirming the patients diagnosis of pulmonary arterial hypertension based on right heart catheterization with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 20 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 2 Wood units
E. The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms

RENEWAL CRITERIA
Our guideline named EPOPROSTENOL (Flolan, Veletri) requires the following rule(s) be met for renewal:

A. The patient has pulmonary arterial hypertension
B. The patient meets ONE of the following:
    1. They have shown improvement from baseline in the 6-minute walk distance test
    2. They have remained stable in the 6-minute walk distance test AND their 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)

(Criteria continued on next page)

REQUIREMENTS: EPOPROSTENOL (CONTINUED)

References:

1. Flolan package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised August 2021. Accessed March 2024.
2. Veletri package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised October 2020.Accessed. February 2023.
3. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. Chest.2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.
4. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619. doi:10.1016/j.jacc.2009.01.004.
5. 2022 ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension: Developed by the Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Eur Heart J 2022;Aug 26:[Epub ahead of print].

Generic	Brand	Reviewed	Effective Date
PRALSETINIB Edition 2	GAVRETO	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named PRALSETINIB (Gavreto) requires the following rule(s) be met for approval:

A. The patient has ONE of the following:
    1. Metastatic non-small cell lung cancer (NSCLC)
    2. Advanced or metastatic medullary thyroid cancer (MTC)
    3. Advanced or metastatic thyroid cancer
B. If the patient has metastatic non-small cell lung cancer, approval also requires:
    1. They are 18 years of age or older
    2. The patient has a rearranged during transfection (*RET:* type of gene) fusion-positive tumor that has been detected by a Food and Drug Administration (FDA)- approved test
C. If the patient has advanced or metastatic medullary thyroid cancer, approval also requires:
    1. They are 12 years of age or older
    2. The patient has a rearranged during transfection (*RET:* type of gene) mutant tumor
    3. The patient needs systemic therapy
D. If the patient has advanced or metastatic thyroid cancer, approval also requires:
    1. They are 12 years of age or older
    2. The patient has a rearranged during transfection (*RET:* type of gene) fusion-positive tumor
    3. The patient needs systemic therapy
    4. They have received treatment with radioactive iodine, and it did not work or is no longer working, if radioactive iodine is appropriate

References:
1. Gavreto package insert. Cambridge, MA. Blueprint Medicines Corporation. Revised March 2024. Accessed March 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ETRANACOGENE DEZAPARVOVEC-DRLB Edition 1	HEMGENIX	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named ETRANACOGENE DEZAPARVOVEC-DRLB (Hemgenix) requires the following rule(s) be met for approval:

A. Diagnosis of hemophilia B, and
B. The patient is 18 years of age or older, and
C. The patient is a biological male
D. The patient meets at least ONE of the following:
    i. Currently using Factor IX prophylaxis therapy
    ii. Has current or historical life-threatening hemorrhage
    iii. Has repeated, spontaneous bleeding episodes
E. Therapy will be prescribed by, or in consultation with, a hematologist

References:

1. Hemgenix™ intravenous infusion [prescribing information]. King of Prussia, PA; Kankakee, IL; and Lexington, MA: CSL Behring and uniQure; November 2022.

Generic	Brand	Reviewed	Effective Date
PONATINIB HCL Edition 3	ICLUSIG	4/29/2024	6/1/2021

REQUIREMENTS:
Our guideline for the drug named PONATINIB (Iclusig) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Chronic Phase (CP) Chronic Myeloid Leukemia (CML)
    2. Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
    3. T315I-positive (a genetic mutation) chronic myeloid leukemia (CML) OR T315I-positive (a genetic mutation) Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
B. The patient is 18 years of age or older
C. If the patient has Chronic Phase (CP) Chronic Myeloid Leukemia (CML), approval also requires:
    1. The patient has trialed, is resistant to, or not able to safely use at least two kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib)
D. If the patient has Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:
    1. No other kinase inhibitors treatment, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib), can be used for your disease

References:
1. Iclusig package insert. Lexington, MA. Takeda Pharmaceuticals America, Inc. Revised February 2022. Accessed March 2023.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TREMELIMUMAB-ACTL Edition 1	IMJUDO	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named TREMELIMUMAB-ACTL (Imjudo) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of unresectable hepatocellular carcinoma
B. The patient is 18 years of age or older, and
C. The requested medication is prescribed by or in consultation with a hematologist/oncologist, and
D. The requested medication will be used in combination with Imfinzi (durvalumab), and
E. The patient has Child-Pugh Score class A and Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

References:

1. Imjudo® intravenous infusion [prescribing information]. Wilmington, DE: AstraZeneca; October 2022.

INFERTILITY Edition 2			
Generic	Brand	Reviewed	Effective Date
CETRORELIX ACETATE	CETROTIDE	04/29/2024	04/29/2022
CHORIONIC GONADOTROPIN	NOVAREL PREGNYL		
CHORIONICGONADOTROPIN ALPHA	OVIDREL		
FOLLITROPIN ALFA	GONAL-F GONAL-F RFF		
FOLLITROPIN BETA	FOLLISTIM AQ		
GANIRELIX ACETATE	FYREMADEL		
LEUPROLIDE ACETATE	LUPRON		
MENOTROPINS	MENOPUR		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named INFERTILITY requires the following rule(s) be met for approval:

A. The patient is using the requested drug for ONE of the following:
    1. They are undergoing ovulation induction and they, or their partner, have a diagnosis of infertility
    2. They are undergoing assisted reproductive technology (ART) and they, or their partner, have a diagnosis of infertility
    3. They are undergoing treatment of hypogonadotropic hypogonadism and have a diagnosis of infertility
    4. They are undergoing fertility preservation
B. Submitted documentation indicates the patient has been approved for infertility services or fertility preservation through medical authorization for the requested timeframe. [*Note: a legible copy of the approval letter must be submitted by the requesting provider*.]
C. The request is for human chorionic gonadotropin (hCG) (e.g., Novarel, Pregnyl, Ovidrel, etc) and ONE of the following:
    1. The patient is undergoing ovulation induction
    2. The patient is undergoing assisted reproductive technology (ART)

(Criteria continued on next page)

REQUIREMENTS: INFERTILITY (CONTINUED)

D. If the request is for human chorionic gonadotropin (hCG) (e.g., Novarel, Pregnyl, Ovidrel, generic) for treatment of hypogonadotropic hypogonadism, approval also requires ALL of the following:
    1. The patient does not have primary testicular failure
    2. The patient has low pretreatment testosterone levels
    3. The patient has low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels
E. If the request is for Menopur for follicle stimulation while undergoing ovulation induction or ART, approval also requires ONE of the following:
    1. The patient has completed three or more previous cycles of clomiphene or letrozole
    2. The patient has a risk factor for poor ovarian response to clomiphene or letrozole
    3. The patient has a contraindication or exclusion to clomiphene and letrozole
    4. The patient is 37 years of age or older
F. If the request is for Menopur for stimulation of sperm production, approval also requires ALL of the following:
    1. The patient does not have primary testicular failure
    2. The patient has low pretreatment testosterone levels
    3. The patient has low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels
G. If the request is for Follistim AQ for follicle stimulation while undergoing ovulation induction or ART, approval also requires ONE of the following:
    1. The patient has completed three or more previous cycles of clomiphene or letrozole
    2. The patient has a risk factor for poor ovarian response to clomiphene or letrozole
    3. The patient has a contraindication or exclusion to clomiphene and letrozole
    4. The patient is 37 years of age or older
    5. The patient has a previous trial and failure with Gonal-f or Gonal-f RFF
H. If the request is for Follistim AQ for stimulation of sperm production, approval also requires ALL of the following:
    1. The patient does not have primary testicular failure
    2. The patient has low pretreatment testosterone levels
    3. The patient has low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels
    4. The patient has a previous trial and failure with Gonal-f or Gonal-f RFF

(Criteria continued on next page)

REQUIREMENTS: INFERTILITY (CONTINUED)

I. If the request is for Gonal-f or Gonal-f RFF for follicle stimulation while undergoing ovulation induction or ART, approval also requires ONE of the following:
    1. The patient has completed three or more previous cycles of clomiphene or letrozole
    2. The patient has a risk factor for poor ovarian response to clomiphene or letrozole
    3. The patient has a contraindication or exclusion to clomiphene and letrozole
    4. The patient is 37 years of age or older
J. If the request is for Gonal-f or Gonal-f RFF for stimulation of sperm production, approval also requires ALL of the following:
    1. The patient does not have primary testicular failure (testicles are unable to produce sperm)
    2. The patient has low pretreatment testosterone levels
    3. The patient has low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels
K. If the request is for cetrorelix acetate (e.g., Cetrotide), approval also requires ONE of the following:
    1. The patient is undergoing ovulation induction
    2. The patient is undergoing assisted reproductive technology (ART)
L. If the request is for ganirelix, approval also requires ONE of the following:
    1. The patient is undergoing ovulation induction
    2. The patient is undergoing assisted reproductive technology (ART)
M. If the request is for leuprolide acetate, approval also requires ONE of the following:
    1. The patient is undergoing ovulation induction
    2. The patient is undergoing assisted reproductive technology (ART)

DEFINTIONS:

assisted reproductive technology (ART) - procedures involving surgical removal of eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to a female patient or gestational carrier or donating them to another patient.
follicle stimulation – process by which hormones stimulate the growth of the ovarian follicle which then triggers ovulation.
intrauterine insemination (IUI) – procedure that involves placing sperm into a woman's uterus to facilitate fertilization.
in vitro fertilization (IVF) – an assisted reproductive technology procedure involving the removal of eggs from a woman's ovaries, fertilizing them outside the body with sperm and then transferring the embryos into the uterus through the cervix.
ovulation induction - use of hormonal medications to stimulate the development and release of one or more eggs from the ovary for fertilization.

(Criteria continued on next page)

REQUIREMENTS: INFERTILITY (CONTINUED)

References:

1. Cetrotide package insert. Rockland, MA. EMD Serono, Inc. Revised May 2018. Accessed March 2024.
2. Pregnyl package insert. Roseland, NJ. Organon USA Inc. Revised April 2011. Accessed March 2024.
3. Novarel package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised September 2018. Accessed March 2024.
4. Ganirelix acetate package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised June 2021. Accessed March 2024.
5. Menopur package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised May 2018. Accessed March 2024.
6. Ovidrel package insert. Rockland, MA. EMD Serono, Inc. Revised June 2018. Accessed March 2024.
7. Gonal-F package insert. Rockland, MA. EMD Serono, Inc. Revised December 2020. Accessed March 2024.
8. Gonal -F RFF package insert. Rockland, MA. EMD Serono, Inc. Revised December 2020 Accessed March 2024.
9. Follistim AQ package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised August 2011. Accessed March 2024.
10. Infertility Workup for the Women's Health Specialist: ACOG Committee Opinion, Number 781. Obstet Gynecol. 2019;133(6):e377-e384. doi:10.1097/AOG.0000000000003271.
11. ACOG Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists number 34, February 2002. Management of infertility caused by ovulatory dysfunction. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2002;99(2):347-358. doi:10.1016/s0029-7844(01)01768-9.
12. Practice Committee of American Society for Reproductive Medicine, Birmingham, Alabama. Gonadotropin preparations: past, present, and future perspectives. Fertil Steril. 2008;90(5 Suppl):S13-S20. doi:10.1016/j.fertnstert.2008.08.031.
13. Practice Committees of the American Society for Reproductive Medicine and Society for Reproductive Endocrinology and Infertility. Electronic address: asrm@asrm.org. Use of exogenous gonadotropins for ovulation induction in anovulatory women: a committee opinion. Fertil Steril. 2020;113(1):66-70. doi:10.1016/j.fertnstert.2019.09.020.
14. American Association of Clinical Endocrinologists (AACE) Hypogonadism Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients--2002 update. Endocr Pract. 2002;8(6):439-456.
15. Minhas S, Bettocchi C, Boeri L, et al. European Association of Urology Guidelines on Male Sexual and Reproductive Health: 2021 Update on Male Infertility [published online ahead of print, 2021 Sep 9]. Eur Urol. 2021;S0302-2838(21)01982-5. doi:10.1016/j.eururo.2021.08.014.
16. Centers for Disease Control and Prevention. 2018 Assisted Reproductive Technology Fertility Clinic Success Rates Report. Atlanta (GA): US Dept of Health and Human Services; 2020.
17. Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. Fertil Steril. 2013;99(1):37-43. doi:10.1016/j.fertnstert.2012.09.028
18. Oocyte cryopreservation. Committee Opinion No. 584. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:221–2.

Generic	Brand	Reviewed	Effective Date
DECITABINE/ CEDAZURIDINE Edition 2	INQOVI	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named DECITABINE/CEDAZURIDINE (Inqovi) requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    a. Myelodysplastic syndromes (MDS)
    b. Chronic myelomonocytic leukemia (CMML)
B. You are 18 years of age or older
C. If you have myelodysplastic syndromes (MDS), approval also requires:
    a. You meet ONE of the following International Prognostic Scoring System groups :
        i. Intermediate-1
        ii. Intermediate-2
        iii. High-risk

References:
1. Inqovi package insert. Princeton, NJ. Taiho Oncology, Inc. Revised March 2023. Accessed March 2024.

Generic	Brand	Reviewed	Effective Date
FEDRATINIB Edition 3	INREBIC	4/29/2024	4/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named FEDRATINIB (Inrebic) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested medication will be prescribed by or in consultation with an oncologist or hematologist
C. The patient has intermediate-2 or high-risk primary or secondary myelofibrosis
D. The patient has a platelet count of at least 50×10^9/L (50,000/mcL) or greater
E. The patient 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. The patient has intermediate-2 or high-risk primary or secondary myelofibrosis
B. The patient had symptom improvement by ONE of the following:
    1. Spleen volume reduction of 35% or greater from baseline after 6 months of therapy
    2. A 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
    3. A 50% or greater reduction in palpable spleen length

References:
1. Inrebic package insert. Summit, NJ. Celgene Corporation. Revised May 2023. Accessed March 2024.
2. Tefferi A, Cervantes F, Mesa R, et al. Revised response criteria for myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report. Blood. 2013;122(8):1395-1398. doi:10.1182/blood-2013-03-488098.
3. Rumi E, Cazzola M. Diagnosis, risk stratification, and response evaluation in classical myeloproliferative neoplasms. Blood. 2017;129(6):680-692. doi:10.1182/blood-2016-10-695957.

Generic	Brand	Reviewed	Effective Date
RUXOLITINIB PHOSPHATE Edition 4	JAKAFI	4/29/2024	4/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named RUXOLITINIB (Jakafi) requires the following rule(s) be met for approval:

A. The patient has 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
    4. Chronic 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
    2. Prescribed by or in consultation with an oncologist or hematologist
    3. The patient hasa platelet count of at least 50×10^9/L (50,000/mcL)
C. If you have polycythemia vera, approval also requires:
    1. You are 18 years of age or older
    2. Prescribed by or in consultation with an oncologist or hematologist
    3. The patient has had a trial of hydroxyurea, unless there is a medical reason why they cannot
D. If you have steroid -refractory acute graft-versus-host disease, approval also requires:
    1. You are 12 years of age or older
    2. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist
    3. The patient has had a trial and failure of a systemic corticosteroid, unless there is a medical reason why they cannot
E. If you have chronic graft-versus-host disease, approval also requires:
    1. You are 12 years of age or older
    2. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist
    3. The patient has been previously treated with one or two lines of systemic therapy (e.g., corticosteroids, methotrexate, mycophenolate mofetil, everolimus, sirolimus, infliximab, rituximab, pentostatin, imatinib, ibrutinib, etc.)

(Criteria continued on next page)

REQUIREMENTS: RUXOLITINIB PHOSPHATE (CONTINUED)

RENEWAL CRITERIA

Our guideline named RUXOLITINIB (Jakafi) requires the following rule(s) be met for renewal:

A. If the patient has intermediate or high-risk myelofibrosis, renewal requires that they have experienced or maintained symptom improvement as evidenced by one of the following:
    1. A 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
    2. A 50% or greater reduction in palpable spleen length
    3. Spleen reduction of 35 percent or greater from baseline spleen volume after 6 months of therapy

A. If the patient has polycythemia vera, renewal requires documentation that they have experienced or maintained symptom improvement as evidenced by ONE of the following:
    1. Spleen reduction of 35 percent or greater from baseline spleen volume after 6 months of therapy
    2. They are not eligible for therapeutic phlebotomy (Hematocrit (Hct) of 48% or less)

B. If the patient has chronic graft-versus-host disease, renewal requires documentation that they have experienced or maintained symptom improvement from baseline (e.g., skin rash, mouth pain, nausea, vomiting, diarrhea, etc.)

References:

1. Jakafi package insert. Wilmington, DE. Incyte Corporation. Revised January 2023. Accessed March 2024.
2. Tefferi A, Cervantes F, Mesa R, et al. Revised response criteria for myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report. Blood. 2013;122(8):1395-1398. doi:10.1182/blood-2013-03-488098.
3. Rumi E, Cazzola M. Diagnosis, risk stratification, and response evaluation in classical myeloproliferative neoplasms. Blood. 2017;129(6):680-692. doi:10.1182/blood-2016-10-695957.
4. Barosi G, Mesa R, Finazzi G, et al. Revised response criteria for polycythemia vera and essential thrombocythemia: an ELN and IWG-MRT consensus project. Blood. 2013;121(23):4778-4781. doi:10.1182/blood-2013-01-478891.
5. Penack O, Marchetti M, Ruutu T, et al. Prophylaxis and management of graft versus host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. Lancet Haematol. 2020;7(2):e157-e167. doi:10.1016/S2352-3026(19)30256-X.

RIBOCICLIB Edition 3			
Generic	Brand	Reviewed	Effective Date
RIBOCICLIB SUCCINATE	KISQALI	4/29/2024	4/29/2022
RIBOCICLIB SUCCINATE/ LETROZOLE	KISQALI/FEMARA CO-PACK		

REQUIREMENTS:

Our guideline named RIBOCICLIB (Kisqali, Kisqali/Femara co-pack) requires the following rule(s) be met for approval:

A. The patient has advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative
B. For Kisqali-Femara Co-Pack, approval also requires:
    1. The patient has NOT received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
C. For Kisqali, approval also requires ONE of the following:
    1. Kisqali will be used in combination with an aromatase inhibitor and the patient has NOT received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
    2. Kisqali will be used in combination with Faslodex (fulvestrant) and meets ONE of the following:
        i. The patient has NOT received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        ii. The patient has experienced disease progression on endocrine therapy AND had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

References:
1. Kisqali package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2023. Accessed March 2024.
2. Kisqali Femara co-pack package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised October 2022. Accessed March 2024.

Generic	Brand	Reviewed	Effective Date
ADAGRASIB Edition 1	KRAZATI	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named ADAGRASIB (Krazati) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. The requested medication will be prescribed by, or in consultation with, an oncologist
C. The patient has locally advanced or metastatic non-small cell lung cancer
D. The patient has a tumor with an abnormal KRAS G12C gene mutation as determined by an FDA-approved test
E. Patient has received at least ONE prior systemic therapy

References:

1. Krazati™ tablets [prescribing information]. San Diego, CA: Mirati Therapeutics; December 2022.
2. FDA grants accelerated approval to adagrasib for KRAS G12C-mutated NSCLC. Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-adagrasib-kras-g12c-mutated-nsclc. Accessed on December 13, 2022.
3. Veluswamy R, Mack PC, Houlsworth J, et al. KRAS G12C-mutant non-small cell lung cancer biology, developmental therapeutics, and molecular testing. *J Mol Diagn*. 2021;23:507-520.
4. Martin P, Leighl NB, Tsao MS, Shepherd F. KRAS mutations as prognostic and predictive markers in non-small cell lung cancer. *J Thorac Oncol*. 2013;8:530-542.
5. Jänne PA, Riely GJ, Gadgeel SM, et al. Adagrasib in non-small-cell lung cancer harboring a $KRAS^{G12C}$ mutation. *N Engl J Med*. 2022;387:120-131.
6. Ou S-HI, Jänne PA, Leal TA, et al. First-in-human phase I/IB dose-finding study of adagrasib (MRTX849) in patients with advanced $KRAS^{G12C}$ solid tumors (KRYSTAL-1). *J Clin Oncol*. 2022;40;2530-2538.
7. Cascetta P, Marinello A, Lazzari C, et al. KRAS in NSCLC: state of the art and future perspectives. *Cancers*. 2022;14:5430.
8. Spagnuolo A, Maione P, and Grisdelli C. The treatment of advanced non-small cell lung cancer harboring KRAS mutation: a new class of drugs for an old target – a narrative review. *Transl Lung Cancer Res*. 2022;11:1199-1216.
9. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 21, 2022.
10. Paver E, O'Toole S, Cheng XM, et al. Updates in the molecular pathology of non-small cell lung cancer. *Semin Diagn Pathol*. 2021;38(5):54-61.
11. Ceddia S, Landi L, Cappuzzo F. KRAS-mutant non-small cell lung cancer: from past efforts to future challenges. *Int J Mol Sci*. 2022;23:9391.
12. Xie M, Xu X, Fan X. KRAS-mutant non-small cell lung cancer; an emerging promisingly treatable subgroup. *Front. Oncol*; 2021:11:672612.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MOSUNETUZUMAB-AXGB Edition 1	LUNSUMIO	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named Mosunetuzumab-axgb (Lunsumio) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of relapsed or refractory follicular lymphoma
B. The patient is 18 years of age or older, and
C. The requested medication is prescribed by or in consultation with an oncologist, and
D. The patient has previously received at least TWO systemic therapies for their diagnosis.

References:

1. Lunsumio™ intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; December 2022.
2. Budde LE, Sehn LH, Matasar M, et al. Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicentre, phase 2 study. *Lancet Oncol*. 2022;23:1055-1065.
3. Freedman A, Jacobsen E. Follicular lymphoma: 2020 update on diagnosis and management. *Am J Hematol*. 2019;95:316-327.
4. Dada R. Diagnosis and management of follicular lymphoma: A comprehensive review. *Eur J Haematol*. 2019;103:152-163.

Generic	Brand	Reviewed	Effective Date
VOCLOSPORIN Edition 2	LUPKYNIS	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA
Our guideline named VOCLOSPORIN (Lupkynis) requires the following rule(s) be met for approval:

A. The patient has active lupus nephritis (LN)
B. The patient is 18 years of age or older
C. Therapy is prescribed by or given in consultation with a rheumatologist or nephrologist
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. The patient has active lupus nephritis (LN)
B. The patient has had improvement in renal response from baseline determined by laboratory values (eGFR or proteinuria) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

References:

1. Lupkynis package insert. Rockville, MD. Aurinia Pharma U.S., Inc. Revised January 2021. Accessed March 2024.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Annals of the Rheumatic Diseases 2019;78:736-745.

Generic	Brand	Reviewed	Effective Date
VORETIGENE NEPARVOVEC-RZYL Edition 2	LUXTURNA	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named VORETIGENE NEPARVOVEC-RZYL (Luxturna) requires the following rule(s) be met for approval:

A. The patient has confirmed biallelic RPE65 mutation-associated retinal dystrophy
B. The patient is 3 years of age or older
C. The patients diagnosis of biallelic RPE65 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 or retinal specialist
E. The patient has a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
F. The patient has enough retinal cells as demonstrated by sufficient retinal thickness
G. The patient does NOT have pre-existing eye conditions that may lead to blindness independently of RPE65-mutation associated retinal dystrophy. Pre-existing eye conditions may include leukemia with Central Nervous System/optic nerve involvement, macular edema or cytomegalovirus retinitis
H. The patient has 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

References:
1. Luxturna package insert. Philadelphia, PA. Spark Therapeutics, Inc. Revised May 2022. Accessed March 2024.
2. Dias MF, Joo K, Kemp JA, et al. Molecular genetics and emerging therapies for retinitis pigmentosa: Basic research and clinical perspectives [published correction appears in Prog Retin Eye Res. 2018 Sep;66:220-221]. Prog Retin Eye Res. 2018;63:107-131. doi:10.1016/j.preteyeres.2017.10.004.

Generic	Brand	Reviewed	Effective Date
OLAPARIB Edition 3	LYNPARZA	4/29/2024	04/29/2022

REQUIREMENTS:

Our guideline named OLAPARIB (Lynparza) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Advanced ovarian cancer
    2. Recurrent or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
    3. HER2-negative metastatic breast cancer
    4. HER2-negative high risk early breast cancer
    5. Metastatic pancreatic adenocarcinoma
    6. Metastatic castration-resistant prostate cancer (mCRPC)
B. The patient is 18 years of age or older
C. If the patient has advanced ovarian cancer, approval also requires:
    1. The requested medication will be used as monotherapy
    2. The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm), as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    3. The patient has been treated with at least three prior lines of chemotherapy (such as, paclitaxel, docetaxel, cisplatin, carboplatin)
D. If the patient has recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
    1. The patient is in complete or partial response to your most recent platinum-based chemotherapy
    2. The patient has completed at least two or more lines of platinum-based chemotherapy
    3. The requested medication will be used alone as monotherapy for maintenance treatment

(Criteria continued on next page)

REQUIREMENTS: OLAPARIB (CONTINUED)

E. If the patient has advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
    1. The requested medication will be used for maintenance treatment
    2. The patient is in complete or partial response to first-line platinum-based chemotherapy
    3. The patient meets ONE of the following:
        a. They have a deleterious or suspected deleterious germline or somatic BRCA mutation (type of gene mutation) as confirmed by a Food and Drug Administration (FDA)- approved companion diagnostic for Lynparza
        b. Their cancer is homologous recombination deficiency (HRD) positive. HRD status is defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    4. Lynparza will be used in combination with bevacizumab
F. If the patient has HER2-negative metastatic breast cancer, approval also requires:
    1. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    2. 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)
    3. 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
G. If the patient has HER2-negative high risk early breast cancer, approval also requires:
    1. The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    2. The patient has been treated with chemotherapy in the neoadjuvant adjuvant (add-on to main treatment)

(Criteria continued on next page)

REQUIREMENTS: OLAPARIB (CONTINUED)

H. If the patient has metastatic pancreatic adenocarcinoma, approval also requires:
    1. The requested medication will be used for maintenance treatment
    2. The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    3. The patient's disease has not progressed on at least 16 weeks of a first-line platinum- based chemotherapy regimen
I. If you have metastatic castration-resistant prostate cancer, approval also requires:
    1. The patient has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation, as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    2. The patient's disease has worsened following prior treatment with enzalutamide or abiraterone
    3. The patient meets ONE of the following:
        a. They previously had a bilateral orchiectomy
        b. They have a castrate level of testosterone (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)

References:
1. Lynparza package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised November 2023. Accessed March 2024.

Generic	Brand	Reviewed	Effective Date
VESTRONIDASE ALFA-VJBK Edition 2	MEPSEVII	4/29/2024	6/1/2021

REQUIREMENTS:

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. The patient has Mucopolysaccharidosis VII (MPS VII, Sly syndrome)
B. The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders
C. The patient has a documented urinary GAG (glycosaminoglycan) level of greater than three times the upper level of normal based on a laboratory test
D. The diagnosis of Mucopolysaccharidosis VII is confirmed by documentation of betaglucuronidase enzyme activity deficiency or genetic testing
E. The patient has at least ONE of the following clinical signs of Mucopolysaccharidosis VII:
    1. Enlarged liver and spleen
    2. Joint limitations
    3. Airway obstructions or pulmonary dysfunction
F. The patient has not undergone successful bone marrow or stem cell treatment for Mucopolysaccharidosis VII
G. The patient has 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. The patient has Mucopolysaccharidosis VII (MPS VII, Sly syndrome)
B. The patient has improved, maintained, or demonstrated less than expected decline in ambulatory ability based on a six-minute walk test compared to baseline

References:
1. Mepsevii package insert. Novato, CA. Ultragenyx Pharmaceutical Inc. Revised December 2020. Accessed March 2024.
2. Montaño AM, Lock-Hock N, Steiner RD, et al. Clinical course of sly syndrome (mucopolysaccharidosis type VII). J Med Genet. 2016;53(6):403-418. doi:10.1136/jmedgenet-2015-103322.
3. Poswar FO, Henriques Nehm J, Kubaski F, Poletto E, Giugliani R. Diagnosis and Emerging Treatment Strategies for Mucopolysaccharidosis VII (Sly Syndrome). Ther Clin Risk Manag. 2022 Dec 22;18:1143-1155. doi: 10.2147/TCRM.S351300. PMID: 36578769; PMCID: PMC9791935.

Generic	Brand	Reviewed	Effective Date
NERATINIB Edition 2	NERLYNX	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named NERATINIB (Nerlynx) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Early stage (stage I-III) breast cancer
    2. Advanced or metastatic breast cancer
B. The patient is at least 18 years of age or older
C. The patient has HER2-overexpressed/amplified (HER2-positive) tumor(s)
D. If the patient has early stage (stage I-III) breast cancer, approval also requires:
    1. The tumor is hormone-receptor positive
    2. The requested medication will be used as extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
    3. The medication is being requested within 2 years of completing the last trastuzumab dose
E. If the patient has advanced or metastatic breast cancer, approval also requires:
    1. The requested medication will be used in combination with capecitabine
    2. The patient has received two or more prior anti-HER2 based regimens in the metastatic setting

References:
1. Nerlynx package insert. Los Angeles, CA. Puma Biotechnology, Inc. Revised June 2021. Accessed March 2024.

SOMATROPIN Edition 2			
Generic	Brand	Reviewed	Effective Date
SOMATROPIN	GENOTROPIN	4/29/2024	6/1/2021
SOMATROPIN	NORDITROPIN FLEXPRO		
SOMATROPIN	SEROSTIM		
SOMATROPIN	ZORBTIVE		

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

REQUIREMENTS:

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.

A. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
B. The medication is prescribed by or given in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist, or Infectious Disease Specialist
C. The patient is on HIV anti-retroviral therapy
D. The patient has inadequate response to previous therapy (e.g., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
E. The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
F. Alternative causes of wasting has been ruled out; alternative causes include:
    1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    2. Diarrhea
    3. Inadequate energy (caloric) intake
    4. Malignancies
    5. Opportunistic infections
G. The patient meets ONE of the following criteria for weight loss:
    1. 10% unintentional weight loss over 12 months
    2. 7.5% unintentional weight loss over 6 months
    3. 5% body cell mass (BCM) loss within 6 months
    4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
    5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27kg per meter squared
    6. BMI less than 18.5 kg per meter squared

(Criteria continued on next page)

REQUIREMENTS: SOMATROPIN (CONTINUED)

For patients who are hypogonadal (patients with low testosterone levels), approval requires the following:

A. The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)
B. The patient meets one of the following criteria for low testosterone:
    1. Total serum testosterone level of less than 300 ng/dL (10.4 nmol/L)
    2. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
    3. 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.

A. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
B. The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
C. The medication is prescribed by or given in consultation with a gastroenterologist

GENOTROPIN/NORDITROPIN

The guideline named SOMATROPIN (Genotropin/Norditropin) requires ONE of the following diagnoses:

A. Pediatric growth hormone deficiency
B. Growth failure associated with Turner Syndrome
C. Growth failure due to Prader-Willi Syndrome (PWS)
D. Growth failure in children born small for gestational age (SGA)
E. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:

A. Athletic enhancement
B. Anti-aging purposes
C. Idiopathic Short Stature

(Criteria continued on next page)

REQUIREMENTS: SOMATROPIN (CONTINUED)

The following criteria must also be met:
For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. The patient meets at least ONE of the following criteria for short stature:
    1. 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
    2. Height velocity less than the 25th percentile for age
    3. 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:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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:

A. Confirmed diagnosis of PWS
B. The medication is prescribed by or given in consultation with an endocrinologist

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

A. The medication is Prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. Patient with no catch-up growth by age 2 years
D. 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:

A. The medication is prescribed by or in consultation with an endocrinologist
B. 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

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: GENOTROPIN/NORDITROPIN (CONTINUED)

RENEWAL CRITERIA

SEROSTIM
The guideline named SOMATROPIN (Serostim) renewal requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.

A. NOT prescribed for athletic enhancement or anti-aging purposes
B. The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
    1. ≥ 10% increase in weight or BCM from baseline (NOTE: current and baseline weight must be documented including dates of measurement)
C. The patient must be on HIV anti-retroviral therapy

ZORBTIVE

A. The guideline named SOMATROPIN (Zorbtive) renewal requires a diagnosis of short bowel syndrome. Therapy is limited to 4 weeks of treatment.

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:

A. Athletic enhancement
B. Anti-aging purposes
C. Idiopathic Short Stature

The following criteria must also be met.
For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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

(Criteria continued on next page)

REQUIREMENTS: GENOTROPIN/NORDITROPIN (CONTINUED)

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:

A. The medication is prescribed by or given in consultation with an endocrinologist
B. Improvement in body composition

For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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:

A. The medication is prescribed by or given in consultation with an endocrinologist

References:

1. Genotropin package insert. New York, NY. Pfizer, Inc. Revised April 2019. Accessed March 2024.
2. Norditropin Flexpro package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised March 2020. Accessed March 2024.
3. Serostim package insert. Rockland, MA. EMDSerono, Inc. Revised May 2017. Accessed March 2024.
4. Zorbtive package insert. Rockland, MA. EMDSerono, Inc. Revised May 2017. Accessed March 2024.
5. Yuen KCJ, Biller BMK, Radovick S, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF GROWTH HORMONE DEFICIENCY IN ADULTS AND PATIENTS TRANSITIONING FROM PEDIATRIC TO ADULT CARE. Endocr Pract. 2019;25(11):1191-1232. doi:10.4158/GL-2019-0405.
6. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth FactorI Deficiency. Horm Res Paediatr. 2016;86(6):361-397. doi:10.1159/000452150.
7. Murray PG, Dattani MT, Clayton PE. Controversies in the diagnosis and management of growth hormone deficiency in childhood and adolescence. Arch Dis Child. 2016;101(1):96-100. doi:10.1136/archdischild-2014-307228.
8. Decker R, Nygren A, Kriström B, et al. Different thresholds of tissue-specific dose-responses to growth hormone in short prepubertal children. BMC Endocr Disord. 2012;12:26. Published 2012 Nov 1. doi:10.1186/1472-6823-12-26.
9. Rosenfeld RG, Albertsson-Wikland K, Cassorla F, et al. Diagnostic controversy: the diagnosis of childhood growth hormone deficiency revisited. J Clin Endocrinol Metab. 1995;80(5):1532-1540. doi:10.1210/jcem.80.5.7538145.
10. Pironi L, Arends J, Bozzetti F. ESPEN guidelines on chronic intestinal failure in adults. Clinical Nutrition. 2016; 35:247-307.
11. Gelato M, McNurlan M, Freedland E. Role of recombinant human growth hormone in HIV-associated wasting and cachexia: pathophysiology and rationale for treatment. Clin Ther. 2007;29(11):2269-2288. doi:10.1016/j.clinthera.2007.11.004.

Generic	Brand	Reviewed	Effective Date
DROXIDOPA Edition 2	NORTHERA	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DROXIDOPA (Northera) requires the following rules be met for approval:

A. The patient has neurogenic orthostatic hypotension
B. The patient is 18 years of age or older
C. The patient has a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or nondiabetic autonomic neuropathy
D. The patient has previously tried midodrine OR fludrocortisone, unless there is a medical reason why they cannot
E. The medication was prescribed or given in consultation with a neurologist or cardiologist
F. The prescribing healthcare provider performed baseline blood pressure readings while the patient was sitting and also within 3 minutes of standing from a supine position
G. The patient has a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
H. The patient has 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. The patient has neurogenic orthostatic hypotension (NOH)
B. The patient has demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like they may black out
C. The patient had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine position

References:
1. Northera package insert. Deerfield, IL. Lundbeck. Revised February 2017. Accessed March 2024.
2. Gibbons CH, Schmidt P, Biaggioni I, et al. The recommendations of a consensus panel for the screening, diagnosis, and treatment of neurogenic orthostatic hypotension and associated supine hypertension. J Neurol. 2017;264(8):1567-1582. doi:10.1007/s00415-016-8375-x.

Generic	Brand	Reviewed	Effective Date
FOSDENOPTERIN HYDROBROMIDE Edition 2	NULIBRY	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named FOSDENOPTERIN (Nulibry) requires the following rule(s) be met for approval:

A. The patient has an expected diagnosis of molybdenum cofactor deficiency (MoCD) Type A
B. Diagnosis of MoCD will be, or has been, confirmed with genetic testing
    a. If diagnosis is not confirmed after testing, use of Nulibry will be discontinued

References:
1. Nulibry package insert. Boston, MA. Origin Biosciences, Inc. Revised October 2022. Accessed March 2024.
2. Misko A, Mahtani K, Abbott J, Schwarz G, Atwal P. Molybdenum Cofactor Deficiency. In: Adam MP, Ardinger HH, Pagon RA, et al., eds. GeneReviews®. Seattle (WA): University of Washington, Seattle; December 2, 2021.

Generic	Brand	Reviewed	Effective Date
NINTEDANIB Edition 2	OFEV	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named NINTEDANIB (Ofev) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Idiopathic pulmonary fibrosis (IPF)
    2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
    3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PFILD)
B. The patient is 18 years of age or older
C. If the patient has idiopathic pulmonary fibrosis (IPF), approval also requires:
    1. Therapy is prescribed by or given in consultation with a pulmonologist
    2. The patient has a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
    3. The patient does NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus infection, viral hepatitis, or cancer
    4. The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline

(Criteria continued on next page)

REQUIREMENTS: NINTEDANIB (CONTINUED)

D. If the patient has systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:
    1. They meet criteria for a diagnosis of Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
    2. Therapy is prescribed by or given in consultation with a pulmonologist or rheumatologist
    3. The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
    4. The patient has a baseline forced vital capacity (FVC) of at least 40% of predicted value
    5. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors], recurrent aspiration such as from GERD, pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or interstitial lung disease caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)
E. If the patient has chronic fibrosing interstitial lung disease with progressive phenotype (PF- ILD), approval also requires:
    1. The patient lung function and respiratory symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (ILD)
    2. Therapy is prescribed by or given in consultation with a pulmonologist or
    3. The patient has at least 10% fibrosis on a chest high resolution computed tomography (HRCT)
    4. The patient has a baseline forced vital capacity (FVC) of at least 45% of predicted value

(Criteria continued on next page)

REQUIREMENTS: NINTEDANIB (CONTINUED)

RENEWAL CRITERIA

Our guideline named NINTEDANIB (Ofev) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Idiopathic pulmonary fibrosis (IPF)
    2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
    3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD)
B. The patient has experienced a clinically meaningful improvement or maintenance in annual rate of decline

References:

1. Ofev package insert. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Revised January 2022. Accessed March 2024.
2. Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2018;198(5):e44-e68. doi:10.1164/rccm.201807-1255ST.
3. Morrow LE, Hilleman D, Malesker MA. Management of patients with fibrosing interstitial lung diseases. Am J Health Syst Pharm. 2022;79(3):129-139. doi:10.1093/ajhp/zxab375.

Generic	Brand	Reviewed	Effective Date
AZACITIDINE Edition 2	ONUREG	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named AZACITIDINE (Onureg) requires the following rule(s) be met for approval:

A. The patient has acute myeloid leukemia (AML)
B. The patient is 18 years of age or older
C. The patient has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
D. The patient is not able to complete intensive curative therapy

References:

1. Onureg package insert. Summit, NJ. Bristol Myers Squibb. Revised May 2021. Accessed March 2024.

Generic	Brand	Reviewed	Effective Date
NITISINONE Edition 2	ORFADIN, NITYR	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named NITISINONE (Orfadin, Nityr) requires the following rule(s) be met for approval:

A. The patient has hereditary tyrosinemia type 1 (HT-1)
B. The patients diagnosis is confirmed by elevated urinary or plasma succinylacetone levels 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. The patient has been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10mg capsules; or Orfadin oral suspension, approval also requires:
    1. The patient has 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. The patient has hereditary tyrosinemia type 1 (HT-1)
B. The patients urinary or plasma succinylacetone levels have decreased from baseline while on treatment with nitisinone

References:
1. Nityr package insert. Manno, Switzerland. Rivopharm SA. Revised September 2020. Accessed March 2024.
2. Orfadin package insert. Sweden. Apotek Produktion & Laboratorier AB. Revised May 2019. Accessed March 2024.
3. Chinsky JM, Singh R, Ficicioglu C, et al. Diagnosis and treatment of tyrosinemia type I: a US and Canadian consensus group review and recommendations. Genet Med. 2017;19(12):. doi:10.1038/gim.2017.101.

Generic	Brand	Reviewed	Effective Date
RELUGOLIX Edition 2	ORGOVYX	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named RELUGOLIX (Orgovyx) requires the following rule(s) be met for approval:

A. The patient has advanced prostate cancer
B. The patient is 18 years of age or older

References:

1. Orgovyx package insert. Kawagoe, Saitama, Japan. Bushu Pharmaceuticals, Ltd. Revised March 2023. Accessed March 2024.

Generic	Brand	Reviewed	Effective Date
ELAGOLIX AND ESTRADIOL AND NORETHINDRONE Edition 2	ORIAHNN	4/29/2024	6/1/2021

REQUIREMENTS:

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)
B. The patient is 18 years of age or older
C. The patient is a premenopausal biological female
D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN)
E. The patient has NOT received a total of 24 months cumulative treatment with Oriahnn
F. The patient is NOT at high risk of arterial, venous thrombotic, or thromboembolic disorders (such as women over 35 who smoke, have vascular disease, uncontrolled hypertension, etc.)

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)
A. The patient has had improvement of heavy menstrual bleeding on therapy
B. The patient has NOT received a total of 24 months cumulative treatment with Oriahnn
C. The patient has been reassessed for high risk of arterial, venous thrombotic, or thromboembolic disorders

References:
1. Oriahnn package insert. North Chicago, IL. AbbVie Inc. Revised June 2023. Accessed March 2024.
2. American College of Obstetricians and Gynecologists. Practice bulletin: clinical management guidelines for obstetrician-gynecologist: alternatives to hysterectomy in the management of leiomyomas. Am J Obstet Gynecol. 2008; 112(2):387-400.
3. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol. 2021 Jun 1;137(6):e100-e115. doi: 10.1097/AOG.0000000000004401. PMID: 34011888.

Generic	Brand	Reviewed	Effective Date
BUDESONIDE Edition 2	ORTIKOS	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named BUDESONIDE (Ortikos) requires the following rule(s) be met for approval:

A. The patient has mild to moderate Crohn's Disease involving the ileum and/or the ascending colon
B. If the patient has mild to moderate ACTIVE Crohn's Disease, approval also requires:
    1. The patient is 8 years of age or older
    2. The patient has previously tried generic budesonide 3mg capsules OR they cannot tolerate the pill burden associated with the generic product
C. If the patient has mild to moderate Crohn's Disease in clinical remission, approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is being used for the maintenance of clinical remission
    3. The patient has previously tried generic budesonide 3mg capsules OR they cannot tolerate the pill burden associated with the generic product

References:

1. Ortikos package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised June 2022. Accessed March 2024.
2. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.

Generic	Brand	Reviewed	Effective Date
VOXELOTOR Edition 4	OXBRYTA	04/29/2024	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named VOXELOTOR (Oxbryta) requires the following rule(s) be met for approval:

A. The patient has sickle cell disease
B. The patient is 4 years of age or older
C. The patient has a hemoglobin level less than or equal to 10.5 g/dL
D. The medication is prescribed by or given in consultation with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease.
E. The patient meets ONE of the following:
    1. A baseline hemoglobin (Hb) less than or equal to 10.5 g/dL (must be confirmed within the past 30 days)
    2. The patient has experienced at least 1 sickle cell-related vaso-occlusive crisis (VOC) within the past 12months (A sickle cell-related VOC is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism, or splenic sequestration)
F. The patient has had a previous trial of hydroxyurea, unless there is a medical reason why they cannot
G. The patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)
H. The patient is not receiving concomitant chronic, prophylactic red-cell transfusion therapy.
I. The patient will be receiving Oxbryta concurrently with hydroxyurea, unless there is a medical reason why they cannot

(Criteria continued on next page)

REQUIREMENTS: VOXELOTOR (CONTINUED)

RENEWAL CRITERIA

Our guideline named VOXELOTOR (Oxbryta) requires the following rule(s) be met for renewal:

A. The patient has sickle cell disease
B. The patient has maintained an improvement in symptoms associated with sickle cell anemia as evidenced by ONE of the following:
    1. They have an increase in Hb level from baseline of at least 1 g/dL
    2. They have a reduction in the number of sickle cell-related vaso-occlusive crises (VOC) from pre-treatment baseline.
C. The patient is not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)
D. The patient is not receiving concomitant chronic, prophylactic red-cell transfusion therapy.
E. The patient is receiving Oxbryta concurrently with hydroxyurea, unless there is a medical reason why they cannot

References:

1. Oxbryta package insert. South San Francisco, CA. Global Blood Therapeutics, Inc. Revised August 2023. Accessed March 2024.
2. Vichinsky E, Hoppe CC, Ataga KI, et al. A phase 3 randomized trial of voxelotor in sickle cell disease. N Engl J Med. 2019 Aug 8;381(6):509-519.
3. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease:summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.

Generic	Brand	Reviewed	Effective Date
LUMASIRAN SODIUM Edition 2	OXLUMO	4/29/2024	4/29/2022

REQUIREMENTS:

Our guideline named LUMASIRAN (Oxlumo) requires the following rule(s) be met for approval:

A. The patient has primary hyperoxaluria type 1 (PH1) confirmed by one of the following:
    1. Presence of mutations in the AGXT gene determined by genetic testing
    2. AGT enzyme deficiency determined by liver biopsy
B. The requested product will be prescribed by or in consultation with an endocrinologist, hepatologist, or nephrologist
C. The patient has documentation of ONE of the following baseline values:
    1. Urinary oxalate (UOx) excretion > 0.70 mmol/1.73 m2/24 h
    2. Spot urinary oxalate-to-creatinine (UOx:Cr) molar ratio greater than normal for age
D. The patient has documentation of estimated glomerular filtration rate (eGFR) greater than 30 mL/min/1.73m2
E. The patient has had a previous trial of or contraindication to at least 3 months of treatment with pyridoxine (vitamin B6)

RENEWAL CRITERIA

Our guideline named LUMASIRAN (Oxlumo) requires the following rule(s) be met for renewal:

A. The patient has experienced a positive response to therapy as evidenced by ONE of the following:
    1. Decrease from baseline in urinary oxalate (UOx) excretion of greater than 30%
    2. Improvement in PH1 symptoms and ONE of the following:
        a. Decrease from baseline in urinary oxalate (UOx) excretion
        b. Improvement from baseline in spot urinary oxalate: creatinine (UOx:Cr) molar ratio
B. The patient has documentation of estimated glomerular filtration rate (eGFR) greater than 30 mL/min/1.73m2

References:
1. Oxlumo package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised September 2023. Accessed March 2024.
2. Hoppe B, Beck BB, Milliner DS. The primary hyperoxalurias. Kidney Int. 2009;75(12):1264-1271. Doi:10.1038/ki.2009.32.
3. Milliner DS, Harris PC, Sas DJ, Cogal AG, Lieske JC. Primary Hyperoxaluria Type 1. In: Adam MP, Ardinger HH, Pagon RA, et al., eds. GeneReviews®. Seattle (WA): University of Washington, Seattle; June 19, 2002.

Generic	Brand	Reviewed	Effective Date
MITAPIVAT Edition 2	PYRUKYND	04/29/2024	04/29/2022

REQUIREMENTS:

Our guideline named MITAPIVAT (Pyrukynd) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested medication will be prescribed by or in consultation with a hematologist
C. The patient has a diagnosis of pyruvate kinase (PK) deficiency
D. The patient has a documented presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant, confirmed by biochemical testing
E. The patient does NOT have presence of the following:
    1. Homozygous for the c.1436G>A (p.R479H) variant in the PKLR gene
    2. 2 non-missense variants (without the presence of another missense variant) in the PKLR gene
F. The patient has symptoms of chronic hemolysis (i.e., anemia, iron overload, jaundice, etc.)
G. The patient has a hemoglobin (Hb) less than or equal to 10 g/dL

RENEWAL CRITERIA

Our guideline named MITAPIVAT (Pyrukynd) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of pyruvate kinase (PK) deficiency confirmed by biochemical testing
B. The patient has shown a response to therapy as indicated by at least 1.5 g/dL improvement in hemoglobin (Hb) from baseline and no recent (within the previous 3 months) transfusions.

References:

1. Pyrukynd package insert. Cambridge, MA. Agios Pharmaceuticals, Inc. Revised February 2022. Accessed March 2024.
2. Grace RF, Barcellini W. Management of pyruvate kinase deficiency in children and adults. Blood. 2020;136(11):1241-1249. doi:10.1182/blood.2019000945.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
METHYLNALTREXONE BROMIDE Edition 2	RELISTOR	4/29/2024	6/1/2021

REQUIREMENTS:

The guideline for METHYLNALTREXONE (Relistor) requires the following rule(s) be met for approval:

A. The patient has 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.
B. The patient must be 18 years of age or older.
C. The patient does not have a known or suspected gastrointestinal obstruction.
D. 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:
E. For patients with chronic non-cancer pain, approval requires all of the following:
    1. The patient has been taking opioids for at least four weeks

References:

1. Relistor package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised May 2018. Accessed March 2024.
2. Crockett SD, Greer KB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. Gastroenterology. 2019;156(1):218-226. doi:10.1053/j.gastro.2018.07.016.

CYCLOSPORINE OPHTHALMIC Edition 3			
Generic	Brand	Reviewed	Effective Date
CYCLOSPORINE OPHTHALMIC	RESTASIS RESTASIS MULTIDOSE	4/29/2024	04/29/2022
CYCLOSPORINE OPHTHALMIC	CEQUA		

REQUIREMENTS:

The guideline named CYCLOSPORINE OPHTHALMIC requires that the patient has a diagnosis of dry eye disease, 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:

A. The patient is aged 16 years or older.
B. The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
C. The patient does not have punctal plugs and will not be using concurrently with Xiidra, Eysuvis, Cequa, or Tyrvaya.
D. 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.
E. The patient had a previous trial of or contraindication to at least 4 weeks of treatment with an artificial tears product.

For the approval of Cequa:

A. The patient is aged 18 years or older.
B. The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
C. The patient does not have punctal plugs and will not be using concurrently with Xiidra, Eysuvis, Restasis, or Tyrvaya.
D. 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.
E. The patient had a previous trial of or contraindication to at least 4 weeks of treatment with an artificial tears product.
F. The patient has had a previous trial and failure of Restasis.

(Criteria continued on next page)

REQUIREMENTS: CYCLOSPORINE OPHTHALMIC (CONTINUED)

For renewal of therapy, the patient must meet ALL the following criteria for approval:

A. 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.
B. The requested medication will not be used in combination with punctal plugs, topical ophthalmic anti-inflammatory drugs, Xiidra, Eysuvis, or Tyrvaya.

References:

1. Restasis package insert. Irvine, CA. Allergan. Revised July 2017. Accessed March 2024.
2. Cequa package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised September 2019. Accessed March 2024.
3. Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2019;126(1):P286-P334. doi:10.1016/j.ophtha.2018.10.023.

Generic	Brand	Reviewed	Effective Date
LASMIDITAN SUCCINATE Edition 2	REYVOW	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named LASMIDITAN (Reyvow) requires the following rule(s) be met for approval:

A. The patient is being treated for acute (quick onset) migraine
B. The patient is 18 years of age or older
C. The patient has previously tried ONE triptan (such as sumatriptan, rizatriptan, etc.), unless there is a medical reason why they cannot them

RENEWAL CRITERIA
Our guideline named LASMIDITAN (Reyvow) requires the following rule(s) be met for renewal:

A. The patient is being treated for acute (quick onset) migraine
B. The patient meets ONE of the following:
    1. They have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (such as the Migraine Assessment of Current Therapy [MIGRAINE-ACT])
    2. The patient has experienced clinical improvement as defined by ONE of the following:
        i. Ability to function normally within 2 hours of dose
        ii. Headache pain disappears within 2 hours of dose
        iii. Treatment works consistently in majority of migraine attacks

References:
1. Reyvow package insert. Indianapolis, IN. Eli Lilly and Company. Revised September 2022. Accessed March 2024.
2. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society [published correction appears in Neurology. 2013 Feb 26;80(9):871]. Neurology. 2012;78(17):1337-1345. doi:10.1212/WNL.0b013e3182535d20.
3. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OLUTASIDENIB Edition 1	REZLIDHIA	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named OLUTASIDENIB (Rezlidhia) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of relapsed or refractory acute myeloid leukemia, and
B. The patient is 18 years of age or older, and
C. The patient has a confirmed IDH1 mutation as detected by an FDA-approved test

References:

1. Rezlidhia™ capsules [prescribing information]. San Francisco, CA: Rigel; December 2022.

Generic	Brand	Reviewed	Effective Date
RUCAPARIB Edition 2	RUBRACA	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named RUCAPARIB (Rubraca) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
    2. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer
    3. Metastatic castration-resistant prostate cancer (mCRPC)
B. If the patient has epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient has a deleterious BRCA mutation (such as germline and/or somatic) confirmed by Food and Drug Administration (FDA)-approved test for Rubraca
    3. The patient has been treated with two or more chemotherapies, such as paclitaxel, docetaxel, cisplatin, or carboplatin
C. If the patient has recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient is in a complete or partial response to platinum based-chemotherapy
    3. The requested medication will be used for maintenance treatment

(Criteria continued on next page)

REQUIREMENTS: RUCAPARIB (CONTINUED)

D. If the patient has metastatic castration-resistant prostate cancer (mCRPC), approval also requires:
    1. The patient is 18 years of age or older
    2. The patient has a deleterious BRCA mutation (such as germline and/or somatic)
    3. The patient has been treated with androgen receptor-directed therapy AND a taxane- based chemotherapy
    4. The patient meets ONE of the following:
        i. They have previously received a bilateral orchiectomy
        ii. They have a castrate level of testosterone (blood testosterone level is less than 50 ng/dL)
        iii. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

References:
1. Rubraca package insert. Boulder, CO. Clovis Oncology, Inc. Revised December 2022. Accessed March 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ESKETAMINE Edition 3	SPRAVATO	4/29/2024	4/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW:
Our guideline named ESKETAMINE (Spravato) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Treatment-resistant depression (TRD)
    2. Major depressive disorder (MDD)
B. The requested medication will be utilized under the direct supervision of the prescribing healthcare provider
C. If the patient has treatment-resistant depression (TRD), approval also requires:
    1. The patient is 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
    4. The patient has non-psychotic, unipolar depression (no other mental health conditions except depression)
    5. The patient does NOT have active substance abuse
    6. The patient had a trial of TWO oral anti-depressants from different classes for the treatment of depression. Classes of anti-depressants may 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. The trials musts have been for an adequate time period, defined as at least 6 weeks
D. If the patient has major depressive disorder (MDD), approval also requires:
    1. The patient is 18 years of age or older
    2. Therapy is prescribed by or given in consultation with a psychiatrist
    3. The patient has acute suicidal ideation or behavior
    4. The requested medication will be used in combination with an oral antidepressant
    5. The patient has non-psychotic, unipolar depression (no other mental health conditions except depression)
    6. The patient does NOT have active substance abuse

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ESKETAMINE (CONTINUED)

RENEWAL CRITERIA

Our guideline named ESKETAMINE (Spravato) requires the following rule(s) be met for renewal:

A. The patient has treatment-resistant depression (TRD) OR major depressive disorder (MDD)
B. The patient has demonstrated clinical benefit compared to baseline

References:

1. Spravato package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised October 2023. Accessed March 2024.
2. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, third edition. November 2010. Available at: http://psychiatryonline.org/guidelines.aspx . Accessed February 2022.
3. McAllister-Williams RH, Christmas DMB, Cleare AJ, et al. Multiple-therapy-resistant major depressive disorder: a clinically important concept. Br J Psychiatry. 2018;212(5):274-278. doi:10.1192/bjp.2017.33.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OSIMERTINIB MESYLATE Edition 3	TAGRISSO	4/29/2024	4/29/2024

REQUIREMENTS:

Our guideline named OSIMERTINIB (Tagrisso) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. Metastatic non-small cell lung cancer
    2. Non-small cell lung cancer (type of lung cancer)
    3. Locally advanced or metastatic non-small cell lung cancer
B. The patient is 18 years of age or older
C. If the patient has metastatic non-small cell lung cancer, approval also requires that they meet ONE of the following:
    1. They are positive for an epidermal growth factor receptor (EGFR) T790M mutation as confirmed by an FDA (Food and Drug Administration)- approved test AND meet all of the following:
        a. They have progressed 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. They are not currently receiving therapy with an EGFR tyrosine kinase- inhibitor such as Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
    2. They are positive for epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by an FDA-approved test AND they have not received prior systemic treatment for metastatic non-small cell lung cancer
D. If the patient has non-small cell lung cancer, approval also requires ALL of the following:
    1. The requested medication is being used as adjuvant therapy after tumor resection
    2. The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by a FDA-approved test
E. If the patient has locally advanced or metastatic non-small cell lung cancer, approval also requires:
    1. The patient is positive for an epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as confirmed by a FDA-approved test
    2. The requested medication will be used in combination with pemetrexed and platinum based chemotherapy

References:

1. Tagrisso package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised February 2024. Accessed March 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEPROTUMUMAB-TRBW Edition 2	TEPEZZA	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named TEPROTUMUMAB-TRBW (Tepezza) requires the following rule(s) be met for approval:

A. The patient has thyroid eye disease
B. If the patient is a biological female of reproductive potential, an appropriate form of contraception will be initiated prior to use of Tepezza, during treatment, and for at least 6 months following last dose of Tepezza.

