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: 5/1/2022

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 1	Reviewed	Effective Date
Compounded Drug Prior Authorization Guidelines	01/28/2022	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 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, or standard reference compendia for the treatment of the clinical condition

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Edition 1	Reviewed	Effective Date
Guidelines for Drugs Without PA Criteria - FDA	01/28/2022	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)

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Edition 2	Reviewed	Effective Date
Quantity Limit (QL) Exception Guidelines	04/29/2022	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

(Criteria continued on next page)

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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 Testosterone transdermal patch	50–100 mg/d 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. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [7th Version]. https://www.wpath.org/publications/soc .

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Edition 1	Reviewed	Effective Date
Step Therapy (ST) Exception Guidelines	01/28/2022	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 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 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;
      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
   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.

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Edition 1	Reviewed	Effective Date
Age Limit Exception Guidelines	01/28/2022	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.

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Edition 1	Reviewed	Effective Date
Excluded Formulary Drug Exception Guidelines	01/28/2022	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. You have trialed and failed THREE formulary alternatives with the same route of administration and active ingredients (if available); if the same route of administration and/or active ingredients is not available, then you have trialed and failed THREE formulary alternatives, one of which must be in the same class (or as many up to three if fewer than three alternatives are commercially available)
   2. Your doctor has provided documentation of contraindications or clinically significant adverse effects to ALL preferred agents with the same therapeutic class or preferred drugs that are recognized as standards of care for the treatment of the member's diagnosis
   3. Your doctor has provided documentation which details the absolute clinical need for the immediate use of the excluded drug product without trial and failure of preferred therapeutic alternatives

   If the request is for a combination product or for a product that is an alternative dosage form or strength to an existing commercially available product, your doctor has provided medical justification supporting your inability to use the individual drug products concurrently or alternative dosage forms or strengths (e.g., contraindications to the excipients of all alternative products)

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Edition 1	Reviewed	Effective Date
ACA Zero Cost Share Override Guidelines	04/29/2022	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)
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)

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.

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

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Edition 3	Reviewed	Effective Date
Off Label Policy	01/28/2022	01/28/2022
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:

1. 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)

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REQUIREMENTS: OFF-LABEL POLICY (CONTINUED)

2. 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**, 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. **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

Generic	Brand	Reviewed	Effective Date
ABALOPARATIDE Edition 1	TYMLOS	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Tymlos package insert. Waltham, MA. Radius Health Inc. Revised October 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ACALABRUTINIB Edition 1	CALQUENCE	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have a diagnosis of mantle cell lymphoma (MCL: a type of cancer), chronic lymphocytic leukemia (CLL: cancer of the blood and bone marrow), or small lymphocytic lymphoma (SLL: cancer of the blood and bone marrow)

B. You are 18 years of age or older

C. **If you have mantle cell lymphoma (MCL), approval also requires:**

   1. You have received at least one prior therapy for mantle cell lymphoma

References:

1. Calquence package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised November 2019. Accessed July 2021. .

WELLFLEET RX STUDENT FORMULARY

ACETAMINOPHEN DAILY LIMIT OVERRIDE			
Generic	Brand	Reviewed	Effective Date
Acetaminophen Edition 1	N/A	7/23/2021	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. You will discontinue the other acetaminophen containing drug(s) that cause the daily acetaminophen dose to exceed 4000mg.

References:

1. Acetaminophen package insert. Fort Washington, PA. Revised November 2017. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

ACNE AGE RESTRICTION OVERRIDE Edition 1			
Generic	Brand	Reviewed	Effective Date
ADAPALENE	DIFFERIN, PLIXDA	7/23/2021	6/1/2021
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. You are 26 years of age or older
B. The request is for a non-cosmetic (not for appearance) diagnosis.
C. Approval may also require that you have tried preferred agent(s), unless there is a medical reason why you cannot (contraindication)

References:

1. U.S. Food & Drug Administration. Package Inserts. Drugs@FDA: FDA-Approved Drugs website. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AFATINIB DIMALEATE Edition 1	GILOTRIF	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic squamous non-small cell lung cancer (type of cancer that has spread) or metastatic non-small cell lung cancer (a different type of lung cancer that has spread)

B. **If you have metastatic squamous non-small cell lung cancer, approval also requires:**
   1. Your disease has worsened after using platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)

C. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. Your tumors have non-resistant epidermal growth factor receptor (EGFR; type of protein) mutations as shown by an FDA (Food and Drug Administration)-approved test

References:

1. Gilotrif package insert. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Revised October 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALECTINIB Edition 1	ALECENSA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Alecensa package insert. South San Francisco, CA. Genentech USA, Inc. Revised January 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

ALLERGEN EXTRACT-HOUSE DUST MITE			
Generic	Brand	Reviewed	Effective Date
HOUSE DUST MITE Edition 1	ODACTRA	7/23/2021	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. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by house dust mites, with or without conjunctivitis (type of inflammation of eye and eyelid)
B. Your diagnosis is confirmed by in vitro testing (testing outside of your body in a tube) for IgE (Immunoglobulin E) antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
C. You are between 18 and 65 years old
D. The medication is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
E. You have persistent symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks)
F. You have moderate to severe symptoms of allergic rhinitis (moderate-to-severe symptoms include troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
G. You have a current claim or prescription for auto-injectable epinephrine within the past 365 days

RENEWAL CRITERIA

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

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

References:

1. Odactra package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised August 2019. Accessed July 2021.
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

ALLERGEN EXTRACT-MIXED GRASS POLLEN			
Generic	Brand	Reviewed	Effective Date
GR POL-ORC/SW VER/RYE/KENT/TIM Edition 1	ORALAIR	7/23/2021	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. You have a diagnosis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. Your diagnosis is confirmed by a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You have a current claim or prescription for auto-injectable epinephrine
F. You are between 5 and 65 years of age

RENEWAL CRITERIA

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

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

References:

1. Oralair package insert. Lenoir, N.C. GREER Laboratories, Inc. Revised November 2018. Accessed July 2021.
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

ALLERGEN EXTRACT- SHORT RAGWEED POLLEN			
Generic	Brand	Reviewed	Effective Date
WEED POLLEN- SHORT RAGWEED Edition 2	RAGWITEK	7/23/2021	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. You have allergic rhinitis (itchy, watery eyes, sneezing) caused by short ragweed pollen
B. Your diagnosis is confirmed by a positive skin prick test or in vitro testing (testing outside of your body in a tube) for pollen specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You are 5 – 65 years of age
F. You have a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

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

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

References:

1. Ragwitek package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised April 2021. Accessed July 2021.
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

ALLERGEN EXTRACT- TIMOTHY GRASS POLLEN			
Generic	Brand	Reviewed	Effective Date
GRASS POLLEN TIMOTHY, STD Edition 2	GRASTEK	7/23/2021	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. You have a diagnopesis of allergic rhinitis (itchy, watery eyes, sneezing) caused by grass pollen
B. You have a positive skin prick test and/or a positive titer (the amount of antibodies in the blood) to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
C. Therapy is prescribed by or given in consultation with an allergist (allergy doctor), immunologist (immune system doctor), or other physician experienced in the diagnosis and treatment of allergic diseases
D. You have persistent and moderate-to-severe symptoms of allergic rhinitis (persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
E. You are at least 5 – 65 years old
F. You have a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

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

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

References:

1. Grastek package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised December 2019. Accessed July 2021.
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
ALPELISIB Edition 1	PIQRAY	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Piqray package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised September 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AMIKACIN LIPOSOMAL/NEB. ACCESSR Edition 1	ARIKAYCE	7/23/2021	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. You have *Mycobacterium avium complex* (MAC – group of bacteria that cause serious infections) lung disease with limited or no alternative treatment options
B. You are 18 years of age or older
C. You have NOT achieved negative sputum cultures (mucus tests) after using multidrug background regimen therapy for at least 6 months in a row
D. Arikayce will be used as part of a combination antibacterial drug regimen
E. Arikayce is being prescribed by or given in consultation with a pulmonologist (lung doctor) or infectious disease specialist physician

RENEWAL CRITERIA

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

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

References:

1. Arikayce package insert. Bridgewater, NJ. Insmed Incorporated. Revised March 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

AMLODIPINE SUSPENSION			
Generic	Brand	Reviewed	Effective Date
AMLODIPINE BENZOATE Edition 1	KATERZIA	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **AMLODIPINE SUSPENSION (Katerzia)** requires the following rule(s) be met for approval:

A. You are unable to swallow oral amlodipine tablets at prescribed dose

References:

1. Katerzia package insert. Greenwood Village, CO. Silvergate Pharmaceuticals, Inc. Revised July 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AMLODIPINE BESYLATE/ CELECOXIB Edition 1	CONSENSI	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **AMLODIPINE/CELECOXIB (Consensi)** requires the following rule(s) be met for approval:

A. You have both hypertension (abnormal high blood pressure) and osteoarthritis (a type of arthritis that occurs when tissue at the ends of your bones wears down)
B. You are 18 years of age or older
C. You have previously tried amlodipine AND celecoxib
D. You have an adherence or other challenge requiring the use of the combination product over separate agents
E. You will NOT use Consensi together with any other calcium channel blocker agents (such as diltiazem, felodipine, verapamil)

References:

1. Consensi package insert. Hot Springs, AR. Burke Therapeutics, Revised April 2021. Accessed April July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AMPHETAMINE SULFATE Edition 2	EVEKEO; EVEKEO ODT	7/23/2021	7/23/2021

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

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

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

C. If you have attention deficit disorder with hyperactivity, approval also requires (Evekeo Only):
   1. You are 6 years of age or older
   2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)

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

E. **For Evekeo ODT, you have Attention deficit disorder with hyperactivity, and approval also requires:**
   1. You are 3 – 17 years of age
   2. You had a previous trial of at least ONE of the following stimulant medications: mixed amphetamine salts (Adderall immediate release), methylphenidate (Ritalin immediate release), dextroamphetamine (Dexedrine)

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

(Criteria continued on next page)

REQUIREMENTS: AMPHETAMINE SULFATE (CONTINUED)

References:

1. Evekeo package insert. Atlanta, GA. Arbor Pharmaceuticals, Revised April 2019. Accessed July 2021.
2. Evekeo ODT package insert. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised March 2019. Accessed April 2021
3. Wolraich ML, Hagan JF Jr, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents [published correction appears in Pediatrics. 2020 Mar;145(3):]. Pediatrics. 2019;144(4):e20192528. doi:10.1542/peds.2019-2528
4. Khera R, Murad MH, Chandar AK, et al. Association of Pharmacological Treatments for Obesity With Weight Loss and Adverse Events: A Systematic Review and Meta-analysis [published correction appears in JAMA. 2016 Sep 6;316(9):995]. JAMA. 2016;315(22):2424-2434. doi:10.1001/jama.2016.7602

WELLFLEET RX STUDENT FORMULARY

ANABOLIC STEROIDS Edition 1			
Generic	Brand	Reviewed	Effective Date
OXYMETHOLONE	ANADROL-50	7/23/2021	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. You have anemia (lack of healthy red blood cells) or cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
    3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
    4. Known or suspected hypercalcemia (high calcium levels)
    5. Severe hepatic (liver) dysfunction
D. **If you have anemia, approval also requires:**
    1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi's
E. **If you have cachexia associated with AIDS, approval also requires:**
    1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
    2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months
    3. Therapy is prescribed by or given in recommendation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS), or infectious disease specialist
    4. You meet ONE of the following:

(Criteria continued on next page)

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)
OXANDRIN

i. You have 10% unintentional weight loss over 12 months
ii. You have 7.5% unintentional weight loss over 6 months
iii. You have 5% body cell mass (BCM) loss within 6 months
iv. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27kg per meter squared
v. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
vi. You have a BMI of less than 18.5 kg per meter squared

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

A. You have ONE of the following diagnoses:
    1. Weight loss
    2. Protein catabolism (breakdown) caused by long-term use of corticosteroids
    3. Bone pain accompanying osteoporosis (weak and brittle bones)
    4. Cachexia (condition with extreme weight loss and muscle loss) associated with AIDS (acquired immune deficiency syndrome)
    5. Turner's Syndrome (disorder where female has one X chromosome
B. You will be monitored for peliosis hepatis (blood-filled spaces in the liver), liver cell tumors and blood lipid (fats) changes
C. You do not have ANY of the following reasons why you cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia (high calcium levels)
    3. Known or suspected nephrosis (the nephrotic phase of nephritis-kidney inflammation)
    4. Known or suspected hypercalcemia (high calcium levels)
    5. Severe hepatic (liver) dysfunction
D. **If you have weight loss, approval also requires:**
    1. Your weight loss is caused by extensive surgery, chronic infections, or severe trauma
    2. Medication is being used as add-on therapy to help weight gain
E. **If you have cachexia associated with AIDS, approval also requires:**
    1. You are on anti-retroviral therapy (therapy that treats a type of immune system virus)
    2. You have a documented viral load (amount of virus in your blood) of less than 200 copies per mL dated within the past 3 months

(Criteria continued on next page)

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)

3. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor of the stomach, intestine and related organs), nutritional support specialist (SBS) or infectious disease specialist
4. You meet ONE of the following:
    i. You have 10% unintentional weight loss over 12 months
    ii. You have 7.5% unintentional weight loss over 6 months
    iii. You have 5% body cell mass (BCM) loss within 6 months
    iv. You have a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
    v. You have a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
    vi. You have a BMI of less than 18.5 kg per meter squared

RENEWAL CRITERIA

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

OXANDRIN and ANADROL-50

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

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

References:

1. Anadrol package insert. Marietta,GA.Unimed Pharmaceuticals, Inc.Revised August 2004.Accessed July 2021
2. Oxandrin Package insert.New York,NY.Pfizer co. Revised May 2005. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

ANTI-OBESITY AGENTS Edition 2			
Generic	Brand	Reviewed	Effective Date
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE	7/23/2021	7/23/2021
PHENTERMINE/ TOPIRAMATE	QSYMIA		
ORLISTAT	XENICAL		

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

Our guideline named **ANTI-OBESITY AGENTS (Contrave, Qsymia, Xenical)** requires the following rule(s) be met for approval:

A. The request is for weight loss OR weight loss management
B. You have evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
C. You meet ONE of the following:
    1. Body mass index (BMI) of 30 kg/m^2 or greater
    2. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (disease) such as hypertension (high blood pressure), type 2 diabetes mellitus, or hyperlipidemia (high cholesterol)
D. **If you are requesting Contrave, approval also requires:**
    1. You are 18 years of age or older
E. **If you are requesting, or Qsymia, approval also requires:**
    1. You are 18 years of age or older

RENEWAL CRITERIA
Our guideline named **ANTI-OBESITY AGENTS (Contrave, Qsymia, Xenical)** requires the following rule(s) be met for renewal:

A. The request is for weight loss OR weight loss management
B. **If you are requesting Xenical, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment
C. **If you are requesting Contrave, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)

(Criteria continued on next page)

REQUIREMENTS: ANTI-OBESITY AGENTS (CONTINUED)

D. **If you are requesting Qsymia 7.5/46mg, approval also requires** that you have lost at least 3% of baseline body weight after 3 months of treatment at the requested maintenance dose. The dose should be increased or discontinued if patient has not lost at least 3% of baseline body weight after 3 months of treatment
E. **If you are requesting Qsymia 15/92mg, approval also requires** that you have lost at least 5% of baseline body weight after 3 months of treatment at the requested maintenance dose

References:

1. Contrave package insert. Morristown, NJ. Currax Pharmaceuticals LLC. Revised March 2021. Accessed July 2021.
2. Qysmia package insert. Campbell, Ca. Vivus, Inc. Reviewed October 2020. Accessed July 2021.
3. Xenical package insert. South San Francisco, CA. Roche Laboratories Inc. Reviewed August 2015. Reviewed July 2021

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
APOMORPHINE Edition 1	APOKYN	7/23/2021	6/1/2021

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

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

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

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

A. You have a diagnosis of advanced Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You have had improvement with motor fluctuations during OFF episodes with the use of Apokyn (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

References:

1. Apokyn package insert. Louisville, KY. US WorldMeds LLC.. Revised April 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
APOMORPHINE SUBLINGUAL Edition 1	KYNMOBI	7/23/2021	6/1/2021

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

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

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

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

A. You have Parkinson's disease (central nervous system disorder that affects movement, often including tremors)
B. You had improvement with motor fluctuations during 'OFF' episodes (when symptoms return due to your medications for Parkinson's disease wearing off) with the use of Kynmobi (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

References:

1. Kynmobi package insert. Louisville, KY. US WorldMeds, LLC. Revised April 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

ARIPIPRAZOLE SENSOR TABS			
Generic	Brand	Reviewed	Effective Date
ARIPIPRAZOLE TABLETS WITH SENSOR Edition 1	ABILIFY MYCITE	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Abilify MyCite package insert. Hayward, CA. Otsuka America Pharmaceutical, Inc. Revised December 2020. Accessed July 2021.
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. Qaseem A, Barry MJ, Kansagara D; Clinical Guidelines Committee of the American College of Physicians. Nonpharmacologic Versus Pharmacologic Treatment of Adult Patients With Major Depressive Disorder: A Clinical Practice Guideline From the American College of Physicians. Ann Intern Med. 2016 Mar 1;164(5):350-9.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ASFOTASE ALFA Edition 1	STRENSIQ	7/23/2021	6/1/2021

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

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

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

(Criteria continued on next page)

REQUIREMENTS: ASFOTASE ALFA (CONTINUED)

5. Nephrocalcinosis (high calcium levels in kidney) or history of elevated serum calcium
6. History or presence of fracture after birth not due to injury or delayed fracture healing

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

Strensiq will not be approved for the following patients:

1. Patients with serum calcium or phosphate levels below the normal range
2. Patients with a treatable form of rickets (A softening and weakening of bones in children, usually due to low Vitamin D)

(Criteria continued on next page)

REQUIREMENTS: ASFOTASE ALFA (CONTINUED)

RENEWAL CRITERIA

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

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

References:

1. Strensiq package insert. Boston,MA.Alexion Pharmaceuticals, Inc. Revised June 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ASPIRIN ER Edition 1	DURLAZA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Durlaza package insert. Boston, MA .Alexion Pharmaceuticals, Inc. Revised June 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ASPIRIN/OMEPRAZOLE Edition 1	YOSPRALA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Yosprala package insert. Allentown,PA. Genus Lifesciences Inc. Revised April 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AVAPRITINIB Edition 2	AYVAKIT	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have unresectable (cannot be removed completely through surgery) or metastatic (cancer that has spread to other parts of the body) gastrointestinal stromal tumor (GIST: type of growth in the digestive system tract, most commonly in the stomach or small intestine)
B. You are 18 years of age or older
C. You have unresectable (cannot be removed completely through surgery) or metastatic (cancer that has spread to other parts of the body) gastrointestinal stromal tumor (GIST: type of growth in the digestive system tract, most commonly in the stomach or small intestine)
D. You have a platelet-derived growth factor receptor alpha (PDGFRA: a type of gene/protein) exon 18 mutation, including PDGFRA D842V mutations (a change in your DNA that make up your gene)
E. You have advanced Systemic Mastocytosis (AdvSM) including aggressive systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL).
    1. Your platelet count is 50 X 10^9 /L or greater

References:

1. Ayvakit Package insert. Cambridge, MA. Blueprint Medicines Corporation. Revised June 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AVATROMBOPAG Edition 1	DOPTELET	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

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

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

(Criteria continued on next page)

REQUIREMENTS: AVATROMBOPAG (CONTINUED)

RENEWAL CRITERIA

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

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

References:

1. Doptlet package insert. Durham, North Carolina. AkaRx, Inc. Revised June 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AXITINIB Edition 1	INLYTA	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have advanced renal cell carcinoma (RCC; type of kidney cancer)
B. You also meet ONE of the following:
    1. You have tried at least ONE systemic therapy (treatment that spreads throughout the body) for the treatment of renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), or Avastin (bevacizumab) in combination with interferon
    2. Inlyta will be used in combination with avelumab (Bavencio) as a first-line treatment
    3. Inlyta will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

References:

1. Inlyta package insert. New York, NY. Pfizer inc. Reviewed June 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

AZTREONAM INHALED			
Generic	Brand	Reviewed	Effective Date
AZTREONAM LYSINE Edition 1	CAYSTON	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Cayston package insert. Foster City, Ca. Gilead Sciences, Inc. Revised November 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

BACLOFEN ORAL SOLUTION			
Generic	Brand	Reviewed	Effective Date
BACLOFEN Edition 1	OZOBAX	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Ozobax package insert. Athens,GA .Metacel Pharmaceuticals, LLC. Revised September 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEDAQUILINE FUMARATE Edition 1	SIRTURO	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **BEDAQUILINE FUMARATE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
   2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. **If you have pulmonary multi-drug resistant tuberculosis (MDR-TB), approval also requires ONE of the following:**
   1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
   2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
   3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. **If you have pulmonary extensively drug resistant tuberculosis (XDR-TB), approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Sirturo in combination with pretomanid and linezolid

References:

1. Sirturo package insert.Titusville, NJ. Janssen Products, LP,. Revised May 2020. Accessed July 2021
2. Centers for Disease Control and Prevention. Provisional CDC guidelines for the use and safety monitoring of bedaquiline fumarate (Sirturo) for the treatment of multidrug-resistant tuberculosis [published correction appears in MMWR Recomm Rep. 2013 Nov 15;62(45):906]. *MMWR Recomm Rep*. 2013;62(RR-09):1-12.
3. Jaspard M, Elefant-Amoura E, Melonio I, De Montgolfier I, Veziris N, Caumes E. Bedaquiline and Linezolid for Extensively Drug-Resistant Tuberculosis in Pregnant Woman. *Emerg Infect Dis*. 2017;23(10):1731-1732. doi:10.3201/eid2310.161398

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BENRALIZUMAB Edition 1	FASENRA	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
B. You are 12 years of age or older
C. Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
D. Fasenra will be used as add-on maintenance treatment
E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
F. You had a prior therapy with medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid **AND** at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as tiotropium), leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
G. You have experienced at least ONE asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 or more days)
H. You are NOT receiving concurrent treatment with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Cinqair)

RENEWAL CRITERIA

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

A. You have severe asthma with an eosinophilic phenotype (type of inflammatory asthma)
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)

(Criteria continued on next page)

REQUIREMENTS: BENRALIZUMAB (CONTINUED)

References:

1. Fasenra package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP, Revised October 2019. Accessed July 2021.
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.

WELLFLEET RX STUDENT FORMULARY

BEXAROTENE Edition 1			
Generic	Brand	Reviewed	Effective Date
BEXAROTENE SOFTGEL	TARGRETIN	7/23/2021	6/1/2021
BEXAROTENE 1% TOPICAL GEL	TARGRETIN		

REQUIREMENTS:

Our guideline named **BEXAROTENE (Targretin)** requires the following rule to be met for approval:

A. You have cutaneous T-cell lymphoma (CTCL: a type of cancer that starts in white blood cells and attacks the skin)

B. **If the request is for bexarotene capsules, approval also requires:**
   1. Your condition is refractory (resistant) to previous systemic therapy (therapy that spreads through the blood) such as gemcitabine, methotrexate, liposomal doxorubicin, or Velcade

C. **If the request is for topical bexarotene treatment, approval also requires:**
   1. You have cutaneous T-cell lymphoma (CTCL) Stage IA or IB
   2. You meet ONE of the following:
      a. Your condition is refractory or persistent after previous therapy
      b. You have not tolerated previous therapy

References:

1. Targretin package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised July 2015. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BINIMETINIB Edition 1	MEKTOVI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Mektovi package insert. Boulder, CO. Array BioPharma Inc. Revised January 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BOSUTINIB Edition 1	BOSULIF	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

B. You are 18 years of age or older

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

References:

1. Bosulif package insert. New York, NY. Pfizer inc. Revised May 2021. Accessed July 2021

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BREMELANOTIDE Edition 1	VYLEESI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

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

RENEWAL CRITERIA

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

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

References:

1. Vyleesi package insert. Cranbury, NJ. Palatin Technologies Inc. Revised October 2020. Accessed July 2021
2. Modell JG, May RS, Katholi CR. Effect of bupropion-SR on orgasmic dysfunction in nondepressed subjects: a pilot study. *J Sex Marital Ther*. 2000;26(3):231-240. doi:10.1080/00926 Edition 230050084623

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BRIGATINIB Edition 1	ALUNBRIG	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You are positive for anaplastic lymphoma kinase (ALK) fusion oncogene (a type of gene mutation that causes a change in your DNA) as detected by a Food and Drug Administration (FDA)-approved test

References:

1. Alunbrig package insert. Cambridge, MA. ARIAD Pharmaceuticals, Inc. Revised May 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CAPECITABINE Edition 1	XELODA	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **CAPECITABINE (Xeloda)** requires the following rule(s) to be met for approval:

A. You have ONE of the following diagnoses:
   1. Stage III (Duke's C) colon cancer (cancer has spread to lymph nodes)
   2. Metastatic colorectal cancer (colon cancer that has spread)
   3. Metastatic breast cancer (breast cancer that has spread)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. Capecitabine is being used by itself OR in combination with oxaliplatin (CapeOX or XELOX regimen)

C. **If you have metastatic breast cancer, approval also requires ONE of the following:**
   1. You have previously failed a trial of both paclitaxel AND an anthracycline - containing regimen
   2. You have previously failed a trial of an anthracycline-containing regimen and capecitabine is being used in combination with docetaxel

Note: Required alternative regimens listed above may require prior authorization and may be covered under the medical benefit.

References:

1. Xeloda package insert. San Francisco, CA. Genentech, Inc. Revised May 2021. Accessed July 2021

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CAPLACIZUMAB-YHDP Edition 1	CABLIVI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Cablivi package insert. Cambridge, MA. Genzyme Corporation Revised November 2020. Accessed July 2021.
2. Gould LH, Bopp C, Strockbine N, et al. Recommendations for diagnosis of shiga toxin--producing Escherichia coli infections by clinical laboratories. *MMWR Recomm Rep*. 2009;58(RR-12):1-14.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CAPMATINIB Edition 1	TABRECTA	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping (an abnormal change in a gene that makes MET protein) as detected by an FDA-approved test

References:

1. Tabrecta package insert. East Hanover, NJ, Novartis Pharmaceuticals Corporation. Revised January 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CAPSAICIN 8% PATCH Edition 1	QUTENZA	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **CAPSAICIN (Qutenza)** requires the following rule be met for approval:

A. You have a diagnosis of neuropathic pain associated with ONE of the following conditions:
    1. Postherpetic neuralgia (PHN) (painful condition that affects the nerve fibers and skin after having shingles)
    2. Diabetic peripheral neuropathy (DPN) of the feet (numbness of the feet that is caused by diabetes)

References:

1. Qutenza package insert. Morristown, NJ. Averitas Pharma, Inc. Revised July 2020. Accessed July2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CARBIDOPA/LEVODOPA Edition 1	DUOPA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Duopa package insert. North Chicago, IL. AbbVie, Inc. Revised May 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CENEGERMIN-BKBJ Edition 1	OXERVATE	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Oxervate package insert. Boston, MA. Dompé U.S. Inc. Revised October 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CERITINIB Edition 1	ZYKADIA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Zykadia package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised March 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CHENODIOL Edition 1	CHENODAL	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)