References:

1. Tepezza package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised July 2023. Accessed April 2024.
2. Men CJ, Kossler AL, Wester ST. Updates on the understanding and management of thyroid eye disease. Ther Adv Ophthalmol. 2021;13:25158414211027760. Published 2021 Jun 30. doi:10.1177/25158414211027760.

TEPOTINIB			
Generic	Brand	Reviewed	Effective Date
TEPOTINIB HCL Edition 2	TEPMETKO	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named TEPOTINIB (Tepmetko) requires the following rule(s) be met for approval:

A. The patient has metastatic non-small cell lung cancer (NSCLC)
B. The patient is 18 years of age or older
C. Confirmation that mesenchymal-epithelial transition (MET) exon 14 skipping alterations are present, determined by an FDA approved test
D. Confirmation that the patient dose not have Interstitial Lung Disease/Pneumonitis

References:

1. Tepmetko package insert. Rockland, MA. EMDSerono, Inc. Revised February 2024. Accessed March 2024.

ENDOTHELIN RECEPTOR ANTAGONISTS Edition 3			
Generic	Brand	Reviewed	Effective Date
BOSENTAN	TRACLEER	4/29/2024	4/29/2022
AMBRISENTAN	LETAIRIS		
MACITENTAN	OPSUMIT		

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

REQUIREMENTS:

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:

A. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
B. The patient is 18 years of age or older
C. Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
    1. Mean pulmonary artery pressure (PAP) of ≥ 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    3. Pulmonary vascular resistance (PVR) > 2 Wood units
D. The patient has NYHA-WHO Functional Class II to IV symptoms
E. 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.

A. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
B. The patient is 3 years of age or older
C. Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
    1. Mean pulmonary artery pressure (PAP) of ≥ 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    3. Pulmonary vascular resistance (PVR) > 2 Wood units
D. The patient has NYHA-WHO Functional Class II to IV symptoms
E. The patient does not have idiopathic pulmonary fibrosis (IPF)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ENDOTHELIN RECEPTOR ANTAGONISTS (CONTINUED)

F. The patient is not concurrently taking cyclosporine A or glyburide
G. If the patient is 18 years or older, the patient has tried and failed or has a contraindication to Ambrisentan (generic Letairis)

OPSUMIT

The guideline named ENDOTHELIN RECEPTOR ANTAGONISTS (Opsumit) requires a diagnosis of pulmonary arterial hypertension. The following criteria must also be met.

A. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
B. The patient is 18 years of age or older
C. Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
    1. Mean pulmonary artery pressure (PAP) of ≥ 20 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    3. Pulmonary vascular resistance (PVR) > 2 Wood units
D. The patient has NYHA-WHO Functional Class II to IV symptoms
E. 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:

A. 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.
B. 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).

References:

1. Tracleer package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised February 2024. Accessed March 2024.
2. Letairis package insert. Foster City, CA. Gilead Sciences, Inc. Revised August 2019. Accessed March 2024.
3. Opsumit package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised May 2023. Accessed March 2024.
4. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. Chest. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.

(Criteria continued on next page)

5. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619. doi:10.1016/j.jacc.2009.01.004.

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST Edition 2			
Generic	Brand	Reviewed	Effective Date
TRIPTORELIN PAMOATE	TRIPTODUR, TRELSTAR	04/29/2024	4/29/2022
HISTRELIN ACETATE	SUPPRELIN LA, VANTAS		
LEUPROLIDE ACETATE	ELIGARD, LEUPROLIDE ACETATE (GENERIC), LUPRON DEPOT–PED, LUPRON DEPOT, LUPANETA, FENSOLVI		
GOSERELIN ACETATE	ZOLADEX		
NAFARELIN ACETATE	SYNAREL		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (Eligard, Leuprolide acetate, Lupron Depot – Ped, Lupron Depot, Lupaneta, Zoladex, Supprelin LA, Vantas, Triptodur, Trelstar, Fensolvi, Synarel) requires the following rule(s) be met for approval:

A. The patient has or is using the requested drug for ONE of the following:
    1. Advanced prostate cancer
    2. Moderate to severe pain from endometriosis
    3. Central precocious puberty (CPP)
    4. Gender dysphoria
    5. As an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding
    6. Palliative treatment of advanced breast cancer
    7. Management of locally confined carcinoma of the prostate
    8. Anemia caused by uterine leiomyomata

NOTE: For any diagnoses related to treatment of infertility, see Infertility Policy.

(Criteria continued on next page)

REQUIREMENTS: GNRH AGONIST (CONTINUED)

B. If the patient has advanced prostate cancer, approval also requires:
    1. The request is for Eligard, Lupron Depot, Zoladex, Vantas, or Trelstar
C. If the patient has moderate to severe pain from endometriosis, approval also requires:
    1. The request is for Lupron Depot, Lupaneta, Synarel, or Zoladex
    2. The patient is 18 years of age or older
    3. Therapy is prescribed by or given in consultation with an obstetrician/gynecologist
    4. The patient has 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 they cannot
D. If the patient is a female and has central precocious puberty, approval also requires:
    1. The request is for Triptodur, Supprelin LA, Synarel, leuprolide (generic), Lupron Depot-Ped, or Fensolvi
    2. The patient is 2 years of age or older
    3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist
    4. The patient has 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. The patient is/was younger than 8 years of age when the condition started
    6. There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)
E. If the patient is a male and has central precocious puberty, approval also requires:
    1. The request is for Triptodur, Supprelin LA, Synarel, leuprolide (generic), Lupron Depot-Ped, or Fensolvi
    2. The patient is 2 years of age or older
    3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist
    4. The patient has 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. The patient is/was younger than 9 years of age when your condition started
    6. There is documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

(Criteria continued on next page)

REQUIREMENTS: GNRH AGONIST (CONTINUED)

F. If the patient is using the requested medication as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, approval also requires:
    1. The request is for Zoladex
G. If the patient is using the requested medication for palliative treatment of advanced breast cancer, approval also requires:
    1. The request is for Zoladex
    2. The patient is a premenopausal or perimenopausal female
H. If the patient is 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 the patient has anemia caused by uterine leiomyomata, approval also requires:
    1. The request is for Lupron Depot
    2. The patient is using the requested medication for preoperative hematologic improvement
    1. 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 (Eligard, Leuprolide acetate, Lupron Depot – Ped, Lupron Depot, Lupaneta, Zoladex, Supprelin LA, Vantas, Triptodur, Trelstar, Fensolvi, Synarel) requires the following rule(s) be met for renewal:

A. The patient has or is using the requested drug for ONE of the following:
    1. Advanced prostate cancer
    2. Moderate to severe pain from endometriosis
    3. Central precocious puberty (CPP)
    4. Gender dysphoria
B. If the patient has moderate to severe pain associated with endometriosis, renewal also requires:
    1. The request is for Lupron Depot, Lupaneta, Synarel, or Zoladex
    2. The patient has experienced improvement of pain related to endometriosis while on therapy
    3. The patient is receiving add-back therapy at the same time (combination estrogen- progestin or progestin-only contraceptive preparation)
    4. The patient has NOT received a total course of therapy exceeding 12 months

(Criteria continued on next page)

REQUIREMENTS: GNRH AGONIST (CONTINUED)

C. If the patien has central precocious puberty (CPP), renewal also requires:
    1. The request is for Triptodur, Supprelin LA, Synarel, leuprolide (generic),Lupron Depot-Ped, or Fensolvi
    2. Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
    3. The patient has not reached actual age which corresponds to current pubertal age
D. If the patient has advanced prostate cancer, renewal also requires:
    1. The request is for Eligard, Lupron Depot, Zoladex, Vantas, or Trelstar

References:

1. Fensolvi package insert. Fort Collins, CO. Tolmar, Inc. Revised November 2022. Accessed March 2024.
2. Lupron Depot package insert. North Chicago, IL. AbbVie Inc. Revised March 2024. Accessed March 2024.
3. Lupron Depot-Ped Kit package insert. North Chicago, IL. AbbVie Inc. Revised March 2024. Accessed March 2024.
4. Lupaneta package insert. North Chicago, IL. AbbVie Inc. Revised August 2023. Accessed March 2024.
5. Supprelin LA package insert. Malvern, PA. Endo Pharmaceuticals Solutions, Inc. Revised April 2022. Accessed March 2024.
6. Trelstar package insert. Madison, NJ. Allergan USA, Inc. Revised November 2023. Accessed March 2024.
7. Triptodur package insert. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised December 2022. Accessed March 2024.
8. Vantas package insert. Malvern, PA. Endo Pharmaceuticals Solutions, Inc. Revised August 2022. Accessed March 2024.
9. Zoladex package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised March 2023. Accessed March 2024.
10. Eligard package insert. Fort Collins, CO. Tolmar Pharmaceuticals, Inc. Revised January 2024. Accessed March 2024.
11. Leuprolide acetate package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised January 2019. Accessed March 2024.
12. Synarel package insert. New York, NY. Pfizer Labs, Inc. Revised January 2023. Accessed March 2024.
13. World Professional Association for Transgender Health. (2022). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [8th Version]. https://www.wpath.org/publications/soc .
14. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658.
15. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin Summary, Number 228. Obstet Gynecol. 2021;137(6):1131-1133. doi:10.1097/AOG.0000000000004403.
16. Practice bulletin no. 114: management of endometriosis. Obstet Gynecol. 2010;116(1):223-236. doi:10.1097/AOG.0b013e3181e8b073.
17. Chronic Pelvic Pain: ACOG Practice Bulletin, Number 218. Obstet Gynecol. 2020;135(3):e98-e109. doi:10.1097/AOG.0000000000003716.
18. Kaplowitz P, Bloch C; Section on Endocrinology, American Academy of Pediatrics. Evaluation and Referral of Children With Signs of Early Puberty. Pediatrics. 2016;137(1):10.1542/peds.2015-3732. doi:10.1542/peds.2015-3732.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEPLIZUMAB-MZWV Edition 1	TZIELD	4/29/2024	4/29/2023

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named TEPLIZUMAB-MZWV (Tzield) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Stage 2 Type 1 Diabetes (pre-clinical)
B. The patient is 8 years of age or older, and
C. The requested medication is prescribed by or in consultation with an endocrinologist, and
D. The patient has at least ONE relative with a diagnosis of Type 1 Diabetes

References:

1. Tzield™ intravenous infusion [prescribing information]. Red Bank, NJ: Provention; November 2022.

Generic	Brand	Reviewed	Effective Date
UMBRALISIB TOSYLATE Edition 2	UKONIQ	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named UMBRALISIB (Ukoniq) requires the following rule(s) be met for approval:

A. The patient has relapsed or refractory marginal zone lymphoma or follicular lymphoma (types of immune system cancer that have returned or are not responding to treatment)
B. The patient is 18 years of age or older
C. If the patient has marginal zone lymphoma, approval also requires:
    1. The patient has received at least one prior anti-CD20-based regimen
D. If the patient has follicular lymphoma, approval also requires:
    1. The patient has received at least three prior lines of systemic therapy

References:
1. Ukoniq package insert. Edison, NJ. TG Therapeutics, Inc. Revised February 2021. Accessed March 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VERICIGUAT Edition 2	VERQUVO	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named VERICIGUAT (Verquvo) requires the following rule(s) be met for approval:

A. The patient has symptomatic chronic heart failure
B. The patient has an ejection fraction of less than 45%
C. The patient is18 years of age or older
D. The patient 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. The patient has previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors) unless there is a medical reason why they cannot: Farxiga, Xigduo XR, Jardiance, Synjardy
F. The patient has previously tried ONE agent from EACH of the following groups, unless there is a medical reason why they cannot:
    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, or 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. The patient has symptomatic chronic heart failure
B. The patient has an ejection fraction of less than 45%
C. The patient 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)

(Criteria continued on next page)

REQUIREMENTS: VERICIGUAT (CONTINUED)

References:

1. Verquvo package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised May 2023. Accessed March 2024.
2. Aimo A, et al. Relative efficacy of sacubitril-valsartan, vericiguat, and SGLT2 inhibitors in heart failure with reduced ejection fraction: a systematic review and network meta-analysis. Cardiovasc Drugs Ther. 2020;10.1007/s10557-020-07099-2. doi:10.1007/s10557-020-07099-2.
3. Writing Committee, Maddox TM, Januzzi JL Jr, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2021;77(6):772-810. doi:10.1016/j.jacc.2020.11.022.

Generic	Brand	Reviewed	Effective Date
ELUXADOLINE Edition 2	VIBERZI	4/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline for ELUXADOLINE (Viberzi) requires the following rule(s) to be met for approval:

A. The patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D)
B. The patient is at least 18 years old
C. The medication is being prescribed by or in consultation with a gastroenterologist
D. 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). The following criteria must also be met:

A. The patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
B. 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)

References:

1. Viberzi package insert. Madison, NJ. Allergan USA, Inc. Revised June 2020. Accessed March 2024.
2. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. Am J Gastroenterol. 2021;116(1):17-44. doi:10.14309/ajg.0000000000001036.

Generic	Brand	Reviewed	Effective Date
VILTOLARSEN Edition 3	VILTEPSO	4/29/2024	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named VILTOLARSEN (Viltepso) requires the following rule(s) be met for approval:

A. The patient has Duchenne muscular dystrophy (DMD)
B. The patient has documented genetic testing that confirms they have a mutation in the DMD gene that is responsive to exon 53 skipping
C. Therapy is prescribed by or given in consultation with a neurologist specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. The patient is ambulatory
E. The patient is currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why they cannot
F. Requested medication is not concurrently prescribed with other exon-skipping therapies (e.g., Amondys-45, Exondys 51, Vyondys 53)

RENEWAL CRITERIA
Our guideline named VILTOLARSEN (Viltepso) requires ONE of the following rule(s) be met for renewal:

A. The patient has maintained or demonstrated less than expected decline in ambulatory ability based on muscle function assessments (such as the 6-minute walk test)
B. The patient has maintained or demonstrated less than expected decline in other muscle function (such as pulmonary or cardiac function)

References:
1. Viltepso package insert. Paramus, NJ. NS Pharma, Inc. Revised March 2021. Accessed March 2024.
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267. doi:10.1016/S1474-4422(18)30024-3
3. Rivera SR, Jhamb SK, Abdel-Hamid HZ, et al. Medical management of muscle weakness in Duchenne muscular dystrophy. PLoS One. 2020;15(10):e0240687. Published 2020 Oct 19. doi:10.1371/journal.pone.0240687.

Generic	Brand	Reviewed	Effective Date
PACRITINIB Edition 2	VONJO	04/29/2024	04/29/2022

REQUIREMENTS:

Our guideline named PACRITINIB (Vonjo) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The requested medication is prescribed by or in consultation with an oncologist or hematologist
C. The patient has a diagnosis of intermediate or high-risk primary or secondary (post- polycythemia vera or post-essential thrombocythemia) myelofibrosis
D. The patient has a platelet count less than 50×10^9/L (50,000/mcL)

RENEWAL CRITERIA

Our guideline named PACRITINIB (Vonjo) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
B. The patient has experienced or maintained symptom improvement, as evidenced by ONE of the following:
    1. They have a spleen volume reduction of 35% or greater from baseline after 6 months of therapy
    2. They have a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
    3. They have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

References:

1. Vonjo package insert. Seattle, WA. CTI Biopharma Corp. Revised August 2023. Accessed March 2024.
2. Tefferi A, Cervantes F, Mesa R, et al. Revised response criteria for myelofibrosis: International Working Group-Myeloproliferative Neoplasms Research and Treatment (IWG-MRT) and European LeukemiaNet (ELN) consensus report. Blood. 2013;122(8):1395-1398. doi:10.1182/blood-2013-03-488098.
3. Rumi E, Cazzola M. Diagnosis, risk stratification, and response evaluation in classical myeloproliferative neoplasms. Blood. 2017;129(6):680-692. doi:10.1182/blood-2016-10-695957.

Generic	Brand	Reviewed	Effective Date
GOLODIRSEN Edition 3	VYONDYS-53	4/29/2024	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GOLODIRSEN (Vyondys-53) requires the following rule(s) be met for approval:

A. The patient has Duchenne muscular dystrophy (DMD)
B. The patient has documented genetic testing that confirms they have a mutation in the DMD gene that is responsive to exon 53 skipping
C. Therapy is prescribed by or given in consultation with a neurologist specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. The patient is ambulatory
E. The patient is currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why they cannot
F. Requested medication is not concurrently prescribed with other exon-skipping therapies (e.g., Amondys-45, Exondys 51, Viltepso)

RENEWAL CRITERIA
Our guideline named GOLODIRSEN (Vyondys-53) requires ONE of the following rule(s) be met for renewal:

A. The patient has maintained or demonstrated less than expected decline in ambulatory ability based on muscle function assessments (such as the 6-minute walk test)
B. The patient has maintained or demonstrated less than expected decline in other muscle function (such as pulmonary or cardiac function)

References:

1. Vyondys 53 package insert. Cambridge, MA. Sarepta Therapeutics, Inc. Revised February 2021. Accessed March 2024.
2. Birnkrant DJ, Bushby K, Bann CM, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management [published correction appears in Lancet Neurol. 2018 Apr 4;:]. Lancet Neurol. 2018;17(3):251-267. doi:10.1016/S1474-4422(18)30024-3
3. Rivera SR, Jhamb SK, Abdel-Hamid HZ, et al. Medical management of muscle weakness in Duchenne muscular dystrophy. PLoS One. 2020;15(10):e0240687. Published 2020 Oct 19. doi:10.1371/journal.pone.0240687.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LIFITEGRAST Edition 3	XIIDRA	4/29/2024	04/29/2022

REQUIREMENTS:

The guideline named LIFITEGRAST (XIIDRA) requires that the patient has a diagnosis of dry eye disease or suppressed tear production due to ocular inflammation. In addition, the patient must meet ALL the following criteria for approval:

A. The patient is aged 17 years or older.
B. The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
C. The patient will not be using concurrently with Restasis, Eysuvis, Cequa, or Tyrvaya.
D. 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.
E. The patient had a previous trial of or contraindication to at least 4 weeks of treatment with an artificial tears product.

For renewal of therapy, the patient must meet ALL the following criteria for approval:

A. The patient experienced an objective response to Xiidra therapy such as an increase in tear production or a decrease in dry eye symptoms.
B. The requested medication will not be used in combination with Restasis, Cequa, Eysuvis, or Tyrvaya.

References:

1. Xiidra package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised June 2020. Accessed March 2024.
2. Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2019;126(1):P286-P334. doi:10.1016/j.ophtha.2018.10.023.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SELINEXOR Edition 2	XPOVIO	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named SELINEXOR (Xpovio) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Multiple myeloma (MM)
    2. Relapsed or refractory multiple myeloma (RRMM)
    3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from follicular lymphoma
B. The patient is 18 years of age or older
C. If the patient has multiple myeloma, approval also requires:
    1. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone
    2. The patient has received at least one therapy before Xpovio
D. If the patient has relapsed or refractory multiple myeloma, approval also requires:
    1. The requested medication will be used in combination with dexamethasone
    2. The patient has received at least four prior therapies for the treatment of RRMM
    3. The patients RRMM is refractory (non-responsive) to ALL of the following:
        a. Two proteasome inhibitors (such as bortezomib, carfilzomib)
        b. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
        c. One anti-CD38 monoclonal antibody (such as daratumumab)
E. If the patient has relapsed or refractory diffuse large B-cell lymphoma (DLBCL), approval also requires:
    1. The patient has received at least two lines of systemic therapy

References:

1. Xpovio package insert. Newton, MA. Karyopharm Therapeutics Inc. Revised July 2022. Accessed March 2024.

WELLFLEET RX STUDENT FORMULARY

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 2	Reviewed	Effective Date
ACA Zero Cost Share Override Guidelines	04/29/2024	04/29/2022

Description

This policy applies only to requests for override of cost share on drugs currently available on the formulary without UM requirements or previously approved for coverage via prior authorization process. The scope of this policy is strictly for providing zero cost share override for ACA Preventative Medications and should not be utilized for coverage determination or for a $0 override for non-ACA medications.

REQUIREMENTS:

Our guideline named ACA ZERO COST SHARE OVERRIDE requires the following rule(s) be met for approval:

A. The requested drug is not currently listed on the ACA Preventative Medications Zero Cost Share drug list but is currently covered for you by ONE of the following:
    1. Drug is currently covered by your plan without additional utilization management requirements and requires a cost share copayment
    2. Drug is covered by a prior authorization (i.e., formulary exception, step therapy, age limits, PA, etc.) currently on file and requires a cost share copayment
B. The requested drug is a multi-source brand or considered a therapeutically equivalent alternative to one that is currently listed.
C. You meet the criteria for zero cost share for a drug currently listed on the ACA Preventative Medications Zero Cost Share drug list (See Appendix A)
D. If the request is for a single-source brand that has no preferred generic drugs or therapeutically equivalent 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)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ACA ZERO COST SHARE OVERRIDE (CONTINUED)

E. 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)

Appendix A: ACA Preventative Medications Zero Cost Share

ACA Therapeutic Category	Eligible Criteria
Aspirin	No additional criteria
Fluoride	Age 6 months to 6 years
Folic Acid	No additional criteria
Contraceptives	No additional criteria
Breast Cancer Prevention	No additional criteria
Bowel Preparation	• Age 50-75 years (2 per year)
HIV Pre-Exposure Prophylaxis (PrEP)	• The requested medication is FDA approved for PrEP or recommended by the CDC PrEP guidelines (e.g., emtricitabine/tenofovir disoproxil fumarate, Descovy, etc.) • No concurrent use of antiretroviral medications for the treatment of HIV in the past 120 days
Statin	• Age 40-75 years • Quantity limited to statin dosages at low- to moderate-intensity • No concurrent (within past 120 days) use of any of the following secondary prevention medications: • aspirin/dipyridamole (Aggrenox) • clopidogrel (Plavix) • dipyridamole • nitroglycerin – oral, sublingual, transdermal, translingual • prasugrel (Effient) • Praluent • Repatha • ticagrelor (Brilinta) • ticlopidine • vorapaxar (Zontivity)
Smoking Cessation	Age 18 years and older

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LONAFARIB Edition 2	ZOKINVY	4/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named LONAFARNIB (Zokinvy) requires the following rule(s) be met for approval:

A. The patient has Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies
B. The patient is 1 year of age or older
C. The patient has a body surface area (BSA) of 0.39 meters squared or more
D. If the patient has a processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:
    1. Heterozygous LMNA mutation with progerin-like protein accumulation
    2. Homozygous or compound heterozygous ZMPSTE24 mutations

References:

1. Zokinvy package insert. Palo Alto, CA. Eiger BioPharmaceuticals, Inc. Revised March 2024. Accessed March 2024.
2. Gordon LB, Tuminelli K, Andrés V, et al. The progeria research foundation 10th international scientific workshop; researching possibilities, ExTENding lives - webinar version scientific summary. Aging (Albany NY). 2021;13(6):9143-9151. doi:10.18632/aging.202835.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALECTINIB Edition 2	ALECENSA	7/29/2024	7/29/2024

REQUIREMENTS:

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

A. The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA (Food and Drug Administration)-approved test
C. If the patient is post tumor resection, the requested product will be used as adjuvant treatment
D. Therapy will be prescribed by, or in consultation with, an oncologist

References:

1. Alecensa package insert. South San Francisco, CA. Genentech USA, Inc. Revised April 2024. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BRIGATINIB Edition 2	ALUNBRIG	7/29/2024	7/29/2023

REQUIREMENTS:

Our guideline named BRIGATINIB (Alunbrig) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The patient is 18 years of age or older
D. The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by a Food and Drug Administration (FDA)-approved test

References:

1. Alunbrig package insert. Cambridge, MA. ARIAD Pharmaceuticals, Inc. Revised February 2022. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DALFAMPRIDIN Edition 1	AMPYRA	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DALFAMPRIDINE (Ampyra) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of multiple sclerosis
B. The requested medication is prescribed by or recommended by a neurologist
C. The patient has symptoms of a walking disability

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

A. The patient has experienced or maintained at least a 15% improvement in walking ability.

References:

1. Ampyra package insert. Ardsley, NY. Accorda Therapeutics, Inc. Revised November 2021. Accessed June 2024.
2. Brown TR, Simnad VI. A Randomized Crossover Trial of Dalfampridine Extended Release for Effect on Ambulatory Activity in People with Multiple Sclerosis. Int J MS Care. 2016 Jul-Aug;18(4):170-6.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VUTRISIRAN Edition 1	AMVUTTRA	7/29/2024	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named VUTRISIRAN (Amvuttra) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
D. The patient has symptomatic polyneuropathy as determined by a baseline assessment (i.e., modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, etc.)
E. The patient has a documented diagnosis of hATTR as confirmed by ONE of the following:
    1. Biopsy 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 VUTRISIRAN (Amvuttra) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient has a clinical response to treatment with demonstrated improvement in severity of neuropathy per assessment (i.e., modified Neuropathy Impairment Scale+7 [mNIS+7] composite score, the Norfolk Quality of Life-Diabetic Neuropathy [QoL-DN] total score, polyneuropathy disability [PND] score, FAP disease stage, etc.) compared to baseline.

References:

1. Amvuttra package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised June 2022. Accessed June 2024.
2. Luigetti M, Romano A, Di Paolantonio A, Bisogni G, Sabatelli M. Diagnosis and Treatment of Hereditary Transthyretin Amyloidosis (hATTR) Polyneuropathy: Current Perspectives on Improving Patient Care. Ther Clin Risk Manag. 2020;16:109-123. Published 2020 Feb 21. doi:10.2147/TCRM.S219979.

WELLFLEET RX STUDENT FORMULARY

ANABOLIC STEROIDS Edition 1			
Generic	Brand	Reviewed	Effective Date
OXYMETHOLONE	ANADROL-50	07/29/2024	6/1/2021
OXANDROLONE	OXANDRIN		

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

REQUIREMENTS:

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. The patient has anemia or cachexia associated with AIDS
B. The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes
C. The patient does not have ANY of the following reasons why they 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
    3. Known or suspected nephrosis
    4. Known or suspected hypercalcemia
    5. Severe hepatic dysfunction
D. If the patient has 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 anemia

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)

E. If the patient has cachexia associated with AIDS, approval also requires:
    1. Patient is on anti-retroviral therapy
    2. Patient has a documented viral load 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, nutritional support specialist (SBS), or infectious disease specialist
    4. Patient meets ONE of the following:
        a. Patient has 10% unintentional weight loss over 12 months
        b. Patient has 7.5% unintentional weight loss over 6 months
        c. Patient has 5% body cell mass (BCM) loss within 6 months
        d. Patient has a BCM of less than 35% (men) and a body mass index (BMI) of less than 27kg per meter squared
        e. Patient has 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. Patient has 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. Patient has ONE of the following diagnoses:
    1. Weight loss
    2. Protein catabolism caused by long-term use of corticosteroids
    3. Bone pain accompanying osteoporosis
    4. Cachexia associated with AIDS
    5. Turner's Syndrome
B. Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes
C. Patient does not have ANY of the following reasons why they 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
    3. Known or suspected nephrosis
    4. Known or suspected hypercalcemia
    5. Severe hepatic dysfunction

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)

D. If patient has weight loss, approval also requires:
    1. Patient's 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
E. If patient has cachexia associated with AIDS, approval also requires:
    1. Patient is on anti-retroviral therapy
    2. Patient has a documented viral load 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, nutritional support specialist (SBS) or infectious disease specialist
    4. Patient meets ONE of the following:
        a. Patient has 10% unintentional weight loss over 12 months
        b. Patient has 7.5% unintentional weight loss over 6 months
        c. Patient has 5% body cell mass (BCM) loss within 6 months
        d. Patient has a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
        e. Patient has 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. Patient has 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. Patient has cachexia associated with AIDS
B. Patient is on anti-retroviral therapy
C. Patient's viral load is less than 200 copies per mL within the past 3 months
D. Patient has a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
E. Patient has not received more than 24 weeks of therapy in a calendar year

References:
1. Anadrol package insert. Marietta, GA. Unimed Pharmaceuticals, Inc. Revised August 2004. Accessed June 2024.
2. Oxandrin Package insert. New York, NY. Pfizer co. Revised June 2005. Accessed June 2024.
3. Wanke C, Kotler D; HIV Wasting Collaborative Consensus Committee. Collaborative recommendations: the approach to diagnosis and treatment of HIV wasting. J Acquir Immune Defic Syndr. 2004;37 Suppl 5:S284-S288. doi:10.1097/01.qai.0000144384.55091.0f.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
APOMORPHINE Edition 2	APOKYN	7/29/2024	07/29/2022
APOMORPHINE SUBLINGUAL	KYNMOBI		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named APOMORPHINE (Apokyn, Kynmobi) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of advanced Parkinson's disease
C. The requested medication is being used for acute, intermittent treatment of 'OFF' episodes associated with advanced Parkinson's disease
D. Therapy is prescribed by or given in consultation with a neurologist
E. The prescribing physician has optimized drug therapy as evidenced by BOTH of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Patient has had a trial of or contraindication to at least TWO Parkinson disease agents from two different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), or catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

RENEWAL CRITERIA
Our guideline named APOMORPHINE (Apokyn, Kynmobi) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of advanced Parkinson's disease
B. The patient has had improvement with motor fluctuations during 'OFF' episodes (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)

References:

1. Apokyn package insert. Rockville, MD. MMD US Operations, LLC. Revised June 2022. Accessed June 2024.
2. Kynmobi package insert. Marlborough, MA. Sunovion Pharmaceuticals Inc. Revised June 2022. Accessed June 2024.
3. Pahwa R, Factor SA, Lyons KE, et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2006; 66:983-995.

WELLFLEET RX STUDENT FORMULARY

ERYTHROPOIESIS STIMULATING AGENTS Edition 1			
Generic	Brand	Reviewed	Effective Date
DARBEPOETIN	ARANESP	7/29/2024	6/1/2021
EPOETIN ALFA	EPOGEN PROCRIT		
EPOETIN ALFA-EPBX	RETACRIT		
METHOXY PEGEPOETIN BETA	MIRCERA		

REQUIREMENTS:

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. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
    5. Patients undergoing elective, noncardiac, or nonvascular surgery.
B. For patients with anemia associated with chronic kidney disease, approval also requires:
    1. The patient has a hemoglobin level of less than 10g/dL
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:
    1. The patient has a hemoglobin level of less than 11g/Dl
    2. The patient's hemoglobin level has decreased at least 2g/dL below their baseline level.
D. For patients with anemia related to zidovudine therapy, approval also requires:
    1. The patient has a hemoglobin level of less than 10g/dL

(*Criteria continued on next page)*

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

A. For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
    1. The patient has tried a lower ribavirin dose, unless there is a contraindication
    2. The patient has a hemoglobin level of less than 10g/dL
B. For patients undergoing elective, noncardiac, or nonvascular surgery, approval also requires:
    1. The patient has a hemoglobin level of less than 13g/dL

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. The patient has ONE of the following diagnoses:
    1. Anemia associated with chronic kidney disease
    2. Anemia due to the effects of concomitantly administered cancer chemotherapy
    3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.
B. For patients with anemia associated with chronic kidney disease, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 10g/dL
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 11g/dL OR their hemoglobin level has decreased at least 2g/dL below their baseline level
D. For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
    1. The patient has tried Procrit
    2. The patient has tried a lower ribavirin dose, unless there is a contraindication
    3. The patient has a hemoglobin of less than 10g/dL

(*Criteria continued on next page*)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
    5. The patient is undergoing elective, noncardiac, or nonvascular surgery.
B. For patients with anemia associated with chronic kidney disease, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 10g/dL
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 11g/dL OR their hemoglobin has decreased at least 2g/dL below their baseline level
D. For patients with anemia related to zidovudine therapy, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 10g/dL
E. For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
    1. The patient has tried Procrit
    2. The patient has tried a lower ribavirin dose, unless there is a contraindication
    3. The patient's hemoglobin level is less than 10g/dL
F. For patients undergoing elective, noncardiac, or nonvascular surgery, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 13g/dL

(*Criteria continued on next page*)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
    5. The patient is undergoing elective, noncardiac, or nonvascular surgery
B. For patients with anemia associated with chronic kidney disease, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 10g/dL
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 11g/dL OR their hemoglobin has decreased at least 2g/dL below their baseline level
D. For patients with anemia related to zidovudine therapy, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 10g/dL
E. For patients with have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:
    1. The patient has tried Procrit
    2. The patient has tried a lower ribavirin dose, unless there is a medical reason why you cannot (contraindication)
    3. The patient has a hemoglobin level of less than 10g/dL
F. For patients undergoing elective, noncardiac, or nonvascular surgery, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 13g/dL

(*Criteria continued on next page*)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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. The patient has anemia associated with chronic kidney disease
B. For patients who are 18 years of age or older, approval also requires:
    1. The patient has tried Procrit
    2. The patient has a hemoglobin level of less than 10g/dL
C. For patients who are between 5 and 17 years of age, approval also requires:
    1. The patient is on hemodialysis
    2. The patient is changing from another erythropoiesis-stimulating agent (e.g., epoetin alfa, darbepoetin alfa, etc.) after the hemoglobin level has been stabilized

RENEWAL CRITERIA FOR PROCRIT
Our guideline named ERYTHROPOIESIS STIMULATING AGENTS (Procrit) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Anemia due to with chronic kidney disease
    2. Anemia due to the effects of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
B. For patients who have anemia associated with chronic kidney disease, renewal also requires ONE of the following:
    1. The patient has a hemoglobin level of less than 10g/dL if they are NOT on dialysis
    2. The patient has a hemoglobin level of less than 11g/dL if they are on dialysis
    3. The patient's hemoglobin level has reached 10g/dL (if they are NOT on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. The patient's hemoglobin level has reached 11g/dL (if they are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions

(*Criteria continued on next page*)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

C. For patients who have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL
D. For patients who have anemia related to zidovudine therapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL
E. For patients who have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL

RENEWAL CRITERIA FOR ARANESP

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

A. The patient has ONE of the following diagnoses:
    1. Anemia associated with chronic kidney disease
    2. Anemia due to the effects of concomitantly administered cancer chemotherapy
    3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.
B. For patients who have anemia associated with chronic kidney disease, renewal also requires ONE of the following:
    1. The patient has a hemoglobin level of less than 10g/dL if they are NOT on dialysis
    2. The patient has a hemoglobin level of less than 11g/dL if they are on dialysis
    3. The patient's hemoglobin has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
    4. The patient's hemoglobin has reached 11g/dL (if they are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL
D. For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

RENEWAL CRITERIA FOR EPOGEN

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

A. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
B. For patients with anemia associated with chronic kidney disease, renewal also requires ONE of the following:
    1. The patient has a hemoglobin level of less than 10g/dL if they are NOT on dialysis
    2. The patient has a hemoglobin level of less than 11g/dL if they are on dialysis
    3. The patient's hemoglobin level has reached 10g/dL (if they are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. The patient's hemoglobin level has reached 11g/dL (if they are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12 g/dL
D. For patients with anemia related to zidovudine therapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12 g/dL
E. For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12 g/dL

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WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

RENEWAL CRITERIA FOR RETACRIT

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

A. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
B. For patients with anemia associated with chronic kidney disease, renewal also requires ONE of the following:
    1. The patient has a hemoglobin level of less than 10g/dL if they are NOT on dialysis
    2. The patient has a hemoglobin level of less than 11g/dL if they are on dialysis
    3. The patient's hemoglobin level has reached 10g/dL (if they are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. The patient's hemoglobin level has reached 11g/dL (if they are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
C. For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL
D. For patients with anemia related to zidovudine therapy, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL
E. For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

RENEWAL CRITERIA FOR MIRCERA

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

A. The patient has anemia associated with chronic kidney disease
B. For patients who are 18 years of age or older and are currently receiving dialysis treatment, renewal also requires ONE of the following:
    1. The patient has a hemoglobin level 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. For patients who are 18 years of age or older and are NOT receiving dialysis treatment, renewal also requires ONE of the following:
    1. The patient has a hemoglobin level of less than 10g/dL
    2. The patient has a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
D. For patients who are between 5 and 17 years of age, renewal also requires:
    1. The patient is currently receiving dialysis treatment
    2. The patient has ONE of the following:
        a. A hemoglobin level 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

References:

1. Aranesp package insert. Thousand Oaks, Ca. Amgen Inc. Revised January 2019. Accessed June 2024.
2. Epogen package insert. Thousand Oaks, Ca. Amgen Inc. Revised April 2024. Accessed June 2024.
3. Procrit package insert. Thousand Oaks, Ca. Amgen Inc. Revised. Reviewed April 2024. Accessed June 2024.
4. Retacrit package insert. Lake Forest, IL.Pfizer Company. Reviewed June 2024. Accessed June 2024.
5. Mircera package insert. South San Francisco, CA. Reviewed June 2018. Accessed June 2024.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;2(Suppl):279-335.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AMIKACIN LIPOSOMAL/NEB. ACCESSR Edition 1	ARIKAYCE	07/29/2024	6/1/2021

REQUIREMENTS:

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. The patient is 18 years of age or older
B. The patient has *Mycobacterium avium complex* (MAC) lung disease with limited or no alternative treatment options
C. The patient has NOT achieved negative sputum cultures after using multidrug background regimen therapy for at least 6 months in a row
D. The requested medication will be used as part of a combination antibacterial drug regimen
E. The requested medication is being prescribed by or given in consultation with a pulmonologist or infectious disease specialist physician

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

A. The patient has *Mycobacterium avium complex* (MAC) lung disease
B. The patient has not had a positive *Mycobacterium avium complex* sputum culture after repeated negative cultures
C. The patient has experienced an improvement in symptoms
D. The patient meets ONE of the following:
    1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture 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 for *Mycobacterium avium complex* by 12 months of Arikayce treatment

References:

1. Arikayce package insert. Bridgewater, NJ. Insmed Incorporated. Revised June 2023. Accessed June 2024.
2. Daley CL, Iaccarino JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clin Infect Dis. 2020;71(4):905-913. doi:10.1093/cid/ciaa1125.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DEUTETRABENAZINE Edition 1	AUSTEDO	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient is at least 18 years of age
B. The patient has ONE of the following diagnoses:
    1. chorea associated with Huntington's disease
    2. moderate to severe tardive dyskinesia
C. For patients with chorea associated with Huntington's disease, approval also requires:
    1. The requested medication is prescribed by or given in consultation with a neurologist or movement disorder specialist
D. For patients with moderate to severe tardive dyskinesia, approval also requires:
    1. Moderate to severe tardive dyskinesia has been present for at least 3 months
    2. The requested medication is prescribed by or given in consultation with a neurologist, movement disorder specialist, or psychiatrist
    3. The patient has a prior history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month for patients who are 60 years of age or older) as documented in the prescription claims history

References:

1. Austedo package insert. Parsippany, NJ. Teva Pharmaceuticals USA, Inc. Revised September 2023.Accessed June 2024.
2. Armstrong MJ, Miyasaki JM. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. Neurology. 2012;79:597-603.
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013;81(5):463-469.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AVAPRITINIB Edition 4	AYVAKIT	7/29/2024	7/29/2023

REQUIREMENTS:

Our guideline named AVAPRITINIB (Ayvakit) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has one of the following diagnoses:
    1. Unresectable or metastatic gastrointestinal stromal tumor (GIST)
    2. Advanced Systemic Mastocytosis (AdvSM) including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL).
    3. Indolent Systemic Mastocytosis (ISM)
C. If the patient has unresectable or metastatic gastrointestinal stromal tumor (GIST), approval also requires:
    1. The patient harbors a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations
D. If the patient has advanced Systemic Mastocytosis (AdvSM) or indolent systemic mastocytosis, approval also requires:
    1. Patient's platelet count is 50 X 10^9 /L or greater

References:

1. Ayvakit package insert. Cambridge, MA. Blueprint Medicines Corporation. Revised May 2023. Accessed June 2024.

ACETAMINOPHEN DAILY LIMIT OVERRIDE			
Generic	Brand	Reviewed	Effective Date
Acetaminophen Edition 1	N/A	7/29/2024	6/1/2021

REQUIREMENTS:

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

References:

1. U.S. Food and Drug Administration. (2017, Nov 14). Acetaminophen Information. https://www.fda.gov/drugs/information-drug-class/acetaminophen-information.
2. Agrawal S, Khazaeni B. Acetaminophen Toxicity. In: StatPearls. Treasure Island (FL): StatPearls Publishing; April 30, 2022.

ACNE AGE RESTRICTION OVERRIDE Edition 2			
Generic	Brand	Reviewed	Effective Date
ADAPALENE	DIFFERIN	7/29/2024	7/29/2022
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		

REQUIREMENTS:

Our guideline named ACNE AGE RESTRICTION OVERRIDE requires the following rule(s) be met for approval:

A. The patient is 26 years of age or older
B. The patient's diagnosis is considered a non-cosmetic condition.
    i. Examples of non-cosmetic conditions include: acne vulgaris, acne rosacea, actinic keratosis/treatment of precancerous lesions, ichthyosis, diabetic foot ulcers, mucositis, warts, lichen planus, lichen sclerosis, pseudofolliculitis, oral leukoplakia, molluscum contagiosum, Darier's disease (keratosis follicularis), dermatitis/eczema, folliculitis, keratosis pilaris, basal cell carcinoma (skin cancer), confluent and reticulated papillomatosis, and cutis laxa.

(Criteria continued on next page)

REQUIREMENTS: ACNE AGE RESTRICTION OVERRIDE (CONTINUED)

C. Cosmetic conditions will NOT be approved.
    i. Examples of cosmetic conditions include: liver spots, stretch marks, scarring, solar elastosis, premature aging, treatment of photo-aged or photo-damaged skin, solar lentigines, skin roughness, mottled hyperpigmentation, age spots, wrinkles, geographic tongue, hyperpigmentation (caused by folliculitis, acne, or eczema), melasma/cholasma, alopecia androgenetic, alopecia areata, seborrheic keratosis, milia, nevus, poikiloderma (of Civatte), purpura (actinic/solar), keloids, and sebaceous hyperplasia.
D. Requests for a brand name product that has a generic equivalent approved will require a trial of, or contraindication to, the generic product
E. Approval may also require trial with preferred agent(s), unless the patient has a contraindication.

References:

1. Aklief package insert. Fort Worth, TX. Galderma Laboratories, LP. Revised October 2019. Accessed June 2024.
2. Arazlo package insert. Bridgewater, NJ. Bausch Health US, LLC. Revised December 2019. Accessed June 2024.
3. Altreno package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America. Revised August 2018. Accessed June 2024.
4. Atralin package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America. Revised August 2014. Accessed June 2024.
5. Avita package insert. Morgantown, WV. Mylan Pharmaceuticals Inc. Revised August 2011. Accessed June 2024.
6. Differin Gel 0.3% package insert. Galderma Laboratories, LP. Revised June 2014. Accessed June 2024.
7. Differin Gel 0.1% package insert. Galderma Laboratories, LP. Revised July 2014. Accessed June 2024.
8. Epiduo package insert. Fort Worth, TX. Galderma Laboratories, LP. Revised January 2013. Accessed June 2024.
9. Epiduo Forte package insert. Fort Worth, TX. Galderma Laboratories, LP. Revised April 2022. Accessed June 2024.
10. Fabior package insert. Research Triangle Park, NC. Stiefel Laboratories, Inc. Revised May 2012. Accessed June 2024.
11. Retin-A package insert. Skillman, NJ. Ortho Dermatological. Revised October 2016. Accessed June 2024.
12. Retin-A Micro package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America. January 2014. Accessed June 2024.
13. Tretin-X package insert. Cranford, NJ. Triax Pharmaceuticals, LLC. Revised April 2006. Accessed June 2024.
14. Baldwin HE, Nighland M, Kendall C, Mays DA, Grossman R, Newburger J. 40 years of topical tretinoin use in review. J Drugs Dermatol. 2013;12(6):638-642.

Generic	Brand	Reviewed	Effective Date
INTERFERON GAMMA-1B, RECOMB. Edition 1	ACTIMMUNE	7/29/2024	6/1/2021

REQUIREMENTS:

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. The patient has ONE of the following diagnoses:
    1. Chronic granulomatous disease (CGD)
    2. Severe malignant osteopetrosis (SMO)
B. For patients with chronic granulomatous disease, approval also requires:
    1. The medication is prescribed by or given in consultation with a hematologist, infectious disease specialist, or immunologist
C. For patients with severe malignant osteopetrosis, approval also requires:
    1. The medication is prescribed by or given in consultation with an endocrinologist

RENEWAL CRITERIA
Our guideline named INTERFERON GAMMA-1B, RECOMB (Actimmune) requires the following rules be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Chronic granulomatous disease (CGD)
    2. Severe malignant osteopetrosis (SMO)
B. The patient has shown clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections, etc.)
C. The patient has not received hematopoietic cell transplantation

References:
1. Actimmune package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised March 2021. Accessed June 2024.
2. Wu C, Econs M, DiMeglio L, et al. Diagnosis and management of osteopetrosis: consensus guidelines from the osteopetrosis working group. The Journal of Clinical Endocrinology & Metabolism. 2017;102:9:3111-3123.
3. Arnold D, Heimall J. A review of chronic granulomatous disease. Advanced Therapy. 2017;34:2543-2557.

Generic	Brand	Reviewed	Effective Date
FLIBANSERIN Edition 3	ADDYI	7/29/2024	07/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named FLIBANSERIN (Addyi) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD).
C. The patient meets 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. HSDD is NOT a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
    3. HSDD symptom causes marked distress or interpersonal difficulty
D. The patient is premenopausal
E. The patient has had a previous trial of bupropion, unless there is a contraindication
F. The patient is NOT currently using Vyleesi (bremelanotide)

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

A. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)
A. The patient is premenopausal
B. The patient is not currently using Vyleesi (bremelanotide)
C. The patient has demonstrated continued improvement in symptoms of HSDD (e.g., increased sexual desire, lessened sexual distress, etc.)

References:
1. Addyi package insert. Raleigh, NC. Sprout Pharmaceuticals, Inc. Revised September 2021. Accessed June 2024.
2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Female Sexual Dysfunction: ACOG Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists, Number 213. Obstet Gynecol. 2019;134(1):e1-e18. doi:10.1097/AOG.0000000000003324.

EVEROLIMUS Edition 3			
Generic	Brand	Reviewed	Effective Date
EVEROLIMUS	AFINITOR	7/29/2024	07/29/2024
EVEROLIMUS	AFINITOR DISPERZ		

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

REQUIREMENTS:

AFINITOR DISPERZ

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

A. Patient has ONE of the following diagnoses:
    1. Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC)
    2. Tuberous sclerosis complex (TSC)-associated partial-onset seizures
B. If patient has subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC), approval also requires BOTH of the following:
    1. Patient is 1 year of age or older
    2. Patient's condition requires therapeutic intervention but cannot be curatively resected
C. If patient has tuberous sclerosis complex (TSC)-associated partial-onset seizures, approval also requires BOTH of the following:
    1. Patient is 2 years of age or older
    2. The requested medication will be used as adjunctive treatment

AFINITOR

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

A. Patient has ONE of the following diagnoses:
    1. Advanced renal cell carcinoma
    2. Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC)
    1. Progressive neuroendocrine tumors of pancreatic origin (PNET)
    2. Progressive well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin
    3. Renal angiomyolipoma and tuberous sclerosis complex (TSC)
    4. Advanced breast cancer

(Criteria continued on next page)

REQUIREMENTS: EVEROLIMUS (CONTINUED)

B. If patient has advanced renal cell carcinoma, approval also requires BOTH of the following:
    1. Patient is 18 years of age or older
    2. Patient has previous failure of or contraindication to treatment with sunitinib (Sutent) or sorafenib (Nexavar)
C. If patient has subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC), approval also requires BOTH of the following:
    1. Patient is 1 year of age or older
    2. Patient's condition requires therapeutic intervention but cannot be curatively resected
D. If patient has progressive neuroendocrine tumors of pancreatic origin (PNET), approval also requires BOTH of the following:
    1. Patient is 18 years of age or older
    2. Patient has unresectable, locally advanced or metastatic disease
E. If patient has progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin, approval also requires BOTH of the following:
    1. Patient is 18 years of age or older
    2. Patient has unresectable, locally advanced or metastatic disease
F. If patient has renal angiomyolipoma with tuberous sclerosis complex (TSC), approval also requires BOTH of the following:
    1. Patient is 18 years of age or older
    2. Patient's condition does not require immediate surgery
G. If patient has advanced breast cancer, approval also requires ALL of the following:
    1. Patient is postmenopausal
    2. Patient's cancer is hormone receptor-positive (HR+) AND human epidermal growth factor receptor 2-negative (HER2-)
    3. Patient has previous trial and failure of or contraindication to treatment with Femara (letrozole) or Arimidex (anastrozole)
    4. Requested medication will be used in combination with Aromasin (exemestane)

References:

1. Afinitor/Afinitor Disperz package insert. East Hanover, New Jersey Novartis Pharmaceuticals Corporation. Revised February 2022. Accessed June 2024.

Generic	Brand	Reviewed	Effective Date
INSULIN REGULAR, HUMAN Edition 2	AFREZZA	7/29/2024	7/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named INHALED INSULIN (Afrezza) requires the following rule(s) be met for approval:

A. The patient has type 1 or type 2 diabetes
B. The patient is 18 years of age or older
C. The patient has a baseline spirometry to measure FEV_1
D. For patient with type 1 diabetes, approval also requires:
    1. The patient is using a long-acting insulin with the requested medication, and they have tried a formulary rapid acting insulin
E. For patients with type 2 diabetics, approval also requires:
    1. The patient has tried a formulary rapid acting insulin
    2. The patient's prescriber has indicated that they 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. The patient has type 1 or type 2 diabetes
B. The patient has documentation of follow up spirometry to measure FEV_1 after 6 months of treatment and annually thereafter
C. The patient's FEV_1 has NOT declined 20% or more from baseline
D. For patients with type 1 diabetes, approval requires that they are using a long-acting insulin at the same time with the requested medication

References:
1. Afrezza package insert. Danbury, CT. MannKind Corporation. Revised February 2023. Accessed June 2024.
2. ADA Standards of Medical Care in Diabetes, Diabetes Care January 2020;43(Suppl. 1). Available at: http://care.diabetesjournals.org/content/43/Supplement_1. Accessed June 2024.

Generic	Brand	Reviewed	Effective Date
ERENUMAB-AOOE Edition 3	AIMOVIG	07/29/2024	07/29/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ERENUMAB-AOOE (Aimovig) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches
B. If patient has episodic migraines (0-14 headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE 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
C. If the patient has chronic migraines (15 or more headache days per month), approval also requires:
    1. Patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. Patient has had a previous trial of at least ONE 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 or Botox

RENEWAL CRITERIA
Our guideline named ERENUMAB-AOOE (Aimovig) requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines.
B. Patient has responded to therapy as evidenced by at least ONE of the following:
    1. Patient has experienced less migraines or headache attacks by at least 2 days per month compared to baseline
    2. Patient has experienced a lessening in migraine severity compared to baseline
    3. Patient has experienced a lessening in migraine duration compared to baseline

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERENUMAB-AOOE (CONTINUED)

References:

1. Aimovig package insert. Thousand Oaks, CA. Amgen Inc. Revised October 2022. Accessed June 2024.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FREMANEZUMAB-VFRM Edition 3	AJOVY	07/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named FREMANEZUMAB-VFRM (Ajovy) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches
B. If patient has episodic migraines (0-14 headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE 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
C. If patient has chronic migraines (15 or more headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE 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 the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines
B. Patient has responded to therapy as evidenced by at least ONE of the following:
    1. The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month compared to baseline
    2. The patient has experienced a reduction in migraine severity compared to baseline
    3. The patient has experienced a reduction in migraine duration compared to baseline

References:

1. Ajovy package insert. North Wales, PA. Teva Pharmaceuticals USA, Inc. Revised September 2021. Accessed June 2024.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CAPLACIZUMAB-YHDP Edition 2	CABLIVI	7/29/2024	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP)
C. The requested medication is prescribed by or given in consultation with a hematologist
D. The requested medication is used in combination with plasma exchange and immunosuppressive therapy (e.g., rituximab, corticosteroids, cyclosporine, mycophenolate mofetil, etc.)

RENEWAL CRITERIA

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

A. Patient has a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP)
B. Patient is responding positively to therapy as evidenced by, but not limited to, ANY of the following:
    1. platelet count increase
    2. neurological symptom reduction
    3. organ-damage marker improvement
C. Patient has received no more than 58 days of Cablivi therapy after completion of plasma exchange therapy
D. Patient has experienced less than 3 recurrences of aTTP while on the requested medication.

References:

1. Cablivi package insert. Cambridge, MA. Genzyme Corporation Revised April 2024. Accessed June 2024.
2. Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura. Blood. 2017;129(21):2836-2846. doi:10.1182/blood-2016-10-709857.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ACALABRUTINIB Edition 1	CALQUENCE	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The patient has a diagnosis of ONE of the following:
    1. Mantle cell lymphoma (MCL)
    2. Chronic lymphocytic leukemia (CLL)
    3. Small lymphocytic lymphoma (SLL)
D. If the patient has mantle cell lymphoma (MCL), approval also requires:
    1. Patient has received at least one prior therapy for mantle cell lymphoma

References:

1. Calquence package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised June 2024. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MAVACAMTEN Edition 2	CAMZYOS	07/29/2024	07/29/2023

REQUIREMENTS:

Our guideline named MAVACAMTEN (Camzyos) requires the following rule(s) be met for approval:

A. Patient is 18 years of age or older
B. Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM)
   C. Prescribed by or in consultation with a cardiologist
C. Patient has documented evidence of ALL the following:
   1. Symptomatic New York Heart Association (NYHA) class II or III obstructive HCM
   2. Left ventricular ejection fraction (LVEF) of at least 55%
   3. Valsalva left ventricular outflow tract (LVOT) peak gradient of at least 50 mmHg at rest or with provocation
D. Patient has previous trial with inadequate response or contraindication to ONE of the following:
   1. Non-vasodilating beta blockers (i.e., atenolol, bisoprolol, metoprolol, nadolol, pindolol, propranolol, sotalol, timolol)
   2. Non-dihydropyridine calcium channel blockers (i.e., diltiazem, verapamil)
E. Patient will NOT concurrently be taking any of the following regimens along with the requested medication:
   1. dual therapy with beta blocker and calcium channel blocker
   2. disopyramide
   3. ranolazine

RENEWAL CRITERIA

Our guideline named MAVACAMTEN (Camzyos) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM)
B. Patient has responded positively to therapy as evidenced by ONE of the following when compared to baseline:
   1. Mixed venous oxygen tension (pVO2) improvement by at least 1.5ml/kg/min plus at least one NYHA class reduction
   2. Mixed venous oxygen tension (pVO2) improvement by at least 3.0ml/kg/min without any NYHA class worsening

References:

1. Camzyos package insert. Brisbane, CA. MyoKardia, Inc. Revised April 2024. Accessed June 2024.
2. Writing Committee Members, Ommen SR, Mital S, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Thorac Cardiovasc Surg. 2021;162(1):e23-e106. doi:10.1016/j.jtcvs.2021.04.001.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FLUOROURACIL 0.5% CREAM Edition 1	CARAC	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of actinic or solar keratosis
B. The patient has previously tried at least ONE of the following:
    1. Generic topical agents (e.g., imiquimod 5%, diclofenac 3%, fluorouracil 5%, etc.)
    2. Preferred topical agents (e.g., Picato)

References:

1. Carac package insert. Bridgewater, NJ. Bausch Health US, LLC. Revised May 2022. Accessed June 2024.

AZTREONAM INHALED			
Generic	Brand	Reviewed	Effective Date
AZTREONAM Edition 2	CAYSTON	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. The patient has a diagnosis of cystic fibrosis
B. The patient has a lung infection per culture of the airway demonstrating a gram-negative species, *Pseudomonas aeruginosa*
C. The patient is at least 7 years of age or older

References:

1. Cayston package insert. Foster City, Ca. Gilead Sciences, Inc. Revised November 2019. Accessed June 2024.
2. Borowitz D, Robinson KA, Rosenfeld M, et al. Cystic Fibrosis Foundation evidence-based guidelines for management of infants with cystic fibrosis. J Pediatr. 2009 Dec; 155(6 Suppl):S73-S93.
3. Mogayzel PJ, Naureckas ET, Robinson KA, Brady C, Guill M, Lahiri T, Lubsch L, Matsui J, Oermann CM, Ratjen F, Rosenfeld M, Simon RH, Hazle L, Sabadosa K, Marshall BC, and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. Ann Am Thorac Soc. 2014 11 (10): 1640-50.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELIGLUSTAT TARTRATE Edition 1	CERDELGA	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of type 1 (non-neuronopathic) Gaucher disease
B. The patient is 18 years of age or older
C. Twice daily dosing will be approved if the patient is an extensive or immediate metabolizer of CYP2D6 (cytochrome P450 2D6) inhibitors
D. Once daily dosing will be approved if the patient is a poor metabolizer of CYP2D6 (cytochrome P450 2D6)

References:

1. Cerdelga package insert. Cambridge, MA. Genzyme Corporation. Revised July 2021. Accessed June 2024.
2. Biegstraaten M, Cox TM, Belmatoug N, et al. Management goals for type 1 Gaucher disease: An expert consensus document from the European working group on Gaucher disease. Blood Cells Mol Dis. 2018;68:203-208. doi:10.1016/j.bcmd.2016.10.008.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CHENODIOL Edition 2	CHENODAL	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named CHENODIOL (Chenodal) requires the following rule(s) be met for approval:

A. Patient is 18 years of age or older
B. Patient has one of the following diagnoses:
    1. Radiolucent gallstones in a well-opacifying gallbladder
    2. Cerebrotendinous xanthomatosis
C. For patients with radiolucent gallstones, approval also requires:
    1. Patient is not a candidate for surgery
    2. Patient has tried ursodiol, unless there is a contraindication
    3. Patient has 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. Patient has a diagnosis of radiolucent gallstones (OR cerebrotendinous xanthomatosis)
B. For the patients with radiolucent gallstones, renewal also requires:
    1. Patient has NOT had chenodiol therapy for more than a total of 24 months
    2. Patient does NOT have complete dissolution or no gallstone seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
    3. Patient has partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
C. For the patients with cerebrotendinous xanthomatosis, renewal also requires the patient has 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)

References:

1. Chenodal package insert. Fort Collins, CO. Manchester Pharmaceuticals, Inc. Revised September 2009. Accessed July 2024.
2. Salen G, Steiner RD. Epidemiology, diagnosis, and treatment of cerebrotendinous xanthomatosis (CTX). J Inherit Metab Dis. 2017;40(6):771-781. doi:10.1007/s10545-017-0093-8.
3. European Association for the Study of the Liver (EASL). Electronic address: easloffice@easloffice.eu. EASL Clinical Practice Guidelines on the prevention, diagnosis and treatment of gallstones. J Hepatol. 2016;65(1):146-181. doi:10.1016/j.jhep.2016.03.005.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CHOLIC ACID Edition 2	CHOLBAM	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named CHOLIC ACID (Cholbam) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of a bile acid synthesis disorder due to one of the following:
    1. Peroxisomal disorders including Zellweger spectrum disorder
    2. Single enzyme defects
B. Diagnosis is confirmed by ONE of the following:
    1. Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis
    2. Molecular genetic testing
C. The requested medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or metabolic disease specialist

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

A. Patient has experienced an improvement in liver function as defined by at least ONE of the following criteria:
    a. ALT (alanine aminotransferase) or AST (aspartate transaminase) values have been lowered to less than 50 U/L or baseline levels reduced by 80%
    b. Total bilirubin values reduced to less than 1 mg/dL
    c. No evidence of cholestasis on liver biopsy

References:

1. Cholbam package insert. San Diego, CA, Manchester Pharmaceuticals Inc. Revised October 2020. Accessed July 2024
2. Braverman NE, Raymond GV, Rizzo WB, et al. Peroxisome biogenesis disorders in the Zellweger spectrum: An overview of current diagnosis, clinical manifestations, and treatment guidelines. Mol Genet Metab. 2016;117(3):313-321. doi:10.1016/j.ymgme.2015.12.009.
3. Heubi JE, Setchell KDR, Bove KE. Inborn Errors of Bile Acid Metabolism. Clin Liver Dis. 2018;22(4):671-687. doi:10.1016/j.cld.2018.06.006.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DUVELISIB Edition 2	COPIKTRA	7/29/2024	7/29/2022

REQUIREMENTS:

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

A. Patient has a ONE of the following diagnoses:
    1. Relapsed or refractory chronic lymphocytic leukemia (CLL)
    2. Small lymphocytic lymphoma (SLL)
B. The patient is 18 years of age or older
C. Therapy will be prescribed by, or in consultation with, an oncologist
D. If patient has relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:
    1. Patient received at least two prior therapies for CLL or SLL

References:
1. Copiktra package insert. Needham, MA. Verastem, Inc. Revised February 2022. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
COBIMETINIB FUMARATE Edition 2	COTELLIC	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of unresectable, metastatic melanoma OR histiocytic neoplasms
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If the patient has unresectable or metastatic melanoma, approval also requires:
    a. Patient is positive for BRAF V600E OR V600K mutation
    b. The requested medication will be used in combination with vemurafenib (Zelboraf)

References:

1. Cotellic package insert. South San Francisco, CA. Genentech USA, Inc. Revised May 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CYSTEAMINE HCL Edition 3	CYSTARAN, CYSTADROPS	7/29/2024	07/29/2023

REQUIREMENTS:

Our guideline named CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of cystinosis
B. The requested medication is prescribed by or in consultation with an ophthalmologist
C. The patient requires treatment for corneal cystine crystal accumulation or deposits

References:

1. Cystaran package insert. Gaithersburg, MD. Leadiant Biosciences, Inc.. Revised February 2022. Accessed June 2024.
2. Cystadrops package insert. Lebanon, NJ. Recordati Rare Diseases Inc. Revised August 2020. Accessed June 2024.
3. Wilmer MJ, Schoeber JP, van den Heuvel LP, Levtchenko EN. Cystinosis: practical tools for diagnosis and treatment. Pediatr Nephrol. 2011;26(2):205-215. doi:10.1007/s00467-010-1627-6.
4. Biswas S, Gaviria M, Malheiro L, Marques JP, Giordano V, Liang H. Latest Clinical Approaches in the Ocular Management of Cystinosis: A Review of Current Practice and Opinion from the Ophthalmology Cystinosis Forum. Ophthalmol Ther. 2018;7(2):307-322. doi:10.1007/s40123-018-0146-6.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ERDAFITINIB Edition 2	BALVERSA	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of locally advanced or metastatic urothelial carcinoma (mUC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient is 18 years of age or older
D. Patient has susceptible fibroblast growth factor receptor (FGFR3 or FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
E. Patient meets ONE of the following:
    1. Patient has progressed during or following at least one line of prior platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

References:

1. Balversa package insert. Horsham, PA. Janssen Products. Revised January 2024. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DELAFLOXACIN Edition 1	BAXDELA	7/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named DELAFLOXACIN (Baxdela) requires the following rule(s) be met for approval:

A. The patient meets ONE of the following:
    1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist
    2. The patient has an acute bacterial skin or skin structure infection (ABSSSI) OR community-acquired bacterial pneumonia (CABP)
B. For patients with an acute bacterial skin or skin structure infection, approval also requires:
    1. The patient is 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. The patient does not have a diagnosis of animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitis ulcer formation, myonecrosis or ecthyma gangrenosum
    4. The patient meets ONE of the following criteria:
        a. If antimicrobial susceptibility test is available, the results of the test from the infection site are required to show the bacteria is both 1) resistant to ONE standard of care agent for acute bacterial skin or skin structure infection (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin, etc.), AND 2) delafloxacin will work against the bacteria
        b. If antimicrobial susceptibility test is not available, a trial of or contraindication to ONE of the following agents: a penicillin (e.g., amoxicillin), a fluoroquinolone (e.g., levofloxacin, ciprofloxacin, moxifloxacin, etc.), a cephalosporin (e.g., ceftriaxone, cephalexin, cefazolin, etc.), or a gram-positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, etc.) is required

(Criteria continued on next page)

REQUIREMENTS: DELAFLOXACIN (CONTINUED)

C. For patients with community-acquired bacterial pneumonia (CABP), approval also requires:
    1. The patient is 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. The patient meets ONE of the following criteria:
        a. If antimicrobial susceptibility test is available, the results of the test from the infection site are required to show the bacteria is both 1) resistant to TWO standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid, etc.) AND 2) delafloxacin will work against the bacteria
        b. If antimicrobial susceptibility test is not available, a trial or contraindication to TWO standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid etc.) is required

References
1. Baxdela package insert. Lincolnshire, IL. Melinta Therapeutics, Inc. Revised June 2021. Accessed June 2024.
2. Scott LJ. Delafloxacin: A Review in Acute Bacterial Skin and Skin Structure Infections. Drugs. 2020 Aug;80(12):1247-1258. doi: 10.1007/s40265-020-01358-0. Erratum in: Drugs. 2020 Sep;80(14):1507. PMID: 32666425; PMCID: PMC7497496.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BROLUCIZUMAB-DBLL Edition 2	BEOVU	07/29/2024	07/29/2022

REQUIREMENTS:

Our guideline named BROLUCIZUMAB-DBLL (Beovu) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Neovascular (wet) age-related macular degeneration (AMD)
    2. Diabetic macular edema (DME)
B. The requested medication is prescribed by or given in consultation with an ophthalmologist or retina specialist

References:

1. Beovu package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised September 2023. Accessed June 2024.
2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024.
3. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025.

C1 ESTERASE INHIBITOR Edition 2			
Generic	Brand	Reviewed	Effective Date
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE HAEGARDA	07/29/2024	07/29/2024
C1 ESTERASE INHIBITOR, RECOMBINANT	RUCONEST		

Please use the criteria for the specific drug requested

REQUIREMENTS:

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. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 6 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE (e.g., Takhzyro, Haegarda, danazol, berotralstat, etc.)

HAEGARDA

Our guideline named C1 ESTERASE INHIBITOR (Haegarda) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 6 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE e.g., Takhzyro, Cinryze, danazol, berotralstat, etc.)

(Criteria continued on next page)

REQUIREMENTS: C1 ESTERASE INHIBITOR (CONTINUED)

BERINERT
Our guideline named C1 ESTERASE INHIBITOR (Berinert) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by complement testing
C. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
D. The requested medication is being used for acute attacks of hereditary angioedema, and not daily utilization as a prophylactic
    a. Maximum doses that will be approved is 4 per month unless documentation is provided of more frequent attacks and the patient is also receiving a prophylactic (eg Takhzyro)

RUCONEST
Our guideline named C1 ESTERASE INHIBITOR (Ruconest) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by complement testing
C. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
D. The requested medication is being used for acute attacks of hereditary angioedema, and not daily utilization as a prophylactic
    a. Maximum doses that will be approved is 4 per month unless documentation is provided of more frequent attacks and the patient is also receiving a prophylactic (eg Takhzyro)

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. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

HAEGARDA
Our guideline named C1 ESTERASE INHIBITOR (Haegarda) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: C1 ESTERASE INHIBITOR (CONTINUED)

References:

1. Berinert package insert. Kankakee, IL. CSL Behring LLC. Revised September 2021. Accessed July 2024.
2. Cinryze package insert. Lexington, MA. ViroPharma Biologics LLC. Revised March 2022. Accessed July 2024.
3. Haegarda package insert. Kankakee, IL. CSL Behring LLC. Revised January 2022. Accessed July 2024.
4. Ruconest package insert. Warren, NJ. Pharming Healthcare Inc. Revised April 2020. Accessed July 2024.
5. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3. doi:10.1016/j.jaip.2020.08.046.
6. Betschel S, Badiou J, Binkley K, et al. Correction to: The International/Canadian Hereditary Angioedema Guideline. Allergy Asthma Clin Immunol. 2020;16:33. Published 2020 May 6. doi:10.1186/s13223-020-00430-4.
7. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. Allergy Asthma Clin Immunol. 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8.
8. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018;73(8):1575-1596. doi:10.1111/all.13384.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BOSUTINIB Edition 4	BOSULIF	7/29/2024	7/29/2024

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)
    2. Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)
B. If the patient has a diagnosis of Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), approval also requires:
    1. The patient is 18 years of age or older
C. If the patient has a diagnosis of Newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML), approval also requires:
    1. The patient is 1 years of age or older
D. Therapy will be prescribed by, or in consultation with, an oncologist

References:

1. Bosulif package insert. New York, NY. Pfizer inc. Revised September 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ENCORAFENIB Edition 3	BRAFTOVI	7/29/2024	7/29/2024

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Unresectable or metastatic melanoma
    2. Metastatic colorectal cancer
    3. Metastatic non-small cell lung cancer
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If patient has unresectable or metastatic melanoma, approval also requires:
    1. Patient has a BRAF V600E or V600K mutation as detected by an FDA (Food and Drug Administration)-approved test
    2. The medication will be used in combination with Mektovi (binimetinib)
D. If patient has metastatic colorectal cancer, approval also requires:
    1. Patient has a BRAF V600E mutation as detected by an FDA (Food and Drug Administration)-approved test
    2. The medication will be used in combination with Erbitux (cetuximab)
    3. Patient has previously received treatment
E. If patient has metastatic non-small cell lung cancer, approval also requires
    1. Patient has a BRAF V600E mutation as detected by an FDA (Food and Drug Administration)-approved test
    2. The medication will be used in combination with Mektovi (binimetinib)

References:

1. Braftovi package insert. Boulder, Colorado. Array BioPharma Inc. Reviewed October 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RISDIPLAM Edition 2	EVRYSDI	07/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named RISDIPLAM (Evrysdi) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of type 1, type 2, or type 3 spinal muscular atrophy (SMA)
B. The requested medication is prescribed by or given in consultation with a neurologist, neuromuscular specialist, or spinal muscular atrophy (SMA) specialist
C. The 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) gene reported (i.e., homozygous deletions, homozygous mutations, or compound heterozygous mutations)
D. The patient is not being treated on the requested medication concurrently with Spinraza (nusinersen) or Zolgensma (onasemnogene abeparvovec)
E. There is documentation showing up to four copies of survival motor neuron 2 (SMN2)
F. The patient does not have permanent ventilator dependence (e.g., invasive ventilation/tracheostomy, non-invasive ventilation beyond use for naps and nighttime sleep, etc.)
G. There is documentation showing the patient had a baseline motor function assessment (e.g., Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), etc.)
H. If the patient previously had gene therapy with Zolgensma, then there is documentation they had less than expected clinical benefit per motor function assessment

RENEWAL CRITERIA
Our guideline named RISDIPLAM (Evrysdi) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of type 1, type 2, or type 3 spinal muscular atrophy (SMA)
B. The patient has shown a clinical response as evidenced by at least ONE of the following:
    1. The patient has improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline(e.g., Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE),Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), etc.)
    2. The patient has improved, maintained, or demonstrated a less than expected decline in other muscle function such as pulmonary function (i.e., ventilator dependence)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: RISDIPLAM (CONTINUED)

References:

1. Evrysdi package insert. South San Francisco, CA. Genentech, Inc. Revised February 2024. Accessed June 2024.
2. Committee Opinion No. 691: Carrier Screening for Genetic Conditions. *Obstet Gynecol*. 2017;129(3):e41-e55. doi:10.1097/AOG.0000000000001952
3. Arnold WA, Kassar D, Kissel JT. Spinal Muscular Atrophy: Diagnosis and Management in a New Therapeutic Era. Muscle Nerve 2015 Feb; 51(2): 157-167.
4. Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. *J Neuromuscul Dis*. 2018;5(2):145-158. doi:10.3233/JND-180304.

WELLFLEET RX STUDENT FORMULARY

DEFERASIROX			
Generic	Brand	Reviewed	Effective Date
DEFERASIROX Edition 1	EXJADE, JADENU, JADENU SPRINKLE	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. Chronic iron overload due to blood transfusions
    2. Non-transfusion dependent thalassemia syndromes (NTDT)
B. The medication is prescribed by or given in consultation with a hematologist, hepatologist, or oncologist
C. If the patient has chronic iron overload due to blood transfusions, approval also requires:
    1. The patient is 2 years of age or older
    2. The patient has serum ferritin levels greater than 1000mcg/L (at least 2 lab values taken within the previous 3 months)
D. If the patient has chronic iron overload resulting from non-transfusion dependent thalassemia syndromes (NTDT), approval also requires:
    1. The patient is 10 years of age or older
    2. The patient has serum ferritin levels greater than 300mcg/L (at least 2 lab values taken within the previous 3 months)
    3. The patient has liver iron concentration (LIC) of at least 5mg Fe/g dry weight or greater
E. Requests for brand name Jadenu sprinkle packets, brand name Jadenu, and brand name Exjade require a trial and failure of the equivalent preferred product: generic deferasirox tablets, generic deferasirox tablets for suspension, or generic deferasirox granules

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: DEFERASIROX (CONTINUED)

RENEWAL CRITERIA

Our guideline named DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX) requires the following rule(s) be met for renewal:

A. The patient has one of the following diagnoses:
    1. Chronic iron overload due to blood transfusions
    2. Non-transfusion dependent thalassemia syndromes (NTDT)
B. If the patient has chronic Iron overload due to blood transfusions, renewal also requires:
    1. The patient has serum ferritin levels of at least 500 mcg/L (at least 2 lab values taken within the previous 3 months)
C. If the patient has chronic iron overload resulting from non-transfusion dependent thalassemia syndromes (NTDT), renewal also requires ONE of the following:
    1. The patient has ferritin levels of at least 300mcg/L (at least 2 lab values taken within the previous 3 months)
    2. The patient has liver iron concentration (LIC) of at least 3mg Fe/g dry weight or greater

References:

1. Exjade package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised January 2023. Accessed June 2024.
2. Jadenu package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2020. Accessed June 2024.
3. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013;88(5):409-415. doi:10.1002/ajh.23405.
4. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013;130(2):64-73. doi:10.1159/000345734.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BENRALIZUMAB Edition 3	FASENRA	07/29/2024	07/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named BENRALIZUMAB (Fasenra) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of severe asthma with an eosinophilic phenotype
B. The patient is 6 years of age or older
C. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
D. The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
E. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
F. The patient has asthma that is uncontrolled while maintained on ICS plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE or more of the following:
    1. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
    2. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
G. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler
H. The patient is not being treated on the requested medication concurrently with Xolair, Dupixent, Tezspire or another anti-IL5 asthma biologic (e.g., Nucala, Cinqair, etc.)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: BENRALIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named BENRALIZUMAB (Fasenra) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of severe asthma with an eosinophilic phenotype
B. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) or an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
C. The patient has shown a clinical response as evidenced by at least ONE of the following:
    1. Reduction in asthma exacerbation(s) compared to baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

References:

1. Fasenra package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP, Revised April 2024. Accessed June 2024.
2. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. *J Allergy Clin Immunol.* 2020;146(6):1217-1270.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Date Reviewed	Effective Date
DEFERIPRONE Edition 2	FERRIPROX	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DEFERIPRONE (Ferriprox) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of transfusional iron overload due to a thalassemia syndrome, sickle cell disease or other anemias
B. The patient is 3 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist, hepatologist, or oncologist
D. The patient has a previous trial with generic deferasirox, Exjade, Jadenu, generic deferoxamine, or Desferal
E. The patient meets ONE of the following:
    1. The patient is experiencing intolerable toxicities, clinically significant adverse effects, or a contraindication to current chelation therapy with generic deferasirox, Exjade, Jadenu, generic deferoxamine, or Desferal
    2. The patient has failed chelation therapy with generic deferasirox, Exjade, Jadenu, generic deferoxamine, or Desferal as evidenced by serum ferritin levels remaining above 2500mcg/L (at least 2 lab values in the previous 3 months) despite treatment
F. Requests for brand name Ferriprox require a trial and failure of the equivalent preferred product: generic deferiprone

RENEWAL CRITERIA
Our guideline named DEFERIPRONE (Ferriprox) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of transfusional iron overload due to a thalassemia syndromes, sickle cell disease or other anemias
B. The patient has serum ferritin levels of at least 500mcg/L (at least 2 lab values in the previous 3 months)

References:
1. Ferriprox package insert. Cary, NC. Chiesi USA, Inc., Revised November 2021. Accessed June 2024.
2. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013;88(5):409-415. doi:10.1002/ajh.23405.
3. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013;130(2):64-73. doi:10.1159/000345734.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ICATIBANT Edition 2	FIRAZYR	07/29/2024	07/29/2024

REQUIREMENTS:

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

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient is 18 years of age or older
C. The diagnosis is confirmed via complement testing
A. The requested medication is being used for treatment of acute attacks of hereditary angioedema, and not daily utilization as a prophylactic
    a. Maximum doses that will be approved is 4 per month unless documentation is provided of more frequent attacks and the patient is also receiving a prophylactic (eg Takhzyro)
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist

References:

1. Firazyr package insert. Lexington, MA. Takeda Pharmaceutical Company. Revised April 2022. Accessed July 2024.
2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3. doi:10.1016/j.jaip.2020.08.046.
3. Betschel S, Badiou J, Binkley K, et al. Correction to: The International/Canadian Hereditary Angioedema Guideline. Allergy Asthma Clin Immunol. 2020;16:33. Published 2020 May 6. doi:10.1186/s13223-020-00430-4.
4. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. Allergy Asthma Clin Immunol. 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8.
5. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018;73(8):1575-1596. doi:10.1111/all.13384.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TIVOZANIB HCL Edition 1	FOTIVDA	7/29/2024	7/23/2021

REQUIREMENTS:

Our guideline named TIVOZANIB (Fotivda) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC)
B. Patient is 18 years of age or older
C. The medication is being prescribed by or given in consultation with a hematologist or oncologist
D. The patient previously had two or more prior systemic therapies

References

1. Fotivda package insert. Boston, MA. AVEO Pharmaceuticals, Inc. Revised March 2021. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLASDEGIB MALEATE Edition 2	DAURISMO	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has newly-diagnosed acute myeloid leukemia (AML)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The requested medication will be used in combination with low-dose cytarabine
D. Patient is 75 years of age or older, OR patient has comorbidities that prevents the use of intensive induction chemotherapy

References:

1. Daurismo package insert. New York, NY. Pfizer Labs, Inc. Revised March 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DEFEROXAMINE MESYLATE Edition 2	DESFERAL	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DEFEROXAMINE (Desferal) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of chronic iron overload due to transfusion-dependent anemias
B. The requested medication is prescribed by or given in consultation with a hematologist, hepatologist, or oncologist
C. The patient is 3 years of age or older
D. The patient has serum ferritin levels greater than 1000mcg/L (at least 2 lab values in the previous 3 months)
E. Requests for brand name Desferal require a trial and failure of the equivalent preferred product: generic deferoxamine

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

A. The patient has a diagnosis of chronic iron overload due to transfusion-dependent anemias
B. The patient has serum ferritin levels of at least 500mcg/L (at least 2 lab values in the previous 3 months)

References:

1. Desferal package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised September 2022. Accessed June 2024.
2. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013;88(5):409-415. doi:10.1002/ajh.23405.
3. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013;130(2):64-73. doi:10.1159/000345734.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AVATROMBOPAG Edition 1	DOPTELET	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named AVATROMBOPAG (Doptelet) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has ONE of the following diagnoses:
    1. Thrombocytopenia due to chronic liver disease (CLD)
    2. Chronic immune thrombocytopenia (ITP)
C. The patient is not receiving other thrombocytopenia treatments such as Nplate (romiplostim), Mulpleta (lusutrombopag), Promacta (eltrombopag) or Tavalisse (fostamatinib)
D. If patient has thrombocytopenia due to chronic liver disease, approval also requires:
    1. The patient is scheduled to undergo a procedure 10 to 13 days after starting Doptelet (avatrombopag) therapy
    2. The patient has a platelet count of less than 50 x 10^9/L (50,000/µL) measured within the last 30 days
    3. The requested medication is prescribed by or given in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
E. If patient has chronic immune thrombocytopenia (ITP), approval also requires:
    1. The patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days OR patient has an active bleed
    2. The patient has previously tried or has a contraindication to corticosteroids or immunoglobulins OR patient had an insufficient response to splenectomy
    3. The requested medication is prescribed by or given in consultation with a hematologist or immunologist

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

A. The patient has a diagnosis of chronic immune thrombocytopenia (ITP)
B. The patient had a clinical response to therapy, as defined by an increase in platelet count or a reduction in bleeding events, compared to baseline

NOTE: For the diagnosis of thrombocytopenia due to chronic liver disease (CLD), please refer to the Initial Criteria section. Re-authorization is not permitted. Patients must meet the initial approval criteria for this diagnosis.

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: AVATROMBOPAG (CONTINUED)

References:

1. Doptlet package insert. Durham, North Carolina. AkaRx, Inc. Revised June 2021. Accessed June 2024.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. Blood Adv. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FENTANYL TRANSDERMAL PATCH Edition 2	DURAGESIC	7/29/2024	7/23/2021

REQUIREMENTS:

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

A. The patient meets at least ONE of the following:
    1. The patient meets 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 of another opioid
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The requested medication is not prescribed on an 'as needed' basis
C. Requests for dosing every 48 hours requires a trial of transdermal fentanyl patch dosed every 72 hours

References:

1. Duragesic package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised March 2021. Accessed June 2024.
2. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
3. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GALCANEZUMAB-GNLM Edition 3	EMGALITY	07/29/2024	07/29/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GALCANEZUMAB-GNLM (Emgality) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches or episodic cluster headaches
B. If patient has episodic migraines (0-14 headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE 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
C. If patient has chronic migraines (15 or more headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial t ONE 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
D. If patient has episodic cluster headaches, approval also requires:
    1. The patient is 18 years of age or older

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: GALCANEZUMAB-GNLM (CONTINUED)

RENEWAL CRITERIA

Our guideline named GALCANEZUMAB-GNLM (Emgality) requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headaches
B. If patient has migraines, renewal also requires the patient has responded to therapy as evidenced by at least ONE of the following:
    1. The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month compared to baseline
    2. The patient has experienced a reduction in migraine severity compared to baseline
    3. The patient has experienced a reduction in migraine duration compared to baseline
C. If patient has episodic cluster headaches, renewal also requires:
    1. The patient has had improvement in episodic cluster headache frequency compared to baseline

References:

1. Emgality package insert. Indianapolis, IN. Eli Lilly and Company. Revised May 2022. Accessed June 2024.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.1345.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLUTAMINE (L-GLUTAMINE) Edition 2	ENDARI	07/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named L-GLUTAMINE (Endari) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of sickle cell disease
B. The patient is 5 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
D. The patient has had a previous trial of or contraindication to hydroxyurea
E. The patient will be using the requested medication concurrently with hydroxyurea, unless there is a contraindication
F. The patient has experienced acute complications of sickle-cell disease (e.g., sickle cell-related vaso-occlusive crises (VOC), hospitalizations, acute chest syndrome (ACS), etc.)

RENEWAL CRITERIA
Our guideline named L-GLUTAMINE (Endari) requires the following rule(s) bet met for renewal:

A. The patient has a diagnosis of sickle cell disease
B. The patient has maintained or experienced a reduction in acute complications of sickle-cell disease (e.g., number of sickle cell-related vaso-occlusive crises (VOC), hospitalizations, acute chest syndrome (ACS), etc.)

References:

1. Endari package insert. Torrance, CA. Emmaus Medical, Inc. Revised October 2020. Accessed July 2024.
2. Yawn BP, Buchanan GR, Afenyi-Annan AN, et al. Management of sickle cell disease:summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR/ VELPATASVIR Edition 3	EPCLUSA	07/29/2024	07/29/2022

REQUIREMENTS:

Our guideline named SOFOSBUVIR/VELPATASVIR (Epclusa) requires the following rule(s) be met for approval:

A. The patient is 3 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. For patients with decompensated cirrhosis (Child Pugh B or C), approval also requires:
    1. The requested medication will be used concurrently with ribavirin, unless there is a contraindication

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References:

1. Epclusa package insert. Foster City, CA. Gilead Sciences, Inc. Revised April 2022. Accessed July 2024.
2. Ghany MG, Morgan TR; AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases-Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology. 2020 Feb;71(2):686-721.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AXITINIB Edition 2	INLYTA	7/29/2024	7/29/2023

REQUIREMENTS:

Our guideline named AXITINIB (Inlyta) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of advanced renal cell carcinoma (RCC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The patient also meets ONE of the following:
    1. The patient has tried at least ONE systemic therapy for the treatment of advanced renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), Avastin (bevacizumab) in combination with interferon, etc.
    2. The requested medication will be used in combination with avelumab (Bavencio) as a first-line treatment
    3. The requested medication will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

References:

1. Inlyta package insert. New York, NY. Pfizer inc. Reviewed July 2024. Accessed July 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INTERFERON ALFA-2B Edition 2	INTRON A	7/29/2024	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named INTERFERON ALFA-2B (Intron A) requires 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
    2. Hairy cell leukemia
    3. Condylomata acuminate
    4. AIDS-related Kaposi's sarcoma
    5. Chronic hepatitis B
    6. Malignant melanoma
    7. Chronic phase, Philadelphia chromosome positive chronic myelogenous leukemia
    8. Follicular lymphoma
    9. Multiple myeloma
    10. Polycythemia vera
    11. Renal cell carcinoma
B. If the patient has chronic hepatitis C, approval also requires:
    1. Patient is infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C
    2. Therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis
    3. Patient has compensated liver disease
    4. The requested medication will be used with ribavirin, unless there is a contraindication
    5. Patient has had a previous trial of or contraindication to a peginterferon product

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: INTERFERON ALFA-2B (CONTINUED)

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 patient is being treated for chronic hepatitis C, renewal also requires:
    1. Therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis

References:

1. Intron A. package insert. Whitehouse Station, NJ. Merck & Co, Inc. Revised November 2021. Accessed June 2024.
2. Guilhot F, Chastang C, Michallet M, et al. Interferon alfa-2b combined with cytarabine versus interferon alone in chronic myelogenous leukemia. French Chronic Myeloid Leukemia Study Group. N Engl J Med. 1997;337(4):223-229. doi:10.1056/NEJM199707243370402.
3. Rini BI, Halabi S, Rosenberg JE, et al. Bevacizumab plus interferon alfa compared with interferon alfa monotherapy in patients with metastatic renal cell carcinoma: CALGB 90206. J Clin Oncol. 2008;26(33):5422-5428. doi:10.1200/JCO.2008.16.9847.
4. Barlogie B, Kyle RA, Anderson KC, et al. Standard chemotherapy compared with high-dose chemoradiotherapy for multiple myeloma: final results of phase III US Intergroup Trial S9321 [published correction appears in J Clin Oncol. 2006 Jun 10;24(17):2687. Moore, Dennis F Jr [added]]. J Clin Oncol. 2006;24(6):929-936. doi:10.1200/JCO.2005.04.5807.
5. McMullin MF, Harrison CN, Ali S, et al. A guideline for the diagnosis and management of polycythaemia vera. A British Society for Haematology Guideline [published correction appears in Br J Haematol. 2019 Apr;185(1):198]. Br J Haematol. 2019;184(2):176-191. doi:10.1111/bjh.15648.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GEFITINIB Edition 2	IRESSA	7/29/2024	7/29/2023

REQUIREMENTS:

Our guideline named GEFITINIB (Iressa) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA (Food and Drug Administration)-approved test

References:

1. Iressa package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised May 2021. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

TOPICAL ONYCHOMYCOSIS TREATMENTS			
Generic	Brand	Reviewed	Effective Date
TAVABOROLE Edition 2	KERYDIN	7/29/2024	7/29/2022
EFINACONAZOLE	JUBLIA		

REQUIREMENTS:

Our guideline named TOPICAL ONYCHOMYCOSIS (Kerydin, Jublia) requires the following rule(s) be met for approval:

A. Patient is 6 years of age or older
B. Patient has a diagnosis of onychomycosis of the toenails
C. Patient has 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
D. Patient has previously tried and failed BOTH of the following, unless there is a documented contraindication or clinically significant adverse reaction:
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

References:

1. Kerydin package insert. New York, NY. Pfizer Labs. Revised July 2018. Accessed June 2024.
2. Jublia package insert. Bridgewater, NJ. Bausch Health US, LLC. Revised March 2022. Accessed June 2024.
3. Lipner SR, Scher RK. Onychomycosis: Treatment and prevention of recurrence. J Am Acad Dermatol. 2019 Apr;80(4):853-867. doi: 10.1016/j.jaad.2018.05.1260. Epub 2018 Jun 28.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LOMITAPIDE Edition 3	JUXTAPID	07/29/2024	07/29/2023

REQUIREMENTS:

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

A. Patient is 18 years of age or older
B. Patient has a diagnosis of Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
C. The requested medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
D. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL
E. If patient is statin tolerant, approval also requires:
    1. Patient will continue statin treatment in combination with Juxtapid
    2. Patient meets ONE of the following criteria:
        i. Patient has 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. Patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
F. If patient is statin intolerant, approval also requires ONE of the following:
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.
G. Patient previously had a trial of Repatha (evolocumab) unless the patient does not have functional LDL receptors

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: LOMITAPIDE (CONTINUED)

References:

1. Juxtapid package insert. Cambridge, MA. Aegerion Pharmaceuticals, Inc. Revised June 2022. Accessed June 2024.
2. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2019 Sep 10;74(10):1429-1430] [published correction appears in J Am Coll Cardiol. 2020 Feb 25;75(7):840]. J Am Coll Cardiol. 2019;74(10):e177-e232. doi:10.1016/j.jacc.2019.03.010.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625
4. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AFATINIB DIMALEATE Edition 3	GILOTRIF	7/29/2024	07/29/2023

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Metastatic, squamous non-small cell lung cancer (NSCLC)
    2. Metastatic non-small cell lung cancer (NSCLC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If the patient has metastatic, squamous non-small cell lung cancer, approval also requires:
    1. The patient's disease has worsened after using platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)
D. If patient has metastatic non-small cell lung cancer, approval also requires:
    1. The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as shown by an FDA (Food and Drug Administration)-approved test
    2. The requested medication will be used as first-line treatment

References:

1. Gilotrif package insert. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Revised April 2022. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

ALLERGEN EXTRACT- TIMOTHY GRASS POLLEN			
Generic	Brand	Reviewed	Effective Date
GRASS POLLEN TIMOTHY, STD Edition 2	GRASTEK	7/29/2024	7/23/2021

REQUIREMENTS:

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. The patient has a diagnosis of allergic rhinitis caused by grass pollen
B. The patient is between 5 and 65 years of age
C. The patient's diagnosis is confirmed by a positive skin prick test and/or a positive titer to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent and moderate-to-severe symptoms of allergic rhinitis [Note: 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]
F. The patient has 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. The patient has experienced an improvement in signs and symptoms of allergic rhinitis compared to baseline

References:

1. Grastek package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised March 2022. Accessed July 2024.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LEDIPASVIR/SOFOSBUVIR Edition 2	HARVONI	07/29/2024	07/29/2022

REQUIREMENTS:

The guideline named LEDIPASVIR/SOFOSBUVIR (Harvoni) requires the following rule(s) be met for approval:

A. The patient is 3 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 4, 5, or 6
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. For patients with decompensated cirrhosis (Child-Pugh B or C), approval also requires:
    1. The patient has decompensated cirrhosis (Child-Pugh B or C)
    2. The requested medication will be taken in combination with ribavirin, unless there is a contraindication

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References:

1. Harvoni package insert. Foster City, CA. Gilead Sciences, Inc. Revised March 2020. Accessed July 2024.
2. Ghany MG, Morgan TR; AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases-Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology. 2020 Feb;71(2):686-721.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EMICIZUMAB-KXWH Edition 1	HEMLIBRA	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named EMICIZUMAB-KXWH (Hemlibra) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hemophilia A congenital factor VIII deficiency
B. The requested 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
D. Patients with Factor VIII inhibitors must have a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
E. Patients without Factor VIII inhibitors must meet one of the following criteria:
    1. The patient has severe hemophilia A defined as less than 1% factor VIII activity compared to normal
    2. The patient has *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. The patient has a diagnosis of hemophilia A congenital factor VIII deficiency
B. The patient has shown clinical benefit after using the medication compared to baseline

References:

1. Hemlibra package insert. South San Francisco, CA. Genentech, Inc. Revised January 2024. Accessed June 2024.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders (Revised April 2022). MASAC Document 272. Available at: https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-272-masac-recommendations-concerning-products-licensed-for-the-treatment-of-hemophilia-and-other-bleeding-disorders. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
ENASIDENIB Edition 2	IDHIFA	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of relapsed or refractory acute myeloid leukemia
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient is 18 years of age or older
D. Patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

References:

1. Idhifa package insert. Cambridge, MA. Agios Pharmaceuticals. Revised December 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SETMELANOTIDE ACETATE Edition 3	IMCIVREE	7/29/2024	7/29/2022

REQUIREMENTS:

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. The patient is at least 6 years of age or older
C. The requested medication is prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders
D. The patient has obesity which is due to ONE of the following:
    1. Proopiomelanocortin (POMC) deficiency
    2. Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency
    3. Leptin receptor (LEPR) deficiency
    4. Bardet-Biedl syndrome (BBS)
E. For patients with POMC, PSCK1 or LEPR deficiency, approval requires the patient meets the following criteria:
    1. If the patient is at least 18 years of age, then they currently have body mass index (BMI) of 30 kg/m2 or greater
    2. If the patient is 6 to 17 years of age, then they currently have a BMI in the 95th percentile or greater for age and sex
    3. Confirmed genetic testing shows variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
F. For patients with Bardet-Biedl Syndrome, approval requires the patient meets ONE of the following criteria:
    1. If the patient is at least 18 years of age, then they currently have body mass index (BMI) of 30 kg/m2 or greater
    2. If the patient is 6 to 17 years of age, then they currently have a BMI in the 97th percentile or greater for age and sex

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: SETMELANOTIDE (CONTINUED)

RENEWAL CRITERIA

Our guideline named SETMELANOTIDE (Imcivree) requires the following rule(s) be met for renewal:

A. The request is for chronic weight loss management
B. The patient has obesity which is due to ONE of the following:
    1. Proopiomelanocortin (POMC) deficiency
    2. Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency
    3. Leptin receptor (LEPR) deficiency
    4. Bardet-Biedl syndrome (BBS)
C. The patient has shown a clinical response as evidenced by ONE or more of the following:
    1. At least a 5% loss of baseline body weight
    2. At least a 5% loss of baseline body mass index (BMI)

References:

1. Imcivree package insert. Boston, MA. Rhythm Pharmaceuticals Inc. Revised November 2023. Accessed June 2024.
2. Poitou C, Mosbah H, Clément K. Mechanisms in endocrinology: update on treatments for patients with genetic obesity. Eur J Endocrinol. 2020 Nov;183(5):R149-R166.
3. Guo DF, Rahmouni K. Molecular basis of the obesity associated with Bardet-Biedl syndrome. Trends Endocrinol Metab. 2011;22(7):286-293. doi:10.1016/j.tem.2011.02.009.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OLANZAPINE/SAMIDORPHAN Edition 1	LYBALVI	07/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named OLANZAPINE/SAMIDORPHAN (Lybalvi) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has one of the following diagnoses:
    1. Schizophrenia
    2. Bipolar I disorder
C. The requested medication is prescribed by or given in consultation with a psychiatrist or mental health specialist
D. The patient does not have a known opioid use disorder
E. The patient is not dependent on opioids for a chronic medical condition
F. The patient has tried and failed at least TWO preferred oral generic second-generation antipsychotics (e.g., olanzapine, aripiprazole, quetiapine, risperidone, etc.)
G. For patients with Bipolar I disorder, approval also requires at least ONE of the following:
    1. The requested medication is being used as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
    2. The requested medication is being used as maintenance monotherapy treatment

RENEWAL CRITERIA
The guideline named OLANZAPINE/SAMIDORPHAN (Lybalvi) requires the following rule(s) to be met for renewal:

A. The patient has one of the following diagnoses:
    1. Schizophrenia
    2. Bipolar I disorder
B. The patient has experienced or maintained an improvement in symptoms compared to baseline

References

1. Lybalvi package insert. Waltham, MA. Alkermes, Inc. Revised May 2021. Accessed July 2024.
2. American Psychiatric Association. Practice Guideline for the treatment of patients with bipolar disorder, Second Edition. April 2002. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed July 2022.
3. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. Third Edition. 2021. Available at: https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841. Accessed July 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLECAPREVIR/ PIBRENTASVIR Edition 3	MAVYRET	7/29/2024	07/29/2022

REQUIREMENTS

The guideline named GLECAPREVIR/PIBRENTASVIR (Mavyret) requires the following rule(s) be met for approval:

A. The patient is 3 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. The patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis
G. The patient has previously tried preferred agents, sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) [genotype 1, 4, 5, 6 only], unless they have a contraindication to both. [NOTE: Patients with previous failure (i.e., did not achieve SVR) of a completed full course of treatment with sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) will NOT be approved.]

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has moderate or severe hepatic impairment (Child-Pugh B or C)
B. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References:

1. Mavyret package insert. North Chicago, IL. AbbVie Inc. Revised October 2023. Accessed July 2024.
2. Ghany MG, Morgan TR; AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases-Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology. 2020 Feb;71(2):686-721.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BINIMETINIB Edition 3	MEKTOVI	7/29/2024	7/29/2024

REQUIREMENTS:

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

A. The patient has a diagnosis of unresectable or metastatic melanoma
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The patient has a BRAF V600E or V600K mutation as detected by a Food and Drug Administration-approved test
D. The medication will be used in combination with Braftovi (encorafenib)

References:

1. Mektovi package insert. Boulder, CO. Array BioPharma Inc. Revised October 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEMPEDOIC ACID Edition 4	NEXLETOL	7/29/2024	7/29/2024
BEMPEDOIC ACID AND EZETIMIBE	NEXLIZET		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named BEMPEDOIC ACID (Nexletol, Nexlizet) requires the following rule(s) be met for approval:

B. The patient is 18 years of age or older
C. Patient has ONE of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Primary Hyperlipidemia, including Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
D. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
E. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL
F. If the patient is statin tolerant, approval also requires:
    1. Patient will continue statin treatment in combination with Nexletol or Nexlizet
    2. Patient meets ONE of the following:
        i. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
        ii. Patient has been taking a maximally tolerated dose of any statin given that the patient cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: BEMPEDOIC ACID (CONTINUED)

G. If the patient is statin intolerant, approval also requires ONE of the following:
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has 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 patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named BEMPEDOIC ACID (Nexletol, Nexlizet) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Established cardiovascular disease
    2. Primary Hyperlipidemia, including Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
B. Patient is responding positively to therapy as evidenced by lab results within the past 3 months showing an LDL-C reduction since initiation of therapy
C. The patient meets ONE of the following:
    1. The patient has continued therapy with a maximally tolerated dose of any statin
    2. The patient has an absolute contraindication to statin therapy
    3. The patient has complete statin intolerance

References:

1. Nexletol package insert. Ann Arbor, MI. Esperion Therapeutics, Inc. Revised March 2024. Accessed June 2024.
2. Nexlizet package insert. Ann Arbor, MI. Esperion Therapeutics, Inc. Revised March 2024. Accessed June 2024.
3. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2019 Sep 10;74(10):1429-1430] [published correction appears in J Am Coll Cardiol. 2020 Feb 25;75(7):840]. J Am Coll Cardiol. 2019;74(10):e177-e232. doi:10.1016/j.jacc.2019.03.010.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625.
5. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published correction appears in Stroke. 2021 Jul;52(7):e483-e484]. Stroke. 2021;52(7):e364-e467. doi:10.1161/STR.0000000000000375.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IXAZOMIB CITRATE Edition 2	NINLARO	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of multiple myeloma
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The requested medication will be used in combination with lenalidomide and dexamethasone
D. Patient has received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

References:

1. Ninlaro package insert. Cambridge, MA. Takeda Pharmaceutical Company Limited. Revised March 2024. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ISTRADEFYLLINE Edition 1	NOURIANZ	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of Parkinson's disease
B. The patient is 18 years of age or older
C. The patient is experiencing 'OFF' episodes
D. The requested medication will be used along with levodopa/carbidopa
E. The patient has had a previous trial of or contraindication to TWO Parkinson's agents from TWO different drug classes:
    1. Dopamine agonists (e.g., ropinirole, pramipexole, rotigotine, etc.)
    2. Monoamine oxidase-inhibitors (e.g., selegiline, rasagiline, etc.)
    3. Catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone, etc.)

References:

1. Nourianz package insert. Bedminster, NJ. Kyowa Kirin Inc. Revised May 2020. Accessed June 2024.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidencebased medicine review: Update on treatments for the motor symptoms of Parkinson's disease. Mov Disord. 2018;33(8):1248-1266.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ROMIPLOSTIM Edition 1	NPLATE	07/29/2024	07/29/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ROMIPLOSTIM (Nplate) requires the following rule(s) be met for approval:

A. Patient has ONE of the following diagnoses:
    1. Immune thrombocytopenia (ITP)
    2. Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS)
B. If patient has immune thrombocytopenia (ITP), approval also requires:
    1. Patient is 1 year of age or older
    2. Patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days OR patient has an active bleed
    3. Patient has previously tried or has a contraindication to corticosteroids or immunoglobulins, OR patient had an insufficient response to a splenectomy
    4. The requested medication is prescribed by or given in consultation with a hematologist or immunologist
    5. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)
    6. If patient is between 1 and 17 years old, approval also requires:
        a. Patient has had immune thrombocytopenia (ITP) for at least 6 months
C. If patient has hematopoietic syndrome of acute radiation syndrome, approval also requires:
    1. The requested medication is prescribed by or given in consultation with a hematologist
    2. Patient has been acutely exposed to myelosuppressive doses of radiation

RENEWAL CRITERIA
Our guideline named ROMIPLOSTIM (Nplate) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of immune thrombocytopenia (ITP)
B. Patient had a clinical response to therapy, as defined by an increase in platelet count or a reduction in bleeding events, compared to baseline

NOTE: For the diagnoses of Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS), please refer to the Initial Criteria section. Re-authorization is not permitted. Patients must meet the initial approval criteria for this diagnosis.

(Continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ROMIPLOSTIM (CONTINUED)

References:

1. Nplate package insert. Thousand Oaks, CA. Amgen Inc. Revised February 2022. Accessed June 2024.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. Blood Adv. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966.
3. Christensen DM, Iddins CJ, Parrillo SJ, Glassman ES, and Goans RE. Management of ionizing radiation injuries and illnesses, part 4: acute radiation syndrome. J Am Osteopath Assoc. 2014;114: 702-711. doi: 10.7556/jaoa.2014.138.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MEPOLIZUMAB Edition 3	NUCALA	07/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named MEPOLIZUMAB (Nucala) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Severe asthma with an eosinophilic phenotype
    2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome
    3. Hypereosinophilic syndrome (HES)
    4. Chronic rhinosinusitis with nasal polyps (CRSwNP)
B. If the patient has eosinophilic granulomatosis with polyangiitis, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient has been stable on oral corticosteroids (OCS) with inadequate response, unless there is a contraindication
C. If the patient has hypereosinophilic syndrome (HES), approval also requires:
    1. The patient is 12 years of age or older
    2. The patient has had HES for 6 months or more without an identifiable non-hematologic secondary cause
    3. The patient has been stable on oral corticosteroids, immunosuppressive, or cytotoxic therapy with inadequate response and will continue as maintenance therapy along with the requested medication, unless there is a contraindication

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

D. If the patient has chronic rhinosinusitis with nasal polyps (CRSwNP), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with an otolaryngologist, allergist, or immunologist
    3. Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
    4. The patient is currently adherent to maintenance therapy with an intranasal corticosteroid (e.g., fluticasone, mometasone, etc.)
    5. The patient has inadequately controlled disease as determined by ONE or more of the following:
        a. Use of systemic corticosteroids in the past 2 years b. Endoscopic sinus surgery
    6. The requested medication will be used as add-on maintenance treatment in conjunction with maintenance intranasal steroids
    7. The patient is not being treated on the requested medication concurrently with Xolair or Dupixent

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

E. If the patient has severe asthma with an eosinophilic phenotype, approval also requires:
    1. The patient is 6 years of age or older
    2. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
    3. The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
    4. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA)(e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    5. The patient has asthma that is uncontrolled while maintained on ICS plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE of the following:
        a. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
        b. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
    6. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication [i.e., LAMA, LABA, LTRA, theophylline]) OR an ICS-containing combination inhaler
    7. The patient is not being treated on the requested medication concurrently with Xolair, Dupixent, Tezspire or another anti-IL-5 asthma biologic (e.g., Cinqair, Fasenra, etc.)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has ONE of the following diagnoses:
    1. Severe asthma with an eosinophilic phenotype
    2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome
    3. Hypereosinophilic syndrome (HES)
    4. Chronic rhinosinusitis with nasal polyps (CRSwNP)

B. If the patient has eosinophilic granulomatosis with polyangiitis (EGPA), renewal also requires the following:
    1. The patient has had a clinical benefit compared to baseline (e.g., reduction in number of relapses, reduction in rate of relapse, etc.)

C. If the patient has hypereosinophilic syndrome (HES), renewal also requires the following:
    1. The patient has had a clinical benefit compared to baseline (e.g., reduction in number of disease flares, reduction in total steroid use, reduction in absolute eosinophil count, etc.)

D. If the patient has severe asthma with an eosinophilic phenotype, renewal also requires ALL of the following:
    1. The patient is currently adherent to maintenance therapy with an inhaled

F. corticosteroid (ICS) plus ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    2. The patient has shown a clinical response as evidenced by ONE of the following:
        a. Reduction in asthma exacerbation(s)compared to baseline
        b. Decreased use of rescue medications
        b. Increase in percent predicted FEV_1 from pretreatment baseline
        c. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

E. If the patient has chronic rhinosinusitis with nasal polyps (CRSwNP), renewal also requires:
    1. The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, improved sense of smell, or reduced size of polyps, etc.)

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

References:

1. Nucala package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised March 2023. Accessed June 2024.
2. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. *J Allergy Clin Immunol*. 2020;146(6):1217-1270. doi:10.1016/j.jaci.2020.10.003.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
4. Shomali W, Gotlib J. World Health Organization-defined eosinophilic disorders: 2019 update on diagnosis, risk stratification, and management. Am J Hematol. 2019;94(10):1149-1167. doi:10.1002/ajh.25617.
5. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss) (EGPA) Consensus Task Force recommendations for evaluation and management. Eur J Intern Med. 2015;26(7):545-553. doi:10.1016/j.ejim.2015.04.022.