B. **If you have radiolucent gallstones, approval also requires:**
   1. You have tried ursodiol, unless there is a medical reason why you cannot (contraindication)
   2. You have not received previous chenodiol therapy for more than a total of 24 months

RENEWAL CRITERIA

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

A. You have radiolucent gallstones (hard deposits in your gall bladder that can barely be seen with x-rays) OR cerebrotendinous xanthomatosis (condition of missing an enzyme that changes cholesterol into a bile acid)

B. **If you have radiolucent gallstones, renewal also requires:**
   1. You have **NOT** had chenodiol therapy for more than a total of 24 months
   2. You do **NOT** have complete or no gallstone dissolution (disappearance) seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
   3. You have partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy

C. **If you have cerebrotendinous xanthomatosis, renewal also requires you have experienced an improvement** in **ONE** of the following:
   1. Normalization of elevated serum or urine bile alcohols
   2. Normalization of elevated serum cholestanol levels
   3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

References:

1. Chenodal package insert. Fort Collins, CO. Manchester Pharmaceuticals, Inc. Revised June 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CHOLIC ACID Edition 1	CHOLBAM	7/23/2021	6/1/2021

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

RENEWAL CRITERIA

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

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

References:

1. Cholbam package insert. San Diego, CA, Manchester Pharmaceuticals Inc. Revised October 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CLASCOTERONE Edition 1	WINLEVI	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

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

References:

1. Winlevi package insert. San Diego, CA. Cassiopea Inc. Revised August 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CLOBAZAM Edition 1	SYMPAZAN	7/23/2021	6/1//2021

REQUIREMENTS:

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

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

References:

1. Sympazan package insert. Warren,NJ. Aquestive Therapeutics. Revised March 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
COBIMETINIB FUMARATE Edition 1	COTELLIC	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Cotellic package insert.(per FDA), South San Francisco, CA. Genentech USA, Inc. Revised June 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CRIZOTINIB Edition 1	XALKORI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Xalkori package insert. New York, NY. Pfizer Labs. Revised January 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CYSTEAMINE BITARTRATE Edition 1	PROCYSBI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Procysbi package insert Product Information. Lake Forest, IL, Horizon Pharma USA Inc. Revised February 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CYSTEAMINE HCL Edition 1	CYSTARAN	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **CYSTEAMINE HYDROCHLORIDE (Cystaran/Cystadrops)** requires the following rule(s) be met for approval:

A. You have cystinosis (a type of genetic disorder where a substance called cysteine builds up in body organs)
B. You require treatment for corneal cystine crystal accumulation or deposits (buildup of cysteine in the eye)

References:

1. Cystaran package insert**.** Amityville, NY**.** Hi-Tech Pharmacal Co. Revised April 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DABRAFENIB MESYLATE Edition 1	TAFINLAR	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have unresectable or metastatic melanoma (skin cancer that cannot be completely removed by surgery or has spread), metastatic non-small cell lung cancer, melanoma (skin cancer), or locally advanced or metastatic anaplastic thyroid cancer.

B. If you have unresectable or metastatic melanoma, approval also requires:
   1. You have BRAF V600E mutation (type of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used as a single agent (by itself)

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

D. If you have melanoma, approval also requires:
   1. You have BRAF V600E or V600K mutations (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication has not previously been used for more than one year
   3. The medication will be used in combination with Mekinist (trametinib) for adjuvant (addon) treatment
   4. There is involvement of lymph node(s) following complete resection (removal of a tumor and normal tissue around it)

E. If you have metastatic non-small cell lung cancer, approval also requires:
   1. You have BRAF V600E mutation (types of gene mutation) as detected by an FDA (Food and Drug Administration)-approved test
   2. The medication will be used in combination with Mekinist (trametinib)

F. If you have locally advanced or metastatic anaplastic thyroid cancer, approval also requires:
   1. You have BRAF V600E mutation (type of gene mutation)
   2. The medication will be used in combination with Mekinist (trametinib)
   3. You have no satisfactory locoregional (restricted to a localized region of the body) treatment options available

References:

1. Tafinlar package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Reviewed May 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DACLATASVIR DIHYDROCHLORIDE Edition 1	DAKLINZA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

(Criteria continued on next page)

REQUIREMENTS: (CONTINUED)- DACLATASVIR

3. *Patients status post liver transplant:*
    a. You have previously tried Harvoni and you had adverse effects, intolerance early in therapy, or contraindication to (medical reason why you cannot use) Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
    b. Concurrent (used at the same time with) ribavirin use required

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

(Criteria continued on next page)

REQUIREMENTS: (CONTINUED)- DACLATASVIR

Daklinza will not be approved if you meet ANY of the following:

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

References:

1. Daklinza package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised October 2019. Accessed April 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLECAPREVIR/ PIBRENTASVIR Edition 2	MAVYRET	7/23/2021	7/23/2021

REQUIREMENTS

The guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires a diagnosis of genotype 1, 2, 3, 4, 5, or 6 hepatitis C. The following criteria must also be met:

A. The patient is at least 3 years old
B. The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
C. Documentation of chronic HCV infection (e.g., at least **ONE** detectable HCV RNA level within the last 6 months)
D. The patient meets one of the following:
    1. The patient is post liver transplant with no cirrhosis and is treatment naive or treatment experienced
    2. The patient is post kidney transplant with no cirrhosis or compensated cirrhosis and is treatment naive or treatment experienced, and
    3. The patient is treatment naive with no cirrhosis or with compensated cirrhosis
        i. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa or Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
    4. The patient has genotype 1 or 2 with no cirrhosis and is treatment experienced with sofosbuvir or an NS3 inhibitor
        i. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa or Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]

(Criteria continued on next page)

REQUIREMENTS- (CONTINUED) GLECAPREVIR/PIBRENTASVIR

5. The patient has genotype 1, 2, 4, 5 or 6 infection with compensated cirrhosis and is treatment experienced (previous treatment failure with regimens containing interferon, peginterferon, ribavirin, and/or sofosbuvir)
    i. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa or Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]
6. The patient has genotype 1, 2, 4, 5, or 6 infection with no cirrhosis and is treatment experienced with peginterferon and ribavirin
    i. You have previously tried Epclusa or Harvoni and you had adverse effects, intolerance early in therapy or contraindication to (medical reason why you cannot use) Epclusa or Harvoni; [an individual who has completed a full course of therapy that did not achieve SVR (sustained virological response) will not be approved]

The medication will not be approved for the following:

A. The patient is concurrently taking: rifampin, atazanavir, carbamazepine, efavirenz, darunavir, lopinavir, ritonavir, atorvastatin, lovastatin, simvastatin, rosuvastatin (at doses greater than 10mg), cyclosporine (for patients requiring stable cyclosporine doses greater than 100mg/day) or medications containing ethinyl estradiol
B. The patient has moderate or severe liver impairment (Child-Pugh B or C)
C. The patient is treatment experienced with an NS5A containing regimen and is not a liver or kidney transplant recipient
D. The patient has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

References:

1. Mavyret package insert. North Chicago, IL. AbbVie Inc. Revised June 2021. Accessed July 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR/ VELPATASVIR Edition 2	EPCLUSA	7/23/2021	7/23/2021

REQUIREMENTS:
Our guideline named **SOFOSBUVIR/VELPATASVIR (Epclusa)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C (type of liver inflammation) with genotype 1, 2, 3, 4, 5, or 6
B. You are 3 years of age or older
C. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is documentation showing you have hepatitis C virus infection with at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you have decompensated cirrhosis (symptoms related to liver damage), approval also requires:**
    1. The requested medication will be used with ribavirin
F. **If you do not have cirrhosis (liver damage) OR you have compensated cirrhosis (a condition where liver is extensively scarred, but you do not have symptoms of liver damage), approval also requires ONE of the following:**
    1. You are treatment naive (never previously treated)
    2. You are treatment experienced (have previously been treated) with peginterferon/ribavirin or NS3 protease inhibitor triple therapy (type of hepatitis drug such as Olysio, Incivek or Victrelis with peginterferon/ribavirin)
    3. You have genotype 1b or genotype 2 infection AND you are treatment experienced with a Sovaldi (sofosbuvir)-containing regimen that does not include an NS5A inhibitor (type of hepatitis drug) such as Sovaldi/ribavirin with or without peginterferon or Sovaldi/Olysio

Epclusa will not be approved in the following condition(s):

A. You are using any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV (human immunodeficiency virus) regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir or topotecan
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions

(Criteria continued on next page)

REQUIREMENTS: SOFOSBUVIR/VELPATASVIR (CONTINUED)

References:

1. Epclusa package insert. Foster City, CA. Gilead Sciences, Inc. Revised June 2021. Accessed July 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DACOMITINIB Edition 1	VIZIMPRO	7/23/2021	6//1/2021

REQUIREMENTS:

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

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

References:

1. Vizimpro package New York, NY. Pfizer Labs. Reviewed. December 2020.Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DALFAMPRIDIN Edition 1	AMPYRA	7/23/2021	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. You have multiple sclerosis (disease in which the immune system eats away at the protective covering of nerves)
B. The medication is prescribed by or recommended by a neurologist (doctor who specializes in disorders of the nervous system)
C. You have symptoms of a walking disability

RENEWAL CRITERIA

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

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

References:

1. Ampyra package insert. Ardsley, NY. Accorda Therapeutics, Inc. Revised December 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DASATINIB Edition 1	SPRYCEL	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

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

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

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

References:

1. Sprycel package insert. Princeton, NJ. Bristol-Myers Squibb Company. Reviewed June 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Date Revised	Effective Date
DEFERIPRONE Edition 1	FERRIPROX	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
B. Therapy is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist-oncologist (tumor/cancer doctor)
C. You have tried Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)
D. You meet ONE of the following:
    1. You are experiencing intolerable toxicities, clinically significant adverse effects, or have a contraindication to (medical reason why you cannot use) current chelation therapy (process of removing metals from the blood) with Exjade, Jadenu, or Desferal
    2. Chelation therapy (with Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is not working well enough as shown by ONE of the following:
        a. Serum ferritin levels (amount of iron-containing blood cell proteins) stay above 2500mcg/L (at least 2 lab values in the previous 3 months)
        b. You have evidence of cardiac iron accumulation (iron build up in your heart) as defined by: cardiac T2* MRI less than 10 milliseconds, iron induced cardiomyopathy (heart disease), fall in left ventricular ejection fraction (LVEF: amount of blood your heart pumps out), arrhythmia indicating inadequate chelation (irregular heartbeat because iron was not lowered enough in body)

RENEWAL CRITERIA

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

A. You have transfusional iron overload due to a thalassemia syndrome (you have too much iron in your body due to a blood disorder)
B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

References:

1. Ferriprox package insert. Cary, NC. Chiesi USA, Inc., Revised April 2021. Accessed July 2021.
2. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv*. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DEFEROXAMINE MESYLATE Edition 1	DESFERAL	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

A. You have chronic iron overload due to transfusion-dependent anemias (blood doesn't have enough healthy red blood cells)
B. Your serum ferritin levels (amount of iron-containing blood cell proteins) stay greater than 500mcg/L (at least 2 lab values in the previous 3 months)

References:

1. Desferal package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2020. Accessed July 2021.
2. Brandow AM, Carroll CP, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv*. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DEFLAZACORT Edition 1	EMFLAZA	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

Note: Requests due to side effects while on prednisone or prednisolone that are named or listed in the prescribing information of Emflaza will not be approved

(Criteria continued on next page)

REQUIREMENTS: DEFLAZACORT (CONTINUED)

RENEWAL CRITERIA

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

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

References:

1. Emflaza package insert. South Plainfield, NJ. PTC Therapeutics, Inc. Revised July 2020. Accessed July 2021.
2. Sammaritano LR, Bermas BL, Chakravarty EE, et al. 2020 American College of Rheumatology Guideline for the Management of Reproductive Health in Rheumatic and Musculoskeletal Diseases. *Arthritis Rheumatol*. 2020;72(4):529-556.doi:10.1002/art.41191.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DELAFLOXACIN Edition 1	BAXDELA	7/23/2021	6/1/2021

REQUIREMENTS:
Our guideline named **DELAFLOXACIN (Baxdela)** requires the following rule(s) be met for approval:

A. You meet **ONE** of the following:
    1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist or
    2. You have an acute (serious and short-term) bacterial skin or skin structure infection (ABSSSI); **OR** community-acquired bacterial pneumonia (CABP: type of lung infection)

B. **If you have an acute bacterial skin or skin structure infection, approval also requires:**
    1. You are at least 18 years of age
    2. The infection is caused by any of the following bacteria: Staphylococcus aureus (including methicillin-resistant [MRSA] *and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa*
    3. You do not have a diagnosis of animal or human bite, necrotizing fasciitis (flesh eating disease), diabetic foot infection, decubitis ulcer formation (pressure/bed ulcer), myonecrosis (dead muscle tissue) or ecthyma gangrenosum
    4. You meet **ONE** of the following criteria:
        i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to **ONE** standard of care agent for acute bacterial skin or skin structure infection (such as sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin), **AND** b) delafloxacin will work against the bacteria

(Criteria continued on next page)

REQUIREMENTS: DELAFLOXACIN (CONTINUED)

ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial of or contraindication to (a medical reason why you cannot use) **ONE** of the following agents: a penicillin (such as amoxicillin), a fluoroquinolone (such as levofloxacin, ciprofloxacin, moxifloxacin), a cephalosporin (such as ceftriaxone, cephalexin, cefazolin), or a gram positive targeting antibiotic (such as linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin)

C. **If you have community-acquired bacterial pneumonia (CABP: type of lung infection), approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae*
   3. You meet **ONE** of the following criteria:
      i. If antimicrobial susceptibility test is available (you have a test showing what drugs work on which bacteria of the infection site), we require the results of the test from the infection site show the bacteria is both a) resistant to TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) AND b) delafloxacin will work against the bacteria
      ii. If antimicrobial susceptibility test is not available (you do not have a test showing what drugs work on which bacteria of the infection site), we require you had a trial or contraindication to (a medical reason why you cannot use) **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid)

References

1. Baxdela package insert. Lincolnshire, IL. Melinta Therapeutics, Inc. Revised October 2019. Accessed July 2021.
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
DESIRUDIN Edition 1	IPRIVASK	7/23/2021	6/1/2021

REQUIREMENTS:

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

References:

1. Iprivask package insert. Northbrook, IL. Marathon Pharmaceuticals, LLC. Revised November 2014. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DEUTETRABENAZINE Edition 1	AUSTEDO	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Austedo package insert. Parsippany, NJ. Teva Pharmaceuticals USA, Inc. Revised June 2021.Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DEXTROMETHORPHAN/ QUINIDINE Edition 1	NUEDEXTA	7/23/2021	6/1/2021

REQUIREMENTS:

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

References:

1. Nuedexta package insert. Aliso Viejo, CA. Avanir Pharmaceuticals, Inc. Revised June 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

DIABETIC TEST STRIPS Edition 1			
Generic	Brand	Reviewed	Effective Date
BLOOD SUGAR DIAGNOSTIC BLOOD SUGAR DIAGNOSTIC, DISC BLOOD SUGAR DIAGNOSTIC, DRUM	DIABETIC TEST STRIPS VARIOUS	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

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

References:

1. U.S. Food & Drug Administration. Package Inserts. Drugs@FDA: FDA-Approved Drugs website. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DICHLORPHENAMIDE Edition 1	KEVEYIS	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

References:

1. Keveyis package insert. Trevose, PA. Strongbridge US Inc. Revised December 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

DICLOFENAC ORAL PACKET			
Generic	Brand	Reviewed	Effective Date
DICLOFENAC POTASSIUM Edition 1	CAMBIA	7/23/2021	6/1/2021

REQUIREMENTS:

Our guideline named **DICLOFENAC ORAL PACKET (Cambia)** requires the following rule(s) be met for approval:

A. The request is for acute treatment of migraine attacks
B. You are unable to swallow pills
C. You had a previous trial of generic diclofenac AND over the counter (OTC) or generic aspirin, ibuprofen, or naproxen

References:

1. Cambia package insert. Lake Forest, IL. Assertio Therapeutics. Revised April 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

DICLOFENAC TOPICAL			
Generic	Brand	Reviewed	Effective Date
DICLOFENAC SODIUM 3% Edition 1	SOLARAZE	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Solaraze package insert. Melville, NY. Fougera Pharmaceuticals Inc. Revised April 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DORNASE ALFA Edition 1	PULMOZYME	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Pulmozyme package insert. South San Francisco, CA. Genentech, Inc. Revised December 2014. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DUVELISIB Edition 1	COPIKTRA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Copiktra package insert. Needham, MA. Verastem, Inc. Revised June 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EFINACONAZOLE Edition 1	JUBLIA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Jublia package insert. Bridgewater, NJ. Bausch Health US, LLC. Revised April 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELAGOLIX Edition 1	ORILISSA	7/23/2021	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. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
D. You had a previous trial of or contraindication to (a medical reason why you cannot use) a nonsteroidal anti-inflammatory drug (NSAID; such as ibuprofen, meloxicam, naproxen) **AND** a progestin-containing preparation (such as combination hormonal contraceptive preparation, progestin-only therapy)
E. Requests for Orilissa 200mg twice daily will only be approved if you have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

RENEWAL CRITERIA

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

A. You have moderate to severe pain associated with endometriosis (disorder where uterus tissue grows outside of the uterus)
B. You have improvement of pain related to endometriosis while on therapy
C. You have normal liver function or mild hepatic (liver) impairment (Child-Pugh Class A)

Requests will not be approved if you meet ONE of the following conditions:

A. You have received a 6-month course of Orilissa 200mg twice daily
B. You have received a 6-month course of Orilissa 150mg once daily and you have moderate hepatic (liver) impairment (Child-Pugh Class B)
C. You have received a 24-month course of Orilissa 150mg once daily and you have normal liver function or mild (liver) hepatic impairment (Child-Pugh Class A)

References:

1. Orilissa package insert. North Chicago, IL. AbbVie Inc. Revised February 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELAPEGADEMASE-LVLR Edition 1	REVCOVI	7/23/2021	6/1/2021

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

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

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

RENEWAL CRITERIA

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

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

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

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

References:

1. Revcovi package insert. Gaithersburg, MD. Leadiant Biosciences Inc. Revised December 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELIGLUSTAT TARTRATE Edition 1	CERDELGA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Cerdelga package insert. Cambridge, MA. Genzyme Corporation. Revised August 2018. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELTROMBOPAG Edition 1	PROMACTA	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have one of the following diagnoses:
   1. Chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
   2. Thrombocytopenia (low blood platelet count) due to chronic hepatitis C
   3. Severe aplastic anemia (type of blood disorder)

B. **If you are greater than 12 years of age and the request is for Promacta packets, approval also requires:**
   1. You previously had a trial of Promacta tablets
   2. You have a medical need for powder packets

C. **If you have chronic immune (idiopathic) thrombocytopenia, approval also requires:**
   1. You are 1 year of age or older
   2. You have tried corticosteroids or immunoglobulins, or did not have a good enough response to a splenectomy (removal of spleen) - unless there is a medical reason why you cannot (contraindication)
   3. The medication is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)

D. **If you have thrombocytopenia due to chronic hepatitis C, approval also requires:**
   1. Your thrombocytopenia does not allow you to start interferon-based therapy (type of drug for hepatitis) or limits your ability to maintain interferon-based therapy

E. **If you have severe aplastic anemia, approval also requires ONE of the following:**
   1. You are 2 years of age or older and Promacta will be used in combination with standard immunosuppressive therapy (treatment that prevents activity from your immune system) as first-line treatment
   2. You did not have a good enough response to immunosuppressive therapy

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section.