Generic	Brand	Reviewed	Effective Date
DEXTROMETHORPHAN/ QUINIDINE Edition 1	NUEDEXTA	7/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named DEXTROMETHORPHAN with QUINIDINE (Nuedexta) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of pseudobulbar affect

References:

1. Nuedexta package insert. Aliso Viejo, CA. Avanir Pharmaceuticals, Inc. Revised June 2019. Accessed June 2024.
2. Pioro EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. Ann Neurol. 2010;68:693-702.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RIMEGEPANT Edition 7	NURTEC ODT	07/29/2024	07/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named RIMEGEPANT (Nurtec ODT) requires the following rule(s) be met for approval:

A. Patient is being treated for ONE of the following:
    1. Acute migraine headache
    2. Episodic migraine headaches
B. If patient has acute migraine headache, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient has had a previous trial of at least ONE triptan (e.g., sumatriptan, rizatriptan, etc.), unless there is a contraindication or the patient has established cardiovascular disease
C. If patient has episodic migraines (0-14 headache days per month), approval also requires
    1. The patient is 18 years of age or older
    2. The requested medication is being prescribed for preventive treatment of migraines
    3. The patient has had a previous trial of at least 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, or cyproheptadine

RENEWAL CRITERIA
Our guideline named RIMEGEPANT (Nurtec ODT) requires the following rule(s) be met for renewal:

B. Patient is being treated for ONE of the following:
    1. Acute migraine headache
    2. Episodic migraine headaches

(Criteria continued on next page)

REQUIREMENTS: RIMEGEPANT CONTINUED)

C. B. If patient has acute migraines, renewal also requires ONE of the following:
    1. Patient has 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 [MIGRAINEACT])
    2. Patient has 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

D. If patient has episodic migraines, renewal also requires:
    1. The requested medication is being prescribed for preventive treatment of migraines
    2. Patient has responded to therapy as evidenced by at least ONE of the following:
        a. The patient has experienced less migraines or headache attacks by at least 2 days per month compared to baseline
        b. The patient has experienced a lessening in migraine severity compared to baseline
        c. The patient has experienced a lessening in migraine duration compared to baseline

References:
1. Nurtec ODT package insert. New Haven, CT. Biohaven Pharmaceuticals, Inc. Reviewed April 2022. Accessed June 2024.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IVACAFTOR Edition 1	KALYDECO	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named IVACAFTOR (Kalydeco) requires the following rule(s) be met for approval:

A. Patient is 4 months of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Documentation that patient is NOT homozygous for the F508del mutation in the CFTR gene
E. If patient is between 4 months and less than 6 years of age, Ivacaftor packets will be approved. Documentation of patient weight is required
F. Documentation that patient has ONE of the following mutations in the CFTR gene

RENEWAL CRITERIA
Our guideline named IVACAFTOR (Kalydeco) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    1. Patient has maintained, or demonstrated less than expected decline in FEV_1
    2. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    3. Patient has experienced a reduction in rate of pulmonary exacerbations

References:

1. Kalydeco package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised August 2023. Accessed June 2024.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Pulmonary Guidelines: Use of CFTR Modulator Therapy in Patients with Cystic Fibrosis. Ann Am Thorac Soc. 2018 Mar. doi: 10.1513/AnnalsATS.201707-539OT.PMID: 29342367.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DICHLORPHENAMIDE Edition 2	KEVEYIS	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DICHLORPHENAMIDE (Keveyis) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Primary hypokalemic periodic paralysis (HypoPP)
    2. Primary hyperkalemic periodic paralysis (HyperPP)
    3. Paramyotonia Congenita
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist or a physician who specializes in primary periodic paralysis
D. The patient has had a previous trial of or contraindication to treatment with acetazolamide

RENEWAL CRITERIA
Our guideline named DICHLORPHENAMIDE (Keveyis) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Primary hypokalemic periodic paralysis (HypoPP)
    2. Primary hyperkalemic periodic paralysis (HyperPP)
    3. Paramyotonia Congenita
B. The patient has experienced at least two fewer attacks per week compared to baseline

References:

1. Keveyis package insert. Trevose, PA. Strongbridge US Inc. Revised December 2019. Accessed June 2024
2. Sansone V, Meola G, Links TP, Panzeri M, Rose MR. Treatment for periodic paralysis. Cochrane Database Syst Rev. 2008;(1):CD005045. Published 2008 Jan 23. doi:10.1002/14651858.CD005045.pub2.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PEGLOTICASE Edition 1	KRYSTEXXA	07/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PEGLOTICASE (Krystexxa) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of chronic gout that is refractory to conventional therapy
B. The patient is 18 years of age or older
C. The patient has symptomatic gout as evidenced by at least ONE of the following:
    i. At least 3 or more gout flares in the previous 18 months
    ii. History of at least 1 gout tophus
    iii. Gouty arthritis
D. The patient has had baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications (e.g., allopurinol [Zyloprim], lesinurad [Zurampic], febuxostat [Uloric], etc.)
E. The patient does not have a glucose-6-phosphate dehydrogenase (G6PD) deficiency
F. The patient will NOT be taking urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad, etc.) concurrently with the requested medication
G. The patient has experienced failure, contraindication, intolerance or inadequate response to previous trial with a maximum tolerated dose for TWO conventional gout medications for at least 3 months (e.g., allopurinol, probenecid, lesinurad, febuxostat etc.)

RENEWAL CRITERIA
Our guideline named PEGLOTICASE (Krystexxa) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of chronic gout
B. The patient has experienced a clinical response to therapy as evidenced by a sustained serum uric level below 6 mg/dL

References:

1. Krystexxa package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised July 2022. Accessed July 2024.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in Arthritis Care Res (Hoboken). 2020 Aug;72(8):1187] [published correction appears in Arthritis Care Res (Hoboken). 2021 Mar;73(3):458]. Arthritis Care Res (Hoboken). 2020;72(6):744-760. doi:10.1002/acr.24180.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FENTANYL NASAL SPRAY Edition 2	LAZANDA	7/29/2024	7/23/2021

REQUIREMENTS:

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

A. The patient has at least ONE of the following diagnoses:
    1. Cancer-related pain
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The patient is currently taking a maintenance dose of a controlled-release pain medication (e.g., MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. The patient has had a trial of an oral immediate-release pain medication (e.g., morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless they have difficulty swallowing tablets or capsules OR there is a contraindication
D. The patient has had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a contraindication
E. The patient has had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a contraindication

References:

1. Lazanda package insert. Northbrook, IL. West Therapeutic Development. Revised December 2022. Accessed June 2024.
2. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
3. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SODIUM ZIRCONIUM CYCLOSILICATE Edition 1	LOKELMA	7/29/2024	6/1/2021

REQUIREMENTS:

The guideline named SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of non-life threatening hyperkalemia
C. The requested drug is NOT being used as an emergency treatment for life-threatening hyperkalemia
D. The requested drug will NOT be used in a patient currently receiving dialysis
E. The requested drug is being prescribed by or in consultation with a nephrologist or cardiologist
F. The patient has attempted any ONE of the following approaches in an effort to reduce the modifiable risks for hyperkalemia:
    a. Limit to taking no more than one of the following drugs at any given time:
        1. Angiotensin converting enzyme inhibitor (ACE-I)
        2. Angiotensin receptor blocker (ARB)
    b. Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)
    c. 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 30mL/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

References:

1. Lokelma package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised February 2024. Accessed July 2024.
2. Palmer BF, Carrero JJ, Clegg DJ, et al. Clinical Management of Hyperkalemia. *Mayo Clin Proc*. 2021;96(3):744-762. doi:10.1016/j.mayocp.2020.06.014.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOTORASIB Edition 1	LUMAKRAS	7/29/2024	7/23/2021

REQUIREMENTS:

Our guideline named SOTORASIB (Lumakras) requires the following rule(s) be met for approval:

A. Patient is 18 years or older
B. Prescribed by or in consultation with a hematologist/oncologist
C. The patient has locally advanced or metastatic non-small cell lung cancer (NSCLC)
D. The patient has a tumor with an abnormal KRAS G12C gene mutation as determined by an FDA-approved test
E. Patient has received at least ONE prior systemic therapy

References:

1. Lumakras package insert. Thousand Oaks, CA. Amgen Inc. Revised April 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELAGOLIX Edition 1	ORILISSA	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ELAGOLIX (Orilissa) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of moderate to severe pain associated with endometriosis
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist
D. The patient has had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, meloxicam, naproxen, etc.) AND a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy, etc.)
E. Requests for Orilissa 200mg twice daily will only be approved if the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

RENEWAL CRITERIA
Our guideline named ELAGOLIX (Orilissa) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of moderate to severe pain associated with endometriosis
B. The patient has had improvement of pain related to endometriosis while on therapy
C. The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

Requests will NOT be approved if the patient meets ONE of the following conditions:

A. The patient has received a 6-month course of Orilissa 200mg twice daily
B. The patient has received a 6-month course of Orilissa 150mg once daily and they have moderate hepatic impairment (Child-Pugh Class B)
C. The patient has received a 24-month course of Orilissa 150mg once daily and you have normal liver function or mild hepatic impairment (Child-Pugh Class A)

References:

1. Orilissa package insert. North Chicago, IL. AbbVie Inc. Revised June 2023. Accessed June 2024.
2. Management of Endometriosis. ACOG Practice Bulletin. Clinical Management Guidelines for ObstetricanGynecologists. Number 114, July 2010. (Reaffirmed 2018) Obstetrics & Gynecology. 2010; 116(1): 223-236.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEROTRALSTAT HYDROCHLORIDE Edition 1	ORLADEYO	07/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named BEROTRALSTAT (Orladeyo) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 12 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, danazol, etc.)

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

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

References:

1. Orladeyo package insert. Durham, N.C. BioCryst Pharmaceuticals, Inc. Revised March 2022. Accessed July 2024.
2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3. doi:10.1016/j.jaip.2020.08.046.
3. Betschel S, Badiou J, Binkley K, et al. Correction to: The International/Canadian Hereditary Angioedema Guideline. Allergy Asthma Clin Immunol. 2020;16:33. Published 2020 May 6. doi:10.1186/s13223-020-00430-4.
4. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. Allergy Asthma Clin Immunol. 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8.
5. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018;73(8):1575-1596. doi:10.1111/all.13384.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CENEGERMIN-BKBJ Edition 2	OXERVATE	7/29/2024	07/29/2022

REQUIREMENTS:

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

A. Patient is 2 years of age or older
B. Patient has a diagnosis of neurotrophic keratitis
C. Therapy is prescribed by or given in consultation with an ophthalmologist
D. Patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
E. Patient is refractory to at least ONE conservative treatment that includes artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses

References:

1. Oxervate package insert. Boston, MA. Dompé U.S. Inc. Revised October 2019. Accessed July 2024.
2. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014;8:571-579. Published 2014 Mar 19. doi:10.2147/OPTH.S45921.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ETELCALCETIDE Edition 2	PARSABIV	07/29/2024	07/29/2022

REQUIREMENTS:

Our guideline named ETELCALCETIDE (Parsabiv) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of secondary hyperparathyroidism
C. The requested medication is prescribed by or in consultation with an endocrinologist or nephrologist
D. The patient has a diagnosis of chronic kidney disease
E. The patient is on hemodialysis
F. The patient 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.)
G. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to ONE vitamin analog (e.g., calcitriol, doxercalciferol, paricalcitol, etc.)
H. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to cinacalcet (Sensipar)
I. The patient is NOT taking another calcimimetic agent (i.e., cinacalcet [Sensipar])

RENEWAL CRITERIA

Our guideline named ETELCALCETIDE (Parsabiv) requires the following rule(s) be met for renewal:

A. The patient has experienced a reduction in serum calcium level compared to baseline

References:

1. Parsabiv package insert. Thousand Oaks, CA. KAI Pharmaceuticals, Inc. Revised February 2021. Accessed July 2024.
2. Erratum: Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2017;7:1-59. Kidney Int Suppl (2011). 2017;7(3):e1. doi:10.1016/j.kisu.2017.10.001.
3. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) [published correction appears in Kidney Int Suppl (2011). 2017 Dec;7(3):e1]. Kidney Int Suppl (2011). 2017;7(1):1-59. doi:10.1016/j.kisu.2017.04.001.

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON) Edition 2			
Generic	Brand	Reviewed	Effective Date
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	07/29/2024	07/29/2022
PEGINTERFERON ALFA-2B	PEGINTRON		

REQUIREMENTS:

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

A. The patient has one of the following diagnoses:
    1. Chronic hepatitis C virus (HCV) infection
    2. Chronic hepatitis B infection
B. The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, a doctor specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
C. For patients with chronic hepatitis B, approval also requires:
    1. The patient is 3 years of age or older
    2. The patient does not have cirrhosis
    3. The patient has tested positive for HBeAg
    4. The patient has evidence of viral replication with high serum ALT

D. For patients with chronic hepatitis C, approval also requires:

1. The patient is 3 years of age or older
2. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
3. The requested medication is being used in combination with ribavirin, unless there is a contraindication
4. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months

References:

1. Pegasys package insert. South San Francisco, CA. Genentech USA, Inc. Revised March 2021. Accessed July 2024.
2. Pegintron package insert. Whitehouse Station, NJ. Marck Shapr & Dohme Corp. Revised January 2019. Accessed July 2022.
3. Ghany MG, Morgan TR; AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases-Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Hepatology*. 2020;71(2):686-721. doi:10.1002/hep.31060.
4. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALPELISIB Edition 2	PIQRAY	7/29/2024	7/29/2024

REQUIREMENTS:

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

A. The patient has a diagnosis of advanced or metastatic breast cancer
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The patient's breast cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative
D. The requested medication will be used in combination with Faslodex (fulvestrant)
E. Patient has the presence of PIK3CA-mutation as detected by a Food and Drug Administration approved test
F. The patient has experienced disease progression on or after an endocrine-based regimen

References:

1. Piqray package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised January 2024. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALIROCUMAB Edition 5	PRALUENT	7/29/2024	7/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ALIROCUMAB (Praluent) requires the following rule(s) be met for approval:

A. The patient is 8 years of age or older
B. The patient has ONE of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
    3. Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
C. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
D. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70mg/dL
E. If the patient is statin tolerant, approval also requires:
    1. Patient will continue statin treatment in combination with Praluent
    2. Patient meets ONE of the following:
        i. Patient has 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. Patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: ALIROCUMAB (CONTINUED)

F. If patient is statin intolerant, approval also requires ONE of the following:
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has 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 patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group
G. The patient previously had a trial of Repatha (evolocumab), has a contraindication to Repatha, or for whom Repatha would be inappropriate.

RENEWAL CRITERIA

Our guideline named ALIROCUMAB (Praluent) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Established cardiovascular disease
    2. Heterozygous familial hypercholesterolemia (HeFH)
    3. Homozygous familial hypercholesterolemia (HoFH)
B. The patient meets ONE of the following:
    1. Patient has continued to take a high intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with the requested medication
    2. Patient has continued therapy with a maximally tolerated dose of any statin along with the requested medication
    3. Patient has an absolute contraindication to statin therapy
    4. Patient has complete statin intolerance

References:

1. Praulent package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised March 2024. Accessed June 2024.
2. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2019 Sep 10;74(10):1429-1430] [published correction appears in J Am Coll Cardiol. 2020 Feb 25;75(7):840]. J Am Coll Cardiol. 2019;74(10):e177-e232. doi:10.1016/j.jacc.2019.03.010.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625
4. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CYSTEAMINE BITARTRATE Edition 4	PROCYSBI, CYSTAGON	07/29/2024	07/29/2024

REQUIREMENTS:

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

A. The patient has a diagnosis of nephropathic cystinosis
B. The patient is at least 1 year of age or older
C. If the request is for Procysbi, approval also requires:
    a. The patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

References:

1. Procysbi package insert. Lake Forest, IL, Horizon Pharma USA Inc. Revised February 2022 Accessed June 2024
2. Cystagon package insert. Morgantown, WV. Mylan Pharmaceuticals Inc. Revised June 2007. Accessed June 2024.
3. Vaisbich MH, Satiro CAF, Roz D, et al. Multidisciplinary approach for patients with nephropathic cystinosis: model for care in a rare and chronic renal disease. J Bras Nefrol. 2019;41(1):131-141. doi:10.1590/2175-8239-JBN-2018-0139.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELTROMBOPAG Edition 1	PROMACTA	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ELTROMBOPAG (Promacta) requires the following rule(s) be met for approval:

A. Patient has ONE of the following diagnoses:
    1. Chronic immune thrombocytopenia (ITP)
    2. Thrombocytopenia due to chronic hepatitis C
    3. Severe aplastic anemia
B. If patient is greater than 12 years of age and the request is for Promacta packets, approval also requires:
    1. Patient has previously had a trial of Promacta tablets
    2. Patient has a medical need for powder packets
C. If patient has chronic immune thrombocytopenia, approval also requires:
    1. Patient is 1 year of age or older
    2. Patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days OR patient has an active bleed
    3. Patient has previously tried or has a contraindication to corticosteroids or immunoglobulins, or patient had an insufficient response to a splenectomy
    4. The requested medication is prescribed by or given in consultation with a hematologist or immunologist
    5. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)
D. If patient has thrombocytopenia due to chronic hepatitis C, approval also requires:
    1. The patient's thrombocytopenia does not allow them to start interferon-based therapy or limits the patient's ability to maintain interferon-based therapy
    2. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)
E. If patient has severe aplastic anemia, approval also requires ONE of the following:
    1. Patient is 2 years of age or older and the requested medication will be used in combination with standard immunosuppressive therapy as first-line treatment
    2. Patient did not have a good enough response to immunosuppressive therapy

(*Criteria continued on next page)*

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ELTROMBOPAG CONTINUED)

RENEWAL CRITERIA

Our guideline named ELTROMBOPAG (Promacta) requires the following rules be met for renewal:

A. Patient has a diagnosis of chronic immune thrombocytopenia (ITP)
B. Patient had a clinical response to therapy, as defined by an increase in platelet count or reduction in bleeding events, compared to baseline

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section. Re-authorization is not permitted. Patients must meet the initial approval criteria for these diagnoses.

References:

1. Promacta package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised July 2023. Accessed June 2024.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. Blood Adv. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966.
3. Killick SB, Bown N, Cavenagh J, et al. Guidelines for the diagnosis and management of adult aplastic anaemia [published correction appears in Br J Haematol. 2016 Nov;175(3):546]. Br J Haematol. 2016;172(2):187-207. doi:10.1111/bjh.13853.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DORNASE ALFA Edition 3	PULMOZYME	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of cystic fibrosis
B. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
C. If the request is for twice daily dosing, we require that the patient has tried and failed once daily dosing

References:

1. Pulmozyme package insert. South San Francisco, CA. Genentech, Inc. Revised February 2024. Accessed June 2024.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. April 1, 2013; 187(7): 680-689.

WELLFLEET RX STUDENT FORMULARY

ANTI-OBESITY AGENTS Edition 4			
Generic	Brand	Reviewed	Effective Date
LIRAGLUTIDE	SAXENDA	7/29/2023	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

NOTE: Requests will NOT be approved if your plan has weight-loss medication exclusions

Our guideline named ANTI-OBESITY AGENTS (Saxenda)
requires the following rule(s) be met for approval:

A. The request is for weight loss OR weight loss management
B. Documentation the patient has active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
C. For Saxenda requests, approval also requires:
    1. The patient is NOT currently taking a GLP-1 receptor agonist (e.g., Wegovy, Victoza, Byetta, Bydureon, Trulicity, Ozempic, Mounjaro, etc.)
    2. If the patient is aged 12 years to 17 years, approval also requires:
        a. The patient has a body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs (International Obesity Task Force [IOTF] BMI Cut-Offs)
    3. If the patient is 18 years of age or older, approval also requires the patient meets ONE of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater AND at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

RENEWAL CRITERIA
Our guideline named ANTI-OBESITY AGENTS (Saxenda)
requires the following rule(s) be met for renewal:

A. The request is for weight loss OR weight loss management
B. If the patient is requesting Saxenda, renewal also requires:
    1. The patient has lost at least 4% of baseline body weight after 4 months of treatment

References:

1. Qysmia package insert. Campbell, CA. Vivus, Inc. Reviewed June 2022. Accessed June 2023.
2. Saxenda package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised April 2023. Accessed June 2023.
3. Styne DM, Arslanian SA, Connor EL, et al. Pediatric Obesity-Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(3):709-757. doi:10.1210/jc.2016-2573.
4. Garvey WT, Mechanick JI, Brett EM, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY COMPREHENSIVE CLINICAL PRACTICE GUIDELINES FOR MEDICAL CARE OF PATIENTS WITH OBESITY. Endocr Pract. 2016;22 Suppl 3:1-203. doi:10.4158/EP161365.GL.
5. Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for thinness, overweight and obesity. Pediatr Obes. 2012;7(4):284-294. doi:10.1111/j.2047-6310.2012.00064.x.

WELLFLEET RX STUDENT FORMULARY

ALLERGEN EXTRACT-HOUSE DUST MITE			
Generic	Brand	Reviewed	Effective Date
HOUSE DUST MITE Edition 1	ODACTRA	7/29/2024	6/1/2021

REQUIREMENTS:

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. The patient has a diagnosis of allergic rhinitis caused by house dust mites, with or without conjunctivitis
B. The patient's diagnosis is confirmed by in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
C. The patient is between 18 and 65 years old
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent symptoms of allergic rhinitis presenting at least 4 days a week or for at least 4 weeks
F. The patient has moderate to severe symptoms of allergic rhinitis (i.e., troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
G. The patient has 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. The patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline

References:

1. Odactra package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised August 2019. Accessed June 2024.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

WELLFLEET RX STUDENT FORMULARY

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 4	Reviewed	Effective Date
Off Label Policy	07/29/2024	07/29/2023
Description		
Off-label Use means use of an FDA-approved* medication that has been prescribed by a provider for treatment of a condition or disease other than for an indication specifically designated in the product's FDA-approved labeling. This policy provides parameters for coverage of off-label and unproven indications of a drug that has been approved* for marketing by the Federal Food and Drug Administration (FDA)		

REQUIREMENTS:

A drug that has been approved* for marketing by the Federal Food Drug Administration may be covered for the requested off-label or unproven indication when ALL of the criteria are met: (*see VT specific criteria for exception)

1. VT specific criteria: The drug is approved by the FDA, except for drugs which are medically accepted for treatment of cancer
2. Off-Label use is supported by sufficient scientific evidence which includes ONE of the following:
    a. Supported by at least ONE nationally recognized drug database such as the following authoritative compendia (list is not all-inclusive):
        i. NCCN: The level of evidence for the indication is Category 1 or 2A
        ii. DrugDex: The level of evidence for the indication is Class III
        iii. AHFS-DI (The American Hospital Formulary Service Drug Information): The narrative text is supportive
        iv. Clinical Pharmacology: The narrative text is supportive
        v. Lexi-Drugs: The indication is listed as "Use: Off-Label" and rated as "Evidence Level A."
        vi. The American Medical Association Drug Evaluations
        vii. The United States Pharmacopoeia Dispensing Information, volume 1 viii. Drug Information for Health Care Professionals
    b. Supported by TWO separate articles in major peer reviewed medical journals/clinical practice guidelines. (Exception: Cancer indications will only require evidence from ONE article or clinical practice guideline); AND

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: OFF-LABEL POLICY (CONTINUED)

3. The drug is prescribed for the treatment of a life-threatening condition including cancer, HIV or AIDS (This requirement DOES NOT apply to the following states: IL, MA, CA and TN [see below for state specific criteria])
    a. IL specific criteria: The drug is prescribed for ONE of the following:
        i. Treatment of a life-threatening condition including cancer, HIV, or AIDS
        ii. Inhalants used for asthma or other life-threatening bronchial ailments
        iii. Opioid antagonists, including, but not limited to, naloxone hydrochloride or any other similarly acting drug approved by the FDA.
    b. MA specific criteria: The drug is prescribed for the treatment of a life-threatening condition, including, but not limited to cancer, HIV or AIDS, or for the treatment of Lyme Disease.
    c. CA specific criteria: n/a
    d. TN specific criteria: n/a

As it pertains to this benefit, life threatening means either or both of the following:

a. Disease or conditions where the likelihood of death is high unless the course of the disease is interrupted; or
b. Disease or conditions with a potentially fatal outcome and where the end point of clinical intervention is survival.

WELLFLEET RX STUDENT FORMULARY

OPIOID-BENZODIAZEPINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/29/2024	7/23/2021

REQUIREMENTS:

Our guideline named OPIOID-BENZODIAZEPINE CONCURRENT USE allows for an approval of the use of an opioid in combination with a benzodiazepine when at least ONE of the following criteria is met:

A. The patient has active cancer
B. The patient is receiving palliative care or end-of-life care
C. The patient is enrolled in a hospice
D. The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
E. The patient has a diagnosis of sickle cell disease
F. The patient's doctor confirms to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication

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

(Continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: OPIOID-BENZODIAZEPINE CONCURRENT USE (CONTINUED)

References:

1. 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 7/6/23].
2. Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at: https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-2021.pdf [Accessed 7/06/22].
3. 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 7/06/22].
4. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
5. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

WELLFLEET RX STUDENT FORMULARY

OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/29/2024	7/23/2021

REQUIREMENTS:

Our guideline named OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE allows an approval for use of an opioid in combination with Soma (carisoprodol) along with a benzodiazepine medication when one of the following criteria is met:

A. The patient has active cancer
B. The patient is receiving palliative care or end-of-life care
C. The patient is enrolled in a hospice
D. The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
E. The patient's doctor confirms that the use of an opioid concurrently with Soma (carisoprodol) along with a benzodiazepine medication is intended and for a clinically appropriate indication

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.

(Continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE (CONTINUED)

References:

1. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
2. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

WELLFLEET RX STUDENT FORMULARY

OPIOID-BUPRENORPHINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/29/2024	7/23/2021

REQUIREMENTS:

Our guideline named OPIOID-BUPRENORPHINE CONCURRENT USE allows approval for use of an opioid in combination with buprenorphine or a buprenorphine-containing agent when at least ONE of the following rule(s) is met:

A. The patient has active cancer
B. The patient is receiving palliative care or end-of-life care
C. The patient is enrolled in a hospice
D. The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
E. The patient's doctor confirms that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and the patient needs to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. The patient's doctor is aware that the patient is 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

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:

1. 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 7/06/23].
2. 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/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-2021.pdf [Accessed 7/06/22].
3. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
4. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

ALLERGEN EXTRACT-MIXED GRASS POLLEN			
Generic	Brand	Reviewed	Effective Date
GR POL-ORC/SW VER/RYE/KENT/TIM Edition 1	ORALAIR	7/29/2024	6/1/2021

REQUIREMENTS:

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. The patient has a diagnosis of allergic rhinitis caused by grass pollen
B. The patient is between 5 and 65 years of age
C. The patient's diagnosis is confirmed by a positive skin prick test and/or a positive titer 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)
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent and moderate-to-severe symptoms of allergic rhinitis [Note: 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]
F. The patient has a current claim or prescription for auto-injectable epinephrine

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

A. The patient has experienced an improvement in signs and symptoms of allergic rhinitis compared to baseline.

References:

1. Oralair package insert. Lenoir, N.C. GREER Laboratories, Inc. Revised November 2018. Accessed July 2024.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

GLYCOPYRRONIUM TOPICAL			
Generic	Brand	Reviewed	Effective Date
GLYCOPYRRONIUM 2.4% CLOTH Edition 1	QBREXZA	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of primary axillary hyperhidrosis
B. The patient is 9 years of age or older
C. The patient has had a trial of a prescription strength aluminum chloride product (e.g., Drysol)

References:

1. Qbrexza package insert. Menlo Park, California. Dermira, Inc. Revised October 2022. Accessed June 2024.
2. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated September 23, 2018. Available at: https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focalhyperhidrosis/primary-focal-axillary.html. Accessed June 2022.

WELLFLEET
RX PLAN

The following guidelines applies to Prior Authorization exception requests to formulary Utilization Management Edits such as Quantity Limits, Step Therapy, Age Limits, or when PA criteria is not available. Your coverage and/or copayment/coinsurance may vary based on your benefit plan. Please check your plan documents. This document is subject to change.

Edition 3	Reviewed	Effective Date
Quantity Limit (QL) Exception Guidelines	07/29/2024	4/29/2022

Description

Quantity Limits (QLs) are in place on certain classes of agents based on manufacturer's safety and dosing guidelines and is intended to promote safe, appropriate use of medications. A QL is a restriction on the amount or quantity of medication that is covered by your plan during a specific period of time. The following exception guidelines are used when a prescription exceeds current QLs established by your plan.

REQUIREMENTS:

1. The request involves endocrine treatment of gender-dysphoric/gender-incongruent persons (see Appendix A), OR
2. There is medical literature to support that the quantity requested is within the recommended dosing guidelines for the drug, AND
3. The quantity allowed under the formulary has been ineffective in the treatment of the member's disease or medical condition, OR
4. Based on clinical evidence and medical literature, the known relevant physical or mental characteristics of the member, and the known characteristics of the drug regimen, the lower quantity is likely to be ineffective, OR
5. Patient is currently on the requested dose, AND
6. No higher dosage strength can be used to achieve the same total daily dose, and no dose consolidation is possible

**Please note, if the requested product is FDA approved as an acute use medication, evidence must be provided to support more frequent use for an exception to be granted

(Criteria continued on next page)

REQUIREMENTS: QUANTITY LIMIT EXCEPTION (CONTINUED)

Appendix A:
Requests for endocrine treatment of gender-dysphoric/gender-incongruent persons should utilize the following dosing chart taken from the Endocrine Society Clinical Practice Guidelines. Doses outside these parameters will require the provider to submit medical literature supporting the requested dose.

Transgender females		
Estrogen		
Oral	Estradiol	2.0–6.0 mg/d
Transdermal	Estradiol transdermal patch (New patch placed every 3–5 d)	0.025–0.2 mg/d
Parenteral	Estradiol valerate or cypionate	5–30 mg IM every 2 wk 2–10 mg IM every week
Anti-androgens		
	Spironolactone	100–300 mg/d
	GnRH agonist (Lupron Depot)	3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly
Transgender males		
Testosterone		
Parenteral testosterone	Testosterone enanthate or cypionate	100–200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week
	Testosterone undecanoate	1000 mg every 12 wk
Transdermal testosterone	Testosterone gel	50–100 mg/d
	Testosterone transdermal patch	2.5–7.5 mg/d

References:

1. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658.
2. World Professional Association for Transgender Health. (2022). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [8th Version]. https://www.wpath.org/publications/soc .

ALLERGEN EXTRACT- SHORT RAGWEED POLLEN			
Generic	Brand	Reviewed	Effective Date
WEED POLLEN- SHORT RAGWEED Edition 2	RAGWITEK	7/29/2024	7/23/2021

REQUIREMENTS:

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. The patient has a diagnosis of allergic rhinitis caused by short ragweed pollen
B. The patient is between 5 and 65 years of age
C. The patient's diagnosis is confirmed by a positive skin prick test and/or a positive titer to specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent and moderate-to-severe symptoms of allergic rhinitis [Note: 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]
F. The patient has 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. The patient has experienced an improvement in signs and symptoms of allergic rhinitis compared to baseline

References:

1. Ragwitek package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised March 2022. Accessed July 2024.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLYCEROL PHENYLBUTYRATE Edition 1	RAVICTI	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GLYCEROL PHENYLBUTYRATE (Ravicti) requires the following rule(s) be met for approval:

A. The patient has a urea cycle disorder
B. Documentation of confirmation of urea cycle disorder via enzymatic, biochemical, or genetic testing
C. The patient is 2 months of age or older
D. The requested medication will be used as adjunctive therapy along with dietary protein restriction
E. The patient's 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 or acute hyperammonemia
G. The patient has previously tried Buphenyl (sodium phenylbutyrate), unless there is a contraindication

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

A. The patient has a urea cycle disorder
B. The patient has had clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity, etc.).

References:

1. Ravicti package insert. Lake Forest, IL. Horizon Therapeutics USA, Inc. Revised September 2021. Accessed June 2024.
2. Diaz GA, Krivitzky LS, Mokhtarani M, et al. Ammonia control and neurocognitive outcome among urea cycle disorder patients treated with glycerol phenylbutyrate. Hepatology. 2013;57(6):2171-2179.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EVOLOCUMAB Edition 3	REPATHA	07/29/2024	7/29/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named EVOLOCUMAB (Repatha) requires the following rule(s) be met for approval:

A. Patient has ONE of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
    3. Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
B. If patient has diagnosis of established cardiovascular disease, approval also requires:
    1. Patient is 18 years of age or older
C. If patient has a diagnosis of Heterozygous familial hypercholesterolemia (HeFH) or Homozygous familial hypercholesterolemia (HoFH), approval also requires:
    1. Patient is 10 years of age or older
D. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
E. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70mg/dL
F. If patient is statin tolerant, approval also requires:
    1. Patient will continue statin treatment in combination with the requested medication
    2. Patient meets ONE of the following:
        a. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for at least 8 weeks
        b. Patient has 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)

(Criteria continued on next page)

REQUIREMENTS: EVOLOCUMAB (CONTINUED)

G. If patient is statin intolerant, approval also requires ONE of the following:
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction
    2. Patient has 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 patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named EVOLOCUMAB (Repatha) requires the following rules be met for renewal:

A. Patient has ONE of the following diagnoses:
    1. Established cardiovascular disease
    2. Heterozygous familial hypercholesterolemia (HeFH)
    3. Homozygous familial hypercholesterolemia (HoFH)
B. Patient meets ONE of the following:
    1. Patient has continued to take a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) with the requested medication
    2. Patient has continued therapy with a maximally tolerated dose of any statin with the requested medication
    3. Patient has an absolute contraindication to statin therapy
    4. Patient has complete statin intolerance

References:

1. Repatha package insert. Thousand Oaks, CA. Amgen Inc. Revised August 2022. Accessed July 2024.
2. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2019 Sep 10;74(10):1429-1430] [published correction appears in J Am Coll Cardiol. 2020 Feb 25;75(7):840]. J Am Coll Cardiol. 2019;74(10):e177-e232. doi:10.1016/j.jacc.2019.03.010.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625
4. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELAPEGADEMASE-LVLR Edition 1	REVCOVI	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ELAPEGADEMASE-LVLR (Revcovi) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as shown by ONE of the following:
    1. Confirmatory genetic test (detection of bi-allelic mutations in the ADA 1 gene)
    2. Suggestive laboratory findings such as elevated deoxyadenosine nucleotide (dAXP) levels or very low adenosine deaminase (ADA) catalytic activity AND the patient has hallmark signs/symptoms (e.g., recurrent infections, failure to thrive, persistent diarrhea, etc.)
B. The requested medication is prescribed by or given in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders
C. The patient has failed or is not a candidate for hematopoietic cell transplant 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. The patient has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)
B. The patient has a clinical response to therapy as evidenced by improvement in trough plasma adenosine deaminase (ADA) activity, improvement in trough erythrocyte deoxyadenosine nucleotide (dAXP) levels and/or improvement in/maintenance of immune function compared to baseline (i.e., decrease in number and severity of infections)
C. The patient has not received successful hematopoietic cell transplantation (HCT) or gene therapy

References:
1. Revcovi package insert. Gaithersburg, MD. Leadiant Biosciences Inc. Revised December 2020. Accessed July 2024.
2. Kohn DB, Hershfield MS, Puck JM, et al. Consensus approach for the management of severe combined immune deficiency caused by adenosine deaminase deficiency. J Allergy Clin Immunol. 2019;143(3):852-863.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LENALIDOMIDE Edition 2	REVLIMID	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Multiple myeloma (MM)
    2. Anemia due to a myelodysplastic syndrome (MDS)
    3. Mantle cell lymphoma (MCL)
    4. Follicular lymphoma (FL)
    5. Marginal zone lymphoma (MZL)
B. The patient is 18 years of age or older
C. Therapy will be prescribed by, or in consultation with, an oncologist
D. If the patient has anemia due to a myelodysplastic syndrome, approval also requires:
    1. The patient has a deletion 5q abnormality
E. If the patient has mantle cell lymphoma, approval also requires:
    1. Patient has relapsed or progressed after two prior therapies and one of the therapies tried must be Velcade (bortezomib) (Note: Velcade may be covered under the medical benefit and/or require prior authorization).
F. If the patient has follicular lymphoma, approval also requires:
    1. Patient has previously been treated for follicular lymphoma
    2. The requested medication is being taken in combination with a rituximab product
G. If the patient has marginal zone lymphoma, approval also requires:
    1. Patient has previously been treated for marginal zone lymphoma
    2. The requested medication is being taken in combination with a rituximab product

References:

1. Revlimid package insert. Summit, NJ. Celgene Corporation. Revised March 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ENTRECTINIB Edition 3	ROZLYTREK	7/29/2024	7/29/2024

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Metastatic non-small cell lung cancer
    2. Solid tumor (e.g., sarcoma, breast cancer, colorectal cancer, etc.)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If patient has metastatic non-small cell lung cancer (NSCLC), approval also requires BOTH of the following:
    1. Patient is 18 years of age or older
    2. Patient has *ROS1*-positive tumors, as detected by an FDA approved test
D. If patient has a solid tumor, approval also requires ALL of the following:
    1. Patient is 1 month of age or older
    2. The solid tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, as detected by an FDA approved test
    3. The tumor is metastatic or surgical resection is likely to result in severe morbidity
    4. There are no satisfactory alternative treatments, or patient has progressed after treatment

References:
1. Rozlytrek package insert. South San Francisco, Ca. Genentech, Inc. Revised January 2024. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FOSTEMSAVIR Edition 1	RUKOBIA	7/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named FOSTEMSAVIR (Rukobia) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection
B. The patient is 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s)
D. The patient is treatment experienced
E. The patient has multidrug-resistant HIV-1 infection
F. The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

References:

1. Rukobia package insert. Research Triangle Park, NC. ViiV Healthcare. Revised February 2024. Accessed June 2024.
2. Saag MS, Gandhi RT, Hoy JF, et al. Antiviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. JAMA. 2020;324(16):1651-1669.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CINACALCET Edition 2	SENISPAR	7/29/2024	07/29/2022

REQUIREMENTS:

Our guideline named CINACALCET (Sensipar) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has one of the following diagnoses:
    1. Parathyroid carcinoma
    2. Primary hyperparathyroidism and is unable to undergo parathyroidectomy
    3. Secondary hyperparathyroidism
C. The requested medication is prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist
D. For patients with secondary hyperparathyroidism, approval also requires ALL of the following:
    1. The patient has a diagnosis of chronic kidney disease (CKD)
    2. The patient is on hemodialysis.
    3. The patient has an intact parathyroid hormone (iPTH) level above normal range as defined by the laboratory reference values
    4. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to ONE phosphate binder (e.g. calcium acetatate, PhosLo, lanthanum carbonate, Fosrenol, sevelamer, Renvela, Renagel, etc.)
    5. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to ONE vitamin 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 CRITERIA

Our guideline named CINACALCET (Sensipar) requires the following rule(s) be met for renewal:

A. The patient has experienced a reduction in serum calcium level compared to baseline.

References:

1. Sensipar package insert. Thousand Oaks, CA. Amgen Inc. Revised December 2019. Accessed July 2024.
2. Bilezikian JP, Brandi ML, Eastell R, et al. Guidelines for the management of asymptomatic primary hyperparathyroidism: summary statement from the Fourth International Workshop. J Clin Endocrinol Metab. 2014;99(10):3561-3569. doi:10.1210/jc.2014-1413.
3. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) [published correction appears in Kidney Int Suppl (2011). 2017 Dec;7(3):e1]. Kidney Int Suppl (2011). 2017;7(1):1-59. doi:10.1016/j.kisu.2017.04.001.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEDAQUILINE FUMARATE Edition 2	SIRTURO	7/29/2024	7/29/2022

REQUIREMENTS:

Our guideline named BEDAQUILINE FUMARATE (Sirturo) requires the following rule(s) be met for approval:

A. The patient is 5 years of age or older
B. Patient has ONE of the following diagnoses:
    1. Pulmonary multi-drug resistant tuberculosis (MDR-TB)
    2. Pulmonary extensively drug resistant tuberculosis (XDR-TB)
C. The patient weighs at least 15kg
D. The requested medication is prescribed by or in consultation with an infectious disease specialist or a pulmonologist.
E. The requested medication will be used in combination with other anti-tuberculosis agents (e.g., levofloxacin, moxifloxacin, clofazimine, cycloserine, terizidone, pretomanid, linezolid, etc.).

References:

1. Sirturo package insert.Titusville, NJ. Janssen Products, LP. Revised June 2024. Accessed June 2024.
2. World Health Organization – Global Tuberculosis Report. 2021. Available at: https://apps.who.int/iris/rest/bitstreams/1379788/retrieve. Accessed on June 2, 2022.
3. World Health Organization – Consolidated guidelines on drug-resistant tuberculosis treatment. 2019. Available at: https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf Accessed on June 2, 2022.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
RISANKIZUMAB-RZAA Edition 6	SKYRIZI	7/29/2024	7/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named RISANKIZUMAB-RZAA (Skyrizi) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
    3. Moderately to severely active Crohn's disease (CD)
    4. Ulcerative Colitis
B. The patient is 18 years of age or older
C. For patients with moderate to severe plaque psoriasis (PsO), approval requires:
    1. The requested medication is prescribed by or given in consultation with a dermatologist
    2. 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
    3. The patient had a previous trial of or contraindication to 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
D. For patients with psoriatic arthritis (PsA), approval requires:
    1. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    2. The patient has had a previous trial of or contraindication to at least one of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
E. For patients with moderately to severely active Crohn's disease (CD), approval requires:
    1. The requested medication is prescribed by or given in consultation with a gastroenterologist
    2. The patient meets at least ONE of the following:
        a. 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
        b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
        c. The patient has a history of ileocolonic resection
F. For patients with Ulcerative Colitis (UC), approval requires:
    1. The requested medication is prescribed by or in consultation with a gastroenterologist

2. The patient has received three induction doses with Skyrizi IV within the past 3 months
3. The patient meets ONE of the following:
    a. Has had a trial of one previous systemic agent for UC (Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested drug also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count.)
    b. The patient meets both of the following:
        1. Has pouchitis
        2. Has tried an antibioitic, probiotic, corticosteroid enema, or mesalamine enema

RENEWAL CRITERIA

The guideline named RISANKIZUMAB-RZAA (Skyrizi) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
    3. Moderately to severely active Crohn's disease (CD)
B. For patients with moderate to severe plaque psoriasis (PsO), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with psoriatic arthritis (PsA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with moderate to severe Crohn's disease (CD), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with Ulcerative Colitis (UC), renewal requires:
    1. The patient has successfully been utilizing Skyrizi for at least six months
    2. The patient meets ONE of the following:
        i. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR
        ii. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or decreased rectal bleeding.

References

1. Skyrizi package insert. North Chicago, IL. AbbVie Inc. Revised September 2022. Accessed August 2023.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
4. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
5. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
6. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.

Generic	Brand	Reviewed	Effective Date
DEUCRAVACITINIB Edition	SOTYKTU	7/24/2024	7/24/2024

REQUIREMENTS:

Our guideline named DEUCRAVACITINIB (Sotyktu) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO).
B. The following criteria must also be met:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient has had a previous trial of or contraindication to 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 OR had a previous trial of or contraindication to a biologic, such as Humira (or biosimilar), Otezla, Enbrel, Skyrizi, Stelara SC, Taltz, or Tremfya

RENEWAL CRITERIA

Our guideline named DEUCRAVACITINIB (Sotyktu) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO)
B. The following criterion must also be met for renewal:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Sotyktu package insert. Princeton, NJ Bristol-Myers Squibb Company, Revised September 2022. Accessed July2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DASATINIB Edition 3	SPRYCEL	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic, accelerated, or myeloid or lymphoid blast phase
    2. Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If patient has Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:
    1. Patient is 18 years of age or older AND newly diagnosed
    2. Patient is 18 years of age or older AND has resistance or intolerance to prior therapy including imatinib (Gleevec)
    3. Patient is between 1 and 17 years of age
D. If patient has Philadelphia chromosome-positive chronic myeloid leukemia in accelerated phase, or myeloid or lymphoid blast phase, approval also requires:
    1. Patient is 18 years of age or older
    2. Patient has resistance or intolerance to prior therapy including imatinib (Gleevec)
E. If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:
    1. Patient is 18 years of age or older AND has a resistance or intolerance to prior therapy such as imatinib (Gleevec), nilotinib (Tasigna), etc.
    2. Patient is between 1 and 17 years of age, newly diagnosed, AND using requested medication in combination with chemotherapy

References:

1. Sprycel package insert. Princeton, NJ. Bristol-Myers Squibb Company. Reviewed February 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ASFOTASE ALFA Edition 1	STRENSIQ	7/29/2024	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ASFOTASE ALFA (Strensiq) requires the following rules be met for approval:

A. The patient has a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) or juvenile-onset hypophosphatasia (HPP).
B. The patient was 18 years of age or younger at hypophosphatasia onset
C. Requested medication is prescribed by or given in consultation with an endocrinologist, geneticist, metabolic disorder specialist or physician who specializes in treatment of hypophosphatasia.
D. Presence of ONE of the following laboratory markers:
    1. The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) mutation in the *ALPL* gene as confirmed by genetic testing
    2. Patient meets at least TWO of the following criteria:
        i. Serum alkaline phosphatase level below that of normal range for patient's age
        ii. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B6 supplementation in the previous week
        iii. Urine phosphoethanolamine (PEA) level above that of normal range for patient's age
E. Presence of one or more of the following clinical manifestations of HPP:
    1. Rachitic chest deformity
    2. Craniosynostosis
    3. Delay in skeletal growth resulting in delay of motor development
    4. Dental abnormalities such as premature loss of primary teeth
    5. Failure to thrive or growth failure/short stature
    6. Respiratory insufficiency
    7. Compromised exercise capacity
    8. History of vitamin B6 dependent seizures
    9. Nephrocalcinosis or history of elevated serum calcium
    10. History or presence of fracture after birth not due to injury or delayed fracture healing

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ASFOTASE ALFA (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has experienced response to therapy as evidenced by improvement and/or stabilization in the any of the following:
    1. Skeletal manifestations according to radiographic findings
    2. Motor function
    3. Respiratory status
    4. Height velocity

References:

1. Strensiq package insert. Boston,MA. Alexion Pharmaceuticals, Inc. Revised July 2024. Accessed July 2024.
2. Millán JL, Plotkin H. Hypophosphatasia - pathophysiology and treatment. Actual osteol. 2012;8(3):164-182.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FENTANYL SUBLINGUAL SPRAY Edition 2	SUBSYS	7/29/2024	7/23/2021

REQUIREMENTS:

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

A. The patient has at least ONE of the following diagnoses:
    1. Cancer-related pain
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The patient is currently using the requested medication with a controlled-release pain medication (e.g., MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. The patient has had a trial of an oral immediate-release pain medication (e.g., morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless they have difficulty swallowing tablets or capsules OR there is a contraindication
D. The patient has had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a contraindication
E. The patient has had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a contraindication

References:

1. Subsys package insert. Northbrook, IL. West Therapeutic Development, LLC. Revised December 2022. Accessed June 2024.
2. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
3. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEZACAFTOR/IVACAFTOR Edition 1	SYMDEKO	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named TEZACAFTOR/IVACAFTOR (Symdeko) requires the following rule(s) be met for approval:

A. Patient is 6 years of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Documentation that patient is either homozygous for the *F508del*-CFTR gene mutation; OR documentation that patient has at least one of the following mutations in the CFTR gene:

RENEWAL CRITERIA
Our guideline named TEZACAFTOR/IVACAFTOR (Symdeko) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    a. Patient has improved, maintained, or demonstrated less than expected decline in FEV_1
    b. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    c. Patient has experienced a reduction in rate of pulmonary exacerbations

References:

1. Symdeco package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised August 2023. Accessed June 2024.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Pulmonary Guidelines: Use of CFTR Modulator Therapy in Patients with Cystic Fibrosis. Ann Am Thorac Soc. 2018 Mar. doi: 10.1513/AnnalsATS.201707-539OT.PMID: 29342367.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CLOBAZAM Edition 1	SYMPAZAN	07/29/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of Lennox-Gastaut Syndrome
B. The requested medication will be used for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (e.g., in combination with lamotrigine or topiramate, etc.)
C. The patient is 2 years of age or older
D. The patient is unable to take tablets or suspension
E. The patient has had a trial of or contraindication to generic/branded clobazam products (Onfi)

References:

1. Sympazan package insert. Warren,NJ. Aquestive Therapeutics. Revised March 2024. Accessed June 2024.
2. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018;91(24):1117. doi:10.1212/WNL.0000000000006636.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR Edition 2	TRIKAFTA	7/29/2024	7/23/2021

REQUIREMENTS:

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. Patient is 2 years of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Patient meets ONE of the following:
    1. Documentation that the patient has at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
    2. Documentation that the patient has at least ONE of the following mutations in the CFTR gene:

Table 5: List of *CFTR* Gene Mutations that are Responsive to TRIKAFTA

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*
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*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data *[see Clinical Studies (14)]*.
† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (CONTINUED)

RENEWAL CRITERIA

Our guideline named ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    a. Patient has improved, maintained, or demonstrated less than expected decline in FEV_1
    b. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    c. Patient has experienced a reduction in rate of pulmonary exacerbations

References:
1. Trikafta package insert. Boston, Ma. Vertex Pharmaceuticals Incorporated. Revised April 2023. Accessed June 2024.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Pulmonary Guidelines: Use of CFTR Modulator Therapy in Patients with Cystic Fibrosis. Ann Am Thorac Soc. 2018 Mar. doi: 10.1513/AnnalsATS.201707-539OT.PMID: 29342367.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INFIGRATINIB Edition 1	TRUSELTIQ	7/29/2024	7/23/2021

REQUIREMENTS:

Our guideline named INFIGRATINIB (Truseltiq) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma)
B. Prescribed by or in consultation with a hematologist/oncologist
C. Patient is 18 years of age or older
D. You have a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test

References:

1. Truseltiq package insert. Brisbane, CA. QED Therapeutics, Inc. Revised May 2021. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LAPATINIB DITOSYLATE Edition 2	TYKERB	7/29/2024	07/29/2022

REQUIREMENTS:

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

A. Patient has a diagnosis of advanced or metastatic breast cancer
B. The patient has tumors which are human epidermal growth factor receptor 2 (HER2) positive
C. Prescribed by or in consultation with a hematologist or oncologist
D. If the requested medication will be used in combination with Xeloda (capecitabine), approval also requires ALL of the following:
    1. The patient has advanced or metastatic breast cancer
    2. Patient has previously received treatment with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)
E. If the requested medication will be used in combination with Femara (letrozole), approval also requires ALL of the following:
    1. The patient has tumors which are hormone receptor-positive
    2. The patient has metastatic breast cancer
    3. The patient is postmenopausal

References:

1. Tykerb package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised March 2022. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ABALOPARATIDE Edition 3	TYMLOS	7/29/2024	07/29/2023

REQUIREMENTS:

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

A. The patient meets ONE of the following:
    1. The patient is a biological female and has a diagnosis of postmenopausal osteoporosis
    2. The patient is a biological male and has a diagnosis of osteoporosis at high risk for fracture
B. The patient has not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo
C. The patient meets ONE of the following criteria:
    1. The patient is at high risk for fractures as defined by ONE of the following:
        i. History of fragility or osteoporoticfracture(s)
        ii. Bone mineral density (BMD) T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip and/or 33% (one third) radius (wrist)
        iii. T-score between -1.0 and -2.5 AND FRAX score greater than or equal to 20% for any major fracture or greater than or equal to 3% for hip fracture
    2. The patient is unable to use oral therapy (e.g., 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 in their daily routine)
    3. The patient has had a previous trial and failure of ONE oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication

References:

1. Tymlos package insert. Boston, MA. Radius Health Inc. Revised December 2023. Accessed June 2024.
2. Camacho PM, Petak SM, Binkley N, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS/AMERICAN COLLEGE OF ENDOCRINOLOGY CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS-2020 UPDATE. Endocr Pract. 2020;26(Suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL.
3. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's Guide to Prevention and Treatment of Osteoporosis [published correction appears in Osteoporos Int. 2015 Jul;26(7):2045-7]. Osteoporos Int. 2014;25(10):2359-2381. doi:10.1007/s00198-014-2794-2.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
UBROGEPANT Edition 2	UBRELVY	07/29/2024	07/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named UBROGEPANT (Ubrelvy) requires the following rule(s) be met for approval:

A. The patient is being treated for acute migraine headache
B. The patient 18 years of age or older
C. The patient has had previous trial of at least ONE triptan (e.g., sumatriptan, rizatriptan, etc.), unless there is a contraindication or the patient has confirmed cardiovascular disease

RENEWAL CRITERIA
Our guideline named UBROGEPANT (Ubrelvy) requires the following rule(s) be met for renewal:

A. Patient is being treated for acute migraine headache
B. The patient meets ONE of the following:
    1. The patient has 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 [MIGRAINEACT])
    2. The patient has 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

References:

1. Ubrelvy package insert. Madison, NJ. Allergan, Inc. Revised February 2023. Accessed June 2024.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RAVULIZUMAB-CWVZ Edition 4	ULTOMIRIS	7/29/2024	7/29/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named RAVULIZUMAB-CWVZ (Ultomiris) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Paroxysmal nocturnal hemoglobinuria (PNH)
    2. Atypical hemolytic uremic syndrome (aHUS)
    3. Generalized myasthenia gravis (gMG)
    4. Neuromyelitis optica spectrum disorder (NMOSD)
B. For patients with paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:
    1. The patient is 1 month of age or older weighing 5kg or greater
    2. There is documentation of the patient's current weight
    3. The requested medication is prescribed by or given in consultation with a hematologist
    4. The patient has confirmed paroxysmal nocturnal hemoglobinuria as supported by ALL of the following via flow cytometry:
        a. At least 2 different GPI-protein deficiencies (i.e., CD55, CD59) on at least 2 cell lineages (i.e., erythrocytes, granulocytes)
        b. Paroxysmal nocturnal hemoglobinuria granulocyte clone size of 10% or greater
    5. The patient meets ONE of the following:
        a. The patient is transitioning from alternative complement inhibitor therapy (such as Soliris)
        b. There is evidence of intravascular hemolysis (e.g., lactate dehydrogenase level of at least 1.5 times the upper limit of normal, hemoglobinuria, etc.)
        c. The patient has history of major adverse vascular event from thromboembolism
C. For patients with atypical hemolytic uremic syndrome (aHUS), approval also requires:
    1. The patient is one month of age or older weighing 5kg or greater
    2. There is documentation of the patient's current weight
    3. NOTE: The request will not be approved if the patient has a diagnosis of Shiga toxin E. coli related hemolytic uremic syndrome

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: RAVULIZUMAB-CWVZ (CONTINUED)

D. For patients with generalized myasthenia gravis (gMG), approval also requires:
    1. The patient is 18 years of age or older weighing 40kg or greater
    2. Therapy is prescribed by or in consultation with a neurologist
    3. The patient diagnosis is confirmed by a positive anti-acetylcholine receptor (AChR) antibody test
    4. The patient has Myasthenia Gravis Foundation of America class II, III, or IV
    5. The patient has had a trial of corticosteroids, unless there is contraindication
    6. The patient meets ONE of the following:
        a. Failure of treatment with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate, etc.)
        b. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange
E. For patients with Neuromyelitis optica spectrum disorder (NMOSD), approval also requires:
    1. The patient is at least 18 years of age or older weighing 40kg or greater
    2. Therapy is prescribed by or in consultation with a neurologist
    3. The patients diagnosis is confirmed by a positive serological test for anti-aquporin-4 (AQP4) antibodies
    4. The patient has at least ONE of the following core clinical characteristics:
        a. Optic neuritis
        b. Acute myelitis
        c. Area postrema syndrome
        d. Acute brainstem syndrome
        e. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
        f. Symptomatic cerebral with NMOSD-typical brain lesions
    5. The patient will NOT concomitantly use rituximab, inevlizumab, satralizumab, or eculizumab with Ultomiris

RENEWAL CRITERIA

Our guideline named RAVULIZUMAB-CWVZ (Ultomiris) requires the following rule(s) be met for renewal:

A. The patient has 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)
    3. Generalized myasthenia gravis (gMG)
B. For patients with paroxysmal nocturnal hemoglobinuria, renewal also requires:
    1. The patient has shown a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels, etc.) compared to baseline
    2. There is documentation patient's current weight is 5kg or greater
C. For patients with atypical hemolytic uremic syndrome, renewal also requires:
    1. There is documentation patient's current weight is 5kg or greater

D. For patients with generalized myasthenia gravis, renewal also requires:
    1. The patient has shown clinical benefit according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool, etc.) compared to baseline
    2. There is documentation patient's current weight is 40kg or greater
E. For patients with Neuromyelitis optica spectrum disorder (NMOSD), approval also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms while on Ultomiris therapy

REQUIREMENTS: RAVULIZUMAB-CWVZ (CONTINUED)

References:

1. Ultomiris package insert. Boston, MA. Alexion Pharmaceuticals, Inc. Reviewed June 2024. Accessed June 2024.
2. Borowitz MJ, Craig FE, Digiuseppe JA, et al. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Cytometry B Clin Cytom. 2010;78(4):211-230. doi:10.1002/cyto.b.20525.
3. Loirat C, Fakhouri F, Ariceta G, et al. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. Pediatr Nephrol. 2016;31(1):15-39. doi:10.1007/s00467-015-3076-8.
4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790.
5. Jaretzki A 3rd, Barohn RJ, Ernstoff RM, et al. Myasthenia gravis: recommendations for clinical research standards. Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America. Ann Thorac Surg. 2000;70(1):327-334. doi:10.1016/s0003-4975(00)01595-2.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CAPMATINIB Edition 1	TABRECTA	7/29/2024	6/1/2021

REQUIREMENTS:

Our guideline named CAPMATINIB (Tabrecta) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient is 18 years of age or older
D. Patient has tumors with a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

References:

1. Tabrecta package insert. East Hanover, NJ, Novartis Pharmaceuticals Corporation. Revised March 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DABRAFENIB MESYLATE Edition 3	TAFINLAR	7/29/2024	07/29/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Unresectable or metastatic melanoma
    2. Metastatic non-small cell lung cancer (NSCLC)
    3. Resectable melanoma
    4. Locally advanced or metastatic anaplastic thyroid cancer (ATC)
    5. Unresectable or metastatic solid tumors
    6. Low-grade Glioma (LGG)
B. For patients with unresectable or metastatic melanoma, approval also requires ONE of the following:
    1. Patient has BRAF V600E mutation as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent
    2. Patient has BRAF V600E or V600K mutations as detected by an FDA-approved test AND the requested medication will be used in combination with Mekinist (trametinib)
C. For patients with resectable melanoma, approval also requires ALL of the following:
    1. Patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
    2. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
    3. The patient had involvement of lymph node(s) following complete resection of the melanoma and complete lymphadenectomy
D. For patients with metastatic non-small cell lung cancer, approval also requires ALL of the following:
    1. Patient has BRAF V600E mutation as detected by an FDA-approved test
    2. The requested medication will be used in combination with Mekinist (trametinib)
E. For patients with locally advanced or metastatic anaplastic thyroid cancer, approval also requires ALL of the following:
    1. Patient has BRAF V600E mutation as detected by an FDA-approved test
    2. The requested medication will be used in combination with Mekinist (trametinib)
    3. Patient has no satisfactory locoregional treatment options available

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: DABRAFENIB (CONTINUED)

F. For patients with unresectable or metastatic solid tumors, approval also requires:
    1. The patient is 6 years of age or older
    2. The patient has BRAF V600E mutation as detected by an FDA-approved test
    3. The requested medication will be used in combination with Mekinist (trametinib)
    4. The patient has progressed following prior treatment and does not have any satisfactory alternative treatment options
G. For patients with low-grade glioma, approval also requires:
    1. The patient is 1 year of age or older
    2. The patient has BRAF V600E mutation as detected by an FDA-approved test

References:

1. Tafinlar package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Reviewed July 2024. Accessed July 2024

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LANADELUMAB-FLYO Edition 1	TAKHZYRO	07/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named LANADELUMAB (Takhzyro) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 2 years of age or older
    a. If the patient is between 2 and 12 years of age, therapy will be administered by either a healthcare provider or a properly trained caregiver
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat, etc.)

RENEWAL CRITERIA
Our guideline named LANADELUMAB (Takhzyro) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

References:

1. Takhzyro package insert. Lexington, MA. Dyax Corp. Revised February 2023. Accessed July 2024.
2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132-150.e3. doi:10.1016/j.jaip.2020.08.046.
3. Betschel S, Badiou J, Binkley K, et al. Correction to: The International/Canadian Hereditary Angioedema Guideline. Allergy Asthma Clin Immunol. 2020;16:33. Published 2020 May 6. doi:10.1186/s13223-020-00430-4.
4. Betschel S, Badiou J, Binkley K, et al. The International/Canadian Hereditary Angioedema Guideline [published correction appears in Allergy Asthma Clin Immunol. 2020 May 6;16:33]. Allergy Asthma Clin Immunol. 2019;15:72. Published 2019 Nov 25. doi:10.1186/s13223-019-0376-8.
5. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema-The 2017 revision and update. Allergy. 2018;73(8):1575-1596. doi:10.1111/all.13384.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ERLOTINIB Edition 2	TARCEVA	7/22/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses
    1. Metastatic non-small cell lung cancer
    2. Locally advanced, unresectable, or metastatic pancreatic cancer
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If patient has metastatic non-small cell lung cancer (NSCLC), approval also requires:
    1. Patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA (Food and Drug Administration)-approved test
D. If patient has locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires BOTH of the following:
    1. The requested medication will be used in combination with gemcitabine
    2. The medication will be used as a first line treatment

References:

1. Tarceva package insert. South San Francisco, CA. Genentech USA, Inc. Revised October 2016. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

BEXAROTENE Edition 2			
Generic	Brand	Reviewed	Effective Date
BEXAROTENE SOFTGEL	TARGRETIN	7/29/2024	7/29/2023
BEXAROTENE 1% TOPICAL GEL	TARGRETIN		

REQUIREMENTS:

Our guideline named BEXAROTENE (Targretin) requires the following rule to be met for approval:

A. The patient has a diagnosis of cutaneous T-cell lymphoma (CTCL)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. If the request is for oral bexarotene, approval also requires:
    1. The patient's condition is refractory to at least ONE previous systemic therapy such as gemcitabine, methotrexate, liposomal doxorubicin, bortezomib, etc.
D. If the request is for topical bexarotene treatment, approval also requires:
    1. The patient has cutaneous T-cell lymphoma (CTCL) Stage IA or IB
    2. The patient meets ONE of the following:
        a. The patient's condition is refractory or persistent after previous therapy
        b. The patient has not tolerated previous therapy

References:

1. Targretin topical package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised October 2016. Accessed June 2024.
2. Targretin oral package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised April 2020. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FOSTAMATINIB Edition 2	TAVALISSE	7/29/2024	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named FOSTAMATINIB (Tavalisse) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of chronic immune thrombocytopenia (ITP)
B. Patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist or immunologist
D. Patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days OR patient has an active bleed
E. Patient has had a previous trial of or contraindication to corticosteroids or immunoglobulins OR an insufficient response to a splenectomy
F. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Promacta (eltrombopag)
G. Patient has a previous trial of or contraindication to Doptelet (avatrombopag), Nplate (romiplostim), or Promacta (eltrombopag)

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

A. Patient has chronic immune thrombocytopenia (ITP)
B. Patient has had a clinical response to therapy, as defined by an increase in platelet count or a reduction in bleeding events, compared to baseline

References:

1. Tavalisse package insert. South San Francisco, CA. Rigel Pharmaceuticals, Inc. Revised April 2018. Accessed June 2024.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia [published correction appears in Blood Adv. 2020 Jan 28;4(2):252]. Blood Adv. 2019;3(23):3829-3866. doi:10.1182/bloodadvances.2019000966.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INOTERSEN SODIUM Edition 3	TEGSEDI	7/29/2024	07/29/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named INOTERSEN (Tegsedi) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
    1. Prescribing provider is registered with the TEGSEDI REMS PROGRAM and attests to applicable requirements within.
D. The patient has symptomatic polyneuropathy as determined by a baseline assessment (i.e., modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, etc.)
E. The patient has a documented diagnosis of hATTR as confirmed by ONE of the following:
    1. Biopsy 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. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient has a clinical response to treatment with demonstrated improvement in severity of neuropathy per assessment (i.e., modified Neuropathy Impairment Scale+7 [mNIS+7] composite score, the Norfolk Quality of Life-Diabetic Neuropathy [QoL-DN] total score, polyneuropathy disability [PND] score, FAP disease stage, etc.) compared to baseline.

References:

1. Tegsedi package insert. Waltham, MA. Sobi, Inc. Revised January 2024. Accessed June 2024.
2. Luigetti M, Romano A, Di Paolantonio A, Bisogni G, Sabatelli M. Diagnosis and Treatment of Hereditary Transthyretin Amyloidosis (hATTR) Polyneuropathy: Current Perspectives on Improving Patient Care. Ther Clin Risk Manag. 2020;16:109-123. Published 2020 Feb 21. doi:10.2147/TCRM.S219979.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BREMELANOTIDE Edition 2	VYLEESI	7/29/2024	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named BREMELANOTIDE (Vyleesi) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)
C. The patient meets 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 condition, a problem within the relationship or the effects of a medication or drug substance
    3. HSDD symptom causes marked distress or interpersonal difficulty
D. The patient is a premenopausal female
E. The patient has had a previous trial of bupropion, unless there is a contraindication
F. Patient is NOT currently using Addyi (flibanserin)

RENEWAL CRITERIA
Our guideline named BREMELANOTIDE (Vyleesi) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)
B. Patient is a premenopausal female
C. Patient is NOT currently using Addyi (flibanserin)
D. The patient has demonstrated continued improvement in symptoms of HSDD (e.g., increased sexual desire, lessened sexual distress, etc.)

References:

1. Vyleesi package insert. Cranbury, NJ. Palatin Technologies Inc. Revised October 2020. Accessed June 2024.
2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Female Sexual Dysfunction: ACOG Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists, Number 213. Obstet Gynecol. 2019;134(1):e1-e18. doi:10.1097/AOG.0000000000003324.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LEFAMULIN Edition 2	XENLETA	7/29/2024	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient's infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
C. The patient meets at least ONE of the following criteria:
    1. Request is for continuation of therapy initiated in a hospital from which member was discharged
    2. Request is for continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication
    3. The patient has a diagnosis of community-acquired bacterial pneumonia (CABP) and meets ONE of the following criteria :
        i. Antimicrobial susceptibility test is available AND the infection site culture results indicate pathogenic organism(s) exhibiting BOTH of the following:
            i. Resistance to at least TWO standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
            ii. Susceptibility to lefamulin (Xenleta)
        ii. Antimicrobial susceptibility test is unavailable AND the patient has had a trial of at least TWO standard of care agents (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid, etc.) for community-acquired bacterial pneumonia, unless there is a contraindication

References:

1. Xenleta package insert. Fort Washington, PA. Nabriva Therapeutics US, Inc. Revised June 2021. Accessed July 2024.
2. Metlay JP, Waterer GW, Long AC et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia: An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Disease Society of America, Am J Respir Crit Care Med. 2019 Oct; 200(7): e45-67.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OMALIZUMAB Edition 3	XOLAIR	7/29/2024	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named OMALIZUMAB (Xolair) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Nasal polyps
    2. Chronic spontaneous urticaria (CSU)
    3. Moderate to severe persistent asthma
B. For patients with nasal polyps, approval also requires ALL of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with an otolaryngologist, allergist, or immunologist
    3. Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
    4. The patient is currently adherent to maintenance therapy with an intranasal corticosteroid (e.g., fluticasone, mometasone, etc.)
    5. The patient has inadequately controlled disease as determined by ONE of the following:
        a. Use of systemic corticosteroids in the past 2 years
        b. Endoscopic sinus surgery
    6. The requested medication will be used as add-on maintenance treatment in conjunction with maintenance intranasal steroids
    7. The patient is not being treated on the requested medication concurrently with Dupixent or an anti-IL-5 biologic (e.g., Nucala, etc.)

(Criteria continued on next page)

REQUIREMENTS: OMALIZUMAB (CONTINUED)

C. For patients with chronic spontaneous urticaria (CSU), approval also requires ALL of the following:
    1. The patient is 12 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
    3. The patient still experiences hives on most days of the week for at least 6 weeks
    4. The patient remains symptomatic despite a trial with second generation (non- sedating) H1 antihistamine therapy (i.e., cetirizine, desloratadine, fexofenadine, levocetirizine, or loratadine) at maximized dosing used continuously for at least 2 weeks
    5. Patient remains symptomatic despite a two-week continuous trial of at least ONE of the following:
        a. Higher dose (up to four times the recommended dose) of the second generation (non-sedating) H1 antihistamine therapy
        b. Addition of another second generation (non-sedating) H1 antihistamine to existing therapy
        c. Addition of a leukotriene receptor antagonist (LTRA) to existing therapy d. Addition of a H2-antagonist to existing therapy
        d. Addition of a first generation H1 antihistamine taken at bedtime to existing therapy

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: OMALIZUMAB (CONTINUED)

D. For patients with moderate to severe persistent asthma, approval requires ALL of the following:
    1. The patient is 6 years of age or older
    2. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
    3. The patient has a baseline positive skin prick or RAST test to a perennial aeroallergen
    4. The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
    5. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    6. The patient has asthma that is uncontrolled while maintained on an ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE or more of the following:
        a. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
        b. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
    7. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler
    8. The patient is not being treated on the requested medication concurrently with Dupixent, Tezspire, or an anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra, etc.)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: OMALIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named OMALIZUMAB (Xolair) the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Nasal polyps
    2. Chronic spontaneous urticaria (CSU)
    3. Moderate to severe persistent asthma
B. For patients with nasal polyps, renewal also requires:
    1. The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, improved sense of smell, reduced size of polyps, etc.)
C. For patients with chronic spontaneous urticaria, renewal also requires:
    1. The patient has had a clinical benefit compared to baseline (e.g., decreased severity of itching, decreased number of hives, decreased size of hives, etc.)
D. For patients with moderate to severe persistent asthma, renewal also requires:
    1. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    2. The patient has shown a clinical response as evidenced by at least ONE of the following:
        a. Reduction in asthma exacerbation(s) compared to baseline
        b. Decreased use of rescue medications
        c. Increase in percent predicted FEV_1 from pretreatment baseline
        d. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

References:

1. Xolair package insert. South San Francisco, CA. Genentech, Inc. Revised February 2024. Accessed June 2024.
2. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. J Allergy Clin Immunol. 2020;146(6):1217-1270. doi:10.1016/j.jaci.2020.10.003.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
4. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. Allergy. 2019;74(12):2312-2319. doi:10.1111/all.13875.
5. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-1277. doi:10.1016/j.jaci.2014.02.036.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GILTERITINIB FUMARATE Edition 2	XOSPATA	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient is 18 years of age or older
D. The patient has a FMS-like tyrosine kinase 3 (FLT3) mutation, as detected by a Food and Drug Administration-approved test

References:

1. Xospata package insert. Northbrook, Illinois. Astellas Pharma US, Inc. Revised January 2022. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IDELALISIB Edition 2	ZYDELIG	7/29/2024	7/29/2022

REQUIREMENTS:

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

A. Patient has a diagnosis of relapsed chronic lymphocytic leukemia (CLL)
B. The requested medication will be used in combination with rituximab in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities

References:

1. Zydelig package insert. Foster City, CA. Gilead Sciences, Inc. Revised July 2022. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CERITINIB Edition 2	ZYKADIA	7/29/2024	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient has a tumor that is anaplastic lymphoma kinase (ALK) positive as confirmed by a Food and Drug Administration-approved test

References:

1. Zykadia package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised October 2021. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ILOPROST Edition 1	VENTAVIS	7/29/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ILOPROST (Ventavis) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization Group 1
B. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient has documentation confirming a diagnosis of pulmonary arterial hypertension based on right heart catheterization with the following 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. The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms

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

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization Group 1
B. The patient meets at least ONE of the following:
    1. The patient has shown improvement from baseline in the 6-minute walk distance test
    2. The patient has remained stable in the 6-minute walk distance test AND their New York Heart Association-World Health Organization (NYHA-WHO) functional class has remained stable or improved

References:

1. Ventavis package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised March 2022. Accessed July 2024
2. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. Chest. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.
3. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619. doi:10.1016/j.jacc.2009.01.004.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALPELISIB Edition 1	VIJOICE	07/29/2024	07/29/2022

REQUIREMENTS:

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

A. Patient is 2 years of age or older
B. Patient has a diagnosis of PIK3CA-related overgrowth spectrum (PROS)
C. Patient has documented evidence of mutation in the PIK3CA gene
D. Prescribed by or in consultation with a PROS specialist (i.e., plastic surgeon, dermatologist, medical geneticist, oncologist, otolaryngologist, etc.)

RENEWAL CRITERIA

Our guideline named ALPELISIB (Vijoice) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of PIK3CA-related overgrowth spectrum (PROS)
B. Patient has experienced ONE of the following:
    a. Reduction in size or volume of lesion(s) compared to baseline
    b. No appearance of new lesion(s) compared to baseline

References:

1. Vijoice package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised April 2024. Accessed May 2024.
2. Keppler-Noreuil KM, Rios JJ, Parker VE, et al. PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. Am J Med Genet A. 2015;167A(2):287-295. doi:10.1002/ajmg.a.36836.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LAROTRECTINIB Edition 2	VITRAKVI	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a solid tumor
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. The patient's tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation, as determined by an FDA approved test
D. The patient's tumor is metastatic or surgical resection is likely to result in severe morbidity
E. There are no satisfactory alternative treatments, or the patient's tumor has gotten worse after treatment
F. Requests for Vitrakvi oral solution also require ONE of the following:
    1. The patient is a pediatric patient (less than 18 years of age)
    2. Patient is unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. The patient has other medical need for the oral solution

References:

1. Vitrakvi package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Reviewed November 2023. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DACOMITINIB Edition 2	VIZIMPRO	7/29/2024	7/29/2023

REQUIREMENTS:

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

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Therapy will be prescribed by, or in consultation with, an oncologist
C. Patient has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA (Food and Drug Administration)-approved test
D. The requested medication will be used as first-line treatment

References:

1. Vizimpro package insert. New York, NY. Pfizer Labs. Reviewed. December 2020. Accessed June 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR Edition 2	VOSEVI	07/29/2024	07/29/2022

REQUIREMENTS:

Our guideline named SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (Vosevi) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
D. The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
G. For patients with chronic HCV genotype 1b, 2, 4, 5, or 6, approval also requires:
    1. The patient has previously failed a full course of therapy with a direct-acting antiviral (DAA) regimen that contains an NS5A inhibitor (e.g., ledipasvir/sofosbuvir (Harvoni), sofosbuvir/velpatasvir (Epclusa), Mavyret, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination, etc.)
H. For patients with chronic HCV genotype 1a or genotype 3, approval also requires ONE of the following:
    1. The patient has previously failed a full course of therapy with a DAA regimen that contains an NS5A inhibitor (e.g., ledipasvir/sofosbuvir (Harvoni), sofosbuvir/velpatasvir (Epclusa), Mavyret, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination, etc.)
    2. The patient has previously failed a full course of therapy with a DAA regimen that contains sofosbuvir (Sovaldi) without an NS5A inhibitor (e.g., Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi, etc.)

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has moderate or severe hepatic impairment (Child-Pugh B or C)
B. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (CONTINUED)

References:

1. Vosevi package insert. Foster City, CA. Gilead Sciences, Inc. Revised November 2019. Accessed July 2024.
2. Ghany MG, Morgan TR; AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases-Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. Hepatology. 2020 Feb;71(2):686-721.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EPTINEZUMAB-JJMR Edition 4	VYEPTI	07/29/2024	07/29/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named EPTINEZUMAB-JJMR (Vyepti) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches
B. If patient has episodic migraines (0-14 headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least 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, or cyproheptadine
    4. The patient has had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, Emgality, or Nurtec ODT
C. If patient has chronic migraines (15 or more headache days per month), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has 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
    4. Patient has had a previous trial of TWO of the preferred CGRP inhibitors:
        1. Aimovig, Ajovy, or Emgality

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: EPTINEZUMAB-JJMR (CONTINUED)

RENEWAL CRITERIA

Our guideline named EPTINEZUMAB-JJMR (Vyepti) requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines
B. Patient has responded to therapy as evidenced by at least ONE of the following:
    a. The patient has experienced a reduction in migraine or headache frequency by at least 2 days per month compared to baseline
    b. The patient has experienced a reduction in migraine severity compared to baseline
    c. The patient has experienced a reduction in migraine duration compared to baseline

References:

1. Vyepti package insert. Bothell, WA. Lundbeck Seattle BioPharmaceuticals, Inc. Revised October 2022. Accessed June 2024.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Ce
phalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

Generic	Brand	Reviewed	Effective Date
DONANEMAB Edition 1	KISUNLA	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named DONANEMAB (Kisunla) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Alzheimer's disease
B. The patient has mild cognitive impairment or mild dementia stage of the disease, defined as an MMSE of 10-26

References:

1. Kisunla™ intravenous infusion [prescribing information]. Indianapolis, IN: Lilly; July 2024.

Generic	Brand	Reviewed	Effective Date
LAZERTINIB Edition 1	LAZCLUZE	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named LAZERTINIB (Lazcluze) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations in tumor or plasma specimens
B. The patient is at least 18 years of age or older
C. Therapy will be used in conjunction with amivantamab
D. Therapy will be prescribed by, or in consultation with, an oncologist

References:

1. Lazcluze™ tablets [prescribing information]. Horsham, PA: Janssen; August 2024.

Generic	Brand	Reviewed	Effective Date
ATIDARSAGENE Edition 1	LENMELDY	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named ATIDARSAGENE requires the following rule(s) be met for approval:

A. The patient has a diagnosis of presymptomatic late infantile (PSLI), presymptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD)
B. Therapy will be prescribed by, or in consultation with, an MLD specialist
C. The diagnosis was confirmed by all of the following: Biochemical testing documenting ARSA activity below the normal range for the laboratory performing the test; the presence of two disease-causing ARSA alleles, either known or novel mutations, identified on genetic testing; AND if novel mutations are identified, a 24-hour urine collection showing elevated sulfatide levels

References:

1. Lenmeldy Package insert. Northbrook, IL. Marathon Pharmaceuticals. Revised August 2022. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
PONESIMOD Edition 1	PONVORY	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named BREXPIPRAZOLE (Rexulti) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of a relapsing form of multiple sclerosis.
B. The patient is at least 18 years of age
C. The patient has had a trial and failure to at least ONE oral preferred generic option

References:

1. Ponvory Package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised March 2021. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
BREXPIPRAZOLE Edition 1	REXULTI	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named BREXPIPRAZOLE (Rexulti) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    a. Schizophrenia
    b. Alzheimer's Disease
    c. Major Depressive Disorder
B. For a diagnosis of Schizophrenia, approval also requires:
    a. The patient is at least 13 years of age or older
C. For a diagnosis of Alzheimer's Disease, approval also requires:
    a. The requested product will be used to treat agitation associate with the diagnosis
D. For a diagnosis of Major Depressive Disorder, approval also requires:
    a. The patient is at least 18 years of age or older

References:

1. Rexulti Package insert. Deerfield, IL. Otsuko Pharmaceuticals, Inc. Revised May 2023. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
VORASIDENIB Edition 1	VORANIGO	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named VORASIDENIB (Voranigo) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Grade 2 astrocytoma or oligodendroglioma
B. The patient is at least 12 years of age or older
C. Therapy will be prescribed by, or in consultation with, an oncologist

References:

1. Voranigo® tablets [prescribing information]. Boston, MA: Servier; August 2024.

Generic	Brand	Reviewed	Effective Date
ROFLUMILAST Edition 1	ZORYVE	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named ROFLUMILAST (Zoryve) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of plaque psoriasis
B. The requested medication is prescribed by or given in consultation with a dermatologist
C. The patient has had a previous trial of or contraindication to 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

References:

1. Zoryve Package insert. Westlake Village, CA. Arcutis Biotherapeutics, Inc. Revised July 2022. Accessed August 2024.

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Generic	Brand	Reviewed	Effective Date
ARIPIPRAZOLE Edition 1	ABILIFY MYCITE	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named ARIPIPRAZOLE (Abilify Mycite) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. The patient has one of the following diagnoses:
    a. Schizophrenia
    b. Bipolar I Disorder
    c. Major Depressive Disorder
C. For a diagnosis of Bipolar I Disorder, approval also requires:
    a. Therapy will be used as acute treatment of manic or mixed episodes either as monotherapy or as an adjunct to lithium or valproate OR
    b. Therapy will be used as maintenance treatment either as monotherapy or as an adjunct to lithium or valproate
D. For a diagnosis of Major Depressive Disorder, approval also requires:
    a. Therapy will be used as adjunct therapy, not as monotherapy

References:
1. Abilify Mycite Package insert. Tokyo, Japan. Otsuko America Pharmaceuticals, Inc. Revised December 2020. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
LIFILEUCEL INFUSION Edition 1	AMTAGVI	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named LIFILEUCEL INFUSION requires the following rule(s) be met for approval:

A. The patient has a diagnosis of unresectable or metastatic melanoma
B. The patient is at least 18 years of age or older
C. The patient has had a trial of a programmed death receptor-1 (PD-1) blocking antibody, and if *BRAF V600* mutation positive, a BRAF inhibitor with or without a MEK inhibitor.
D. Therapy will be prescribed by, or in consultation with, an oncologist

References:

1. Amtagvi Package insert. Philadelphia PA. Iovance Biotherapeutics, Inc. Revised February 2024. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
LEVACETYLLEUCINE Edition 1	AQNEURSA	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named LEVACETYLLEUCINE (Aqneursa) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Niemann-Pick disease type C (NPC)
B. The patient weighs at least 15 kg
C. The requested therapy will be utilized for the treatment of the neurological manifestations of NPC

References:

1. Aqneursa™ granules [prescribing information]. Austin, TX: IntraBio; September 2024.

Generic	Brand	Reviewed	Effective Date
DEXTROMETHORPHAN/ BUPROPION Edition 1	AUVELITY	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named DEXTROMETHORPHAN/BUPROPION requires the following rule(s) be met for approval:

A. Diagnosis of major depressive disorder (MDD), and
B. The patient is 18 years of age or older, and
C. The patient has had a previous trial of or contraindication to at least TWO antidepressant therapies (e.g. selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), bupropion, mirtazapine, vilazodone, etc).

References:

1. Auvelity Package insert. New York, NY. Axsome Therapeutics. Revised August 2022. Accessed August 2024.

Generic	Reviewed	Effective Date
DEFLAZACORT Edition 1	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named DEFLAZACORT requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Duchenne muscular dystrophy, and has been confirmed via genetic testing
B. The patient is 5 years of age or older, and
C. Therapy will be prescribed by, or in consultation with, a neurologist specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. The patient has had at least a 6 month trial of prednisone or prednisolone, and there is documented deterioration in ambulation, functional status, or pulmonary function while on these products

References:

1. Emflaza Package insert. Northbrook, IL. Marathon Pharmaceuticals. Revised August 2022. Accessed August 2024.

FACTOR VIII REPLACEMENT THERAPY			
Generic	Brand	Reviewed	Effective Date
ANTIHEMOPHILIC FACTOR, RECOMBINANT Edition 1	ADYNOVATE AFSTYLA ALTUVIIIO ELOCTATE ESPEROCT JIVI KOGENATE KOVALTRY NOVOEIGHT XYNTHA	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named FACTOR VIII REPLACEMENT THERAPY requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Hemophilia A
B. The requested product will be used for ONE of the following:
    a. On-demand treatment and control of bleeding episodes
    b. Perioperative bleed management
    c. Routine prophylaxis to reduce the frequency of bleeding episodes
C. The requested product will be prescribed by, or in consultation with, a hematologist

References:

1. Adynovate Package insert. Lexington, MA. Takeda Pharmaceuticals, Inc. Revised March 2023. Accessed August 2024.
2. Afstyla Package insert. Kankakee, IL.CDL Behring LLC. Revised June 2023. Accessed August 2024.
3. Altuviiio Package insert. Waltham, MA. Sanofi.. Revised May 2024. Accessed August 2024.
4. Eloctate Package insert. Cambridge, MA. Biogen, Inc.. Revised June 2023. Accessed August 2024.
5. Esperoct Package insert. Plainsboro, NJ. NovoNordisk. Revised February 2024. Accessed August 2024.
6. Jivi Package insert. Whippany, NJ. Bayer. Revised June 2023. Accessed August 2024.
7. Kogenate Package insert. Cambridge, MA. Biogen, Inc.. Revised May 2014. Accessed August 2024.
8. Kovaltry Package insert. Whippany, NJ. Bayer. Revised October 2021. Accessed August 2024.
9. Novoeight Package insert. Plainsboro, NJ. NovoNordisk. Revised February 2018. Accessed August 2024.
10. Xyntha Package insert. Philadelphia, PA. Wyeth Pharmaceuticals. Revised August 2020. Accessed August 2024.

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Generic	Reviewed	Effective Date
FINGOLIMOD Edition 1	10/21/2024	1/1/2025

REQUIREMENTS:

Our guideline named FINGOLIMOD requires the following rules be met for approval:

A. The patient has a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
B. The patient is 10 years of age and older

References:

1. Fingolimod package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2023. Accessed August 2024.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

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HIV-1 COMBINATION TREATMENT			
Edition 1 - Generic	Brand	Reviewed	Effective Date
EFAVIRENZ/EMTRICITABINE/ TENOFOVIR DISOPROXIL FUMARATE	ATRIPLA	10/21/2024	1/1/2025
EMTRICITABINE/RILPIVIRINE/ TENOFOVIR DISOPROXIL FUMARATE	COMPLERA		
DORAVIRINE/LAMIVUDINE/ TENOFOVIR DISOPROXIL FUMARATE	DELSTRIGO		
ELVITEGRAVIR/COBICISTAT/ EMTRICITABINE/TENOFOVIR DISOPROXIL FUMARATE	STRIBILD		

REQUIREMENTS:

Our guideline named HIV-1 COMBINATION TREATMENT requires the following rule(s) be met for approval:

A. The patient has a diagnosis of HIV-1 infection
B. The patient has had a previous trial of a formulary preferred generic regimen, or a generic regimen would be inappropriate
C. For Atripla, approval also requires that the patient is at least 12 years of age or older
D. For Complera, approval also requires that the patient weigh at least 35 kg
E. For Delstrigo and Stribild, approval also requires that the patient is at least 18 years of age or older

References:

1. Atripla Package insert. Devens, MA. Bristol Myers Squibb. Revised January 2015. Accessed August 2024.
2. Complera Package insert. Foster City, CA. Gilead Sciences. Revised October 2018. Accessed August 2024.
3. Delstrigo Package insert. Whitehouse Station, NJ. Merck & Co. Revised August 2018. Accessed August 2024.
4. Stribild Package insert. Foster City, CA. Gilead. Revised September 2016. Accessed August 2024.

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Generic	Brand	Reviewed	Effective Date
CABOZANTINIB Edition 2	COMETRIQ, CABOMETYX	10/21/2024	10/29/2021

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

REQUIREMENTS:

COMETRIQ

Our guideline named CABOZANTINIB (Cometriq) requires the following rule be met for approval:

A. The patient has a diagnosis of progressive, metastatic medullary thyroid cancer

CABOMETYX

Our guideline named CABOZANTINIB (Cabometyx) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Advanced renal cell carcinoma
    2. Hepatocellular carcinoma
    3. Locally advanced or metastatic differentiated thyroid cancer (DTC)
B. If Cabometyx will be used in combination with Opdivo (nivolumab), approval also requires ALL of the following:
    1. The patient has advanced renal cell carcinoma
    2. The patient has not received prior treatment for advanced renal cell carcinoma
C. If the patient has hepatocellular carcinoma, approval also requires:
    1. The patient has previously been treated with Nexavar (sorafenib)
D. If the patient has locally advanced or metastatic differentiated thyroid cancer (DTC), approval also requires ALL of the following:
    1. The patient is 12 years of age or older
    2. The patient's disease has progressed following prior treatment with VEGFR-targeted therapy (e.g., Nexavar [sorafenib], Lenvima [lenvatinib], Caprelsa [vandetanib], etc.)
    3. The patient has tried and failed treatment with radioactive iodine or is ineligible to receive radioactive iodine treatment

References:

1. Cabometyx package insert. Alameda, CA. Exelixis, Inc. Revised September 2023. Accessed September 2024.
2. Cometriq package insert. Alameda, CA. Exelixis, Inc. Revised August 2023. Accessed August 2024.

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PENICILLAMINE Edition 2			
Generic	Brand	Reviewed	Effective Date
PENICILLAMINE	CUPRIMINE	10/21/2024	10/29/2021
PENICILLAMINE	DEPEN		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PENICILLAMINE (Cuprimine, Depen) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Wilson's disease
    2. Cystinuria
    3. Active rheumatoid arthritis
B. For patients with Wilson's disease, approval also requires ALL of the following:
    1. The requested medication is prescribed by or given in consultation with a hepatologist
    2. The patient has maintained a low copper diet (less than 2mg copper per day)
    3. For Cuprimine requests, the patient must have tried Depen (penicillamine) unless there is a contraindication
    4. The patient must meet ONE of the following:
        a. The patient has blood levels of the copper-protein ceruloplasmin less than 20mg/dL
        b. The patient's liver biopsy shows an abnormally high amount of copper (greater than 250mcg/g dry weight)
            a. The presence of Kayser-Fleischer rings in the cornea of the eye(s)
            b. The patient's diagnosis has been confirmed by genetic testing for
            c. ATP7B mutations

(Criteria continued in next page)

REQUIREMENTS: PENICILLAMINE (CONTINUED)

C. For patients with cystinuria, approval also requires:
    1. The patient has nephrolithiasis and one (1) or more of the following:
        a. Kidney stone analysis shows that there is cystine
        b. Urine analysis shows there are hexagonal cystine crystals in the urine that are pathognomonic
        c. The patient has a family history of cystinuria with positive tests results in the cyanidenitroprusside screen
    2. The patient has a daily cystine output greater than 300mg per 24 hours after a urine cystine excretion testing
    3. The patient has failed to respond to an adequate trial of conventional therapy which includes ALL of the following, unless there is a contraindication:
        a. Increased fluid intake
        b. Modest reductions in sodium and protein intake
        c. Urinary alkalinization
    4. The requested medication is prescribed by or given in consultation with a nephrologist
    5. For Cuprimine requests, the patient must have a previous trial of Depen (penicillamine) AND Thiola (tiopronin), unless there is a contraindication
D. For patients with active rheumatoid arthritis, approval requires:
    1. The requested medication is prescribed by or given in consultation with a rheumatologist
    2. The patient does not have a history of or other evidence of renal insufficiency
    3. The patient has failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
    4. For Cuprimine requests, the patient must have tried Depen (penicillamine), unless there is a contraindication

(Criteria continued on next page)

REQUIREMENTS: PENICILLAMINE (CONTINUED)

RENEWAL CRITERIA

Our guideline named PENICILLAMINE (Cuprimine, Depen) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Wilson's disease
    2. Cystinuria
    3. Active rheumatoid arthritis
B. For patients with Wilson's disease, renewal also requires:
    1. The patient has achieved free serum copper of less than 10 mcg/dL
C. For patients with cystinuria, renewal also requires:
    1. The patient has achieved cystine excretion of less than 200 mg/day
D. For patients with active rheumatoid arthritis, renewal also requires:
    1. The patient does not have a history of or other evidence of renal insufficiency
    2. The patient has experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

References:

1. Cuprimine package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised October 2004. Accessed August 2024.
2. Depen package insert. Somerset, NJ. Meda Pharmaceuticals Inc. Revised July 2018. Accessed August 2023.
3. Flamm SL, Yang YX, Singh S, Falck-Ytter YT; AGA Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Guidelines for the Diagnosis and Management of Acute Liver Failure. *Gastroenterology*. 2017;152(3):644-647. doi:10.1053/j.gastro.2016.12.026
4. Pearle MS, Goldfarb DS, Assimos DG et al: Medical management of kidney stones: AUA Guideline. J Urol 2014; 192: 316.
5. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2016;68(1):1-25. doi:10.1002/acr.22783
6. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2012;64(5):625-639. doi:10.1002/acr.21641.

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Generic	Brand	Reviewed	Effective Date
PYRIMETHAMINE Edition 1	DARAPRIM	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named PYRIMETHAMINE (Daraprim) requires the following rule(s) be met for approval:

A. The request is ONE of the following:
    1. Acute treatment of toxoplasmosis
    2. Chronic maintenance therapy for toxoplasmosis
    3. Primary prophylaxis of toxoplasmosis
    4. Congenital toxoplasmosis
B. For patients being treated for acute toxoplasmosis, approval also requires:
    1. The medication is prescribed by or given in consultation with an infectious disease specialist
C. For patients being treated for chronic maintenance for toxoplasmosis, approval also requires:
    1. The patient is also infected with human immunodeficiency virus (HIV)
    2. The patient has 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
D. For patients are being treated for primary prophylaxis of toxoplasmosis, approval also requires:
    1. The patient is also infected with human immunodeficiency virus (HIV)
    2. The medication is prescribed by or given in consultation with an infectious disease specialist
    3. The patient had a previous trial of Bactrim (sulfamethoxazole/ trimethoprim), unless there is a contraindication
    4. The patient tested positive for *Toxoplasma gondii* Immunoglobulins (IgG)
    5. The patient's CD4 count is less than 100 cells/mm^3
E. For patients who have congenital toxoplasmosis, approval also requires:
    1. The medication is prescribed by or given in consultation with a neonatologist or pediatric infectious disease specialist

(Criteria continued on next page)

REQUIREMENTS: PYRIMETHAMINE (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
    2. Chronic maintenance therapy for toxoplasmosis
    3. Primary prophylaxis of toxoplasmosis
B. For patients being treated for acute toxoplasmosis, renewal also requires:
    1. The patient has persistent clinical disease (i.e., headache, neurological symptoms, or fever) and persistent radiographic disease (i.e., one or more mass lesions on brain imaging)
C. For patients being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:
    1. The patient is also infected with human immunodeficiency virus (HIV)
    2. The patient's CD4 count is less than 200 cells/mm^3
    3. The patient is currently taking ART

References:

1. Daraprim package insert. New York, New York. Turing Pharmaceuticals LLC. Revised August 2017. Accessed August 2024.
2. Kaplan JE, Benson C, Holmes KK, et al. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR Recomm Rep. 2009;58(RR-4):1-CE4.

Generic	Brand	Reviewed	Effective Date
STIRIPENTOL Edition 3	DIACOMIT	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named STIRIPENTOL (Diacomit) requires the following rule(s) be met for approval:

A. The patient has seizures associated with Dravet syndrome
B. The patient is 6 months of age or older
C. The patient weighs at least 7 kg
D. The patient is currently being treated with clobazam
E. The requested medication is prescribed by or given in consultation with a neurologist

RENEWAL CRITERIA

Our guideline named STIRIPENTOL (Diacomit) requires the following rule(s) be met for renewal:

A. The patient has seizures associated with Dravet syndrome
B. The patient is currently being treated with clobazam

References:

1. Diacomit package insert. Redwood City, CA. Biocodex. Revised July 2022. Accessed August 2024.
2. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2012;78(24):1974-1980. doi:10.1212/WNL.0b013e318259e2cf
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91(2):74-81. doi:10.1212/WNL.0000000000005755
4. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society [published correction appears in Neurology. 2018 Dec 11;91(24):1117]. *Neurology*. 2018;91(2):82-90. doi:10.1212/WNL.0000000000005756.

Generic	Brand	Reviewed	Effective Date
PHENOXYBENZAMINE Edition 1	DIBENZYLINE	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named PHENOXYBENZAMINE (Dibenzyline) requires the following rules be met for approval:

A. The patient has a diagnosis of pheochromocytoma
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, an endocrine surgeon, or a hematologist/oncologist
D. The patient must have tried an alpha-1 selective adrenergic receptor blocker (i.e., doxazosin, terazosin, or prazosin), unless there is a contraindication

References:

1. Dibenzyline package insert. Bradenton, FL. WellSpring Pharmaceutical. Revised March 2008. Accessed August 2024.
2. Taïeb D, Hicks RJ, Hindié E, et al. European Association of Nuclear Medicine Practice Guideline/Society of Nuclear Medicine and Molecular Imaging Procedure Standard 2019 for radionuclide imaging of phaeochromocytoma and paraganglioma. *Eur J Nucl Med Mol Imaging*. 2019;46(10):2112-2137. doi:10.1007/s00259-019-04398-1
3. Brunt LM. SAGES Guidelines for minimally invasive treatment of adrenal pathology. *Surg Endosc*. 2013;27(11):3957-3959. doi:10.1007/s00464-013-3168-0.

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Generic	Brand	Reviewed	Effective Date
DUPILUMAB Edition 4	DUPIXENT	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DUPILUMAB (Dupixent) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe atopic dermatitis
    2. Moderate to severe asthma
    3. Chronic rhinosinusitis with nasal polyposis (CRSwNP)
    4. Eosinophilic esophagitis (EoE)
    5. Prurigo nodularis (PN)
B. If the patient has moderate to severe atopic dermatitis, approval also requires:
    1. The patient is 6 months of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
    3. The patient meets 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
    4. The patient has had at least a 4-week trial with an inadequate response to at least ONE of the following, unless contraindication to all listed:
        a. moderate-or higher-potency topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate, etc.]
        b. topical calcineurin inhibitors [i.e., Elidel (pimecrolimus), Protopic (tacrolimus)]
        c. topical PDE-4 inhibitors [i.e., Eucrisa (crisaborole)]

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

C. If the patient has moderate to severe asthma, approval also requires:
    1. The patient is 6 years of age or older
    2. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
    3. The patient has moderate-to-severe asthma that is characterized as ONE of the following:
        a. Eosinophilic phenotype asthma with a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
        b. Oral corticosteroid-dependent asthma
    4. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    5. The patient has asthma that is uncontrolled while maintained on an ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE or more of the following:
        a. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or increase in dose if already on oral corticosteroid) within the past 12 months
        b. At least ONE asthma exacerbation requiring hospitalization, urgent care, or emergency room visit within the past 12 months
    6. The requested medication will be used as an add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler
    7. The patient is not being treated on the requested medication concurrently with Xolair, Tezspire, or an anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra, etc.)

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

D. If the patient has chronic rhinosinusitis with nasal polyposis, approval also requires:
    1. The patient is 18 years of age or older
    2. The medication is prescribed by or given in consultation with an otolaryngologist allergist, or immunologist
    3. Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
    4. The patient is currently adherent to maintenance therapy with an intranasal corticosteroid (e.g., fluticasone, mometasone, etc.)
    5. The patient has inadequately controlled disease as determined by ONE of the following:
        a. Use of systemic corticosteroids in the past 2 years
        b. Endoscopic sinus surgery
    6. The requested medication will be used as add-on maintenance treatment in conjunction with maintenance intranasal steroids
    7. The patient is not being treated on the requested medication concurrently with Xolair or an anti-IL-5 biologic (e.g., Nucala, etc.)
E. If the patient has eosinophilic esophagitis, approval also requires:
    1. The patient is 12 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist, allergist, or immunologist
    3. The patient weighs at least 40 kg (88 lbs)
    4. The patient exhibits symptoms of dysphagia
    5. The patient has failed to achieve less than 15 eosinophils/high power field (eos/hpf) despite a trial with at least ONE of the following pharmacological treatments:
        a. High dose proton pump inhibitor (e.g., omeprazole, esomeprazole, lansoprazole, etc.)
        b. Topical corticosteroid (i.e., budesonide, fluticasone propionate)
F. If the patient has prurigo nodularis, approval also requires:
    1. The patient is 18 years age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
    3. The patient has had a previous trial with an inadequate response to at least ONE of the following conventional treatments, unless contraindication to all listed:
        a. Topical or intralesional corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate, triamcinolone acetonide, etc.]
        b. topical calcineurin inhibitors [i.e., Elidel (pimecrolimus), Protopic (tacrolimus)]
        c. topical vitamin D3 analogs [e.g., Dovonex (calcipotriene)]

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

RENEWAL CRITERIA

Our guideline named DUPILUMAB (Dupixent) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe atopic dermatitis
    2. Moderate to severe asthma
    3. Chronic rhinosinusitis with nasal polyposis (CRSwNP)
    4. Eosinophilic esophagitis (EoE)
    5. Prurigo nodularis (PN)
B. If the patient has moderate to severe atopic dermatitis, renewal also requires:
    1. The patient has shown a clinical response as evidenced by an improvement in symptoms (e.g., reduced body surface area affected, reduced pruritus, improvements in cracking, oozing, or bleeding of affected skin, reduced erythema, etc.)
C. If the patient has moderate to severe asthma, renewal also requires:
    1. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    2. The patient has shown a clinical response as evidenced by at least ONE of the following:
        a. Reduction in asthma exacerbation(s) as compared to baseline
        b. Decreased use of rescue medications
        c. Increase in percent predicted FEV1 from pretreatment baseline
        d. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
D. If the patient has chronic rhinosinusitis with nasal polyposis, renewal also requires:
    1. The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, improved sense of smell, reduced size of polyps, etc.)
E. If the patient has eosinophilic esophagitis, renewal also requires:
    1. The patient has had a clinical benefit compared to baseline as evidenced by BOTH of the following:
        a. Esophageal intraepithelial eosinophil count of 6 eosinophils/high power field (eos/hpf) or less
        b. Improvement in symptoms of dysphagia
F. If the patient has prurigo nodularis, renewal also requires:
    1. The patient has shown a clinical response as evidenced by an improvement in symptoms (e.g., reduced number of nodular lesions, reduced pruritus, etc.)

(Criteria continued on next page)

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CRITERIA CONTINUED- DUPILUMAB

References:

1. Dupixent package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised September 2024. Accessed September 2024.
2. Beck LA, Thaçi D, Hamilton JD, et al. Dupilumab treatment in adults with moderate-to-severe atopic dermatitis. *N Engl J Med*. 2014;371(2):130-139. Doi:10.1056/NEJMoa1314768.
3. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. J Allergy Clin Immunol. 2020;146(6):1217-1270. Doi:10.1016/j.jaci.2020.10.003.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
5. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132. Doi:10.1016/j.jaad.2014.03.023.
6. Hirano I, Chan ES, Rank MA, et al. AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. Gastroenterology. 2020;158(6):1776-1786. Doi:10.1053/j.gastro.2020.02.038.
7. Satoh T, Yokozeki H, Murota H, et al. 2020 guidelines for the diagnosis and treatment of prurigo. *J Dermatol*. 2021;48(9):e414-e431. Doi:10.1111/1346-8138.16067.
8. Kowalski E, Kneiber D, Valdebran M, et al. Treatment resistant prurigo nodularis: challenges and solutions. Clin Cosmet Investig Dermatol. 2019;12:163-172.
9. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. *J Am Acad Dermatol*. 2021;84(3):747-760. doi:10.1016/j.jaad.2020.07.025.

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Generic	Brand	Reviewed	Effective Date
TOCILIZUMAB - IV Edition 4	ACTEMRA - IV	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named TOCILIZUMAB - IV (Actemra - IV) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Polyarticular juvenile idiopathic arthritis (PJIA)
    3. Systemic juvenile idiopathic arthritis (SJIA)
    4. Giant cell arteritis (GCA)
    5. Cytokine Release Syndrome (CRS)
    6. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
B. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), hydroxychloroquine, sulfasalazine, or leflunomide
    4. The patient had a previous trial of the following preferred immunomodulator: Humira
C. For patients with polyarticular juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient had a previous trial of the following formulary preferred immunomodulator: Humira
D. For patients with systemic juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or immunologist
    3. The patient had a previous trial of at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Criteria continued next page)

REQUIREMENTS: TOCILIZUMAB - IV (CONTINUED)

E. For the treatment of cytokine release syndrome, approval requires all:
    1. The patient is 2 years of age or older
    2. The patient's condition is severe or life-threatening and induced by chimeric antigen receptor (CAR) T cell therapy
F. For the treatment of giant cell arteritis, approval requires:
    1. The patient is 18 years of age or older
G. For the treatment of Systemic Sclerosis-Associated Interstitial Lung Disease, approval requires:
    1. The patient is 18 years of age or older

RENEWAL CRITERIA

Our guideline named TOCILIZUMAB - IV (Actemra - IV) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Polyarticular juvenile idiopathic arthritis (PJIA)
    3. Systemic juvenile idiopathic arthritis (SJIA)
    4. Giant cell arteritis (GCA)
B. For patients with moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with giant cell arteritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Actemra package insert. South San Francisco, CA. Genentech, Inc.. Revised September 2024. Accessed September 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.
5. Maz M, Chung SA, Abril A, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Rheumatol. 2021;73(8):1349-1365. doi:10.1002/art.41774.

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Generic	Brand	Reviewed	Effective Date
TOCILIZUMAB - SQ Edition 4	ACTEMRA – SQ	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named TOCILIZUMAB - SQ (Actemra - SQ) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Giant cell arteritis (GCA)
    3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
    4. Polyarticular juvenile idiopathic arthritis (PJIA)
    5. Systemic juvenile idiopathic arthritis (SJIA)
    6. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
B. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient had a previous trial of the following preferred immunomodulator: Humira (or biosimilar)
C. For patients with giant cell arteritis, approval requires:
    1. The patient is 18 years of age or older
D. For patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval requires:
    1. The patient is 18 years of age or older
E. For patients with polyarticular juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient had a previous trial of the following preferred immunomodulator: Humira (or biosimilar)

(Criteria continued next page)

REQUIREMENTS: TOCILIZUMAB-SQ (CONTINUED)

F. For patients with systemic juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or immunologist
    3. The patient had a previous trial of at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
G. For the treatment of Systemic Sclerosis-Associated Interstitial Lung Disease, approval requires:
    1. The patient is 18 years of age or older

RENEWAL CRITERIA

Our guideline named TOCILIZUMAB - SQ (Actemra - SQ) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Giant cell arteritis (GCA)
    3. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
    4. Systemic juvenile idiopathic arthritis (SJIA)
    5. Polyarticular juvenile idiopathic arthritis (PJIA)
B. For patients with moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with giant cell arteritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with systemic sclerosis-associated interstitial lung disease, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms

References:

1. Actemra package insert. South San Francisco, CA. Genentech, Inc. Revised September 2024. Accessed September 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.5. Maz M, Chung SA, Abril A, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for

REQUIREMENTS: TOCILIZUMAB-SQ (CONTINUED)

the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Rheumatol. 2021;73(8):1349-1365. doi:10.1002/art.41774.
6. Kowal-Bielecka OK, Fransen J, Avouac J, et al. Update of EULAR recommendations for the treatment of systemic sclerosis. Ann Rheum Dis. 2017;76(8):1327-1339.

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Generic	Brand	Reviewed	Effective Date
NIRAPARIB ABIRATERONE Edition 1	AKEEGA	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

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

A. Patient is at least 18 years of age
B. Therapy is prescribed by, or in consultation with, an oncologist
C. The patient has a diagnosis of Metastatic castration-resistant prostate cancer
D. The patient has a BRCA mutation, as detected by an FDA approved test

1. Akeega Package insert. Horsham, PA. Janssen Biotech, Revised August 2023. Accessed August 2024.

MINOCYCLINE HCL MICROSPHERES			
Generic	Brand	Reviewed	Effective Date
MINOCYCLINE MICROSPHERES Edition 1	ARESTIN	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)
Our guideline named MINOCYCLINE MICROSPHERES (Arestin) requires the following rule(s) be met for approval:

A. The patient has documentation of confirmed periodontitis
B. The patient is age 18 years or older
C. The requested medication is prescribed by or given in consultation with an oral health care professional
D. The patient does not have a history of minocycline or tetracycline sensitivity or allergy
E. The patient does not have a history of candidiasis 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 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
I. The medication is not being used in an immunocompromised individual, 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, either in preparation for or in conjunction with the placement of endosseous (dental) implants or in the treatment of failing implants

(Criteria continued on next page)

REQUIREMENTS- MINOCYCLINE HCL MICROSPHERES (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has documentation of periodontitis
B. The medication will be used as an adjunct to scaling and root planning procedures OR used as part of a periodontal maintenance program which includes good oral hygiene and scaling and root planning

References:

1. Arestin Package insert. Bridgewater, NJ. Valeant Pharmaceuticals International, Inc. Revised May 2024. Accessed August 2024.
2. Smiley CJ, Tracy SL, Abt E, et al. Evidence-based clinical practice guideline on the nonsurgical treatment of chronic periodontitis by means of scaling and root planing with or without adjuncts. JADA 2015; 146(7): 525-535.

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Generic	Brand	Reviewed	Effective Date
UBLITUXIMAB-XIIY Edition 2	BRIUMVI	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named UBLITUXIMAB-XIIY (Briumvi) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. The patient has a diagnosis of a relapsing form of multiple sclerosis
C. The patient has had a previous trial of generic glatiramer, glatopa, dimethyl fumarate, fingolimod, or teriflunomide

References:

1. Briumvi™ intravenous infusion [prescribing information]. Morrisville, NC: TG Therapeutics; December 2022.
2. Steinman L, Fox E, Hartung HP, et al, for the ULTIMATE I and ULTIMATE II investigators. Ublituximab versus teriflunomide in relapsing multiple sclerosis. *N Engl J Med*. 2022;387(8):704-714.
3. Fox E, Lovett-Racke AE, Formley M, et al. A phase 2 multicenter study of ublituximab, a novel glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis. *Mult Scler*. 2021;27:420-429.
4. McGinley MP, Goldschmidt CH, Rae-Grant A. Diagnosis and treatment of multiple sclerosis: a review. *JAMA*. 2021;325(8):765-779.