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

REQUIREMENTS: ELTROMBOPAG CONTINUED)

Our guideline named **ELTROMBOPAG (Promacta) requires the following rules be met for renewal:**

A. You have chronic immune (idiopathic) thrombocytopenia (low levels of the blood cells that prevent bleeding)
B. You have a clinical response, as defined by an increase in platelet count to at least 50X10(9)/L (at least 50,000 per microliter)

References:

1. Promacta package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised February 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EMICIZUMAB-KXWH Edition 1	HEMLIBRA	7/23/2021	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. You have hemophilia A congenital factor VIII deficiency (a bleeding disorder)
B. The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor)
D. Patients with Factor VIII inhibitors must have a history of a high titer (concentration) of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
E. Patients without Factor VIII inhibitors must meet one of the following criteria:
    1. You have severe hemophilia A defined as less than 1% factor VIII activity compared to normal
    2. You have *mild* or *moderate* hemophilia A and a history of 2 or more bleeds per year

RENEWAL CRITERIA

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

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

References:

1. Hemlibra package insert. South San Francisco, CA. Genentech, Inc. Revised October 2018. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ENASIDENIB Edition 1	IDHIFA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Idhifa package insert. Cambridge, MA. Agios Pharmaceuticals. Revised November 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ENCORAFENIB Edition 1	BRAFTOVI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

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

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

References:

1. Braftovi package insert. Boulder, Colorado. Array BioPharma Inc. Reviewed April 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ENTRECTINIB Edition 1	ROZLYTREK	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread to other parts of body) OR a solid tumor

B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. You have *ROS1*-positive tumors (you have a type of gene mutation)

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

References:

1. Rozlytrek package insert. South San Francisco, Ca. Genentech, Inc. Revised August 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ERDAFITINIB Edition 1	BALVERSA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Balversa package insert. Horsham, PA. Janssen Products. Revised July 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ERLOTINIB Edition 1	TARCEVA	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (type of lung cancer that has spread) OR locally advanced, unresectable, or metastatic pancreatic cancer (pancreas cancer that has spread or cannot be completely removed by surgery)

B. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. Your tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of gene mutations or permanent change in the DNA that makes up a gene) as detected by an FDA (Food and Drug Administration)- approved test

C. **If you have locally advanced, unresectable, or metastatic pancreatic cancer, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine
   2. The medication will be used as a first line treatment

References:

1. Tarceva package insert. South San Francisco, CA. Genentech USA, Inc. Revised October 2016. Accessed July 2021.
2. Lindeman NI, Cagle PT, Beasley MB, et al. Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology. Arch Pathol Lab Med 2013; 137:828.

WELLFLEET RX STUDENT FORMULARY

ERYTHROPOIESIS STIMULATING AGENTS Edition 1			
Generic	Brand	Reviewed	Effective Date
DARBEPOETIN	ARANESP	7/23/2021	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:

1. You have ONE of the following diagnoses:
    1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
    3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
    5. You are undergoing elective, noncardiac (not heart related), or nonvascular surgery.
2. **If you have anemia associated with chronic kidney disease, approval also requires:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL
3. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
    1. You have a hemoglobin level of less than 11g/Dl
    2. Your hemoglobin level has decreased at least 2g/dL below your baseline level.
4. **If you have anemia related to zidovudine therapy, approval also requires:**
    1. You have a hemoglobin level of less than 10g/dL

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

5. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
    1. You have tried a lower ribavirin dose, unless there is medical reason why you cannot (contraindication)
    2. You have a hemoglobin level of less than 10g/dL
6. **If you are undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
    1. You have a hemoglobin level of less than 13g/dL

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

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

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

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

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

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

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

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

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

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

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

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

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

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

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

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

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

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

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

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

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

RENEWAL CRITERIA FOR PROCRIT

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

A. You have ONE of the following diagnoses:
    1. Anemia (low amount of healthy red blood cells) due to with chronic kidney disease
    2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
    3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
    2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
    3. Your hemoglobin level has reached 10g/dL (if you are NOT on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12g/dL

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

RENEWAL CRITERIA FOR ARANESP

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

A. You have ONE of the following diagnoses:
    1. Anemia (low amount of healthy red blood cells) associated with chronic kidney disease
    2. Anemia due to the effects of concomitantly administered (given at the same time) cancer chemotherapy
    3. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa.
B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
    1. You have a hemoglobin level of less than 10g/dL if you are NOT on dialysis
    2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
    3. Your hemoglobin has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. Your hemoglobin has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.
C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12g/dL
D. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12g/dL

(Criteria continued on next page)

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. You have ONE of the following diagnoses:
    1. Anemia (low amount of healthy red blood cells) due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered (given at the same time) cancer chemotherapy
    3. Anemia related to zidovudine therapy (type of drug to treat human immunodeficiency virus)
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
    2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
    3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions.
C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12 g/dL
D. **If you have anemia related to zidovudine therapy, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12 g/dL
E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12 g/dL

RENEWAL CRITERIA FOR RETACRIT

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

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

(Criteria continued on next page)

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

B. **If you have anemia associated with chronic kidney disease, renewal also requires ONE of the following:**
    1. You have a hemoglobin level (amount of oxygen-containing protein) of less than 10g/dL if you are NOT on dialysis
    2. You have a hemoglobin level of less than 11g/dL if you are on dialysis
    3. Your hemoglobin level has reached 10g/dL (if you are not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
    4. Your hemoglobin level has reached 11g/dL (if you are on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions
C. **If you have anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12g/dL
D. **If you have anemia related to zidovudine therapy, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12g/dL
E. **If you have anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
    1. You have a hemoglobin level between 10g/dL and 12g/dL

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

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

(Criteria continued on next page)

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

D. **If you are between 5 and 17 years of age, renewal also requires:**
   1. You are currently receiving dialysis treatment
   2. You have ONE of the following:
      a. A hemoglobin level (amount of oxygen-containing protein) of less than 11g/dL
      b. A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

References:

1. Aranesp package insert. Thousand Oaks, Ca. Amgen Inc. Revised January 2019. Accessed July 2021.
2. Epogen package insert. Thousand Oaks, Ca. Amgen Inc. Revised July 2018. Accessed July 2021.
3. PROCRIT package insert. Thousand Oaks, Ca. Amgen Inc. Revised. Reviewed July 2018. Accessed July 2021.
4. RETACRIT package insert. Lake Forest, IL.Pfizer Company. Reviewed June 2020. Accessed July 2021.
5. MIRCERA package insert. South San Francisco, CA. Reviewed June 2018. Accessed July 2021

WELLFLEET RX STUDENT FORMULARY

EVEROLIMUS Edition 1			
Generic	Brand	Reviewed	Effective Date
EVEROLIMUS	AFINITOR	7/23/2021	6/1/2021
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. You have ONE of the following diagnoses:
    1. Subependymal giant cell astrocytoma (SEGA; a type of brain tumor) with tuberous sclerosis complex (TSC; genetic disorder with many non-cancer tumors)
    2. Tuberous sclerosis complex (TSC)-associated partial-onset seizures

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

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

(Criteria continued on next page)

REQUIREMENTS: EVEROLIMUS (CONTINUED)

AFINITOR

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

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

References:

1. Afinitor/Afinitor Disperz package insert. East Hanover, New Jersey Novartis Pharmaceuticals Corporation. Revised April 2021. Accessed July 2021.
2. Wuerstlein R, Harbeck N. Neoadjuvant Therapy for HER2-positive Breast Cancer. *Rev Recent Clin Trials*. 2017;12(2):81-92. doi:10.2174/1574887112666170202165049

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FEDRATINIB Edition 2	INREBIC	4/29/2022	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. You are 18 years of age or older
B. Prescribed by or in consultation with an oncologist or hematologist
C. You have intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (type of bone marrow cancer)
D. You have a platelet count of at least 50×10^9/L (50,000/mcL) or greater
E. You previously had a trial of or contraindication (medical reason why you cannot use) to Jakafi (ruxolitinib)