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Generic	Brand	Reviewed	Effective Date
ZANUBRUTINIB Edition 4	BRUKINSA	10/21/2024	10/29/2024

REQUIREMENTS:

Our guideline named ZANUBRUTINIB (Brukinsa) requires the following rule(s) be met for approval:

A. The patient has at least ONE of the following diagnoses:
    1. Mantle cell lymphoma (MCL)
    2. Waldenström's macroglobulinemia (WM)
    3. Relapsed or refractory marginal zone lymphoma (MZL)
    4. Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
    5. Follicular Lymphoma
B. The patient is 18 years of age or older
C. For patients with mantle cell lymphoma, approval also requires:
    1. The patient has previously received at least ONE prior therapy for mantle cell lymphoma
D. For patients with relapsed or refractory marginal zone lymphoma, approval also requires:
    1. The patient has previously received at least one anti-CD20-based regimen for marginal zone lymphoma
E. For patients with Follicular Lymphoma, approval also requires:
    1. The requested product will be utilized with Obinutuzumab
    2. The patient has previously received at least TWO prior systemic therapies

References:
1. Brukinsa package insert. San Mateo, CA. BeiGene USA, Inc. Revised June 2023. Accessed August 2024.

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Generic	Brand	Reviewed	Effective Date
SODIUM PHENYLBUTYRATE Edition 1	BUPHENYL	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SODIUM PHENYLBUTYRATE (Buphenyl) requires the following rule(s) be met for approval:

A. The patient has a urea cycle disorder
B. There is documentation confirming the patient has a urea cycle disorder via enzymatic, biochemical or genetic testing
C. The requested medication will be used as adjunctive therapy along with dietary protein restriction
D. The patient's 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. The patient has a urea cycle disorder
B. The patient has experienced clinical benefit compared to pretreatment baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity)

References:
1. Buphenyl package insert. Scottsdale, AZ. Ucyclyd Pharma, Inc. Revised July 2022. Accessed August 2024.

OCTREOTIDE - SQ			
Generic	Brand	Reviewed	Effective Date
OCTREOTIDE ACETATE Edition 1	BYNFEZIA	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named OCTREOTIDE - SQ (Bynfezia) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Acromegaly
    2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
    3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)
B. For patients with acromegaly, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient had an inadequate response to or cannot be treated with ALL of the following:
        a. Surgical resection
        b. Pituitary irradiation
        c. Bromocriptine mesylate at maximally tolerated doses
C. For patients with severe diarrhea and flushing episodes associated with metastatic carcinoid tumors, approval also requires:
    1. The patient is 18 years of age or older
D. For patients with profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas), approval also requires:
    1. The patient is 18 years of age or older

(Criteria continued on next page)

REQUIREMENTS- OCTREOTIDE – SQ (CONTINUED)

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

A. The patient has ONE of the following diagnoses:
    1. Acromegaly
    2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
    3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)
B. The patient has had improvement or sustained remission of symptoms

References:
1. Bynfezia Package Insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised September 2024. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
AMIFAMPRIDINE Edition 3	FIRDAPSE	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named AMIFAMPRIDINE (Firdapse) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
B. The patient is 6 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist or hematologist-oncologist
D. The patient's diagnosis is confirmed by electrodiagnostic studies and/or voltage-gated calcium channel (VGCC) antibody testing AND clinical triad (3 symptoms) of muscle weakness, autonomic dysfunction, and decreased tendon reflexes
E. The patient's baseline assessment score for disease activity has been documented utilizing an established assessment instrument [e.g., Quantitative Myasthenia Gravis (QMG), Subject Global Impression (SGI) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW), etc.]

RENEWAL CRITERIA
Our guideline named AMIFAMPRIDINE (Firdapse) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
B. Compared to pretreatment baseline, submitted documentation shows the patient has experienced or maintained improvement in disease activity utilizing an established assessment instrument [e.g., Quantitative Myasthenia Gravis (QMG), Subject Global Impression (SGI) score, triple-timed up-and-go test (3TUG), Timed 25-foot Walk test (T25FW), etc.]

References:
1. Firdapse package insert. Coral Gables, FL. Catalyst Pharmaceuticals, Inc. Revised May 2024. Accessed September 2024.
2. Bodkin C, Pascuzzi RM. Update in the Management of Myasthenia Gravis and Lambert-Eaton Myasthenic Syndrome. Neurol Clin. 2021;39(1):133-146. doi:10.1016/j.ncl.2020.09.007.

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Generic	Brand	Reviewed	Effective Date
MIGALASTAT Edition 1	GALAFOLD	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named MIGALASTAT (Galafold) requires the following rule(s) be met for approval:

A. The patient has a confirmed diagnosis of Fabry disease
B. The patient is 18 years of age or older
C. The patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data that is interpreted by clinical genetics professional as the cause of disease
D. The requested medication is prescribed by or given in consultation with a nephrologist, cardiologist, or specialist in genetics or inherited metabolic disorders
E. The patient is NOT concurrently using enzyme replacement therapy (i.e., Fabrazyme)
F. The patient is symptomatic OR has evidence of injury from GL-3 to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR for age, persistent albuminuria, cerebral white matter lesions on brain MRI, cardiac fibrosis on contrast cardiac MRI
G. The patient meets ONE of the following:
    1. If the patient is a female: Confirmation of Fabry disease via genetic test documenting galactosidase alpha gene (GLA) mutation
    2. If the patient is a male patient: Confirmation of Fabry disease via enzyme assay showing the patient has a low amount of alpha galactosidase A (a-Gal -A) OR genetic test documenting galactosidase alpha gene (GLA) mutation

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

A. The patient has a confirmed diagnosis of Fabry disease
B. The patient has demonstrated clinical improvement or maintenance/stabilization while on therapy in at least ONE of the following areas:
    1. Symptoms such as pain, hypohidrosis/anhidrosis, exercise intolerance, gastrointestinal (GI) symptoms, angiokeratomas, abnormal cornea, tinnitus, or hearing loss
    2. Imaging such as brain/cardiac MRI, DEXA, or renal ultrasound
    3. Laboratory or histological testing such as GL-3 in plasma/urine or renal biopsy

References:
1. Galafold package insert. Cranbury, Nj. Amicus Therapeutics U.S., Inc. Revised June 2024. Accessed August 2024.
2. Yogasundaram H, Kim D, Oudit O, Thompson RB, Weidemann F, Oudit GY. Clinical Features, Diagnosis, and Management of Patients With Anderson-Fabry Cardiomyopathy. *Can J Cardiol*. 2017;33(7):883-897. doi:10.1016/j.cjca.2017.04.015.

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Generic	Brand	Reviewed	Effective Date
TEDUGLUTIDE Edition 1	GATTEX	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named TEDUGLUTIDE (Gattex) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of short bowel syndrome (SBS)
B. The patient is 1 year of age or older
C. The patient is dependent on parenteral nutrition, defined as requiring parenteral nutrition at least three times per week

References:

1. Gattex package insert. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. Revised September 2024. Accessed September 2024.
2. Jeppesen P, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. Gastroenterology.2012; 143:1473-1481.

Generic	Brand	Reviewed	Effective Date
LOMUSTINE Edition 2	GLEOSTINE	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Hodgkin's Lymphoma
    2. Primary and metastatic brain tumors
B. For patients with primary and metastatic brain tumors, approval also requires the following:
    1. The patient has previously received appropriate surgical and/or radiotherapeutic procedures

References:
1. Gleostine package insert. Miami, FL. NextSource Biotechnology. Revised January 2016. Accessed August 2024.

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Diabetic GLP-1 Products Edition 2			
Generic	Brand	Reviewed	Effective Date
DULAGLUTIDE	TRULICITY	10/21/2024	1/1/2025
LIRAGLUTIDE	VICTOZA		
SEMAGLUTIDE	OZEMPIC, RYBELSUS		
TIRZEPATIDE	MOUNJARO		

REQUIREMENTS:

NOTE: Requests will NOT be approved if your plan has weight-loss medication exclusions

Our guideline named DIABETIC GLP-1 Products (Trulicity, Victoza, Ozempic, Rybelsus, Mounjaro) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Type II Diabetes Mellitus confirmed by submitted documentation of ONE of the following:
    1. Hemoglobin A1c (HbA1c) greater than or equal to 6.5% OR
    2. Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL OR
    3. 2-hour plasma glucose (2-h PG) greater than or equal to 200 mg/dL
B. The patient has had a trial of ONE of the following: Metformin, Invokana, Farxiga, Jardiance, Steglatro, Brenzavvy
C. For Ozempic, Mounjaro & Rybelsus requests, approval also requires:
    1. The patient is at least 18 years of age or older
D. For Trulicity, & Victoza requests, approval also requires:
    1. The patient is at least 10 years of age or older

Coverage will not be authorized for the following situations:

A. Weight Loss Treatment
B. Type I Diabetes Mellitus
C. Prediabetes/Diabetes Prevention
D. Metabolic Syndrome
E. Concomitant Use with Glucagon-Like Peptide-1 Agonists (GLP-1) or GLP-1/Glucose-Dependent Insulinotropic Polypeptide (GIP) Agonist
F. Other diagnoses not listed above

References

1. Adlyxin® subcutaneous injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; June 2022.
2. Mounjaro® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.
3. Bydureon BCise® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
4. Byetta® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2022.
5. Ozempic® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; September 2023.
6. Rybelsus® tablets [prescribing information]. Plainsboro, NJ: Novo Nordisk; January 2023.
7. Trulicity® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; November 2022.
8. Victoza® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2023.
9. American Diabetes Association. Standards of medical care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl 1):S1-S321.
10. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: An endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(2):342-362.
11. Grunvald E, Shah R, Hernaez R, et al. AGA clinical practice guideline on pharmacological interventions for adults with obesity. *Gastroenterol.* 2022;163:1198-1225.
12. Samson SL, Vellanki P, Blonde L, et al. American Association of Clinical Endocrinology consensus statement: comprehensive type 2 diabetes management algorithm – 2023 update. *Endocr Pract*. 2023;29:305-340.
13. Kidney Diseases Improving Global Outcomes (KDIGO). KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int.* 2024;105(4S):S117-S314.
14. Gornik HL, Aronow HD, Goodney PP, et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral arterial disease: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *Circulation.* 2024. [Epub ahead of Print 2024 May 14].

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ADALIMUMAB (CONTINUED)

Generic	Brand	Reviewed	Effective Date
ADALIMUMAB	HUMIRA	10/21/2024	10/21/2023
ADALIMUMAB BIOSIMILARS Edition 5	AMJEVITA, IDACIO, YUFLYMA, HYRIMOZ, CYLTEZO, YUSIMRY, HADLIMA, HULIO, ETC.		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ADALIMUMAB (Humira) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)
    4. Ankylosing spondylitis (AS)
    5. Moderate to severe plaque psoriasis (PsO)
    6. Moderate to severe Crohn's disease (CD)
    7. Moderate to severe ulcerative colitis (UC)
    8. Moderate to severe hidradenitis suppurativa (HS)
    9. Uveitis
B. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
C. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a
    3. rheumatologist
    4. The patient has had a previous trial of or contraindication to at least one of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
D. For patients with psoriatic arthritis, approval requires:
    1. The patient is 18 of years of age or older

REQUIREMENTS: ADALIMUMAB (CONTINUED)

2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
3. The patient had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. For patients with ankylosing spondylitis, approval requires:
   1. The patient is 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist
F. For patients with moderate to severe plaque psoriasis, approval requires:
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a dermatologist
   3. The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
   4. The patient has had a previous trial of or contraindication to 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
G. For patients with moderate to severe Crohn's disease, approval requires:
   1. The patient is 6 years of age or older
   2. The requested medication is prescribed by or given in consultation with a gastroenterologist
   3. The patient meets at least ONE of the following:
      a. The patient has had a previous trial of or contraindication to at least one of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
      b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
      c. The patient has a history of ileocolonic resection
H. For patients with moderate to severe ulcerative colitis, approval requires:
   1. The patient is 5 years of age or older
   2. The requested medication is prescribed by or given in consultation with a gastroenterologist
   3. The patient has had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
I. For patients with moderate to severe hidradenitis suppurativa, approval requires:
   1. The patient is 12 years of age or older

(Criteria continued on next page)

REQUIREMENTS: ADALIMUMAB (CONTINUED)

J. For patients with uveitis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with an ophthalmologist
    3. The patient's uveitis is non-infectious
    4. The patient's uveitis is classified as one of the following:
        a. intermediate
        b. posterior
        c. panuveitis

RENEWAL CRITERIA

Our guideline named ADALIMUMAB (Humira) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe juvenile idiopathic arthritis (PJIA)
    4. Ankylosing spondylitis (AS)
    5. Moderate to severe plaque psoriasis (PsO)
    6. Moderate to severe Crohn's disease (CD)
    7. Moderate to severe ulcerative colitis (UC)
    8. Moderate to severe hidradenitis suppurativa (HS)
    9. Uveitis
B. For patients with moderate to severe rheumatoid arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
    2. 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
C. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with psoriatic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: ADALIMUMAB (CONTINUED)

E. For patients with ankylosing spondylitis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
F. For patients with moderate to severe plaque psoriasis, renewal requires:
    1. Compared to pretreatment baseline, the patient has achieved or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms
G. For patients with uveitis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms
H. For patients with Crohn's disease, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
I. For patients with ulcerative colitis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
J. For patients with hidradenitis suppurativa, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms

References:

1. Humira package insert. North Chicago, IL. Abbott Laboratories. Revised November 2023. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.
5. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
6. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
7. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.

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8. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044..
9. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042.
10. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.
11. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol. 2019;114(3):384-413. doi:10.14309/ajg.0000000000000152.
12. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
13. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
14. Dick AD, Rosenbaum JT, Al-Dhibi HA, et al. Guidance on Noncorticosteroid Systemic Immunomodulatory Therapy in Noninfectious Uveitis: Fundamentals Of Care for UveitiS (FOCUS) Initiative. Ophthalmology. 2018;125(5):757-773. doi:10.1016/j.ophtha.2017.11.017.
15. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101. doi:10.1016/j.jaad.2019.02.068.

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Generic	Brand	Reviewed	Effective Date
ELRANATAMAB Edition 1	ELREXFIO	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named ELRANATAMAB (Elrexfio) requires the following rule(s) be met for approval:

A. Patient is at least 18 years of age
B. The patient has a diagnosis of Relapsed or Refractory Multiple Myeloma
C. The patient has an ECOG score of less than or equal to 2
D. The patient has previously trialed at least 4 lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

1. Elrexfio Package insert. Horsham, PA. Janssen Biotech, Revised August 2023. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
MEBENDAZOLE Edition 1	EMVERM	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The requested medication 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. The patient is 2 years of age or older

C. If the patient has *enterobius vermicularis* (pinworm), approval also requires:
   1. The patient previously had a trial of over-the-counter (OTC) pyrantel pamoate, unless there is a contraindication

D. If the patient has trichuris trichiura (whipworm) or ascaris lumbricoides (common roundworm), approval also requires:
   1. There is documentation confirming a diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
   2. The patient previously had a trial of albendazole (Albenza), unless there is a contraindication

E. If the patient has ancylostoma duodenale (common hookworm) or necator americanus (American hookworm), approval also requires:
   1. There is documentation confirming a diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
   2. The patient previously had a trial of albendazole (Albenza), unless there is a contraindication OR the patient has had a trial of over-the-counter (OTC) pyrantel pamoate

References:

1. Emverm package insert. Bridgewater, NJ. Amneal Pharmaceuticals LLC. Revised January 2019. Accessed August 2024.
2. Wendt S, Trawinski H, Schubert S, Rodloff AC, Mössner J, Lübbert C. The Diagnosis and Treatment of Pinworm Infection. Dtsch Arztebl Int. 2019 Mar 29;116(13):213-219. doi: 10.3238/arztebl.2019.0213.

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Generic	Brand	Reviewed	Effective Date
ETANERCEPT Edition 2	ENBREL	10/21/2024	10/21/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ETANERCEPT (Enbrel) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)
    4. Ankylosing spondylitis (AS)
    5. Moderate to severe plaque psoriasis (PsO)
B. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
C. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
D. For patients with psoriatic arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
E. For patients with ankylosing spondylitis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist

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REQUIREMENTS: ETANERCEPT (CONTINUED)

F. For patients with moderate to severe plaque psoriasis, approval requires:
    1. The patient is 4 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient has had a previous trial of or contraindication to 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

RENEWAL CRITERIA

Our guideline named ETANERCEPT (Enbrel) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following a diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)
    3. Psoriatic arthritis (PsA)
    4. Ankylosing spondylitis (AS)
    5. Moderate to severe plaque psoriasis (PsO)
B. For patients with moderate to severe rheumatoid arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a
        i. clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with psoriatic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with ankylosing spondylitis, renewal requires:
        ii. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

F. For patients with moderate to severe plaque psoriasis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms

REQUIREMENTS: ETANERCEPT (CONTINUED)

References:

1. Enbrel package insert. Thousand Oaks, CA. Amgen. Revised September 2024. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.
4. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
5. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
7. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042.

Generic	Brand	Reviewed	Effective Date
SATRALIZUMA-MWGE Edition 1	ENSPRYNG	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SATRALIZUMAB (ENSPRYNG) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist
D. The patient's diagnosis is confirmed by a positive serologic test for anti-aquaporin-4 (AQP4) antibodies
E. The patient has at least ONE of the following core clinical characteristics:
    1. Optic neuritis
    2. Acute myelitis
    3. Area postrema syndrome
    4. Acute brainstem syndrome
    5. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. The patient will not use Rituxan (rituximab), Uplinza (inebilizumab), or Soliris (eculizumab) in combination with the requested medication

RENEWAL CRITERIA
Our guideline named SATRALIZUMAB (ENSPRYNG) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
B. The patient has had a reduction in relapse frequency compared to pretreatment baseline

References:
1. Enspryng package insert. South San Francisco, CA. Genentech, Inc. Revised September 2022. Accessed August 2024.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015;85(2):177-189. doi:10.1212/WNL.0000000000001729.
3. Trebst C, Jarius S, Berthele A, et al. Update on the diagnosis and treatment of neuromyelitis optica: recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol. 2014;261(1):1-16. doi:10.1007/s00415-013-7169-7.

Generic	Brand	Reviewed	Effective Date
EPCORITAMAB-BYSP Edition 2	EPKINLY	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)
Our guideline named EPCORITIMAB (Epkinly) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Relapsed or Refractory Diffuse Large B-cell Lymphoma OR Follicular Lymphoma
B. The patient is age 18 years or older
C. Therapy is prescribed by, or in consultation with, an oncologist
D. The patient has had a previous trial of at least TWO separate lines of therapy

References:
1. Epkinly Package insert. North Chicago, IL. Genmab US, Inc., Revised June 2024. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
APALUTAMIDE Edition 2	ERLEADA	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named APALUTAMIDE (Erleada) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Non-metastatic castration-resistant prostate cancer (nmCRPC)
    2. Metastatic castration-sensitive prostate cancer (mCSPC)
B. The patient meets ONE of the following:
    1. The patient has previously received a bilateral orchiectomy
    2. The requested medication will be used together with a gonadotropin releasing hormone analog (e.g., Lupron [leuprolide], Zoladex [goserelin], Vantas [histrelin], Firmagon [degarelix], Trelstar [triptorelin], etc.)
C. For patients with non-metastatic castration-resistant prostate cancer (nmCRPC), approval also requires:
    1. The patient has high risk prostate cancer
D. For patients with metastatic castration-sensitive prostate cancer (mCSPC), approval also requires:
    1. The patient has previously tried generic Zytiga (abiraterone acetate), unless there is a contraindication

RENEWAL CRITERIA

Our guideline named APALUTAMIDE (Erleada) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Non-metastatic castration-resistant prostate cancer (nmCRPC)
    2. Metastatic castration-sensitive prostate cancer (mCSPC)
B. The patient is responding positively to therapy as evidenced by a lack of disease progression

References:

1. Erleada package insert. Horsham, PA. Janssen Products, LP. Revised August 2024. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
MOBOCERTINIB Edition 1	EXKIVITY	10/21/2024	10/29/2021

REQUIREMENTS:

Our guideline named MOBOCERTINIB (Exkivity) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of non-small cell lung cancer (NSCLC)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or in consultation with an oncologist/hematologist
D. The patient has locally advanced or metastatic disease
E. The patient's tumors have epidermal growth factor receptor (EGFR) exon 20 insertion mutations as shown by an FDA (Food and Drug Administration)-approved test
F. The patient's disease has progressed on or after treatment with a platinum-based (e.g., carboplatin, cisplatin) chemotherapy regimen

References:
1. Exkivity package insert. Lexington, MA. Takeda Pharmaceuticals America, Inc. Revised September 2023. Accessed September 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
PANOBINOSTAT Edition 1	FARYDAK	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PANOBINOSTAT (Farydak) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of multiple myeloma
B. The patient has been treated with at least 2 prior regimens including:
    1. Velcade (bortezomib)
    2. Immunomodulatory medication such as Thalomid, Revlimid, or Pomalyst
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. The patient has tolerated the first 8 weeks of therapy without experiencing any severe or medically significant toxicity

References:
1. Farydak package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised February 2015. Accessed September 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
MIFEPRISTONE Edition 1	KORLYM	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named MIFEPRISTONE (Korlym) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of endogenous Cushing's syndrome (CS)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an endocrinologist
D. The patient has type 2 diabetes mellitus OR glucose intolerance
E. The patient has undergone pituitary surgery OR pituitary surgery is not an option

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

A. The patient has endogenous Cushing's syndrome
B. The patient continues to have clinical improvement of glucose tolerance and/or stable glucose tolerance (i.e., reduced hemoglobin A1C, improved fasting glucose)
C. The patient continues to tolerate the requested medication
D. The patient is not a candidate for surgery or has failed surgery for Cushing's syndrome

References:

1. Korlym package insert. Menlo Park, CA. Corcept Therapeutics Incorporated. Revised November 2019. Accessed August 2024.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818.

Generic	Brand	Reviewed	Effective Date
SELUMETINIB Edition 2	KOSELUGO	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named SELUMETINIB (Koselugo) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of neurofibromatosis type 1 (NF1)
B. The patient is 2 years of age or older
C. The patient has symptomatic, inoperable plexiform neurofibromas (PN)

References:

1. Koselugo package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised January 2024. Accessed August 2024.
2. Ly KI, Blakeley JO. The diagnosis and management of neurofibromatosis type 1. Med Clin N Am. 2019;103:1035-1054.

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Generic	Brand	Reviewed	Effective Date
SAPROPTERIN Edition 2	KUVAN, JAVYGTOR	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SAPROPTERIN (Kuvan, Javygtor) requires the following rule(s) be met for approval:

A. The patient has hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
B. The patient will follow a phenylalanine-restricted diet

RENEWAL CRITERIA
Our guideline named SAPROPTERIN DIHYDROCHLORIDE (Kuvan, Javygtor) requires the following rule(s) be met for renewal:

A. The patient has hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU)
B. The patient has experienced a clinical response to therapy as exhibited by ONE or more of the following:
    1. At least a 20% decrease in blood phenylalanine concentration from pretreatment baseline
    2. Improvement in symptoms (i.e., behavioral and/or cognitive, dietary tolerance to phenylalanine)
C. The patient will continue to follow a phenylalanine-restricted diet

References:
1. Kuvan package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised August 2024. Accessed August 2024.
2. Javygtor package insert. Princeton, NJ. Dr. Reddy's Laboratories Inc. Revised January 2022. Accessed August 2024.
3. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline [published correction appears in Genet Med. 2014 Apr;16(4):356]. Genet Med. 2014;16(2):188-200. doi:10.1038/gim.2013.157.

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Generic	Brand	Reviewed	Effective Date
LENVATINIB MESYLATE Edition 2	LENVIMA	10/21/2024	10/29/2021

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Differentiated thyroid cancer (DTC)
    2. Advanced renal cell cancer (RCC)
    3. Unresectable hepatocellular carcinoma (HCC)
    4. Advanced endometrial carcinoma (EC)
B. If the patient has differentiated thyroid cancer, approval also requires:
    1. The patient's thyroid cancer is locally recurrent or metastatic
    2. The patient's thyroid cancer is progressive
    3. The patient has tried and failed radioactive iodine therapy, unless there is contraindication
C. If the patient has advanced renal cell cancer, approval also requires ONE of the following:
    1. The requested medication is used in combination with Keytruda (pembrolizumab), if used as first line treatment
    2. The requested medication is used in combination with Afinitor (everolimus), if the patient has tried one prior anti-angiogenic therapy (e.g., Sutent [sunitinib], Votrient [pazopanib], Inlyta [axitinib], Nexavar [sorafenib])
D. If the patient has advanced endometrial carcinoma, approval also requires:
    1. The requested medication is used in combination with Keytruda (pembrolizumab)
    2. The patient does not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers
    3. The patient has experienced disease progression following prior systemic therapy in any setting
    4. The patient is not a candidate for curative surgery or radiation

References:
1. Lenvima package insert. Woodcliff Lake, NJ. Eisai Inc., Revised June 2024. Accessed August 2024.

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Generic	Brand	Reviewed	Effective Date
SARGRAMOSTIM Edition 1	LEUKINE	10/21/2024	6/1/2021

REQUIREMENTS:

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 or oncologist, OR the patient meets ONE of the following:
    1. The patient has a diagnosis of acute myeloid leukemia (AML) and using the requested medication to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND the patient is 55 years of age or older
    2. The patient is undergoing autologous transplantation and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis AND the patient is 18 years of age or older
    3. The patient has a diagnosis of non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma and is using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation AND the patient is 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 AND the patient is 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 the patient is 2 years of age or older
    6. The patient was acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase the patient's survival

References:

1. Leukine package inserts. Bridgewater, NJ. Sanofi-aventis U.S. LLC. Revised May 2022. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
LORLATINIB Edition 1	LORBRENA	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named LORLATINIB (Lorbrena) requires the following rule(s) be met for approval:

A. The patient has metastatic non-small cell lung cancer (NSCLC)
B. The patient is 18 years of age or older
C. The patient's tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

References:
1. Lorbrena package insert. New York, New York. Pfizer, Inc. Revised March 2021. Accessed August 2024.

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Generic	Brand	Reviewed	Effective Date
LOFEXIDINE Edition 1	LUCEMYRA	10/21/2024	6/1/2021

REQUIREMENTS:

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

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

References:

1. Lucemyra package insert. Louisville, KY. US WorldMeds, LLC. Revised September 2024. Accessed September 2024.
2. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91.
3. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. 2016 Mar 18;65(1):1-49.
4. Utah Department of Health (2018). Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain. Salt Lake City, UT: Utah Department of Health
5. Society for Adolescent Health and Medicine. Medication for Adolescents and Young Adults With Opioid Use Disorder. *J Adolesc Health*. 2021;68(3):632-636. doi:10.1016/j.jadohealth.2020.12.129.

Generic	Brand	Reviewed	Effective Date
RANIBIZUMAB Edition 2	LUCENTIS	10/21/2024	10/21/2022
RANIBIZUMAB-NUNA	BYOOVIZ		
RANIBIZUMAB-EQRN	CIMERLI		

REQUIREMENTS:

Our guideline named RANIBIZUMAB (Lucentis, Byooviz, Cimerli) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Neovascular (wet) age-related macular degeneration (AMD)
    2. Diabetic macular edema (DME)
    3. Diabetic retinopathy (DR)
    4. Macular edema following retinal vein occlusion (RVO)
    5. Myopic choroidal neovascularization (mCNV)
B. The medication is prescribed by an ophthalmologist or retina specialist

References:

1. Lucentis package insert. South San Francisco, CA. Genentech, Inc. Revised February 2024. Accessed August 2024.
2. Byooviz package insert. Cambridge, MA. Biogen Inc. Revised October 2023. Accessed August 2024.
3. Cimerli package insert. Redwood City, CA. Coherus BioSciences, Inc. Revised August 2022. Accessed August 2024.
4. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-Related Macular Degeneration Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(1):P1-P65. doi:10.1016/j.ophtha.2019.09.024.
5. Flaxel CJ, Adelman RA, Bailey ST, et al. Diabetic Retinopathy Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(1):P66-P145. doi:10.1016/j.ophtha.2019.09.025.
6. Flaxel CJ, Adelman RA, Bailey ST, et al. Retinal Vein Occlusions Preferred Practice Pattern® [published correction appears in Ophthalmology. 2020 Sep;127(9):1279]. Ophthalmology. 2020;127(2):P288-P320. doi:10.1016/j.ophtha.2019.09.029.

Generic	Brand	Reviewed	Effective Date
PALBOCICLIB Edition 2	IBRANCE	10/21/2024	10/21/2023

REQUIREMENTS:

Our guideline named PALBOCICLIB (Ibrance) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic breast cancer
B. The patient is 18 years of age or older
C. The patient meets ONE of the following:
    1. The requested medication will be used with an aromatase inhibitor (i.e., anastrozole, letrozole, or exemestane) AND the patient meets ALL of the following:
        a. The patient is a postmenopausal biological female OR a biological male
        b. The patient has NOT received endocrine-based therapy (i.e., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        c. The patient's disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy
    2. The requested medication will be used in combination with Faslodex (fulvestrant) AND the patient meets ALL of the following:
        a. The patient's disease has worsened after endocrine-based therapy (i.e., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        b. The patient's disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy

References:
1. Ibrance package insert. New York, NY. Pfizer labs, Inc. Revised September 2023. Accessed September 2024.

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Generic	Brand	Reviewed	Effective Date
CANAKINUMAB/PF Edition 4	ILARIS	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named CANAKINUMAB (Ilaris) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle- Wells Syndrome (MWS)
    2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
    3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
    4. Familial Mediterranean Fever (FMF)
    5. Systemic Juvenile Idiopathic Arthritis (SJIA)
    6. Adult-Onset Still's Disease (AOSD)
    7. Gout Flares
B. For patients with Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:
    1. The patient is 4 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
C. For patients with Systemic Juvenile Idiopathic Arthritis (SJIA), approval also requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least ONE DMARD, such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient had a previous trial of the preferred immunomodulator, Actemra, OR Ilaris was started while in the hospital
D. For patients with Familial Mediterranean Fever (FMF), approval also requires:
    1. The patient is 2 years of age or older
    2. The patient has had a previous trial of colchicine, or colchicine is contraindicated
    3. The patient will be using the requested medication concomitantly with colchicine, unless colchicine is contraindicated
    4. The patient meets BOTH of the following criteria:
        i. Has C-reactive protein levels greater than or equal to 10 mg/L OR elevated to at least tow times the upper limit of normal for the reporting laboratory
        ii. Has a history of at least one flare per month despite use of colchicine, OR was hospitalized for a severe flare
    5. The requested medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, or hematologist
E. For patients with Adult-Onset Still's Disease (AOSD), approval also requires:
    1. The requested medication is prescribed by or given in consultation with a rheumatologist

2. The patient is 18 years of age or older
3. The patient meets ONE of the following:
    i. Patient has tried at least ONE other biologic; OR
    ii. Patient was started on Ilaris while in the hospital; AND

F. For patients with Gout Flares, approval also requires:
1. The patient is 18 years of age or older
2. Patient meets ONE of the following (i or ii):
    i. Patient meets BOTH of the following:
        1. Patient has an intolerance, contraindication, or lack of response to nonsteroidal anti-inflammatory drugs (NSAIDs) for the treatment of acute gout flares; AND
        2. Patient has an intolerance, contraindication, or lack of response to colchicine for the treatment of acute gout flares; OR
    ii. Patient meets BOTH of the following:
        1. Patient has been previously treated with corticosteroids (oral or injectable) for an acute gout flare; AND
        2. According to the prescriber, patient is unable to be retreated with a repeat course of corticosteroids (oral or injectable) for acute gout flares; AND
3. According to the prescriber, patient is receiving or will be taking concomitant urate lowering medication for the prevention of gout unless contraindicated (Examples of uric acid lowering drugs include allopurinol, febuxostat, or probenecid) AND
4. The requested medication is prescribed by or in consultation with a rheumatologist.

G. For patients with Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), approval also requires:
1. The patient is ≥ 2 years of age; AND
2. Prior to starting Ilaris, the patient meets BOTH of the following:
    i. C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
    ii. Patient has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare; AND
3. The requested medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, oncologist, or hematologist

H. For patients with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), approval also requires:
1. The patient is ≥ 2 years of age; AND
2. Prior to starting Ilaris, the patient meets BOTH of the following:
    i. C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
    ii. Patient has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare; AND
3. The requested medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, oncologist, or hematologist

RENEWAL CRITERIA

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Our guideline named CANAKINUMAB (Ilaris) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle- Wells Syndrome (MWS)
    2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
    3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
    4. Familial Mediterranean Fever (FMF)
    5. Systemic Juvenile Idiopathic Arthritis (SJIA)
    6. Adult-Onset Still's Disease (AOSD)
    7. Gout Flares

B. Compared to pretreatment baseline, the patient experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Ilaris package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2023. Accessed August 2024.
2. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
3. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. Ann Rheum Dis. 2016;75(4):644-651. doi:10.1136/annrheumdis-2015-208690.
4. Terreri MT, Bernardo WM, Len CA, et al. Guidelines for the management and treatment of periodic fever syndromes Cryopyrin-associated periodic syndromes (Cryopyrinopathies-CAPS). Rev Bras Reumatol Engl Ed 2016 Jan-Feb;56(1):44
5. Koné-Paut I, Galeotti C. Current treatment recommendations and considerations for cryopyrin-associated periodic syndrome. Expert Rev Clin Immunol. 2015;11(10);1083-92.
6. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. Arthritis Care Res (Hoboken). 2013;65(10):1551-1563. doi:10.1002/acr.22087
7. Efthimiou P, Kontzias A, Hur P, Rodha K, Ramakrishna GS, Nakasato P. Adult-onset Still's disease in focus: Clinical manifestations, diagnosis, treatment, and unmet needs in the era of targeted therapies. Semin Arthritis Rheum. 2021;51(4):858-874. doi:10.1016/j.semarthrit.2021.06.004.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
IBRUTINIB Edition 2	IMBRUVICA	10/21/2024	10/21/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Mantle cell lymphoma (MCL)
    2. Chronic lymphocytic leukemia (CLL)
    3. Small lymphocytic lymphoma (SLL)
    4. Waldenström's macroglobulinemia (WM)
    5. Marginal zone lymphoma (MZL)
    6. Chronic graft versus host disease
B. Requests for Ibrutinib 140mg or 280mg tablets requires patient has had a trial of Ibrutinib 140mg capsules, unless there is a contraindication
C. For patients with mantle cell lymphoma, approval also requires:
    1. Patient is 18 years of age or older
    2. Patient has received at least one prior therapy for mantle cell lymphoma
D. For patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), approval also requires:
    1. The patient is 18 years of age or older
E. For patients with Waldenström's macroglobulinemia, approval also requires:
    1. The patient is 18 years of age or older
F. For patients with marginal zone lymphoma, approval also requires:
    1. The patient is 18 years of age or older
    2. Patient needs systemic therapy
    3. Patient has received at least one prior anti-CD20-based therapy (i.e., Rituxan [rituximab])
G. For patients with chronic graft versus host disease, approval also requires:
    1. The patient is 1 year of age or older
    2. Patient has failed one or more lines of systemic therapy

References:
1. Imbruvica package insert. Horsham, PA. Reviewed Janssen Biotech, Inc. Revised May 2023. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
MILTEFOSINE Edition 1	IMPAVIDO	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient is 12 years of age or older
B. The patient has a diagnosis of Leishmaniasis with ONE of the following types of infection:
    1. Visceral leishmaniasis caused by *Leishmania donovani*
    2. Cutaneous leishmaniasis caused by ANY of the following:
        a. *Leishmania braziliensis*
        b. *Leishmania guyanensis*
        c. *Leishmania panamensis*
    3. Mucosal leishmaniasis (affects inside mouth, throat and nose) caused by
        a. *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
    2. Culture medium
    3. Polymerase chain reaction
    4. Serologic testing

References:

1. Impavido Package insert. Orlando, FL. Profounda, Inc. Revised May 2021. Accessed August 2024.
2. Handler MZ, Patel PA, Kapila R, Al-Qubati Y, Schwartz RA. Cutaneous and mucocutaneous leishmaniasis: Differential diagnosis, diagnosis, histopathology, and management. *J Am Acad Dermatol*. 2015;73(6):911-928. doi:10.1016/j.jaad.2014.09.014.

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Generic	Brand	Reviewed	Effective Date
LEVODOPA Edition 1	INBRIJA	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named LEVODOPA INHALATION (Inbrija) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of advanced Parkinson's disease
B. The requested medication is being used for intermittent treatment of "OFF" episodes associated with advanced Parkinson's disease
C. The patient is currently being treated with carbidopa/levodopa
D. The requested medication is prescribed by or given in consultation with a neurologist
E. The patient is NOT currently taking more than 1600mg of levodopa per day
F. The prescribing physician has optimized drug therapy as evidenced by BOTH of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Patient has had a trial of or contraindication to at least TWO Parkinson's agents from TWO different classes: dopamine agonist (i.e., ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (i.e., selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (i.e., entacapone, tolcapone)

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

A. The patient has a diagnosis of advanced Parkinson's disease
B. The patient has had improvement with motor fluctuations during 'OFF' episodes (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)

References:
1. Inbrija package insert. Ardsley, NY. Acorda Therapeutics, Inc. Revised August 2020. Accessed August 2024.
2. Pahwa R, Factor SA, Lyons KE, et al. Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2006; 66:983-995.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
MECASERMIN Edition 2	INCRELEX	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named MECASERMIN (Increlex) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Severe primary insulin growth-like factor 1 (IGF-1) deficiency
    2. Growth hormone gene deletion with developed neutralizing antibodies to growth hormone
B. The patient is at least 2 years of age
C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist or pediatric nephrologist
D. The patient's bone growth plates (epiphyses) are open as confirmed by radiograph of the wrist and hand
E. For patients with primary IGF-1 deficiency, approval also requires ALL of the following:
    1. The patient has a height standard deviation score less than or equal to -3.0
    2. The patient has a basal IGF-1 standard deviation score less than or equal to -3.0
    3. The patient has 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)]

RENEWAL CRITERIA
Our guideline named MECASERMIN (Increlex) requires the following rule(s) be met for renewal:

A. The patient has shown a clinical response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (i.e., increase in height, increase in height velocity)
B. The patient's bone growth plates (epiphyses) are open as confirmed by radiograph of the wrist and hand

References:
1. Increlex package insert. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. Revised March 2024. Accessed August 2024.
2. Cohen J, Blethen S, Kuntze J, et al. Managing the child with severe primary insulin-like growth factor-1 deficiency (IGFD): IGFD diagnosis and management. Drugs R D. 2014;14(1):25-29.

Generic	Brand	Reviewed	Effective Date
OSILODROSTAT Edition 1	ISTURISA	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named OSILODROSTAT (Isturisa) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Cushing's disease (CD)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an endocrinologist
D. The patient has undergone pituitary surgery or pituitary surgery is not an option
E. The patient previously had a trial of oral ketoconazole, unless there is a contraindication

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

A. The patient has a diagnosis of Cushing's disease (CD)
B. The patient continues to have clinical improvement of Cushing's disease (i.e., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease)
C. The patient continues to tolerate treatment with the requested medication

References:
1. Isturisa package insert. North Chicago, IL. AbbVie Inc. Revised March 2020. Accessed August 2024.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818.

WELLFLEET RX STUDENT FORMULARY

SOMATROPIN Edition 2			
Generic	Brand	Reviewed	Effective Date
SOMATROPIN	GENOTROPIN	10/21/2024	1/1/2025
SOMATROPIN	NORDITROPIN FLEXPRO		
SOMATROPIN	SEROSTIM		
SOMATROPIN	ZORBTIVE		
SOMATROPIN	OMNITROPE		

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

REQUIREMENTS:

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.

A. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
B. The medication is prescribed by or given in consultation with one of the following specialist: Gastroenterologist, Nutritional Support Specialist, or Infectious Disease Specialist
C. The patient is on HIV anti-retroviral therapy
D. The patient has inadequate response to previous therapy (e.g., exercise training, nutritional supplements, appetite stimulants, or anabolic steroids)
E. The patient has an inadequate response to previous pharmacological therapy including one of the following: cyproheptadine, Marinol (dronabinol), or Megace (megestrol acetate)
F. Alternative causes of wasting has been ruled out; alternative causes include:
    1. Altered metabolism (from metabolic and hormonal abnormalities) including testosterone deficiency or peripheral growth hormone resistance
    2. Diarrhea
    3. Inadequate energy (caloric) intake
    4. Malignancies
    5. Opportunistic infections
G. The patient meets ONE of the following criteria for weight loss:
    1. 10% unintentional weight loss over 12 months
    2. 7.5% unintentional weight loss over 6 months
    3. 5% body cell mass (BCM) loss within 6 months
    4. BCM less than 35% (men) and a body mass index (BMI) less than 27 kg per meter squared
    5. BCM less than 23% (women) of total body weight and a body mass index (BMI) less than 27kg per meter squared
    6. BMI less than 18.5 kg per meter squared

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: SOMATROPIN (CONTINUED)

For patients who are hypogonadal (patients with low testosterone levels), approval requires the following:

A. The patient has tried testosterone therapy (e.g., testosterone cypionate, AndroGel, Androderm, Axiron, Delatestryl, Fortesta, Striant, Testim, Testopel, Vogelxo, Natesto)
B. The patient meets one of the following criteria for low testosterone:
    1. Total serum testosterone level of less than 300 ng/dL (10.4 nmol/L)
    2. A low total serum testosterone level as indicated by a lab result, with a reference range, obtained within 90 days
    3. 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.

A. The requested agent is NOT prescribed for athletic enhancement or anti-aging purposes
B. The patient is currently on specialized nutritional support (such as high carbohydrate, low-fat diet, adjusted for individual requirements and preferences)
C. The medication is prescribed by or given in consultation with a gastroenterologist

GENOTROPIN/NORDITROPIN/OMNITROPE

The guideline named SOMATROPIN (Genotropin/Norditropin) requires ONE of the following diagnoses:

A. Pediatric growth hormone deficiency
B. Growth failure associated with Turner Syndrome
C. Growth failure due to Prader-Willi Syndrome (PWS)
D. Growth failure in children born small for gestational age (SGA)
E. Adult growth hormone deficiency

This medication will not be approved for treatment of ANY of the following conditions:

A. Athletic enhancement
B. Anti-aging purposes
C. Idiopathic Short Stature

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: SOMATROPIN (CONTINUED)

The following criteria must also be met:
For the diagnosis of pediatric growth hormone deficiency (GHD), approval requires:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. The patient meets at least ONE of the following criteria for short stature:
    1. 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
    2. Height velocity less than the 25th percentile for age
    3. 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:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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:

A. Confirmed diagnosis of PWS
B. The medication is prescribed by or given in consultation with an endocrinologist

For the diagnosis of growth failure in children born small for gestational age (SGA), approval requires:

A. The medication is Prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. Patient with no catch-up growth by age 2 years
D. 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:

A. The medication is prescribed by or in consultation with an endocrinologist
B. 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

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: GENOTROPIN/NORDITROPIN (CONTINUED)

RENEWAL CRITERIA

SEROSTIM

The guideline named SOMATROPIN (Serostim) renewal requires a diagnosis of HIV wasting/cachexia. The following criteria must also be met.

A. NOT prescribed for athletic enhancement or anti-aging purposes
B. The patient has shown clinical benefit in muscle mass and weight as indicated by the following criteria:
    1. ≥ 10% increase in weight or BCM from baseline (NOTE: current and baseline weight must be documented including dates of measurement)
C. The patient must be on HIV anti-retroviral therapy

ZORBTIVE

A. The guideline named SOMATROPIN (Zorbtive) renewal requires a diagnosis of short bowel syndrome. Therapy is limited to 4 weeks of treatment.

GENOTROPIN/NORDITROPIN/OMNITROPE

The guideline named SOMATROPIN (Genotropin/Norditropin/Omnitrope) 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:

A. Athletic enhancement
B. Anti-aging purposes
C. Idiopathic Short Stature

The following criteria must also be met.
For the diagnosis of pediatric growth hormone deficiency (GHD), renewal requires:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: GENOTROPIN/NORDITROPIN (CONTINUED)

For the diagnosis of growth failure due to Prader-Willi Syndrome (PWS), renewal requires:

A. The medication is prescribed by or given in consultation with an endocrinologist
B. Improvement in body composition

For the diagnosis of growth failure in children born small for gestational age (SGA), renewal requires:

A. The medication is prescribed by or in consultation with an endocrinologist
B. The patient's epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand)
C. 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:

A. The medication is prescribed by or given in consultation with an endocrinologist

References:

1. Genotropin package insert. New York, NY. Pfizer, Inc. Revised April 2019. Accessed March 2024.
2. Norditropin Flexpro package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised March 2020. Accessed March 2024.
3. Serostim package insert. Rockland, MA. EMDSerono, Inc. Revised May 2017. Accessed March 2024.
4. Zorbtive package insert. Rockland, MA. EMDSerono, Inc. Revised May 2017. Accessed March 2024.
5. Yuen KCJ, Biller BMK, Radovick S, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF GROWTH HORMONE DEFICIENCY IN ADULTS AND PATIENTS TRANSITIONING FROM PEDIATRIC TO ADULT CARE. Endocr Pract. 2019;25(11):1191-1232. doi:10.4158/GL-2019-0405.
6. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth FactorI Deficiency. Horm Res Paediatr. 2016;86(6):361-397. doi:10.1159/000452150.
7. Murray PG, Dattani MT, Clayton PE. Controversies in the diagnosis and management of growth hormone deficiency in childhood and adolescence. Arch Dis Child. 2016;101(1):96-100. doi:10.1136/archdischild-2014-307228.
8. Decker R, Nygren A, Kriström B, et al. Different thresholds of tissue-specific dose-responses to growth hormone in short prepubertal children. BMC Endocr Disord. 2012;12:26. Published 2012 Nov 1. doi:10.1186/1472-6823-12-26.
9. Rosenfeld RG, Albertsson-Wikland K, Cassorla F, et al. Diagnostic controversy: the diagnosis of childhood growth hormone deficiency revisited. J Clin Endocrinol Metab. 1995;80(5):1532-1540. doi:10.1210/jcem.80.5.7538145.
10. Pironi L, Arends J, Bozzetti F. ESPEN guidelines on chronic intestinal failure in adults. Clinical Nutrition. 2016; 35:247-307.
11. Gelato M, McNurlan M, Freedland E. Role of recombinant human growth hormone in HIV-associated wasting and cachexia: pathophysiology and rationale for treatment. Clin Ther. 2007;29(11):2269-2288. doi:10.1016/j.clinthera.2007.11.004.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
DAROLUTAMIDE Edition 2	NUBEQA	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named DAROLUTAMIDE (Nubeqa) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Non-metastatic castration resistant prostate cancer (nmCRPC)
    2. Metastatic hormone sensitive prostate cancer (mHSPC)
B. The patient meets ONE of the following:
    1. The patient has previously received a bilateral orchiectomy
    2. The requested medication will be used together with a gonadotropin releasing hormone analog (e.g., Lupron [leuprolide], Zoladex [goserelin], Vantas [histrelin], Firmagon [degarelix], Trelstar [triptorelin], etc.)
C. For patients with non-metastatic castration-resistant prostate cancer (nmCRPC), approval also requires:
    1. The patient has high risk prostate cancer
D. For patients with metastatic hormone-sensitive prostate cancer (mHSPC), approval also requires:
    1. The patient has previously tried generic Zytiga (abiraterone acetate), unless there is a contraindication
    2. The requested medication will be used in combination with docetaxel

RENEWAL CRITERIA
Our guideline named DAROLUTAMIDE (Nubeqa) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Non-metastatic castration resistant prostate cancer (nmCRPC)
    2. Metastatic hormone sensitive prostate cancer (mHSPC)
B. The patient is responding positively to therapy as evidenced by a lack of disease progression

References:
1. Nubeqa package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised October 2023. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
PIMAVANSERIN Edition 1	NUPLAZID	10/21/2024	6/1/2021

REQUIREMENTS:

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. The patient has a diagnosis of psychosis associated with Parkinson's disease
B. The patient is at least 18 years old
C. The requested medication is prescribed by or given in consultation with a doctor specializing in one of the following areas: neurology, geriatric medicine, or behavioral health (such as a psychiatrist)

RENEWAL CRITERIA
Our guideline named PIMAVANSERIN (Nuplazid) requires the following rule(s) be met for renewal:

A. The patient has experienced an improvement in psychosis symptoms from baseline and the patient shows a continued need for treatment

References:
1. Nuplazid Package Insert. San Diego, CA. Acadia Pharmaceuticals Inc. Revised September 2023. Accessed August 2024.
2. Seppi K, Chaudhuri KR, Coelho M, et al. Movement Disorders Society: Update on treatments for nonmotor symptoms of Parkinson's disease—An evidence-based medicine review. Movement Disorders. 2019; 34(2): 180-198.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
OMADACYCLINE Edition 2	NUZYRA	10/21/2024	10/29/2022

REQUIREMENTS:

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

A. The patient meets ONE of the following:
    1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
    2. The patient has a community-acquired bacterial pneumonia (CABP) OR an acute bacterial skin or skin structure infection (ABSSSI)
B. For patients with community-acquired bacterial pneumonia, approval also requires:
    1. The patient is 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. The patient meets ONE of the following criteria:
        a. If antimicrobial susceptibility test is available, the results of the test from the infection site are required to show the bacteria is both 1) resistant to TWO standard of care agents for community acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid, etc.), AND 2) the requested medication will work against the bacteria
        b. If antimicrobial susceptibility test is not available, a trial or contraindication to TWO standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone,linezolid, etc.) is required

(Criteria continued on next page)

REQUIREMENTS: OMADACYCLINE (CONTINUED)

C. For patients with acute bacterial skin or skin structure infection (ABSSSI), approval also requires:
    1. The patient is 18 years of age or older
    2. The infection is caused by any of the following bacteria: *Staphylococcus aureus* (methicillinsusceptible 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. The patient meets ONE of the following criteria:
        a. If antimicrobial susceptibility test is available, the results of the test from the infection are required to show the bacteria is both 1) resistant to ONE standard of care agent for acute bacterial skin or skin structure infection (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin, etc.), AND 2) the requested medication will work against the bacteria
        b. If antimicrobial susceptibility test is not available, a trial of or contraindication to ONE standard of care agent for acute bacterial skin or skin structure infection (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, vancomycin, etc.) is required

References:
1. Nuzyra package insert. Boston, MA. Paratek Pharmaceuticals, Inc. Revised May 2021. Accessed September 2024.
2. Lee RA, Centor RM, Humphrey LL, et al. Appropriate Use of Short-Course Antibiotics in Common Infections: Best Practice Advice From the American College of Physicians. *Ann Intern Med*. 2021;174(6):822-827. doi:10.7326/M20-7355.
3. Kalil AC, Metersky ML, Klompas M, et al. Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society [published correction appears in Clin Infect Dis. 2017 May 1;64(9):1298] [published correction appears in Clin Infect Dis. 2017 Oct 15;65(8):1435] [published correction appears in Clin Infect Dis. 2017 Nov 29;65(12):2161]. *Clin Infect Dis*. 2016;63(5):e61-e111. doi:10.1093/cid/ciw353.

WELLFLEET
RX PLAN

NIMODIPINE SOLUTION			
Generic	Brand	Reviewed	Effective Date
NIMODIPINE Edition 1	NYMALIZE	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named NIMODIPINE SOLUTION (Nymalize) requires the following rule(s) be met for approval:

A. The patient has a history of subarachnoid hemorrhage (SAH) from a ruptured intracranial berry aneurysm within the past 21 days
B. The patient is 18 years of age or older
C. The patient is unable to swallow nimodipine oral capsules

References:

1. Nymalize Package Insert. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised August 2024. Accessed August 2024.
2. Connolly ES, Rabinstein AA, Carhuapoma JR, Derdeyn CP, Dion J, Higashida RT, et al.; American Heart Association Stroke Council; Council on Cardiovascular Radiology and Intervention; Council on Cardiovascular Nursing; Council on Cardiovascular Surgery and Anesthesia; Council on Clinical Cardiology. Guidelines for the management of aneurysmal subarachnoid hemorrhage: a guideline for healthcare professionals from the American Heart Association/american Stroke Association.Stroke. 2012; 43:1711–1737. doi: 10.1161/STR.0b013e3182587839.

WELLFLEET
RX PLAN

OCTREOTIDE - ORAL			
Generic	Brand	Reviewed	Effective Date
OCTREOTIDE Edition 1	MYCAPSSA	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named OCTREOTIDE (Mycapssa) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of acromegaly
B. The requested medication is prescribed by or given in consultation with an endocrinologist
C. The patient has responded to and is currently stable on an injectable somatostatin analog therapy (i.e., octreotide, lanreotide, or pasireotide)

RENEWAL CRITERIA
Our guideline named OCTREOTIDE (Mycapssa) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of acromegaly
B. The patient has had reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1) levels based on their age and gender
C. The patient has shown improvement or sustained remission of clinical symptoms of acromegaly

References:
1. Mycapssa package Insert. Cincinnati, OH. Chiasma Inc. Revised July 2024. Accessed August 2024.
2. Katznelson L, Laws ER Jr, Melmed S, et al; Endocrine Society. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.

Generic	Brand	Reviewed	Effective Date
PARATHYROID HORMONE Edition 1	NATPARA	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of hypocalcemia secondary to hypoparathyroidism
B. The patient has previously tried activated vitamin D (calcitriol) and calcium
C. The patent's hypoparathyroidism is not due to a calcium-sensing receptor (CSR) mutation
D. The patient's hypoparathyroidism is not considered acute post-surgical hypoparathyroidism
E. The requested medication is prescribed by or given in consultation with an endocrinologist

References:

1. Natpara package insert. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. Revised April 2022. Accessed August 2024.
2. Cooper MS, Gittoes NJ. Diagnosis and management of hypocalcaemia [published correction appears in BMJ. 2008 Jun 28;336(7659): doi: 10.1136/bmj.a334]. *BMJ*. 2008;336(7656):1298-1302. doi:10.1136/bmj.39582.589433.BE.

Generic	Brand	Reviewed	Effective Date
SORAFENIB TOSYLATE Edition 1	NEXAVAR	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline for SORAFENIB (Nexavar) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Advanced renal cell carcinoma (RCC)
    2. Unresectable hepatocellular carcinoma (HCC)
    3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment

References:

1. Nexavar package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised August 2023. Accessed August 2024.

WELLFLEET
RX PLAN

GRANULOCYTE COLONY-STIMULATING FACTORS Edition 3			
Generic	Brand	Reviewed	Effective Date
FILGRASTIM-AAFI	NIVESTYM	10/21/2024	10/21/2022
FILGRASTIM-SNDZ	ZARXIO		
PEGFILGRASTIM	NEULASTA		
PEGFILGRASTIM-JMDB	FULPHILA		
PEGFILGRASTIM-BMEZ	ZIEXTENZO		

REQUIREMENTS:

Our guideline named GRANULOCYTE COLONY-STIMULATING FACTORS (GCSF) requires the following rule(s) be met for approval:

A. The requested medication is prescribed by or given in consultation with a hematologist or oncologist
B. Requests for Nivestym or Zarxio require ONE of the following indications:
    1. Non-myeloid malignancy in a patient receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
    2. Acute myeloid leukemia (AML) in a patient undergoing induction or consolidation chemotherapy treatment
    3. Non-myeloid malignancy in a patient undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
    4. Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
    5. Congenital neutropenia
    6. Cyclic neutropenia
    7. Idiopathic neutropenia
C. Requests for Neulasta requires the following indication:
    1. Increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)
D. Requests for Fulphila or Ziextenzo require the following indication:
    1. Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

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REQUIREMENTS: GRANULOCYTE COLONY-STIMULATING FACTORS (CONTINUED)

References:

1. Nivestym package insert. Lake Forest, IL. Hospira, Inc. Revised February 2024. Accessed September 2024.
2. Zarxio package insert. Princeton, NJ. Sandoz Inc. Revised March 2021. Accessed September 2024
3. Neulasta package insert. Thousand Oaks, CA. Amgen Inc. Revised February 2021. Accessed September 2024.
4. Fulphila package insert. Morgantown, WV. Mylan Pharmaceuticals Inc. Revised October 2021. Accessed September 2024.
5. Ziextenzo package insert. Princeton, NJ. Sandoz Inc. Revised March 2021. Accessed September 2024.
6. Taplitz RA, Kennedy EB, Bow EJ, et al. Outpatient Management of Fever and Neutropenia in Adults Treated for Malignancy: American Society of Clinical Oncology and Infectious Diseases Society of America Clinical Practice Guideline Update. J Clin Oncol. 2018;36(14):1443-1453. doi:10.1200/JCO.2017.77.6211.
7. Luo C, Wang L, Wu G, et al. Comparison of the efficacy of hematopoietic stem cell mobilization regimens: a systematic review and network meta-analysis of preclinical studies. Stem Cell Res Ther. 2021;12(1):310. Published 2021 May 29. doi:10.1186/s13287-021-02379-6.

WELLFLEET
RX PLAN

OPIOID CUMULATIVE DOSING OVERRIDE Edition 3			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	10/21/2024	10/29/2021

REQUIREMENTS

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 the patient to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. The patient has ONE of the following conditions:
    1. Diagnosis of active cancer
    2. Receiving palliative care or end-of-life care
    3. Enrolled in hospice
    4. Resident of a long-term care facility or intermediate care for intellectually disabled
    5. Diagnosis of sickle cell disease
B. The prescriber is aware that there is more than one provider prescribing opiates for the patient, and meets TWO of the following:
    1. Documentation showing current level of opioid use is necessary and required for the level of pain management needed
    2. Patient has been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
    3. Patient has a pain contract in place
    4. Patient does not have a history of substance abuse or addiction
    5. Patient's 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 (120 mg morphine milligram equivalent (MME)), except in the state of Pennsylvania. There are also specific quantity limits for particular medications, based on FDA approved dosing guidelines. Not all opioid medications will have the same quantity limit.

(Continued on next page)

REQUIREMENTS- OPIOID CUMULATIVE DOSING OVERRIDE (CONTINUED)

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. 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 overridden 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:

1. 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 8/15/24].
2. Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.
3. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.Available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html. [Accessed 8/15/24].
4. Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed 8/15/22].
5. 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 8/15/24].
6. 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.
7. The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. Available at: https://www.ssa.gov/OP_Home/ssact/title18/1861.htm [Accessed 8/15/24].
8. Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-2021.pdf [Accessed 8/15/24].
9. 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 8/15/24].

10. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
11. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

WELLFLEET
RX PLAN

OPIOID NAIVE FILL LIMIT Edition 3			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	10/21/2024	10/29/2021

REQUIREMENTS:

Our guideline named OPIOID NAIVE FILL LIMIT allows opioid naïve members (those who have not used opioid drugs within the past 60 days) to receive up to a 5-day supply at the lowest effective dose of an immediate-release formulation without a prior authorization.

Cumulative Morphine Milligram Equivalents (MME) Limit:

- 90 MME total (all prescriptions in last 120 days included) has soft rejection at pharmacy that can be overridden, except in the state of Pennsylvania
- 120 MME total has hard rejection, requires prior authorization

Quantity limits on medications handled at the individual medication level

If a member requires a subsequent prescription within 60 days of the initial prescription, a PA (Prior Authorization) will be required and the following conditions must be met:

A. Prescriber will determine, after a consultation with the member that an additional supply is necessary and does not present a risk of abuse, addiction or diversion, AND
B. Prescribe lowest effective dose with no more than a 30 day supply, OR

A subsequent prescription will be approved if the member meets at least ONE of the following conditions:

A. Active cancer
B. Enrolled in hospice
C. Receiving palliative care or end-of-life care
D. Resident of a long-term care facility or intermediate care for intellectually disabled
E. Sickle cell disease
F. NOT opioid naïve
G. Physician attests that the additional fill of the requested opioid analgesic medication is intended and clinically appropriate for the member

(Continued on next page)

OPIOID NAÏVE FILL LIMIT (CONTINUED)

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:

1. 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 8/15/24]
2. 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 8/15/24].
3. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
4. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

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OPIOID-NAÏVE DAY SUPPLY LIMITATION Edition 3			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	10/21/2024	10/29/2021

REQUIREMENTS

Our guideline named OPIOID-NAIVE DAY SUPPLY LIMITATION allows opioid naïve members (those who have not used opioid drugs within the past 60 days) to receive up to a 5-day supply at the lowest effective dose of an immediate-release formulation without a prior authorization.

Maximum day supply for opioid prescriptions without prior authorization:

- Prescriber Type:
  - General Practitioners – 5-day supply
  - Dentists – 3-day supply
  - Oncologists – No limit

A longer day supply will be approved when the patient is opioid-naïve and meets at least ONE of the following conditions:

A. Diagnosis of active cancer
B. Enrolled in hospice
C. Receiving palliative care or end-of-life care
D. Resident of a long-term care facility or intermediate care for intellectually disabled
E. Diagnosis of sickle cell disease
F. NOT opioid naïve
G. Physician attestation that the prescribed dose of opioids with the requested day supply is intended and medically necessary

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.

(Continued on next page)

REQUIREMENTS- OPIOID NAÏVE DAY SUPPLY LIMITATION (CONTINUED)

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 naïve 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.

References:

1. 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 8/15/24].
2. The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.ssa.gov/OP_Home/ssact/title18/1861.htm [Accessed 8/15/24].
3. Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-2021.pdf [Accessed 8/15/24].
4. 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 8/15/24].
5. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
6. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

Generic	Brand	Reviewed	Effective Date
ABATACEPT/MALTOSE Edition 4	ORENCIA – IV	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ABATACEPT - IV (Orencia - IV) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis
    2. Moderate to severe polyarticular juvenile idiopathic arthritis
    3. Psoriatic arthritis
    4. Prophylaxis of acute graft versus host disease (aGVHD)
B. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient has had a previous trial of TWO of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR
C. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient has had a previous trial of TWO of the formulary preferred immunomodulators: Enbrel, Humira, Xeljanz/XR, or Actemra SC

(Criteria continued on next page)

REQUIREMENTS: ABATACEPT-IV (CONTINUED)

D. For patients with psoriatic arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient has had a previous trial of any TWO of the following formulary
    5. preferred immunomodulators: Enbrel, Humira, Stelara, Otezla, Tremfya, Taltz, or Xeljanz/XR
E. For patients using for prophylaxis of acute graft versus host disease (aGVHD), approval requires:
    1. The patient is 2 years of age or older
    2. Therapy is prescribed by or given in consultation with a hematologist or oncologist
    3. The requested medication will be used in combination with a calcineurin inhibitor (i.e., cyclosporine, tacrolimus, or pimecrolimus) and methotrexate
    4. The patient will be undergoing hematopoietic stem cell transplantation (HSCT)
    5. from a matched or 1 allele-mismatched unrelated donor

RENEWAL CRITERIA

Our guideline named ABATACEPT - IV (ORENCIA - IV) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis
    2. Psoriatic arthritis
    3. Moderate to severe polyarticular juvenile idiopathic arthritis
B. For patients with moderate to severe rheumatoid arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with psoriatic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids.

REQUIREMENTS: ABATACEPT-IV (CONTINUED)

References:

1. Orencia package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised December 2021. Accessed October 2024.
2. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.
3. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
5. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
6. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.

Generic	Brand	Reviewed	Effective Date
LUMACAFTOR/IVACAFTOR Edition 3	ORKAMBI	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named LUMACAFTOR-IVACAFTOR (Orkambi) requires the following rule(s) be met for approval:

A. Patient is 1 years of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Documentation that patient is homozygous for the *F508del*-CFTR mutation
E. If the patient is between 2 years and less than 6 years of age, Orkambi packets will be approved. Documentation of patient weight is required

RENEWAL CRITERIA
Our guideline named LUMACAFTOR-IVACAFTOR (Orkambi) requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    a. Patient has improved, maintained, or demonstrated less than expected decline in FEV_1
    b. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    c. Patient has experienced a reduction in rate of pulmonary exacerbations

References:
1. Orkambi package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised August 2023. Accessed September 2024.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Pulmonary Guidelines: Use of CFTR Modulator Therapy in Patients with Cystic Fibrosis. Ann Am Thorac Soc. 2018 Mar. doi: 10.1513/AnnalsATS.201707-539OT.PMID: 29342367.

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Generic	Brand	Reviewed	Effective Date
APREMILAST Edition 2	OTEZLA	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named APREMILAST (Otezla) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Psoriatic arthritis (PsA)
    2. Mild to moderate plaque psoriasis (PsO)
    3. Moderate to severe plaque psoriasis (PsO)
    4. Oral ulcers associated with Behcet's disease
B. For patients with psoriatic arthritis (PsA), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. For patients with mild to moderate plaque psoriasis, 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 dermatologist
    3. The patient has plaque psoriasis involving 2% to 15% of body surface area (BSA)
    4. The patient had previous trial of or contraindication to at least ONE or more forms of standard topical therapies such as topical corticosteroids, topical calcipotriene, or topical tazarotene.
    5. The patient has not received prior therapy with a biologic (e.g., Humira, Skyrizi, Taltz, etc.)

(Criteria continued on next page)

REQUIREMENTS: APREMILAST (CONTINUED)

D. For patients with moderate to severe plaque psoriasis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. The patient has plaque psoriasis involving at least 10% of body surface area (BSA) or psoriatic lesions affecting the face, hands, feet, or genital area
    4. The patient has had a previous trial of or contraindication to 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
E. For patients with oral ulcers associated with Behcet's disease, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to ONE or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid

RENEWAL CRITERIA

The guideline named APREMILAST (Otezla) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Psoriatic arthritis (PsA)
    2. Mild to moderate plaque psoriasis (PsO)
    3. Moderate to severe plaque psoriasis (PsO)
    4. Oral ulcers associated with Behcet's disease
B. For patients with psoriatic arthritis (PsA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with mild to moderate plaque psoriasis (PsO), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with moderate to severe plaque psoriasis (PsO), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with oral ulcers associated with Behcet's disease, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

REQUIREMENTS: APREMILAST (CONTINUED)

References:

1. Otezla package insert. Thousand Oaks, CA. Amgen Inc. Revised July 2023. Accessed August 2024.
2. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
3. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
5. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
6. Criteria for diagnosis of Behçet's disease. International Study Group for Behçet's Disease. Lancet. 1990;335(8697):1078-80.

Generic	Brand	Reviewed	Effective Date
OBETICHOLIC ACID Edition 1	OCALIVA	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named OBETICHOLIC ACID (Ocaliva) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of primary biliary cholangitis, as confirmed by TWO of the following criteria:
    1. An alkaline phosphatase level of at least 1.5 times the upper limit of normal
    2. The presence of antimitochondrial antibodies at a titer of 1:40 or higher
    3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts
B. The patient is 18 years of age and older
C. The medication is prescribed by or given in consultation with a gastroenterologist or hepatologist
D. The patient meets ONE of the following:
    1. The patient has had an inadequate response to ursodeoxycholic acid (i.e., 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. The patient is unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy
E. The patient does not have complete biliary obstruction

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

A. The patient has a diagnosis of primary biliary cholangitis
B. The patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal or have decreased by at least 15% from baseline while on treatment with obeticholic acid
C. The patient has not developed complete biliary obstruction

References:
1. Ocaliva Package Insert. New York, NY. Intercept Pharmaceuticals. Revised February 2022. Accessed August 2024.
2. Lindor KD, Bowlus CL, Boyer J, Levy C, Mayo M. Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. *Hepatology*. 2019;69(1):394-419. doi:10.1002/hep.30145.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OCRELIZUMAB Edition 3	OCREVUS OCREVUS ZUNOVO	10/21/2024	10/21/2024

REQUIREMENTS:

Our guideline named OCRELIZUMAB (Ocrevus) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Primary progressive multiple sclerosis (PPMS)
    2. Relapsing form of multiple sclerosis which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
B. The patient is at least 18 years of age
C. If the patient has a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, approval also requires:
    1. The patient meets ONE of the following:
        a. Has previously had a trial of generic glatiramer, glatopa, dimethyl fumarate, fingolimod, or teriflunomide
        b. Shows 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

References:

1. Ocrevus package insert. South San Francisco, CA. Genentech, Inc. Revised August 2023. Accessed December 2024.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.

Generic	Brand	Reviewed	Effective Date
SONIDEGIB Edition 2	ODOMZO	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named SONIDEGIB (Odomzo) requires the following rule(s) be met for approval:

A. The patient has diagnosis of locally advanced basal cell carcinoma (BCC)
B. The patient meets one of the following:
    1. The patient has recurrent basal cell carcinoma following surgery or radiation therapy
    2. The patient is not a candidate for surgery or radiation therapy

References:

1. Odomzo package inserts. Cranbury, NJ. Sun Pharmaceutical Industries, Inc., Revised August 2023. Accessed August 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MOMELOTINIB Edition 1	OJJAARA	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named MOMELOTINIB (Ojjaara) requires the following rule(s) be met for approval:

A. Patient is at least 18 years of age
B. The patient has a diagnosis of Intermediate or high risk myelofibrosis with anemia
C. The patient has an ECOG score of less than or equal to 2 and a life expectancy greater than 24 weeks

1. Ojjaara Package insert. Durham, NC. GSK, Revised September 2023. Accessed September 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OMIDUBICEL-ONLV Edition 1	OMISIRGE	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named omidubicel-onlv (Omisirge) requires the following rule(s) be met for approval:

A. The patient is at least 12 years of age
B. The patient is undergoing umbilical cord blood transplantation
C. Therapy is prescribed by, or in consultation with, HSCT specialist

1. Omisirge Package insert. Boston, MA. Gamida Cell LTD, Revised April 2023. Accessed August 2024.

CYCLOSPORINE OPHTHALMIC Edition 3			
Generic	Brand	Reviewed	Effective Date
CYCLOSPORINE OPHTHALMIC	RESTASIS RESTASIS MULTIDOSE	10/21/2024	01/01/2025
CYCLOSPORINE OPHTHALMIC	CEQUA		

REQUIREMENTS:

The guideline named CYCLOSPORINE OPHTHALMIC requires that the patient has a diagnosis of dry eye disease, 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:

A. The patient is aged 16 years or older.
B. The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
C. The patient does not have punctal plugs and will not be using concurrently with Xiidra, Eysuvis, Cequa, or Tyrvaya.
D. 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.
E. The patient had a previous trial of or contraindication to at least 4 weeks of treatment with an artificial tears product.

For the approval of Cequa:

A. The patient is aged 18 years or older.
B. The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
C. The patient does not have punctal plugs and will not be using concurrently with Xiidra, Eysuvis, Restasis, or Tyrvaya.
D. 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.
E. The patient had a previous trial of or contraindication to at least 4 weeks of treatment with an artificial tears product.
F. The patient has had a previous trial and failure of Restasis Multidose or Xiidra.

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: CYCLOSPORINE OPHTHALMIC (CONTINUED)

For renewal of therapy, the patient must meet ALL the following criteria for approval:

A. 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.
B. The requested medication will not be used in combination with punctal plugs, topical ophthalmic anti-inflammatory drugs, Xiidra, Eysuvis, or Tyrvaya.

References:

1. Restasis package insert. Irvine, CA. Allergan. Revised July 2017. Accessed March 2024.
2. Cequa package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised September 2019. Accessed March 2024.
3. Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2019;126(1):P286-P334. doi:10.1016/j.ophtha.2018.10.023.

Generic	Brand	Reviewed	Effective Date
SELPERCATINIB Edition 3	RETEVMO	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named SELPERCATINIB (Retevmo) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC)
    2. Advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC)
    3. Advanced or metastatic *RET* fusion-positive thyroid cancer
    4. Locally advanced or metastatic *RET* fusion-positive solid tumors
B. For patients with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), approval also requires:
    1. The patient is 18 years of age or older
C. For patients with advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC), approval also requires:
    1. The patient is 2 years of age or older
    2. The patient requires systemic therapy
D. For patients with advanced or metastatic *RET* fusion-positive thyroid cancer, approval also requires:
    1. The patient is 2 years of age or older
    2. The patient requires systemic therapy
    3. The patient is radioactive iodine-refractory, if radioactive iodine is appropriate
E. For patients with locally advanced or metastatic *RET* fusion-positive solid tumors, approval also requires:
    1. The patient is 2 years of age or older
    2. The patient has progressed on or is following prior systemic treatment or has no satisfactory alternative treatment options

References:
1. Retevmo Package insert Indianapolis, IN. Lilly USA, LLC. Revised September 2024. Accessed September 2024.

WELLFLEET
RX PLAN

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION Edition 1			
Generic	Brand	Reviewed	Effective Date
SILDENAFIL	REVATIO	10/21/2024	6/1/2021
TADALAFIL	ADCIRCA, ALYQ		

Please use the criteria for the specific drug requested

REQUIREMENTS:

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. The patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization Group I)
B. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient has documentation confirming a diagnosis of pulmonary arterial hypertension based on right heart catheterization 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. The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms
E. The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis (tadalafil), Viagra (sildenafil), etc.) or any organic nitrates in any form
F. The patient is NOT concurrently taking guanylate cyclase stimulators (i.e., 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 the patient is unable to swallow pills and have tried crushed sildenafil tablets

(Criteria continued in next page)

REQUIREMENTS: PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization Group 1
B. The patient meets ONE of the following criteria:
    1. The patient has shown improvement from baseline in the 6-minute walk distance test
    2. The patient has remained stable in the 6-minute walk distance test AND their New York Heart Association-World Health Organization (NYHA-WHO) functional class has remained stable or improved

References:

1. Revatio package insert. New York, NY. Pfizer Inc. Revised January 2023. Accessed August 2024.
2. Adcirca package insert. Indianapolis, IN. Eli Lilly and Company. Revised September 2020. Accessed August 2024.
3. Alyq package insert. Parsippany, NJ. Teva Pharmaceuticals. Revised January 2019. Accessed August 2024.
4. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. *Chest*. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.
5. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619. doi:10.1016/j.jacc.2009.01.004.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
UPADACITINIB Edition 9	RINVOQ	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named UPADACTINIB (Rinvoq) requires the following rules be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe atopic dermatitis (AD)
    4. Moderately to severely active ulcerative colitis (UC)
    5. Ankylosing spondylitis (AS)
    6. Non-Radiographic Axial Spondyloarthritis (Nr-axSpA)
    7. Moderate to Severe Crohn's Disease
B. For patients with moderate to severe rheumatoid arthritis (RA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has previously tried any ONE of the following preferred TNF blockers: Enbrel OR Humira (or biosimilar)
        i. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars) or Simponi (Aria or subcutaneous) also counts.
C. For patients with psoriatic arthritis (PsA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has previously tried any ONE of the following preferred TNF blockers: Enbrel or Humira (or biosimilar)
        i. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars) or Simponi (Aria or subcutaneous) also counts.
D. For patients with moderate to severe atopic dermatitis (AD), approval also requires:
    1. The patient is 12 years of age or older
    2. The patient meets at least ONE of the following for disease severity:
        i. Atopic dermatitis involving at least 10% of body surface area (BSA)
        ii. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas.
    3. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist

4. The patient has had at least a 4-week trial with an inadequate response to at least ONE of the following, unless contraindication to all listed:
    i. Moderate-or higher-potency topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate, etc.] OR
    ii. Topical calcineurin inhibitors [i.e., Elidel (pimecrolimus), Protopic (tacrolimus)] OR
    iii. Topical PDE-4 inhibitors [i.e., Eucrisa (crisaborole)] OR
5. The patient meets at least ONE of the following:
    i. Patient has had at least a 4-month trial with inadequate response to at least ONE traditional systemic therapy (e.g., methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil)
    ii. Patient has tried at least ONE traditional systemic therapy but was unable to tolerate a 4-month trial

NOTE: If the patient already has a previous trial with a biologic (i.e., Dupixent, Adbry, etc.), then this can be accepted in place of traditional systemic therapy

E. For patients with moderately to severely active ulcerative colitis, approval also requires:
    1. The patient is 18 years of age or older
    2. Therapy is prescribed by or given in consultation with a gastroenterologist
    3. The patient has previously tried the following formulary preferred TNF blocker: Humira (or biosimilar)
        i. A trial with an infliximab product (i.e., Remicade, biosimilars) or Simponi subcutaneous also counts
F. For patients with ankylosing spondylitis (AS), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has previously tried any ONE of the following preferred TNF blockers: Enbrel or Humira (or biosimilar)
        i. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars) or Simponi (Aria or subcutaneous) also counts.
G. For patients with non-radiographic axial spondyloarthritis (Nr-axSpA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has objective signs of inflammation, shown by at least ONE of the following:
        i. C-reactive protein elevated beyond the upper limit of normal
        ii. Sacroiliitis reported on magnetic resonance imaging
    4. The patient has previously had a 3-month trial of the following formulary preferred TNF blocker: Cimzia
H. For patients with moderate to severe Crohn's Disease, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient meets at least ONE of the following:

i. Has had a previous trial of one or more of the following conventional agents: corticosteroids, azathioprine, mercaptopurine, methorexate, or mesalamine
ii. Has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
iii. Has a history of ileocolonic resection

4. The patient has previously had a trial of the following formulary preferred product: Humira (or biosimilar)

RENEWAL CRITERIA

The guideline named UPADACTINIB (Rinvoq) requires the following rules be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe atopic dermatitis (AD)
    4. Moderately to severely active ulcerative colitis (UC)
    5. Ankylosing spondylitis (AS)
    6. Non-Radiographic Axial Spondyloarthritis (Nr-axSpA)
    7. Moderate to Severe Crohn's Disease
B. For patients with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or ankylosing spondylitis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms
C. For patients with moderate to severe atopic dermatitis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has shown a clinical response as evidenced by an improvement in symptoms (e.g., reduced body surface area affected, reduced pruritus, improvements in cracking, oozing, or bleeding of affected skin, reduced erythema, etc.)
D. For patients with moderate to severe ulcerative colitis (UC) or non-radiographic axial spondyloarthritis (Nr-axSPA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with moderate to severe Crohn's Disease, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Rinvoq package insert. North Chicago, IL. AbbVie Inc. Revised June 2023. Accessed August 2024.
2. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.

3. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.

4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
5. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132. doi:10.1016/j.jaad.2014.03.023.
6. Drucker AM, Ellis AG, Bohdanowicz M, et al. Systemic Immunomodulatory Treatments for Patients With Atopic Dermatitis: A Systematic Review and Network Meta-analysis. JAMA Dermatol. 2020;156(6):659-667. doi:10.1001/jamadermatol.2020.0796.
7. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413.
9. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042. .

Generic	Brand	Reviewed	Effective Date
MIDOSTAURIN Edition 1	RYDAPT	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Newly diagnosed acute myeloid leukemia (AML)
    2. Aggressive systemic mastocytosis (ASM)
    3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
    4. Mast cell leukemia (MCL)

B. If you have newly diagnosed acute myeloid leukemia (AML), approval also requires:
    1. The patient is 18 years of age or older
    2. The patient has FLT3 mutation-positive disease 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
    4. The requested medication will not be used by itself to start treatment

References:
1. Rydapt Package Insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised May 2023. Accessed August 2024.

PEANUT ALLERGEN POWDER-DNFP			
Generic	Brand	Reviewed	Effective Date
PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER Edition 2	PALFORZIA	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PEANUT ALLERGEN POWDER (Palforzia) requires the following rule(s) be met for approval:

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

(Criteria continued on next page)

REQUIREMENTS: PALFORZIA (CONTINUED)

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

A. The patient has an allergy to peanuts
B. The requested medication is prescribed by or given in consultation with an allergist/immunologist
C. The requested medication will be used together with a peanut-avoidance diet
D. The patient is not currently on peanut-specific immunotherapy (such as Viaskin Peanut)
E. The patient meets ONE of the following:
    1. The patient has a persistent peanut allergy
    2. The patient has undergone a purposeful food challenge: documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 3 mm or greater) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) within the past 24 months
    3. The patient has NOT undergone a purposeful food challenge: documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 8 mm or greater) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) within the past 24 months

References:
1. Palforzia Package Insert. Brisbane, CA. Aimmune Therapeutics, Inc. Revised July 2024. Accessed August 2024.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

Generic	Brand	Reviewed	Effective Date
PEGVALIASE Edition 1	PALYNZIQ	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PEGVALIASE (Palynziq) requires the following rules be met for approval:

A. The patient has a diagnosis of phenylketonuria (PKU)
B. The patient is 18 years of age or older
C. The patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
D. The patient has previously tried Kuvan (sapropterin)
E. The patient is NOT receiving Kuvan (sapropterin) at the same time as the requested medication

RENEWAL CRITERIA
Our guideline named PEGVALIASE (Palynziq) requires the following rules be met for renewal:

A. The patient has a diagnosis of phenylketonuria (PKU)
B. The patient's phenylalanine levels have dropped by at least 20% from baseline and/or to a level under 600 micromol/L.

References:

1. Palynziq package Insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised November 2020. Accessed August 2024.
2. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline [published correction appears in Genet Med. 2014 Apr;16(4):356]. *Genet Med*. 2014;16(2):188-200. doi:10.1038/gim.2013.157.

Generic	Brand	Reviewed	Effective Date
PEMIGATINIB Edition 2	PEMAZYRE	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named PEMIGATINIB (Pemazyre) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Unresectable locally advanced or metastatic cholangiocarcinoma
    2. Relapsed or refractory myeloid/lymphoid neoplasms (MLNs)
B. The patient is 18 years of age or older
C. For patients with unresectable locally advanced or metastatic cholangiocarcinoma, approval requires:
    1. The patient has previously been treated
    2. The patient has a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test
D. For patients with relapsed or refractory myeloid/lymphoid neoplasms, approval requires:
    1. The patient has a fibroblast growth factor receptor 1 (FGFR1) rearrangement as detected by a Food and Drug Administration (FDA)-approved test

References:
1. Pemazyre package insert. Wilmington, DE. Incyte Corporation. Revised August 2022. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
POMALIDOMIDE Edition 2	POMALYST	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named POMALIDOMIDE (Pomalyst) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Multiple myeloma (MM)
    2. Kaposi sarcoma (KS)
B. For patients with multiple myeloma, approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is used in combination with dexamethasone
    3. The patient has tried at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g., Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib], etc.)
    4. The patient has demonstrated disease progression on or within 60 days of completion of the last therapy
C. If you have Kaposi sarcoma, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient meets ONE of the following:
        a. The patient has acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART)
        b. The patient is human immunodeficiency virus (HIV)-negative

References:
1. Pomalyst package inserts. Summit, NJ. Celgene Corporation. Revised March 2023. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
RIPRETINIB Edition 1	QINLOCK	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named RIPRETINIB (Qinlock) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of advanced gastrointestinal stromal tumor (GIST)
B. The patient is 18 years of age or older
C. The patient has previously received prior treatment with three (3) or more kinase inhibitors (e.g., Sutent (sunitinib), Stivarga (regorafenib), etc.), including Gleevec (imatinib)

References:

1. Qinlock package insert. Waltham, MA. Deciphera Pharmaceuticals, LLC. Revised December 2022. Accessed August 2024.

WELLFLEET
RX PLAN

PREDNISONE DELAYED-RELEASE TABS			
Generic	Brand	Reviewed	Effective Date
PREDNISONE Edition 1	RAYOS	10/21/2024	6/1/2021

REQUIREMENTS:

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. The patient has had a previous trial of ONE of the following, unless there is a contraindication: generic immediate-release formulations of prednisone, prednisolone, or methylprednisolone
C. The patient has had a subclinical response or treatment failure of generic immediate-release formulations of 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. The patient has had a clinical benefit from using the requested medication (i.e., improvement in inflammatory condition from baseline)
C. The patient cannot be tapered off corticosteroid

References:
1. Rayos package insert. Deerfield, IL Horizon. Therapeutics USA, Inc. Revised June 2024. Accessed August 2024.
2. Buttgereit F, Gibofsky A. Delayed-release prednisone - a new approach to an old therapy. Expert Opin Pharmacother. 2013;14(8):1097-1106. doi:10.1517/14656566.2013.782001.

Generic	Brand	Reviewed	Effective Date
SODIUM PHENYLBUTYRATE/ TAURURSODIOL Edition 1	RELYVRIO	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SODIUM PHENYLBUTYRATE/TAURURSODIOL (Relyvrio) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS)
B. The patient is 18 years of age or older
B. The medication is prescribed by or given in consultation with a neurologist, neuromuscular disease specialist, or ALS specialist at an ALS Specialty Center or Care Clinic
C. The patient has symptom onset within the past 18 months
D. The patient has a Slow Vital Capacity (SVC) of greater than 60% of predicted value for gender, height, and age

RENEWAL CRITERIA
Our guideline named SODIUM PHENYLBUTYRATE/TAURURSODIOL (Relyvrio) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS)
B. The patient has improved or maintained baseline functional ability or demonstrated a less-than expected decline in functional ability from baseline as measured by functional assessments (i.e., ALS Functional Rating Scale-Revised [ALSFRS-R])

References:

1. Relyvrio package insert. Cambridge, MA. Amylyx Pharmaceuticals, Inc. Revised September 2022. Accessed September 2024.
2. Brooks BR, Miller RG, Swash M, Munsat TL; World Federation of Neurology Research Group on Motor Neuron Diseases. El Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293-299. doi:10.1080/146608200300079536.
3. Cedarbaum JM, Stambler N, Malta E, Fuller C, Hilt D, Thurmond B, et al. The ALSFRS-R: a revised ALS functional rating
4. scale that incorporates assessments of respiratory function. J Neurol Sci. 1999; 169(1): 13–21.

Generic	Brand	Reviewed	Effective Date
INFLIXIMAB Edition 3	REMICADE	10/21/2024	10/21/2022
INFLIXIMAB	INFLIXIMAB (JANSSEN)		
INFLIXIMAB-ABDA	RENFLEXIS		
INFLIXIMAB-AXXQ	AVSOLA		
INFLIXIMAB-DYYB	INFLECTRA		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named INFLIXIMAB requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Severe plaque psoriasis (PsO)
    5. Moderate to severe Crohn's disease (CD)
    6. Moderate to severe ulcerative colitis (UC)
B. For patients with moderate to severe rheumatoid arthritis (RA), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient is currently using or has a contraindication to methotrexate
    4. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    5. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA: The patient has previously tried ONE of the following preferred agents unless there is contraindication: Renflexis

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

C. For patients with psoriatic arthritis (PsA), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has a previous trial of or contraindication to at least ONE DMARD such as, methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA: The patient has previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis
D. For patients with ankylosing spondylitis (AS), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA: The patient has a previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis
E. For patients with severe plaque psoriasis (PsO), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient has had a previous trial of or contraindication to 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
    5. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA: The patient has a previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

F. For patients with moderate to severe Crohn's disease (CD), approval also requires:
    1. The requested medication is prescribed by or given in consultation with a gastroenterologist
    2. The patient meets at least ONE of the following:
        a. The patient has had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
        b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
        c. The patient has a history of ileocolonic resection
    3. The patient meets ONE of the following:
        a. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA: The patient is 6 to 17 years of age AND has previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis
        b. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA: The patient is 18 years of age or older AND has previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis
        c. THIS CRITERIA ONLY APPLIES TO RENFLEXIS: The patient is 6 years of age or older
G. For patients with moderate to severe ulcerative colitis (UC), approval also requires:
    1. The requested medication is prescribed by or given in consultation with a gastroenterologist
    2. The patient has had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
    3. The patient meets ONE of the following:
        a. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLECTRA, INFLIXIMAB (JANSSEN), AND AVSOLA: The patient is 6 to 17 years of age AND has previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis
        b. THIS CRITERIA ONLY APPLIES TO REMICADE, INFLECTRA, INFLIXIMAB (JANSSEN), AND AVSOLA: The patient is 18 years of age or older AND has previously tried ONE of the following preferred agents unless there is a contraindication: Renflexis
        c. THIS CRITERIA ONLY APPLIES TO RENFLEXIS: The patient is 6 years of age or older

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

RENEWAL CRITERIA
Our guideline named INFLIXIMAB requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Severe plaque psoriasis (PsO)
    5. Moderate to severe Crohn's disease (CD)
    6. Moderate to severe ulcerative colitis (UC)
B. For patients with moderate to severe rheumatoid arthritis (RA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
    2. The patient is currently using or has a contraindication to methotrexate
C. For patients with psoriatic arthritis (PsA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with ankylosing spondylitis (AS), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with severe plaque psoriasis (PsO), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms
F. For patients with moderate to severe Crohn's disease (CD), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
G. For patients with moderate to severe ulcerative colitis (UC), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

References:

1. Remicade package insert. Horsham, PA. Janssen Biotech, Inc. Revised October 2021. Accessed August 2024.
2. Avsola package insert. Thousand Oaks, CA. Amgen, Inc. Revised September 2021. Accessed August 2024.
3. Inflectra package insert. New York, NY. Pfizer Inc. Revised March 2022. Accessed August 2024.
4. Infliximab package insert. Horsham, PA. Janssen Biotech, Inc. Revised October 2021. Accessed August 2024.
5. Renflexis package insert. Jersey City, NJ. Organon & Co. Revised January 2022. Accessed August 2024.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413. 10.
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158(5):1450-1461. doi:10.1053/j.gastro.2020.01.006.
9. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
10. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021;160(7):2496- 2508.
11. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042.
12. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
13. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
14. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
15. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EVOLOCUMAB Edition 4	REPATHA	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named EVOLOCUMAB (Repatha) requires the following rule(s) be met for approval:

A. Patient has ONE of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
    3. Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
B. If patient has diagnosis of established cardiovascular disease, approval also requires:
    1. Patient is 18 years of age or older
C. If patient has a diagnosis of Heterozygous familial hypercholesterolemia (HeFH) or Homozygous familial hypercholesterolemia (HoFH), approval also requires:
    1. Patient is 10 years of age or older
D. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
E. Attestation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70mg/dL
F. If patient is statin tolerant, approval also requires:
    1. Patient will continue statin treatment in combination with the requested medication
    2. Patient meets ONE of the following:
        a. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for at least 8 weeks
        b. Patient has 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)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: EVOLOCUMAB (CONTINUED)

G. If patient is statin intolerant, approval also requires ONE of the following:
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction
    2. Patient has complete statin intolerance as defined by rhabdomyolysis to 1 statin OR skeletal-muscle related symptoms from trials of both rosuvastatin and atorvastatin which resolved upon discontinuation.

RENEWAL CRITERIA

Our guideline named EVOLOCUMAB (Repatha) requires the following rules be met for renewal:

A. Patient has ONE of the following diagnoses:
    1. Established cardiovascular disease
    2. Heterozygous familial hypercholesterolemia (HeFH)
    3. Homozygous familial hypercholesterolemia (HoFH)
B. Patient meets ONE of the following:
    1. Patient has continued to take a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) with the requested medication
    2. Patient has continued therapy with a maximally tolerated dose of any statin with the requested medication
    3. Patient has an absolute contraindication to statin therapy
    4. Patient has complete statin intolerance

References:

1. Repatha package insert. Thousand Oaks, CA. Amgen Inc. Revised August 2022. Accessed September 2024.
2. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2019 Sep 10;74(10):1429-1430] [published correction appears in J Am Coll Cardiol. 2020 Feb 25;75(7):840]. J Am Coll Cardiol. 2019;74(10):e177-e232. doi:10.1016/j.jacc.2019.03.010.
3. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625
4. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

Generic	Brand	Reviewed	Effective Date
DEUCRAVACITINIB Edition 2	SOTYKTU	10/21/2024	10/21/2024

REQUIREMENTS:

Our guideline named DEUCRAVACITINIB (Sotyktu) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO).
B. The following criteria must also be met:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient has had a previous trial of or contraindication to 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

RENEWAL CRITERIA

Our guideline named DEUCRAVACITINIB (Sotyktu) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO)
B. The following criterion must also be met for renewal:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Sotyktu package insert. Princeton, NJ Bristol-Myers Squibb Company, Revised September 2022. Accessed September 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.

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Generic	Brand	Reviewed	Effective Date
USTEKINUMAB Edition 3	STELARA	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named USTEKINUMAB (Stelara) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis
    2. Psoriatic arthritis
    3. Moderately to severely active Crohn's disease
    4. Moderately to severely active ulcerative colitis
B. For patients with moderate to severe plaque psoriasis (PsO), approval requires all of the following criteria:
    1. The patient is 6 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
    4. The patient has 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
C. For patients with psoriatic arthritis (PsA), approval requires all of the following criteria:
    1. The patient is 6 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

(Criteria continued on next page)

REQUIREMENTS: USTEKINUMAB (CONTINUED)

D. For patients with moderately to severely active Crohn's disease (CD), approval requires all of the following criteria:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient meets at least ONE of the following:
        a. 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
        b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
        c. The patient has a history of ileocolonic resection
E. For patients with moderately to severely active ulcerative colitis (UC), approval requires all the following criteria:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient has had a previous trial of or contraindication to at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine

RENEWAL CRITERIA
Our guideline named USTEKINUMAB (Stelara) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Psoriatic arthritis (PsA)
    2. Moderate to severe plaque psoriasis (PsO)
    3. Moderately to severely active Crohn's disease (CD)
    4. Moderately to severely active ulcerative colitis (UC)
B. For patients with psoriatic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with moderate to severe plaque psoriasis, renewal requires:
    1. The patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms

(Criteria continued on next page)

REQUIREMENTS: USTEKINUMAB (CONTINUED)

D. For patients with Crohn's disease, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with ulcerative colitis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Stelara package insert. Horsham, PA. Janssen Biotech, Inc. Revised March 2023. Accessed August 2024.
2. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
3. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
4. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413. 10.
9. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.

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Generic	Brand	Reviewed	Effective Date
REGORAFENIB Edition 2	STIVARGA	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named REGORAFENIB (Stivarga) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. Metastatic colorectal cancer (CRC)
    2. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST)
    3. Hepatocellular carcinoma (HCC)
B. For patients with metastatic colorectal cancer (CRC), approval also requires:
    1. If colorectal cancer is wild type KRAS, the patient must have had previous treatment with ALL of the following therapies:
        a. An anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept], etc.)
        b. A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine, etc.)
        c. An anti-EGFR therapy (e.g., Erbitux [cetuximab], Vectibix [panitumumab], etc.)
    2. If colorectal cancer has KRAS mutation, the patient must have had previous treatment with ALL of the following therapies:
        a. An anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv- aflibercept], etc.)
        b. A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, infusional 5-FU/LV, capecitabine, etc.)
C. For patients with locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:
    1. The patient must have had previous treatment with both Gleevec (imatinib) and Sutent (sunitinib)
D. For patients with hepatocellular carcinoma (HCC), approval also requires:
    1. The patient must have had previous treatment with Nexavar (sorafenib).

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References:
1. Stivarga package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised December 2020. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
SACROSIDASE Edition 1	SUCRAID	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named SACROSIDASE (Sucraid) requires the following rule be met for approval:

A. The patient has been diagnosed with a congenital sucrase-isomaltase deficiency (CSID)

References:

1. Sucraid package insert. Vero Beach, FL. QOL Medical, LLC. Revised August 2024. Accessed August 2024.
2. Naim HY, Heine M, Zimmer KP. Congenital sucrase-isomaltase deficiency: heterogeneity of inheritance, trafficking, and function of an intestinal enzyme complex. J Pediatr Gastroenterol Nutr. 2012;55 Suppl 2:S13-S20. doi:10.1097/01.mpg.0000421402.57633.4b.

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Generic	Brand	Reviewed	Effective Date
SOLRIAMFETOL Edition 2	SUNOSI	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SOLRIAMFETOL (Sunosi) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Excessive daytime sleepiness (EDS) with narcolepsy
    2. Excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or in consultation with a neurologist or specialist in sleep medicine
D. 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)
E. The requested medication will not be used in combination with Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium, sodium oxybates) and/or Wakix (pitolisant)
F. For the diagnosis of excessive daytime sleepiness (EDS) with narcolepsy, approval also requires the following:
    1. Provide clinical documentation the patient's diagnosis of narcolepsy has been confirmed by both polysomnography and a multiple sleep latency test (MLST).
    2. Provide clinical documentation showing symptoms of excessive daytime sleepiness (EDS) associated with narcolepsy occurring for at least 3 months
    3. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Modafinil
        b. Armodafinil
        c. Generic stimulant (e.g., amphetamine, dextroamphetamine, or methylphenidate)

(Criteria continued on next page)

REQUIREMENTS: SOLRIAMFETOL (CONTINUED)

G. For the diagnosis of excessive daytime sleepiness with obstructive sleep apnea (OSA), approval also requires the following:
    1. Provide clinical documentation the patient's diagnosis of OSA has been confirmed by polysomnography
    2. Provide clinical documentation of excessive daytime sleepiness (EDS) symptoms occurring for at least 3 months
    3. The patient has tried and failed modafinil or armodafinil, unless there is contraindication to both
    4. The patient has been on a treatment for the obstructive causes of OSA, for at least one month since initiation (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP])

RENEWAL CRITERIA

Our guideline named SOLRIAMFETOL (Sunosi) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Excessive daytime sleepiness (EDS) with narcolepsy
    2. Excessive daytime sleepiness (EDS) with Obstructive sleep apnea (OSA)
B. Documentation of sustained improvement of excessive daytime sleepiness (EDS) as shown by sustained Epworth Sleepiness Scale (ESS) improvement compared to baseline since initial authorization

References:
1. Sunosi package Insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised June 2023. Accessed August 2024.
2. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.
3. Morgenthaler TI, Kapen S, Lee-Chiong T, et al. Practice parameters for the medical therapy of obstructive
4. sleep apnea. Sleep. 2006;29(8):1031-1035.

Generic	Brand	Reviewed	Effective Date
SUNITINIB MALATE Edition 1	SUTENT	10/21/2024	6/1/2021

REQUIREMENTS:

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)
    2. Gastrointestinal stromal tumor (GIST)
    3. Unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET)
    4. Adjuvant treatment of renal cell carcinoma (RCC)
B. The patient is 18 years of age or older
C. For patients with gastrointestinal stromal tumor (GIST), approval also requires:
    1. The patient has had a previous trial of imatinib (Gleevec), unless there is a contraindication
D. For patients with unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:
    1. The patient's tumor is progressive and well-differentiated
E. For patients with adjuvant treatment of renal cell carcinoma, approval also requires:
    1. The patient is at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy

References:
1. Sutent package insert. New York, NY. Pfizer, Inc. Revised August 2021. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
PEG-INTERFERON ALFA-2B Edition 1	SYLATRON, SYLATRON 4-PACK	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient meets ONE of the following:
    1. The patient is currently taking Sylatron and has NOT received 5 years of treatment with Sylatron
    2. The patient has melanoma with the presence of cancer cells in your lymph nodes, within 84 days of surgical removal of the cancer

References:
1. Sylatron package Insert. Whitehouse Station, NJ. Merck & Co Inc. Revised December 2018. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
OMACETAXINE MEPESUCCINATE Edition 2	SYNRIBO	10/21/2024	10/21/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of chronic myeloid leukemia (CML)
B. The patient's disease is chronic or accelerated phase
C. The patient has previously tried or has a contraindication to TWO or more of the following therapies: Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib), or Iclusig (ponatinib)

References:
1. Synribo package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised May 2021. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
PASIREOTIDE Edition 1	SIGNIFOR	10/21/2024	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PASIREOTIDE (Signifor) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of Cushing's disease (CD)
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an endocrinologist
D. The patient has undergone pituitary surgery OR pituitary surgery is not an option
E. The patient has previously tried oral ketoconazole, unless there is a contraindication

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

A. The patient has a diagnosis of Cushing's disease (CD)
B. The patient continues to have improvement of Cushing's disease (i.e., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of the disease)
C. The patient continues to tolerate treatment with the requested medication

References:

1. Signifor package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2024. Accessed August 2024.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015;100(8):2807-2831. doi:10.1210/jc.2015-1818.

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Generic	Brand	Reviewed	Effective Date
GOLIMUMAB – IV Edition 3	SIMPONI ARIA – IV	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named GOLIMUMAB - IV (Simponi Aria - IV) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Polyarticular juvenile idiopathic arthritis (PJIA)
B. For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3months of treatment with at least ONE DMARD such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), hydroxychloroquine, sulfasalazine, or leflunomide
    4. The patient is concurrently use methotrexate, unless contraindicated
    5. The patient has had a previous trial of or contraindication to any TWO of the following formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR
C. For the diagnosis of psoriatic arthritis (PsA), approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient had a previous trial of or contraindication to at least one of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient had a previous trial of or contraindication to any TWO of the following formulary preferred immunomodulators: Enbrel, Humira, Stelara, Skyrizi, Taltz, Otezla, Tremfya, Rinvoq, or Xeljanz/XR

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-IV (CONTINUED)

D. For the diagnosis of ankylosing spondylitis (AS), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to any TWO of the following formulary preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz/Xeljanz XR, or Taltz
E. For the diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), approval requires:
    1. The patient is 2 years of age or older
    2. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

The guideline named GOLIMUMAB - IV (Simponi Aria - IV) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Polyarticular juvenile idiopathic arthritis (PJIA)
B. For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
    2. The patient is concurrently using or has a contraindication to methotrexate
C. For the diagnosis of psoriatic arthritis (PsA), approval requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For the diagnosis of ankylosing spondylitis (AS), approval requires:
    i. 1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-IV (CONTINUED)

E. For the diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), approval requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Simponi package insert. Horsham, PA. Janssen Biotech, Inc. Revised February 2021. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
4. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042.
6. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.

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MOMETASONE SINUS IMPLANT			
Generic	Brand	Reviewed	Effective Date
MOMETASONE FUROATE Edition 2	SINUVA	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named MOMETASONE IMPLANT (Sinuva) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an otolaryngologist
D. The patient previously had ethmoid sinus surgery
E. The patient is a candidate for repeat ethmoid sinus surgery due to refractory moderate to severe symptoms of nasal obstruction, nasal congestion or nasal polyps in both ethmoid sinuses
F. The patient previously had a 90-day trial of ONE intranasal corticosteroid (i.e., fluticasone, beclomethasone, flunisolide, ciclesonide, mometasone)
G. The patient has not received 4 implants (2 per nostril) in their lifetime

RENEWAL CRITERIA
Our guideline named MOMETASONE IMPLANT (Sinuva) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of nasal polyps
B. The patient has ethmoid sinus polyps grade 1 or greater on any side
C. The patient does 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. The patient has not previously received 4 implants (2 per nostril) in their lifetime

References:

1. Sinuva Package Insert. Menlo Park, CA. Intersect ENT, Inc. Revised January 2023. Accessed August 2024.
2. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. 2015;152(2 Suppl):S1-S39. doi:10.1177/0194599815572097.

Generic	Brand	Reviewed	Effective Date
ELIVALDOGENE AUTOTEMCEL Edition 1	SKYSONA	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named ELIVALDOGENE AUTOTEMCEL (Skysona) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) as defined by ALL the following:
    1. The patient has confirmed mutations in the *ABCD1* gene
    2. The patient has elevated very long chain fatty acid (VLCFA) levels
    3. The patient has Loes scores between 0.5 to 9 on the 34-point scale
    4. The patient has gadolinium enhancement (GdE+) on brain magnetic resonance imaging (MRI) of demyelinating lesions
    5. The patient has asymptomatic or mildly symptomatic disease with neurologic function score (NFS) equal to or less than 1
B. The patient is between 4 and 17 years of age
C. The patient is a biological male
D. The requested medication is prescribed by or in consultation with a neurologist, endocrinologist, hematologist/oncologist, gastroenterologist, hepatologist, or specialist in adrenoleukodystrophy

References:
1. Skysona package insert. Somerville, MA. bluebird bio, Inc. Revised September 2022. Accessed September 2024.
2. Engelen M, van Ballegoij WJC, Mallack EJ, et al. International Recommendations for the Diagnosis and Management of Patients With Adrenoleukodystrophy: A Consensus-Based Approach [published online ahead of print, 2022 Sep 29]. Neurology. 2022;10.1212/WNL.0000000000201374. doi:10.1212/WNL.0000000000201374.
3. Gupta AO, Raymond G, Pierpont EI, et al. Treatment of cerebral adrenoleukodystrophy: allogeneic transplantation and lentiviral gene therapy. Expert Opin Biol Ther. 2022;22(9):1151-1162. doi:10.1080/14712598.2022.2124857.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PALOVAROTENE Edition 2	SOHONOS	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named PALOVAROTENE (Sohonos) requires the following rule(s) be met for approval:

A. Patient is EITHER a biological female over 8 years of age OR a biological male over 10 years of age
B. The patient has a diagnosis of Fibrodysplasia ossificans progressive
C. Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene
D. Therapy will be used in order to reduce the volume of new heterotopic ossification

1. Sohonos Package insert. Cambridge, MA. Ipsen Pharmaceutical, Revised August 2023. Accessed September 2024.

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Generic	Brand	Reviewed	Effective Date
NATALIZUMAB Edition 3	TYSABRI	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named NATALIZUMAB (Tysabri) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe Crohn's disease (CD)
    2. A relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease
B. For patients with moderate to severe Crohn's disease, approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient meets at least ONE of the following:
        a. The patient has had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
        b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
        c. The patient has a history of ileocolonic resection
    4. The patient has had a previous trial of or contraindication to ONE of the following formulary preferred immunomodulators: Humira, Skyrizi, or Stelara
C. For patients with a relapsing form of multiple sclerosis (MS), approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is being used as monotherapy
    3. The patient has had a previous trial of generic glatiramer, glatopa, dimethyl fumarate, fingolimod, or teriflunomide

(Criteria continued on the next page)

REQUIREMENTS: NATALIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named NATALIZUMAB (Tysabri) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe Crohn's disease (CD)
    2. A relapsing form of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
B. For patients with moderate to severe Crohn's disease, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Tysabri package insert. Cambridge, MA. Biogen Inc. Revised October 2023. Accessed August 2024.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology [published correction appears in Neurology. 2019 Jan 8;92(2):112]. Neurology. 2018;90(17):777-788. doi:10.1212/WNL.0000000000005347.
3. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
4. Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. Gastroenterology. 2021;160(7):2496- 2508.

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SELEXIPAG Edition 2			
Generic	Brand	Reviewed	Effective Date
SELEXIPAG Tablets	UPTRAVI	10/21/2024	10/29/2021
SELEXIPAG Injection	UPTRAVI		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SELEXIPAG (Uptravi) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH)
B. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient has documentation confirming a diagnosis of pulmonary arterial hypertension based on right heart catheterization 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. The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms

RENEWAL CRITERIA
Our guideline named SELEXIPAG (Uptravi) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH)
B. The patient meets ONE of the following:
    1. The patient has shown improvement from baseline in the 6-minute walk distance test
    2. The patient has remained stable in the 6-minute walk distance test AND their New York Heart Association-World Health Organization (NYHA-WHO) functional class has remained stable or improved

(Criteria continued in next page)

REQUIREMENTS: SELEXIPAG (Uptravi) (CONTINUED)

References:

1. Uptravi package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised July 2021. Accessed August 2024.
2. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. *Chest*. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030.
3. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association developed in collaboration with the American College of Chest Physicians; American Thoracic Society, Inc.; and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009;53(17):1573-1619. doi:10.1016/j.jacc.2009.01.004.

MECHLORETHAMINE GEL			
Generic	Brand	Reviewed	Effective Date
MECHLORETHAMINE Edition 1	VALCHLOR	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of stage IA or IB mycosis fungoides-type cutaneous T-cell lymphoma
B. The patient has had prior skin-directed therapy such as corticosteroids, carmustine, topical retinoids (Targretin, Tazorac), imiquimod, or local radiation therapy

References:

1. Valchlor package insert. Iselin, NJ. Helsinn Therapeutics, (U.S.), Inc. Revised January 2020. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
MECAMYLAMINE HCL Edition 1	VECAMYL	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has one of the following diagnoses:
    1. Moderately severe to severe essential (or primary) hypertension
    2. Uncomplicated malignant hypertension
B. The patient has had a trial of at least three of the following, unless there is a 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.

References:

1. Vecamyl package insert. New York, NY. Vyera Pharmaceuticals, LLC. Revised July 2018. Accessed August 2024.
2. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2018 May 15;71(19):2275-2279]. *J Am Coll Cardiol*. 2018;71(19):e127-e248. doi:10.1016/j.jacc.2017.11.006.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
POZELIMAB Edition 1	VEOPOZ	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named POZELIMAB (Veopoz) requires the following rule(s) be met for approval:

A. Patient is 1 year of age or older
B. The patient has a diagnosis of CD55-deficient protein-losing enteropathy (CHAPLE Disease)
C. Therapy will be prescribed by, or in consultation with, a CHAPLE disease specialist

1. Veopoz Package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Revised August 2023. Accessed September 2024.

Generic	Brand	Reviewed	Effective Date
PAZOPANIB Edition 1	VOTRIENT	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Advanced renal cell carcinoma (RCC)
    2. Advanced soft tissue sarcoma (STS)
B. For patients with advanced soft tissue sarcoma (STS), approval also requires:
    1. The patient has had a trial of chemotherapy, unless there is a contraindication
    2. The patient does NOT have adipocytic soft tissue sarcoma or gastrointestinal stromal tumors (GIST)

References:

1. Votrient package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised January 2024. Accessed August 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FECAL MICROBIOTA SPORES, LIVE-BRPK Edition 1	VOWST	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named Fecal microbiota spores, live-brpk (Vowst) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of recurrent CDI infection
B. Therapy is prescribed by, or in consultation with, a gastroenterologist
C. The patient has previously received antibiotic treatment for recurrent C. dif. infection
D. The patient is at least 18 years of age

1. Vowst Package insert. Brisbane, CA. Seres Therapeutics, Revised May 2023. Accessed August 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CARIPRAZINE Edition 1	VRAYLAR	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named Cariprazine (Vraylar) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. The patient has ONE of the following diagnoses:
    1. Schizophrenia
    2. Bipolar I disorder
    3. Major Depressive Disorder
C. For a diagnosis of Bipolar I Disorder, approval also requires:
    1. Therapy will be used as acute treatment of manic or mixed episodes OR
    2. Therapy will be used for treatment of depressive episodes (bipolar depression)
D. For a diagnosis of Major Depressive Disorder, approval also requires:
    1. The requested medication will be used as adjunct therapy, not as monotherapy

1. Vraylar Package insert. Parsippany, NJ. Actavis, Inc, Revised September 2015. Accessed August 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEREMAGENE GEPERPAVEC-SVDT Edition 1	VYJUVEK	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named Beremagene geperpavec-svdt (Vyjuvek) requires the following rule(s) be met for approval:

A. Patient has a diagnosis of dystrophic epidermolysis bullosa (DEB)
B. Patient has a mutation in the collagen type VII alpha 1 chain (COL7A1) gene, as confirmed by an FDA approved test
C. Patient is at least 6 months of age
D. Therapy will be prescribed by, or in consultation with, a dermatologist or DEB specialist

1. Vyjuvek Package insert. Pittsburgh, PA. Krystal Biotech, Revised May 2023. Accessed August 2024.

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TAFAMIDIS Edition 1			
Generic	Brand	Reviewed	Effective Date
TAFAMIDIS MEGLUMINE	VYNDAQEL	10/21/2024	10/21/2022
TAFAMIDIS	VYNDAMAX		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named TAFAMIDIS (Vyndaqel, Vyndamax) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)
B. The patient's diagnosis is confirmed by ONE of the following:
    1. Nuclear scintigraphy (i.e., radionuclide imaging with technetium-99)
    2. Biopsy of tissue demonstrating ATTR amyloid deposits
C. The patient's cardiac involvement is confirmed by diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic resonance imaging)
D. The patient is 18 years of age or older
E. The requested medication is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
F. The patient has New York Heart Association (NYHA) class I, II or III heart failure

RENEWAL CRITERIA
Our guideline named TAFAMIDIS (Vyndaqel, Vyndamax) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM)
B. The patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

References:
1. Vyndaqel package insert. New York, NY. Pfizer labs. Revised June 2021. Accessed August 2024.
2. Vyndamax package insert. New York, NY. Pfizer labs. Revised June 2021. Accessed August 2024.
3. Maurer MS, Bokhari S, Damy T, et al. Expert consensus recommendations for the suspicion and diagnosis of transthyretin cardiac amyloidosis. Circ Heart Fail. 2019 Sep;12(9):e006075.
4. Siddiqi OK, Ruberg FL. Cardiac amyloidosis: an update on pathophysiology, diagnosis, and treatment. Trends Cardiovasc Med. 2018;28(1):10-21.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EFGARTIGIMOD ALFA AND HYALURONIDASE-QVFC Edition 1	VYVGART	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart) requires the following rule(s) be met for approval:

A. Patient is at least 18 years of age
B. Therapy is prescribed by, or in consultation with, a neurologist or MG specialist
C. The patient has a diagnosis of Myasthenia Gravis
D. The patient has is anti-acetylcholine receptor antibody positive, as determined by an FDA approved test

1. Vyvgart Package insert. Boston, MA. Argenx BC, Revised December 2021. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
IXEKIZUMAB Edition 3	TALTZ	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named IXEKIZUMAB (Taltz) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Non-radiographic axial spondyloarthritis (nr-axSpA)
B. For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:
    1. The patient is 6 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient has had a previous trial of or contraindication to 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
C. For the diagnosis of psoriatic arthritis (PsA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient had a previous trial of or contraindication to at least one of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
D. For the diagnosis of ankylosing spondylitis (AS), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist

(Criteria continued on next page)

REQUIREMENTS: IXEKIZUMAB (CONTINUED)

E. For the diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
    4. The patient meets ONE of the following objective signs of inflammation:
        a. C-reactive protein (CRP) levels above the upper limit of normal
        b. Sacroiliitis on magnetic resonance imaging (MRI)

RENEWAL CRITERIA

Our guideline named IXEKIZUMAB (Taltz) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Non-radiographic axial spondyloarthritis (nr-axSpA)
B. For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms.
C. For the diagnosis of psoriatic arthritis (PsA), approval requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For the diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: IXEKIZUMAB (CONTINUED)

References:

1. Taltz package insert. Indianapolis, IN. Eli Lilly and Company. Revised July 2022. Accessed August 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
4. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
5. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
6. Ward MM, Deodhar A, Gensler LS, Dubreuil M, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TALQUETAMAB Edition 1	TALVEY	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named TALQUETAMAB (Talvey) requires the following rule(s) be met for approval:

A. Patient is 18 years of age or older
B. The patient has a diagnosis of Relapsed or Refractory Multiple Myeloma
C. The patient has previously trialed at least 4 lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

1. Talvey Package insert. Horsham, PA. Janssen Biotech, Revised August 2023. Accessed September 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
TALAZOPARIB TOSYLATE Edition 3	TALZENNA	10/21/2024	10/21/2023

REQUIREMENTS:

Our guideline named TALAZOPARIB (Talzenna) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of ONE of the following:
    a. Human epidermal growth factor receptor 2 (HER2)- negative locally advanced or metastatic breast cancer
    b. HRR gene-mutated metastatic castration-resistant prostate cancer
B. The patient is 18 years of age or older
C. For a diagnosis of HER2-negative locally advanced or metastatic breast cancer, approval also requires:
    a. The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by a Food and Drug Administration-approved test
D. For a diagnosis of HRR gene-mutated metastatic castration-resistant prostate cancer, approval also requires:
    a. The patient will be using the requested product in combination with enzalutamide

References:
1. Talzenna package insert. New York, NY. Pfizer, Inc. Revised February 2024. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
NILOTINIB HCL Edition 2	TASIGNA	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
    2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase
B. For patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
    1. The patient is 1 year of age or older
C. For patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic or accelerated phase, approval also requires:
    1. The patient is 18 years of age or older
    2. The patient is resistant or intolerant to prior therapy including Gleevec (imatinib)
D. For patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:
    1. The patient is 1 to 17 years of age
    2. The patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)

References:
1. Tasigna Package Insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised February 2024. Accessed August 2023.

Generic	Brand	Reviewed	Effective Date
TAZEMETOSTAT Edition 1	TAZVERIK	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named TAZEMETOSTAT (Tazverik) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Metastatic or locally advanced epithelioid sarcoma
    2. Relapsed or refractory follicular lymphoma
B. For patients with metastatic or locally advanced epithelioid sarcoma, approval also requires:
    1. The patient is 16 years of age or older
    2. The patient is not eligible for complete resection
C. If you have relapsed or refractory follicular lymphoma, approval also requires:
    1. The patient is 18 years or older
    2. The patient meets ONE of the following:
        i. The patient's tumors are positive for an EZH2 mutation as detected by a Food and Drug Administration (FDA)-approved test AND the patient has received at least 2 prior systemic therapies
        ii. The patient has no satisfactory alternative treatment options

References:
1. Tazverik package Insert. Cambridge, MA. Epizyme, Inc. Revised August 2024. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
IVOSIDENIB Edition 4	TIBSOVO	10/21/2024	10/21/2024

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Acute myeloid leukemia (AML)
    2. Locally advanced or metastatic cholangiocarcinoma
    3. Myelodysplastic Syndromes (MDS)
B. If the patient has relapsed or refractory acute myeloid leukemia (AML), approval also requires:
    1. The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
    2. The patient's condition has relapsed or is refractory to previous treatment
    3. The patient is 18 years of age or older
C. If the patient has a new diagnosis of acute myeloid leukemia (AML), approval also requires:
    1. The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
    2. The patient's condition is newly diagnosed
    3. The requested medication will be used in combination with azacitidine or as monotherapy
    4. The patient meets ONE of the following criteria:
        a. The patient is 75 years of age or older
        b. The patient is 18 years of age or older AND has comorbidities that prevent the use of intensive induction chemotherapy

A. If the patient has a diagnosis of locally advanced or metastatic cholangiocarcinoma, approval also requires:
    1. The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
    2. The patient has been previously treated with at least one treatment regimen for cholangiocarcinoma (e.g. gemcitabine/cisplatin, FOLFOX, FOLFIRI, etc.)
    3. The patient is 18 years of age or older
B. If the patient has a diagnosis of myelodysplastic syndromes (MDS), approval also requires:
    1. The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
    2. The patient is 18 years of age or older
    3. The patient has been previously treated for MDS

References:
1. Tibsovo package insert. Cambridge, MA. Agios Pharmaceuticals, Inc. Revised October 2023. Accessed August 2024.

RILUZOLE SUSPENSION			
Generic	Brand	Reviewed	Effective Date
RILUZOLE Edition 1	TIGLUTIK	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named RILUZOLE SUSPENSION (Tiglutik) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of amyotrophic lateral sclerosis (ALS)
B. The patient is 18 years of age or older
C. The patient has previously tried generic riluzole tablets
D. The patient is unable to take riluzole tablet formulation

References:
1. Tiglutik package insert. Berwyn, PA. ITF Pharma, Inc. Revised March 2020. Accessed August 2024.
2. Onesti E, Schettino I, Gori MC, et al. Dysphagia in Amyotrophic Lateral Sclerosis: Impact on Patient Behavior, Diet Adaptation, and Riluzole Management. Front Neurol. 2017;8:94. Published 2017 Mar 21. doi:10.3389/fneur.2017.00094.

WELLFLEET
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Generic	Brand	Reviewed	Effective Date
GUSELKUMAB Edition 2	TREMFYA	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GUSELKUMAB (Tremfya) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
B. For patients with moderate to severe plaque psoriasis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient had a previous trial of or contraindication to 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
C. For patients with psoriatic arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA
Our guideline named GUSELKUMAB (Tremfya) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
B. For patients with moderate to severe plaque psoriasis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: GUSELKUMAB (CONTINUED)

C. For patients with psoriatic arthritis (PsA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:
1. Tremfya package insert. Horsham, PA. Janssen Biotech, Inc. Revised June 2023. Accessed August 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
4. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
5. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VORTIOXETINE Edition 1	TRINTELLIX	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named Vortioxetine (Trintellix) requires the following rule(s) be met for approval:

A. The patient is at least 18 years of age
B. The patient has a diagnosis of major depressive disorder
C. The patient has been screened for any personal or family history of bipolar disorder, mania, or hypomania

1. Trintellix Package insert. Lexington, MA. Takeda Pharma, Revised August 2023. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
PEXIDARTINIB Edition 2	TURALIO	10/21/2024	10/21/2023

REQUIREMENTS:

Our guideline named PEXIDARTINIB (Turalio) requires the following rules be met for approval:

A. The patient has a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT)
B. The patient is 18 years of age or older
C. Surgical removal of the patient's tumor is predicted to be associated with severe morbidity or functional limitations

References:

1. Turalio package insert. Basking Ridge, NJ. Daiichi Sankyo, Inc. Revised November 2023. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
OLIPUDASE ALFA Edition 1	XENPOZYME	10/21/2024	10/21/2022

REQUIREMENTS:

Our guideline named OLIPUDASE ALFA (Xenpozyme) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of acid sphingomyelinase deficiency (ASMD)
B. The requested medication is prescribed by or given in consultation with a geneticist, endocrinologist, metabolic disorder specialist, or a physician who specializes in the treatment of lysosomal storage diseases or related disorders
C. The patient has non-central nervous system-related manifestations of ASMD including, but not limited to, abnormal enlargement of the liver and/or spleen, impaired lung function, and/or dyslipidemia

References:

1. Xenpozyme package insert. Cambridge, MA. Genzyme Corporation. Revised February 2023. Accessed September 2024.
2. Patterson MC, Clayton P, Gissen P, et al. Recommendations for the detection and diagnosis of Niemann-Pick disease type C: An update. Neurol Clin Pract. 2017;7(6):499-511. doi:10.1212/CPJ.0000000000000399.

Generic	Brand	Reviewed	Effective Date
TELOTRISTAT Edition 1	XERMELO	10/21/2024	6/1/2021

REQUIREMENTS:

Our guideline named TELOTRISTAT (Xermelo) requires the following rule(s) be met for approval:

A. The patient has carcinoid syndrome diarrhea
B. The patient is 18 years of age or older
C. The medication is being prescribed by or given in consultation with an oncologist or gastroenterologist
D. There is documentation showing the patient has been receiving a stable dose of long-acting somatostatin analog therapy (e.g., Sandostatin LAR [octreotide], Somatuline Depot [lanreotide], etc.) for a minimum of 3 months
E. The patient has diarrhea that is inadequately controlled as defined by the presence of at least four bowel movements per day
F. The medication will be used in combination with a somatostatin analog (e.g., Sandostatin LAR [octreotide], Somatuline (lanreotide), etc.)

References:

1. Xermelo package insert. Deerfield, IL. TerSera Therapeutics LLC. Revised September 2022. Accessed August 2024.
2. Maroun. J, Kocha W, Kvols L, et al. Guidelines for the diagnosis and management of carcinoid tumors. Part 1: The gastrointestinal tract. A statement from a Canadian National Carcinoid Expert Group. Current Oncology. 2006 Apr; 13(2):67-76.

Generic	Brand	Reviewed	Effective Date
LIFITEGRAST Edition 3	XIIDRA	10/21/2024	1/1/2025

REQUIREMENTS:

The guideline named LIFITEGRAST (XIIDRA) requires that the patient has a diagnosis of dry eye disease or suppressed tear production due to ocular inflammation. In addition, the patient must meet ALL the following criteria for approval:

A. The patient is aged 17 years or older.
B. The medication is prescribed by or in consultation with an optometrist or ophthalmologist.
C. The patient will not be using concurrently with Restasis, Eysuvis, Cequa, or Tyrvaya.
D. 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 meet ALL the following criteria for approval:

A. The patient experienced an objective response to Xiidra therapy such as an increase in tear production or a decrease in dry eye symptoms.
B. The requested medication will not be used in combination with Restasis, Cequa, Eysuvis, or Tyrvaya.

References:
1. Xiidra package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised June 2020. Accessed August 2024.
2. Akpek EK, Amescua G, Farid M, et al. Dry Eye Syndrome Preferred Practice Pattern®. Ophthalmology. 2019;126(1):P286-P334. doi:10.1016/j.ophtha.2018.10.023.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
ENZALUTAMIDE Edition 2	XTANDI	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ENZALUTAMIDE (Xtandi) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Metastatic castration-resistant prostate cancer (mCRPC)
    2. Non-metastatic castration-resistant prostate cancer (nmCRPC)
    3. Metastatic castration-sensitive prostate cancer (mCSPC)
B. The patient meets ONE of the following:
    1. The patient has previously received a bilateral orchiectomy
    2. The requested medication will be used together with a gonadotropin releasing hormone analog (e.g., Lupron [leuprolide], Zoladex [goserelin], Vantas [histrelin], Firmagon [degarelix], Trelstar [triptorelin], etc.)
C. For patients with non-metastatic castration-resistant prostate cancer (nmCRPC), approval also requires:
    1. The patient has high-risk prostate cancer
D. For patients with metastatic castration-resistant prostate cancer (mCRPC), approval also requires:
    1. The patient has previously tried generic Zytiga (abiraterone acetate) unless there is a contraindication
E. For patients with metastatic castration-sensitive prostate cancer (mCSPC), approval also requires:
    1. The patient has previously tried generic Zytiga (abiraterone acetate), unless there is a contraindication

RENEWAL CRITERIA
Our guideline named ENZALUTAMIDE (Xtandi) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Metastatic castration-resistant prostate cancer (mCRPC)
    2. Non-metastatic castration-resistant prostate cancer (nmCRPC)
    3. Metastatic castration-sensitive prostate cancer (mCSPC)
B. The patient is responding positively to therapy as evidenced by a lack of disease progression

References:
1. Xtandi package insert. Northbrook, IL. Astellas Pharma US, Inc. Revised November 2023. Accessed August 2024.

WELLFLEET
RX PLAN

Generic	Brand	Date Revised	Effective Date
SODIUM OXYBATE Edition 3	XYREM	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SODIUM OXYBATE (XYREM) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Cataplexy in narcolepsy
    2. Excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2)
B. The patient is 7 years of age or older
C. The requested medication is prescribed by or in consultation with a neurologist or specialist in sleep medicine
D. 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)
E. Provide clinical documentation the patient's diagnosis of narcolepsy has been confirmed by both polysomnography and a multiple sleep latency test (MLST) PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.
F. The requested medication will not be used in combination with Wakix (pitolisant), Xywav (Sodium/Calcium/Mag/Pot Oxybate) and/or Sunosi (solriamfetol).
G. For the diagnosis of cataplexy in narcolepsy, approval also requires the following:
    1. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Venlafaxine
        b. Selective serotonin reuptake inhibitor (e.g., fluoxetine, sertraline, paroxetine, etc.)
        c. Tricyclic antidepressant (e.g., amitriptyline, clomipramine, imipramine, etc.)
    2. 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.

(Criteria continued on next page)

REQUIREMENTS: SODIUM OXYBATE (XYREM) (CONTINUED)

H. For the diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2), approval also requires the following:
    1. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Modafinil
        b. Armodafinil
        c. Generic stimulant (i.e., methylphenidate, dextroamphetamine, or amphetamine)
    2. Provide clinical documentation of symptoms of excessive daytime sleepiness associated with narcolepsy without cataplexy occurring for at least 3 months. PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met

RENEWAL CRITERIA

Our guideline for SODIUM OXYBATE (XYREM) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Cataplexy in narcolepsy
    2. Excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2)
B. The patient meets at least ONE of the following:
    1. Documentation of sustained improvement of cataplexy symptoms compared to baseline since initial authorization PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met
    2. Documentation of sustained improvement of excessive daytime sleepiness (EDS) as shown by sustained Epworth Sleepiness Scale (ESS) improvement compared to baseline since initial authorization PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.

References:
1. Xyrem package insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised April 2023. Accessed August 2024.
2. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.

WELLFLEET
RX PLAN

Generic	Brand	Date Reviewed	Effective Date
SODIUM, CALCIUM, MAG, POT OXYBATE Edition 3	XYWAV	10/21/2024	10/21/2022

REQUIREMENTS:

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. The patient has ONE of the following diagnoses:
    1. Cataplexy in narcolepsy
    2. Excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2)
    3. Idiopathic hypersomnia (IH)
B. The requested medication is prescribed by or in consultation with a neurologist or specialist in sleep medicine
C. 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)
D. Provide clinical documentation the patient's diagnosis has been confirmed by both polysomnography and a multiple sleep latency test (MLST). PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.
E. The requested medication will not be used in combination with Wakix (pitolisant), Xyrem (sodium oxybate) and/or Sunosi (solriamfetol).
F. For the diagnosis of cataplexy in narcolepsy, approval also requires the following:
    1. The patient is 7 years of age or older
    2. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Venlafaxine
        b. Selective serotonin reuptake inhibitor (e.g., fluoxetine, sertraline, paroxetine, etc.)
        c. Tricyclic antidepressant (e.g., amitriptyline, clomipramine, imipramine, etc.)
    3. 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.

(Criteria continued on next page)

REQUIREMENTS: SODIUM/CALCIUM/MAG/POT OXYBATE (XYWAV) (CONTINUED)

G. For the diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2), approval also requires the following:
    1. The patient is 7 years of age or older
    2. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Modafinil (in doses up to 400 mg daily)
        b. Armodafinil (in doses up to 250 mg daily)
        c. Generic stimulant (i.e., methylphenidate, dextroamphetamine, or amphetamine)
    3. Provide clinical documentation of symptoms of excessive daytime sleepiness associated with narcolepsy without cataplexy occurring for at least 3 months. PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.
H. For the diagnosis of idiopathic hypersomnia (IH), approval also requires the following:
    1. The patient is 18 years of age or older
    2. Patient has diagnosis of idiopathic hypersomnia (IH)
    3. Cataplexy is not present
    4. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Modafinil
        b. Armodafinil
        c. Generic stimulant (i.e., methylphenidate, dextroamphetamine, or amphetamine)
    5. Provide clinical documentation of symptoms of idiopathic hypersomnia occurring for at least 3 months PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.

(Criteria continued on next page)

REQUIREMENTS: SODIUM/CALCIUM/MAG/POT OXYBATE (XYWAV) (CONTINUED)

RENEWAL CRITERIA
Our guideline named SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Cataplexy in narcolepsy,
    2. Excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2)
    3. Idiopathic hypersomnia (IH)
B. For diagnosis of narcolepsy (with or without cataplexy), the patient meets at least ONE of the following:
        1. Documentation of sustained improvement of cataplexy symptoms compared to baseline since initial authorization PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.
        2. Documentation of sustained improvement of excessive daytime sleepiness (EDS) as shown by sustained Epworth Sleepiness Scale (ESS) improvement compared to baseline since initial authorization PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.
C. For diagnosis of idiopathic hypersomnia, documentation of sustained excessive daytime sleepiness (EDS) improvement as shown by sustained Epworth Sleepiness Scale (ESS) improvement or Idiopathic Hypersomnia Severity Scale (IHSS) improvement compared to baseline since initial authorization. PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.

References:
1. Xywav package insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised April 2023. Accessed August 2024.
2. Maski K, Trotti LM, Kotagal S, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2021;17(9):1881–1893.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CANTHARIDIN Edition 1	YCANTH	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named CANTHARIDIN (Ycanth) requires the following rule(s) be met for approval:

A. Patient is 2 years of age or older
B. The patient has a diagnosis of molluscum contagiosum
C. Therapy will be administered by a healthcare professional

1. Ycanth Package insert. Irvine, CA. Tarsus Pharmaceuticals, Revised July 2023. Accessed September 2024.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
MIGLUSTAT Edition 1	ZAVESCA	10/21/2024	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of mild to moderate type 1 Gaucher disease
B. The patient is 18 years of age or older
C. The requested medication will be used as monotherapy
D. Enzyme replacement therapy is not a therapeutic option for this patient (i.e., due to allergy, hypersensitivity, or poor venous access)

References:

1. Zavesca package insert. South San Francisco, CA. Janssen Pharmaceutical. Revised July 2022. Accessed August 2024.

Generic	Brand	Reviewed	Effective Date
OZANIMOD Edition 3	ZEPOSIA	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named OZANIMOD (Zeposia) requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has one of the following diagnoses:
    1. Relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease
    2. Moderately to severe active ulcerative colitis (UC)
C. For patients with a relapsing form of multiple sclerosis, approval also requires:
    1. The patient has had a previous trial of generic glatiramer, dimethyl fumarate, glatopa, fingolimod, or teriflunomide
D. For patients with a moderate to severe ulcerative colitis approval also requires:
    1. The requested medication is prescribed by or given in consultation with a gastroenterologist
    2. The patient has had a trial of or contraindication to at least ONE of the following conventional therapies, such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
    3. The patient has had a previous trial of or contraindication BOTH of the following preferred immunomodulators: Humira (or biosimilar), Stelara SC

RENEWAL CRITERIA
Our guideline named OZANIMOD (Zeposia) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Relapsing forms of multiple sclerosis
    2. Moderate to severe ulcerative colitis
B. For patients with ulcerative colitis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: OZANIMOD (CONTINUED)

References:

1. Zeposia package insert. Summit, NJ. Celgene Corporation, Revised August 2024. Accessed August 2024.
2. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413. 10.
3. Rae-grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018;90(17):777-788.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
PITOLISANT HCL Edition 3	WAKIX	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named PITOLISANT (Wakix) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. Excessive daytime sleepiness (EDS) associated with narcolepsy without cataplexy
    2. Cataplexy in narcolepsy
B. The patient is 6 years of age or older
C. The requested medication is prescribed by or in consultation with a neurologist or specialist in sleep medicine
D. 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)
E. Provide clinical documentation the patient's diagnosis of narcolepsy has been confirmed by both polysomnography and a multiple sleep latency test (MLST).
F. The requested medication will not be used in combination with Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium, sodium oxybates) and/or Sunosi (solriamfetol)
G. For the diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy, approval also requires the following:
    1. Provide clinical documentation showing symptoms of excessive daytime sleepiness (EDS) associated with narcolepsy without cataplexy occurring for at least 3 months
    2. The patient has tried and failed at least ONE of the following, unless contraindication to ALL:
        a. Modafinil
        b. Armodafinil
        c. Generic stimulant (i.e., dextroamphetamine, amphetamine, or methylphenidate)

(Criteria continued on next page)

REQUIREMENTS: PITOLISANT (CONTINUED)

H. For the diagnosis of cataplexy with narcolepsy, approval also requires:
    1. The patient has tried and failed at least ONE of the following:
        a. Venlafaxine
        b. Selective serotonin reuptake inhibitor (e.g., fluoxetine, sertraline, paroxetine, etc.)
        c. Tricyclic antidepressant (e.g., amitriptyline, clomipramine, imipramine, etc.)
    2. Provide clinical documentation of narcolepsy with cataplexy symptoms occurring for at least 3 months.

RENEWAL CRITERIA

Our guideline named PITOLISANT (Wakix) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Excessive daytime sleepiness (EDS) with narcolepsy without cataplexy (narcolepsy type 2)
    2. Cataplexy in narcolepsy
B. The patient meets at least ONE of the following:
    1. Documentation of sustained improvement of excessive daytime sleepiness (EDS) as shown by sustained Epworth Sleepiness Scale (ESS) improvement compared to baseline since initial authorization
    2. Documentation of sustained improvement of cataplexy symptoms compared to baseline since initial authorization

References:

1. Wakix package Insert. Plymouth Meeting, PA. Harmony Biosciences, LLC. Revised June 2024. Accessed August 2024.
2. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin [published correction appears in Sleep. 2008 Feb 1;31(2):table of contents]. *Sleep*. 2007;30(12):1705-1711. doi:10.1093/sleep/30.12.1705.

WELLFLEET RX STUDENT FORMULARY

ANTI-OBESITY AGENTS Edition 4			
Generic	Brand	Reviewed	Effective Date
PHENTERMINE/ TOPIRAMATE	QSYMIA	10/21/2024	1/1/2025
LIRAGLUTIDE	SAXENDA		
SEMAGLUTIDE	WEGOVY		
TIRZEPATIDE	ZEPBOUND		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

NOTE: Requests will NOT be approved if your plan has weight-loss medication exclusions

Our guideline named ANTI-OBESITY AGENTS requires the following rule(s) be met for approval:

A. The request is for weight loss OR weight loss management
B. Documentation the patient has active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
C. For Qsymia requests, approval also requires:
    1. If the patient is aged 12 years to 17 years, approval also requires:
        a. The patient currently has a BMI of 95th percentile or greater for age and sex
    2. If the patient is 18 years of age or older, approval also requires the patient meets ONE of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater AND at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)
D. For Saxenda requests, approval also requires:
    1. The patient is NOT currently taking a GLP-1 receptor agonist (e.g., Wegovy, Victoza, Byetta, Bydureon, Trulicity, Ozempic, Mounjaro, etc.)
    2. If the patient is aged 12 years to 17 years, approval also requires:
        a. The patient has a body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs (International Obesity Task Force [IOTF] BMI Cut-Offs)
    3. If the patient is 18 years of age or older, approval also requires the patient meets ONE of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater AND at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

E. For Wegovy requests, approval also requires:
    1. The patient is NOT currently taking a GLP-1 receptor agonist (e.g., Saxenda, Victoza, Byetta, Bydureon, Trulicity, Ozempic, Mounjaro, etc.)
    2. If the patient is aged 12 years to 17 years, approval also requires:
        a. The patient has a body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs (International Obesity Task Force [IOTF] BMI Cut-Offs)
    3. If the patient is 18 years of age or older, approval also requires the patient meets ONE of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater AND at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

F. For Zepbound requests, approval also requires:
    1. The patient is NOT currently taking a GLP-1 receptor agonist (e.g., Saxenda, Victoza, Byetta, Bydureon, Trulicity, Ozempic, Mounjaro, etc.)
    2. The patient is 18 years of age or older
    3. The patient meets ONE of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater AND at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

RENEWAL CRITERIA
Our guideline named ANTI-OBESITY AGENTS
requires the following rule(s) be met for renewal:

A. The patient has lost at least 5% of baseline body weight

References:
1. Qysmia package insert. Campbell, CA. Vivus, Inc. Reviewed June 2022. Accessed June 2024.
2. Saxenda package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised April 2023. Accessed June 2024.
3. Styne DM, Arslanian SA, Connor EL, et al. Pediatric Obesity-Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(3):709-757. doi:10.1210/jc.2016-2573.
4. Garvey WT, Mechanick JI, Brett EM, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY COMPREHENSIVE CLINICAL PRACTICE GUIDELINES FOR MEDICAL CARE OF PATIENTS WITH OBESITY. Endocr Pract. 2016;22 Suppl 3:1-203. doi:10.4158/EP161365.GL.
5. Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for thinness, overweight and obesity. Pediatr Obes. 2012;7(4):284-294. doi:10.1111/j.2047-6310.2012.00064.x.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
CRIZOTINIB Edition 4	XALKORI	10/21/2024	10/21/2023

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Metastatic non-small cell lung cancer (NSCLC)
    2. Relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL)
    3. Unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT)
B. If the patient has metastatic non-small cell lung cancer, approval also requires ONE of the following:
    1. Patient is at least 18 years of age or older
    2. Patient is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
    3. Patient is ROS1-positive as detected by an FDA-approved test.
C. If the patient has relapsed or refractory, systemic anaplastic large cell lymphoma, approval also requires BOTH of the following:
    1. Patient is at least 1 year of age and less than 22 years of age
    2. Patient is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
D. If the patient has unresectable, recurrent, or refractory inflammatory myofibroblastic tumor, approval also requires ALL of the following:
    1. Patient is at least 1 year of age or older
    2. The patient's tumor is ALK-positive as detected by an FDA-approved test

References:
1. Xalkori package insert. New York, NY. Pfizer Labs. Revised September 2023. Accessed September 2024.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LOTILANER Edition 1	XDEMVY	10/21/2024	1/1/2024

REQUIREMENTS:

INITIAL CRITERIA

Our guideline named LOTILANER (Xdemvy) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of demodex blepharitis
B. Therapy will be prescribed by, or in consultation with, an ophthalmologist

1. Xdemvy Package insert. Irvine, CA. Tarsus Pharmaceuticals, Revised July 2023. Accessed September 2024.

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Generic	Brand	Reviewed	Effective Date
TOFACITINIB CITRATE Edition 8	XELJANZ, XELJANZ XR	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named TOFACITINIB (Xeljanz, Xeljanz XR) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe ulcerative colitis (UC)
    4. Polyarticular juvenile idiopathic arthritis (pcJIA)
    5. Ankylosing spondylitis (AS)

B. For patients with moderate to severe rheumatoid arthritis (RA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira (or biosimilar)
        a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

C. For patients with psoriatic arthritis (PsA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira (or biosimilar)
        a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

D. For patients with moderate to severe ulcerative colitis (UC), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient has previously tried the following formulary preferred TNF blocker: Humira (or biosimilar)
        a. A trial with an infliximab product (i.e., Remicade, biosimilars) or Simponi subcutaneous also counts.

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REQUIREMENTS- TOFACITINIB (CONTINUED)

E. For patients with polyarticular course juvenile idiopathic arthritis (pcJIA), approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with rheumatologist
    3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira (or biosimilar)
        a. A trial of Simponi (Aria or subcutaneous) also counts.
F. For patients with ankylosing spondylitis (AS), approval also requires:
    1. The patient is 18 years of age or older
    2. The medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira (or biosimilar)
        a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

RENEWAL CRITERIA

The guideline named TOFACITINIB (Xeljanz, Xeljanz XR) requires the following rule(s) to be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe ulcerative colitis (UC)
    4. Polyarticular juvenile idiopathic arthritis (pcJIA)
    5. Ankylosing spondylitis (AS)
B. For patients with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with ankylosing spondylitis (AS), renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with moderate to severe ulcerative colitis (UC), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued next page)

REQUIREMENTS- TOFACITINIB (CONTINUED)

References

1. Xeljanz package insert. New York, New York. Pfizer. Revised December 2021. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
4. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
5. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114(3):384-413. 10.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.
7. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.
8. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
9. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRALOKINUMAB-LDRM Edition 1	ADBRY	1/1/2025	1/1/2025

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named TRALOKINUMAB (Adbry) requires the following rules be met for approval:

A. The patient has a diagnosis of moderate to severe atopic dermatitis (AD)
B. For patients with moderate to severe atopic dermatitis (AD), approval also requires:
    1. The patient is 12 years of age or older
    2. The patient meets at least ONE of the following for disease severity:
        i. Atopic dermatitis involving at least 10% of body surface area (BSA)
        ii. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas.
    3. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
    4. The patient has had at least a 4-week trial with an inadequate response to at least ONE of the following, unless contraindication to all listed:
        i. Moderate-or higher-potency topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate, etc.] OR
        ii. Topical calcineurin inhibitors [i.e., Elidel (pimecrolimus), Protopic (tacrolimus)] OR
        iii. Topical PDE-4 inhibitors [i.e., Eucrisa (crisaborole)] OR

RENEWAL CRITERIA

The guideline named TRALOKINUMAB (Adbry) requires the following rules be met for renewal:

A. The patient has a diagnosis of moderate to severe atopic dermatitis (AD)
B. For patients with moderate to severe atopic dermatitis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has shown a clinical response as evidenced by an improvement in symptoms (e.g., reduced body surface area affected, reduced pruritus, improvements in cracking, oozing, or bleeding of affected skin, reduced erythema, etc.)

References:

1. Adbry package insert. Madison, NJ. LEO pharma. Revised December 2023. Accessed August 2024.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132. doi:10.1016/j.jaad.2014.03.023.

3. Drucker AM, Ellis AG, Bohdanowicz M, et al. Systemic Immunomodulatory Treatments for Patients With Atopic Dermatitis: A Systematic Review and Network Meta-analysis. JAMA Dermatol. 2020;156(6):659-667. doi:10.1001/jamadermatol.2020.0796.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
CERTOLIZUMAB PEGOL Edition 4	CIMZIA	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named CERTOLIZUMAB PEGOL (Cimzia) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Moderate to severe Crohn's disease (CD)
    5. Non-radiographic axial spondyloarthritis (nr-axSpA)
    6. Moderate to severe psoriasis (PsO)
    7. Juvenile Idiopathic Arthritis (JIA)
B. For patients with moderate to severe rheumatoid arthritis (RA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    4. Documentation has been provided to show that the patient has had a previous trial of TWO of the formulary preferred immunomodulators: Actemra SC/Tyenne SC, Enbrel, an adalimumab product, Rinvoq, or Xeljanz/XR
C. For patients with psoriatic arthritis (PsA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least one of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. Documentation has been provided to show that the patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Enbrel, an adalimumab product, Skyrizi, Stelara, Rinvoq, Xeljanz/XR, Otezla, Taltz or Tremfya.
D. For patients with ankylosing spondylitis (AS), approval requires:
    1. The patient is 18 years of age or older

2. The requested medication is prescribed by or given in consultation with a rheumatologist
3. Documentation has been provided to show that the patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Enbrel, an adalimumab product, Rinvoq, Xeljanz/Xeljanz XR or Taltz

E. For patients with moderate to severe Crohn's disease (CD), approval requires:
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a gastroenterologist
   3. The patient meets at least ONE of the following:
      a. 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
      b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
      c. The patient has a history of ileocolonic resection
   4. The patient has had a previous trial of ONE of the formulary preferred immunomodulators: an adalimumab product

F. For patients with non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist
   3. The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
   4. The patient meets ONE of the following objective signs of inflammation:
      a. C-reactive protein (CRP) levels above the upper limit of normal b. Sacroiliitis on magnetic resonance imaging (MRI)

G. For patients with moderate to severe plaque psoriasis (PsO), approval requires:
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a dermatologist
   3. 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
   4. The patient has had a previous trial of or contraindication to 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
   5. Documentation has been provided to show that the patient has had a previous trial of any TWO of the following formulary preferred immunomodulators: An adalimumab product, Enbrel, Otezla, Skyrizi, Sotyktu, Stelara, Taltz or Tremfya.

H. For patients with Juvenile Idiopathic Arthritis, approval requires:

1. The patient is 2 years of age or older
2. The requested medication is prescribed by or given in consultation with a rheumatologist
3. The patient had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
4. Documentation has been provided to show that the patient has had a previous trial of or contraindication to at least TWO of the following formulary preferred immunomodulators: Enbrel, an adalimumab product, Rinvoq, Xeljanz, a tocilizumab IV product, Kevzara, Orencia, an infliximab product, or Simponi Aria

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RENEWAL CRITERIA

The guideline named CERTOLIZUMAB PEGOL (Cimzia) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Ankylosing spondylitis (AS)
    4. Moderate to severe Crohn's disease (CD)
    5. Non-radiographic axial spondyloarthritis (nr-axSpA)
    6. Moderate to severe plaque psoriasis (PsO)
    7. Juvenile Idiopathic Arthritis (JIA)
B. For patients with moderate to severe rheumatoid arthritis (RA), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with psoriatic arthritis (PsA), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with ankylosing spondylitis (AS), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with non-radiographic axial spondyloarthritis (nr-axSpA), renewal requires**:**
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids.
F. For patients with moderate to severe plaque psoriasis (PsO), renewal requires:
    1. Compared to pretreatment baseline, the patient has achieved or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms

REQUIREMENTS: CERTOLIZUMAB PEGOL (CONTINUED)

References:

1. Cimzia package insert, UCB Inc, Smyrna, GA. Revised September 2019. Accessed August 2023.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
5. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
7. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
8. Ward MM, Deodhar A, Gensler LS, Dubreuil M, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.

Generic	Brand	Reviewed	Effective Date
SECUKINUMAB Edition 4	COSENTYX	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SECUKINUMAB (Cosentyx) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
    3. Juvenile psoriatic arthritis (JPsA)
    4. Ankylosing spondylitis (AS)
    5. Non-radiographic axial spondyloarthritis (nr-axSpA)
    6. Enthesitis-related arthritis (ERA)
B. For patients with moderate to severe plaque psoriasis, approval also requires:
    1. The patient is 6 years of age and older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient had a previous trial of or contraindication to 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
    5. Documentation must be provided to show that the patient has tried and failed TWO preferred agents: Enbrel, Humira (or biosimilar), Otezla, Skyrizi SC, Sotyktu, Stelara SC, Taltz, or Tremfya

(Criteria continued next page)

REQUIREMENTS: SECUKINUMAB (CONTINUED)

C. For patients with psoriatic arthritis or juvenile psoriatic arthritis, approval also requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient had a previous trial of or contraindication to at least ONE DMARD such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. If the patient is 2-17 years of age:
        a. Documentation must be provided to show that the patient has tried and failed ONE preferred agents: Enbrel, Stelara SC, Rinvoq
    5. If the patient is 18 years of age or older:
        a. Documentation must be provided to show that the patient has tried and failed TWO preferred agents: Enbrel, an adalimumab product, Otezla, Rinvoq, Skyrizi, Stelara SC, Taltz, Tremfya, or Xeljanz/XR
D. For patients with ankylosing spondylitis, approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. Documentation must be provided to show that the patient has tried and failed TWO preferred agents prior to the use of any non- preferred agent as clinically appropriate: Enbrel, Humira (or biosimilar), Taltz, Xeljanz/Xeljanz XR, Rinvoq, Cimzia, an infliximab product, or Simponi
E. For patients with non-radiographic axial spondyloarthritis, approval also requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
    4. The patient meets ONE of the following signs of inflammation:
        a. C-reactive protein (CRP) levels above the upper limit of normal
        b. Sacroiliitis on magnetic resonance imaging (MRI)
    5. Documentation must be provided to show that the patient has tried and failed TWO preferred agents prior to the use of any non- preferred agent as clinically appropriate: Taltz, Cimzia, Rinvoq, Enbrel, an adalimumab product, an infliximab product, or Simponi
F. For patients with enthesitis-related arthritis, approval also requires:
    1. The patient is 4 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

REQUIREMENTS: SECUKINUMAB (CONTINUED)

(Criteria continued next page)

REQUIREMENTS: SECUKINUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named SECUKINUMAB (Cosentyx) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe plaque psoriasis (PsO)
    2. Psoriatic arthritis (PsA)
    3. Juvenile psoriatic arthritis (JPsA)
    4. Ankylosing spondylitis (AS)
    5. Non-radiographic axial spondyloarthritis (nr-axSpA)
    6. Enthesitis-related arthritis (ERA)
B. For patients with moderate to severe plaque psoriasis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms
C. For patients with psoriatic arthritis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with juvenile psoriatic arthritis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with ankylosing spondylitis or non-radiographic axial spondyloarthritis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
F. For patients with enthesitis-related arthritis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

REQUIREMENTS: SECUKINUMAB (CONTINUED)

References:

1. Cosentyx package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2023. Accessed August 2024.
2. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
3. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
5. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
6. Ward MM, Deodhar A, Gensler LS, Dubreuil M, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.
7. Hahn YS. Enthesitis-related Arthritis. J Rheum Dis 2018;25:221-230. doi: 10.4078/jrd.2018.25.4.221.

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Generic	Brand	Reviewed	Effective Date
VEDOLIZUMAB Edition 5	ENTYVIO	10/21/2024	10/21/2024

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named VEDOLIZUMAB (Entyvio) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe Crohn's disease
    2. Moderate to severe ulcerative colitis
B. For patients with moderate to severe Crohn's disease, approval requires ALL of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient meets at least ONE of the following:
        a. 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
        b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
        c. The patient has a history of ileocolonic resection
    4. Documentation has been provided to show that the patient has had a previous trial of or contraindication to TWO of the following formulary preferred immunomodulators: Humira (or biosimilar), Skyrizi, Stelara, Cimzia, Rinvoq, or an infliximab product
C. For patients with moderate to severe ulcerative colitis, approval requires ALL of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient had a previous trial of or contraindication to at least one of the following
        i. conventional therapies, such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
    4. Documentation has been provided to show that the patient has had a previous trial of or contraindication to TWO of the formulary preferred immunomodulators: Humira (or biosimilar), Skyrizi, Stelara, Zymfentra, Omvoh, Rinvoq, Simponi, Tremfya, Velsipity, or Xeljanz/Xr

(Criteria continued on next page)

REQUIREMENTS: VEDOLIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named VEDOLIZUMAB (Entyvio) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe Crohn's disease
    2. Moderate to severe ulcerative colitis
B. For patients with Crohn’s disease, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with ulcerative colitis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Entyvio package insert. Lexington, MA. Takeda Pharmaceuticals U.S.A., Inc. Revised April 2024. Accessed August 2024.
2. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
3. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.

Generic	Brand	Reviewed	Effective Date
TILDRAKIZUMAB-ASMN Edition 3	ILUMYA	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named TILDRAKIZUMAB-ASMN (Ilumya) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO).
B. The following criteria must also be met:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient has had a previous trial of or contraindication to 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
    5. Documentation must be provided to show that the patient has tried and failed TWO of the following formulary preferred immunomodulators: Humira (or biosimilar), Otezla, Enbrel, Skyrizi, Sotyktu, Stelara SC, Taltz, or Tremfya

RENEWAL CRITERIA
Our guideline named TILDRAKIZUMAB-ASMN (Ilumya) requires the following rule(s) be met for renewal:
A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO)
B. The following criterion must also be met for renewal:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:
1. Ilumya package insert. Whitehouse Station, NJ. Merck & Co, INC., Revised December 2022. Accessed August 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.

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Generic	Brand	Reviewed	Effective Date
SARILUMAB Edition 3	KEVZARA	10/21/2024	10/21/2023

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named SARILUMAB (Kevzara) requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. moderate to severe rheumatoid arthritis
    2. polymyalgia rheumatica
    3. Juvenile idiopathic arthritis/Juvenile Rheumatoid Arthritis
B. The patient is 18 years of age or older
   The requested medication is prescribed by or given in consultation with a rheumatologist
C. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    2. Documentation has been provided to show that the patient had a previous trial of TWO formulary preferred immunomodulators: Actemra SC (or biosimilar), Enbrel, Humira (or biosimilar), Rinvoq, Xeljanz/XR, Cimzia, an infliximab product, Orencia, or Simponi.
D. For patients with polymyalgia rheumatica, approval requires:
    1. The patient had a previous trial of corticosteroids with an inadequate response, OR cannot tolerate a corticosteroid taper
E. For patients with Juvenile idiopathic arthritis/Juvenile Rheumatoid Arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The patient had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    3. The patient meets one of the following:
        i. The patient had a previous trial of TWO of the following formulary preferred immunomodulator: a tocilizumab product, Enbrel, an adalimumab product, Rinvoq, Xeljanz, Cimzia, Orencia, an infliximab product, or Simponi
        ii. The patient has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, OR a demyelinating disorder

RENEWAL CRITERIA
The guideline named SARILUMAB (Kevzara) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of moderate to severe rheumatoid arthritis, polymyalgia rheumatica, or juvenile idiopathic arthritis/juvenile rheumatoid arthritis
B. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum

markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Kevzara package insert. Bridgewater, NJ. Sanofi-Aventis. Revised February 2023. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.

Generic	Brand	Reviewed	Effective Date
BARICITINIB Edition 3	OLUMIANT	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named BARICITINIB (Olumiant) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Severe alopecia areata
B. The patient is 18 years of age or older
C. For patients with moderate to severe rheumatoid arthritis, approval also requires:
    1. The requested medication is prescribed by or given in consultation with a rheumatologist
    2. Documentation has been provided to show that thepatient has had a previous trial of TWO of the formulary preferred immunomodulators: Actemra (or biosimilar), Enbrel, Humira (or biosimilar), Rinvoq, Cimzia, an infliximab product, Kevzara, Orencia, Simponi, or Xeljanz
D. For patients with severe alopecia areata, approval also requires:
    1. The requested medication is prescribed by or given in consultation with a dermatologist
    2. The patient has had least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months
    3. The patient has had a previous trial of or contraindication to treatment with at least ONE conventional first-line therapy (e.g., intralesional corticosteroids, topical corticosteroids, systemic corticosteroids, topical immunotherapy, etc.)
    4. Requests for Olumiant 4mg dose require the patient has had inadequate response to Olumiant 2mg dose or has nearly complete or complete scalp hair loss

NOTE: Olumiant is FDA-approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. This indication does not include outpatient use and will not be approvable under this policy.

(Criteria continued next page)

REQUIREMENTS: BARICITINIB (CONTINUED)

RENEWAL CRITERIA

The guideline named BARICITINIB (Olumiant) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Severe alopecia areata
B. For patients with moderate to severe rheumatoid arthritis, renewal also requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with severe alopecia areata, renewal also requires ONE of the following:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response as evidenced by improvement in scalp hair coverage or assessed by disease activity measurement tools (i.e., Severity of Alopecia Tool (SALT) score, Scalp Hair Assessment PRO™, etc.)
    2. Requests for Olumiant 4mg dose require the patient has had inadequate response to Olumiant 2mg dose or has nearly complete or complete scalp hair loss

References:

1. Olumiant package insert. Indianapolis, IN. Lilly USA, LLC. Revised June 2022. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Messenger AG, McKillop J, Farrant P, McDonagh AJ, Sladden M. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Br J Dermatol. 2012;166(5):916-926. doi:10.1111/j.1365-2133.2012.10955.x.
4. Fukuyama M, Ito T, Ohyama M. Alopecia areata: Current understanding of the pathophysiology and update on therapeutic approaches, featuring the Japanese Dermatological Association guidelines. J Dermatol. 2022;49(1):19-36. doi:10.1111/1346-8138.16207.

WELLFLEET
RX PLAN

Generic	Brand	Reviewed	Effective Date
ABATACEPT – SQ Edition 4	ORENCIA - SQ, ORENCIA CLICKJECT – SQ	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named ABATACEPT - SQ (Orencia - SQ) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis
    2. Moderate to severe polyarticular juvenile idiopathic arthritis (PJIA)
    3. Psoriatic arthritis (PsA)
    4. Prophylaxis of acute graft versus host disease (aGVHD)
B. For patients with moderate to severe rheumatoid arthritis, approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    4. Documentation has been provided to show that thepatient has had a previous trial of TWO of the formulary preferred immunomodulators: Actemra (or biosimilar), Enbrel, Humira (or biosimilar), Rinvoq, Cimzia, an infliximab product, Kevzara, Simponi, or Xeljanz/XR.
C. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. Documentation has been provided to show that thepatient has had a previous trial of TWO of the formulary preferred immunomodulators: Enbrel, Humira (or biosimilar), Xeljanz, Cimzia, Kevzara, Orencia IV, an infliximab product, Simponi, or Actemra (or biosimilar).

(Criteria continued on next page)

REQUIREMENTS: ABATACEPT-SQ (CONTINUED)

D. For patients with psoriatic arthritis (PsA), approval requires:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. Documentation has been provided to show that thepatient has had a previous trial of any TWO of the following formulary preferred immunomodulators: Enbrel, Humira (or biosimilar), Stelara SC, Otezla, Tremfya, Taltz, Cimzia, an infliximab product, Cosentyx, Bimzelx, or Xeljanz/XR.
E. For patients using for prophylaxis of acute graft versus host disease (aGVHD), approval requires:
    1. The patient is 2 years of age or older
    2. The requested medication is prescribed by or given in consultation with a hematologist or oncologist
    3. The requested medication will be used in combination with a calcineurin inhibitor (i.e., cyclosporine, tacrolimus, or pimecrolimus) and methotrexate
    4. The patient will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

RENEWAL CRITERIA

Our guideline named ABATACEPT - SQ (Orencia - SQ) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis
    2. Psoriatic arthritis
    3. Moderate to severe polyarticular juvenile idiopathic arthritis
B. For patients with moderate to severe rheumatoid arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
C. For patients with psoriatic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
D. For patients with moderate to severe polyarticular juvenile idiopathic arthritis, renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools and/or experienced improvement of symptoms and/or reduced dose of corticosteroid

REQUIREMENTS: ABATACEPT-SQ (CONTINUED)

References:

1. Orencia package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised December 2021. Accessed August 2024.
2. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheumatol. 2019;71(6):846-863. doi:10.1002/art.40884.
3. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis Rheumatol. 2022;74(4):553-569. doi:10.1002/art.42037.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
5. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
6. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.

Generic	Brand	Reviewed	Effective Date
BRODALUMAB Edition 3	SILIQ	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named BRODALUMAB (Siliq) requires the following rule(s) be met for approval:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO)
B. The following criteria must be met for approval:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist
    3. 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
    4. The patient had a previous trial of or contraindication to 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
    5. Documentation must be provided to show that the patient has tried and failed TWO of the following formulary preferred immunomodulators: Humira (or biosimilar), Otezla, Enbrel, Skyrizi, Sotyktu, Stelara SC, Taltz, or Tremfya.

RENEWAL CRITERIA
Our guideline named BRODALUMAB (Siliq) requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of moderate to severe plaque psoriasis (PsO)
B. The following criteria must also be met for renewal:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Siliq package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised August 2024. Accessed August 2024.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057.
3. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.

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RX PLAN

Generic	Brand	Reviewed	Effective Date
GOLIMUMAB – SQ Edition 3	SIMPONI – SQ	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named GOLIMUMAB - SQ (Simponi - SQ) requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe ankylosing spondylitis (AS)
    4. Moderate to severe ulcerative colitis (UC)
B. For patients with moderate to severe rheumatoid arthritis (RA), approval requires all of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
    4. The patient will concurrently use methotrexate, unless contraindicated
    5. Documentation has been provided to show that the patient has had a previous trial of TWO of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR
C. For patients with psoriatic arthritis (PsA), approval requires all of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
    3. The patient has had a previous trial of or contraindication to at least one of the following DMARDs such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
    4. Documentation has been provided to show that the patient has had a previous trial of any TWO of the following preferred formulary immunomodulators: Enbrel, Humira, Stelara, Skyrizi, Otezla, Tremfya, Taltz, Rinvoq, or Xeljanz/XR.

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-SQ (CONTINUED)

D. For patients with moderate to severe ankylosing spondylitis (AS), approval requires all of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a rheumatologist
    3. Documentation has been provided to show that the patient has had a previous trial of any TWO of the following preferred immunomodulators: Enbrel, Humira (or biosimilar), Rinvoq, Xeljanz/Xeljanz XR, or Taltz.
E. For patients with moderate to severe ulcerative colitis (UC), approval requires all of the following:
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed by or given in consultation with a gastroenterologist
    3. The patient has had a previous trial of or contraindication to at least ONE of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
    4. The patient has had a previous trial of the formulary preferred immunomodulator: Humira (or biosimilar)

RENEWAL CRITERIA

Our guideline named GOLIMUMAB - SQ (Simponi - SQ) requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Psoriatic arthritis (PsA)
    3. Moderate to severe ankylosing spondylitis (AS)
    4. Moderate to severe ulcerative colitis (UC)
B. For patients with moderate to severe rheumatoid arthritis (RA), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
    2. Concurrent use of methotrexate (unless contraindicated)
C. For patients with psoriatic arthritis (PsA), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-SQ (CONTINUED)

D. For patients with moderate to severe ankylosing spondylitis (AS), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids
E. For patients with moderate to severe ulcerative colitis (UC), renewal requires:
    1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measurement tools, imaging, serum markers, and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

References:

1. Simponi package insert. Horsham, PA. Janssen Biotech, Inc. Revised September 2019. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. American Academy of Dermatology Work Group, Menter A, Korman NJ, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;65(1):137-174. doi:10.1016/j.jaad.2010.11.055.
4. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019;71(1):5-32. doi:10.1002/art.40726.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042.
6. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.

Generic	Brand	Reviewed	Effective Date
ANAKINRA Edition 2	KINERET	10/21/2024	10/21/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis
   2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

B. **For patients with moderate to severe rheumatoid arthritis, approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist
   3. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD, such as methotrexate (dose greater than or equal to 20mg per week or maximally tolerated dose), leflunomide, hydroxychloroquine, or sulfasalazine
   4. Documentation has been provided to show that the patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra (or biosimilar), Enbrel, Humira (or biosimilar), Rinvoq, an infliximab product, Kevzara, Simponi, or Xeljanz/XR

RENEWAL CRITERIA

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

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis
   2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

B. **For patients with moderate to severe rheumatoid arthritis requires:**
   1. Compared to pretreatment baseline, the patient has experienced or maintained a clinical response when assessed by disease activity measures and/or experienced improvement of symptoms and/or reduced dose of corticosteroids

(Criteria continued on next page)

REQUIREMENTS: ANAKINRA (CONTINUED)

References:

1. Kineret package insert. Stockholm, Sweden. Swedish Orphan Biovitrum AB. Revised December 2020. Accessed August 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
3. Terreri MT, Bernardo WM, Len CA, et al. Guidelines for the management and treatment of periodic fever syndromes Cryopyrin-associated periodic syndromes (Cryopyrinopathies-CAPS). Rev Bras Reumatol Engl Ed 2016 Jan-Feb;56(1):44
4. Koné-Paut I, Galeotti C. Current treatment recommendations and considerations for cryopyrin-associated periodic syndrome. Expert Rev Clin Immunol. 2015;11(10);1083-92
5. Aksentijevich I, Masters SL, Ferguson PJ, et al. An autoinflammatory disease with deficiency of the interleukin-1-receptor antagonist. N Engl J Med. 2009;360(23):2426-2437. doi:10.1056/NEJMoa0807865.