RENEWAL CRITERIA

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

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

References:

1. Inrebic package insert. Summit, NJ. Celgene Corporation. Revised December 2021. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FENFLURAMINE Edition 2	FINTEPLA	4/29/2022	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. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life)
   2. Seizures associated with Lennox-Gastaut syndrome

B. You are 2 years of age or older

C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spine, and nerves)

D. If you have seizures associated with Dravet syndrome, approval also requires:
   1. You had a previous trial of clobazam AND valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

E. If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:
   1. You have previously tried TWO of the following, unless there is a medical reason why you cannot (contraindication): clobazam, valproic acid derivative, topiramate, lamotrigine

RENEWAL CRITERIA

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

A. You have seizures associated with Dravet syndrome (severe type of seizure disorder that begins during the first year of life) or Lennox-Gastaut syndrome

B. You have shown continued clinical benefit (such as reduction of seizures, reduced length of seizures, seizure control maintained) while on therapy

References:

1. Fintepla package insert. Emeryville CA. Zogenix Inc. Revised March 2022. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FENTANYL NASAL SPRAY Edition 2	LAZANDA	7/23/2021	7/23/2021

REQUIREMENTS:

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

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

References:

1. Lazanda package insert. Northbrook, IL. West Therapeutic Development. Revised March 2021. Accessed July 2021.
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
FENTANYL SUBLINGUAL SPRAY Edition 2	SUBSYS	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   a. You have cancer-related pain
   b. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   c. You are enrolled in hospice

B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)

C. You had a trial of an oral immediate-release pain medication (morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)

D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a medical reason why you cannot (contraindication)

E. You had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a medical reason why you cannot (contraindication)

References:

1. Subsys package insert. Northbrook, IL. West Therapeutic Development, LLC. Revised March 2021. Accessed July 2021.
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
FENTANYL TRANSDERMAL PATCH Edition 2	DURAGESIC	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You meet ONE of the following:
   a. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain-relieving dose) of another opioid
   b. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   c. You are 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 (absorbed through the skin) fentanyl patch dosed every 72 hours

References:

1. Duragesic package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised March 2021. Accessed July 2021.
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

FENTANYL TRANSMUCOSAL AGENTS			
Generic	Brand	Reviewed	Effective Date
FENTANYL CITRATE Edition 2	ACTIQ, ABSTRAL, FENTORA	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   a. You have cancer-related pain
   b. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   c. You are enrolled in hospice

B. You are currently using the requested medication with a controlled-release pain medication (MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)

C. You had a trial of an oral immediate-release pain medication (such as morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless you have difficulty swallowing tablets or capsules OR there is a medical reason why you cannot (contraindication)

D. You had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a medical reason why you cannot (contraindication)

References:

1. Actiq package insert. Parsippany, NJ. Teva Pharmaceuticals. Revised March 2021. Accessed July 2021.
2. Abstral package insert**.** Solana Beach, CA. Sentynl Therapeutics, Inc. Reviewed October 2019. Accessed July 2021.
3. Fentora package insert**.** Parsippany, NJ. Teva Pharmaceuticals. Reviewed March 2021. Accessed July 2021.
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

Generic	Brand	Reviewed	Effective Date
FLIBANSERIN Edition 1	ADDYI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

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

(Criteria continued on next page)

REQUIREMENTS: FLIBANSERIN (CONTINUED)

RENEWAL CRITERIA

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

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

References:

1. Addyi package insert. Raleigh, NC. Sprout Pharmaceuticals, Inc. Revised December 2019. Accessed July 2021.
2. Modell JG, May RS, Katholi CR. Effect of bupropion-SR on orgasmic dysfunction in nondepressed subjects: a pilot study. *J Sex Marital Ther*. 2000;26(3):231-240. doi:10.1080/00926230050084623.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FLUOROURACIL 0.5% CREAM Edition 1	CARAC	7/23/2021	6/1/2021

GUIDELINE FOR USE

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

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

References:

1. Carac package insert**.** Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised April 2017. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FOSTAMATINIB Edition 1	TAVALISSE	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

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

References:

1. Tavalisse package insert. South San Francisco, CA. Rigel Pharmaceuticals, Inc. Revised April 2018. Accessed July 2021.
2. Sahi PK, Chandra J. Immune Thrombocytopenia: American Society of Hematology Guidelines, 2019. *Indian Pediatr*. 2020;57(9):854-856.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FOSTEMSAVIR Edition 1	RUKOBIA	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
B. You are 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
D. You are treatment experienced (previously treated)
E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
F. You are failing your current antiretroviral regimen due to resistance, intolerance, or safety considerations

References:

1. Rukobia package insert. Research Triangle Park, NC. ViiV Healthcare. Revised July 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GEFITINIB Edition 1	IRESSA	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (NSCLC; type of lung cancer that has spread)
B. Your tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (types of permanent changes in your DNA that make up your gene) as detected by an FDA (Food and Drug Administration)-approved test

References:

1. Iressa package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised April 2004. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GILTERITINIB FUMARATE Edition 1	XOSPATA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Xospata package insert. Northbrook, Illinois. Astellas Pharma US, Inc. Revised May 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLASDEGIB MALEATE Edition 1	DAURISMO	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Daurismo package insert. New York, NY. Pfizer Labs, Inc. Revised March 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GLYCEROL PHENYLBUTYRATE Edition 1	RAVICTI	7/23/2021	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. You have a urea cycle disorder (genetic disorder that causes buildup of ammonia in blood)
B. Documentation of confirmation of urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
C. You are 2 months of age or older
D. Ravicti will be used as adjunctive (add-on) therapy along with dietary protein restriction
E. The disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
F. The patient does **NOT** have a deficiency of N-acetylglutamate synthetase (type of enzyme) or acute hyperammonemia (short and sudden high ammonia levels)
G. You have previously tried Buphenyl (sodium phenylbutyrate), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

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

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

References:

1. Ravicti package insert**.** Lake Forest, IL. Horizon Pharma USA, Inc. Revised October 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

GLYCOPYRRONIUM TOPICAL			
Generic	Brand	Reviewed	Effective Date
GLYCOPYRRONIUM 2.4% CLOTH Edition 1	QBREXZA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Qbrexza package insert. Menlo Park, California. Dermira, Inc. Revised June 2018. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

HYDROMORPHONE ER			
Generic	Brand	Reviewed	Effective Date
HYDROMORPHONE HCL ER Edition 2	EXALGO, HYDROMORPHONE ER	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You meet ONE of the following:
   a. You meet the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose (equal pain relieving dose) of another opioid
   b. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   c. You are enrolled in hospice
B. The requested medication is not prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

References:

1. Exalgo package insert. Webster Groves, MO. SpecGx LLC. Revised December 2019. Accessed July 2021.
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
IBRUTINIB Edition 1	IMBRUVICA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Imbruvica package insert. Horsham, PA. Reviewed Janssen Biotech, Inc. Revised December 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IDELALISIB Edition 1	ZYDELIG	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Zydelig package insert. Foster City, CA. Gilead Sciences, Inc. Revised October 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ILOPROST Edition 1	VENTAVIS	7/23/2021	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. You have pulmonary arterial hypertension (PAH: type of high blood pressure in the arteries from the heart to the lungs; World Health Organization Group 1)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

RENEWAL CRITERIA

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

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

References:

1. Ventavis package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised December 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

INDOMETHACIN RECTAL			
Generic	Brand	Reviewed	Effective Date
INDOMETHACIN Edition 1	INDOCIN	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have dysphagia (difficulty swallowing), difficulty swallowing capsules, or have a feeding tube placed (such as a G-tube, J-tube)

B. You had a previous trial of at least two prescription strength oral NSAIDs (non-steroidal anti-inflammatory drugs such as ibuprofen, meloxicam, diclofenac, sulindac, indomethacin, celecoxib)

References:

1. Indocin package insert. Wayne, PA. Zyla Life Sciences US, Inc. Revised April 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

INHALED INSULIN			
Generic	Brand	Reviewed	Effective Date
INSULIN REGULAR, HUMAN Edition 1	AFREZZA	7/23/2021	6/1/2021

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. You have type 1 or type 2 diabetes
B. You are 18 years of age or older
C. You have a baseline spirometry (test to measure how well your lungs work) to measure FEV_1 (forced expiratory volume)
D. **If you have type 1 diabetes, approval also requires:**
    1. You are using a long-acting insulin with the requested medication and that you have tried a formulary rapid acting insulin: Humalog
E. **If you have type 2 diabetics, approval also requires:**
    1. You tried a formulary rapid acting insulin: Humalog
    2. Your prescriber has indicated that you are physically unable or unwilling to use injectable insulin

RENEWAL CRITERIA

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

A. You have type 1 or type 2 diabetes
B. You have documentation of follow up spirometry (test to measure how well your lungs work) to measure FEV_1 (forced expiratory volume in one second) after 6 months of treatment and annually thereafter
C. Your FEV_1 has NOT declined 20% or more from baseline
D. **If you have type 1 diabetes,** approval requires that you are using a long acting insulin at the same time with the requested medication

References:

1. Afrezza package insert. Danbury, CT. MannKind Corporation. Revised October 2018. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INOTERSEN SODIUM Edition 1	TEGSEDI	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

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

References:

1. Tegsedi package insert. Boston, MA. Akcea Therapeutics, Inc. Revised April 2020. Accessed July 2021.
2. Macedo AVS, Schwartzmann PV, de Gusmão BM, Melo MDT, Coelho-Filho OR. Advances in the Treatment of Cardiac Amyloidosis. *Curr Treat Options Oncol*. 2020;21(5):36. Published 2020 Apr 23. doi:10.1007/s11864-020-00738-8

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INTERFERON ALFA-2B Edition 1	INTRON A	7/23/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

(Criteria continued on next page)

REQUIREMENTS: INTERFERON ALFA-2B (CONTINUED)

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

RENEWAL CRITERIA

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

A. The request is for continuation of current therapy or renewal with Intron A therapy

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

References:

1. Intron A. package insert. Whitehouse Station, NJ. Merck & Co, Inc. Revised May 2018. Accessed July 2021.
2. Expert Panel on Urological Imaging, Allen BC, Oto A, et al. ACR Appropriateness Criteria® Post-Treatment Surveillance of Bladder Cancer: 2021 Update. *J Am Coll Radiol*. 2021;18(5S):S126-S138. doi:10.1016/j.jacr.2021.02.011

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INTERFERON GAMMA-1B, RECOMB. Edition 1	ACTIMMUNE	7/23/2021	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. You have ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
   2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

B. **If you have chronic granulomatous disease, approval also requires:**
   1. The medication is prescribed by or given in consultation with a hematologist (blood doctor), infectious disease specialist (doctor that specializes in treating infections), or immunologist (doctor that specializes in treating and managing allergies, asthma and immunologic disorders)

C. **If you have severe malignant osteopetrosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (doctor that specializes in all things relating to our hormones)

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
   2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

B. You have shown clinical (medical) benefit compared to baseline (such as reduction in frequency and severity of serious infections)

C. You have not received hematopoietic cell transplantation (transplant of stem cells from bone marrow, peripheral blood, or umbilical cord blood)

References:

1. Actimmune package insert. Roswell, GA. HZNP USA Inc. Revised August 2015. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ISTRADEFYLLINE Edition 1	NOURIANZ	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Nourianz package insert. Bedminster, NJ. Kyowa Kirin Inc. Revised August 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ITRACONAZOLE Edition 1	TOLSURA	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Tolsura package insert. Greenville, NC. Mayne Pharma. Revised December 2018. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IXAZOMIB CITRATE Edition 1	NINLARO	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Ninlaro package insert. Cambridge, MA. Takeda Pharmaceutical Company Limited. Revised March 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LACTIC ACID/ CITRIC ACID/ POTASSIUM BITARTRATE Edition 1	PHEXXI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Phexxi package insert. San Diego, Ca. Evofem, Inc. Revised May 2020. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LAPATINIB DITOSYLATE Edition 1	TYKERB	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Tykerb package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised December 2018. Accessed July 2021.
2. Masters GA, Temin S, Azzoli CG, et al. Systemic Therapy for Stage IV Non-Small-Cell Lung Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update [published correction appears in J Clin Oncol. 2016 Apr 10;34(11):1287]. *J Clin Oncol*. 2015;33(30):3488-3515. doi:10.1200/JCO.2015.62.1342.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LAROTRECTINIB Edition 1	VITRAKVI	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Vitrakvi package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Reviewed March 2021. Accessed July2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
nGLUTAMINE (L-GLUTAMINE) Edition 1	ENDARI	7/23/2021	6/1/2021

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. You have sickle cell disease (type of red blood cell disorder)
B. You are 5 years of age or older
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist)
D. The patient had a trial of or contraindication to hydroxyurea
E. **If you are 18 years of age or older, approval also requires ONE of the following:**
    1. You had at least 2 sickle cell crises in the past year (A sickle cell crises is defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered given into the vein, narcotic or parenterally administered ketorolac, the occurrence of chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
    2. You are having sickle-cell associated symptoms such as pain or anemia (your blood doesn't have enough healthy red blood cells and you're tired) which are interfering with activities of daily living
    3. You have a history of or have recurrent acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

RENEWAL CRITERIA

Our guideline named **L-GLUTAMINE (Endari)** requires the following rule(s) bet met for renewal:

A. You have sickle cell disease (type of red blood cell disorder)
B. You have maintained or experienced a reduction in acute complications of sickle-cell disease such as number of sickle cell crises, hospitalizations, acute chest syndrome (ACS: chest pain, cough, fever, low oxygen level)

References:

1. Endari package insert. Torrance, CA. Emmaus Medical, Inc. Revised October 2020. Accessed July 2021.
2. Pham CD, Hua DT. Clinical Guideline Highlights for the Hospitalist: Management of Acute and Chronic Pain in Sickle Cell Disease. *J Hosp Med*. 2021;16(4):228-229. doi:10.12788/jhm.3556

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LEFAMULIN Edition 1	XENLETA	7/23/2021	6/1/2021

REQUIREMENTS:

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

A. You have community-acquired bacterial pneumonia (type of lung infection)
B. You are 18 years of age or older
C. The infection is caused by any of the following susceptible microorganisms (bacteria that the drug can kill): *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
D. You meet **ONE** of the following criteria:
    1. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
    2. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with a) resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), **AND** b) susceptibility to Xenleta
    3. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you had a trial of at least **TWO** standard of care agents (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid) for community-acquired bacterial pneumonia, unless there is a medical reason why you cannot (contraindication)

References:

1. Xenleta package insert. King of Prussia, PA. Nabriva Therapeutics US, Inc. Revised March 2021. Accessed July 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LENALIDOMIDE Edition 1	REVLIMID	7/23/2021	6/1/2021

REQUIREMENTS:

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

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

B. You are 18 years of age or older

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

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

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

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

References:

1. Revlimid package insert. Summit, NJ. Celgene Corporation. Revised October 2019. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

SUFENTANIL			
Generic	Brand	Reviewed	Effective Date
SUFENTANIL CITRATE Edition 2	DSUVIA	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   a. You have acute pain (sudden and severe pain)
   b. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   c. You are enrolled in hospice
B. You are 18 years of age or older
C. Your pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate. Alternative treatments that may be inadequate include non-opioid analgesic products or opioid combination products
D. Your treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

References:

1. Dsuvia package insert. Redwood City, CA. AcelRx Pharmaceuticals, Inc. Revised October 2019. Accessed July 2021.
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

SACITUZUMAB			
Generic	Brand	Reviewed	Effective Date
SACITUZUMAB GOVITECAN-HZIY Edition 2	TRODELVY	7/23/2021	7/23/2021

REQUIREMENTS:
Our guideline named **SACITUZUMAB (Trodelvy)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Unresectable locally advanced (the cancer has spread from where it started to nearby tissue or lymph nodes and cannot be surgically removed) OR metastatic triple negative breast cancer (mTNBC: breast cancer that has spread to other parts of the body and does not have estrogen receptors, progesterone receptors, and human epidermal growth factor receptor 2 [HER2: type of protein])
    2. Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
B. You are 18 years of age or older
C. You have tried two or more previous systemic therapies (treatment that targets the entire body by traveling throughout your bloodstream), at least one of them for metastatic disease (disease that has spread to other parts of the body)

References:

1. Trodelvy package insert. Morris Plains, NJ. Immunomedics, Inc. Revised April 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LEVODOPA Edition 1	INBRIJA	10/29/2021	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. You have Parkinson's disease (a nerve system disorder that affects movement)
B. Inbrija is being used for intermittent treatment of OFF episodes (times when you have symptoms return due to medication wearing off) associated with Parkinson's disease
C. You are currently being treated with carbidopa/levodopa
D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor)
E. You are **NOT** currently taking more than 1600mg of levodopa per day
F. Your doctor has optimized drug therapy as evidenced by **BOTH** of the following:
    1. Change in levodopa/carbidopa dosing strategy or formulation
    2. Trial of or contraindication to (medical reason why you cannot use) at least **TWO** Parkinson's agents from **TWO** different classes of the following: dopamine agonist (such as ropinirole, pramipexole, rotigotine), monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline), catechol-O-methyl transferase (COMT) inhibitors (such as entacapone, tolcapone), adenosine receptor antagonist A2A (such as istradefylline)

RENEWAL CRITERIA

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

A. You have Parkinson's disease (a nerve system disorder that affects movement)
B. You had improvement with motor fluctuations during OFF episodes (times when you have symptoms return due to medication wearing off) with the use of Inbrija. Improvements can be in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair.

References:

1. Inbrija package insert. Ardsley, NY. Acorda Therapeutics, Inc. Revised August 2020. Accessed October 2021.
2. Rughani A, Schwalb JM, Sidiropoulos C, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline on Subthalamic Nucleus and Globus Pallidus Internus Deep Brain Stimulation for the Treatment of Patients With Parkinson's Disease: Executive Summary. *Neurosurgery*. 2018;82(6):753-756. doi:10.1093/neuros/nyy037

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LOFEXIDINE Edition 1	LUCEMYRA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Lucemyra package insert. Louisville, KY. US WorldMeds, LLC. Revised May 2018. Accessed October 2021.
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. J Addict Med. 2020 Mar/Apr;14(2S Suppl 1):1-91.
4. 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.
5. Utah Department of Health (2018). Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain. Salt Lake City, UT: Utah Department of Health
6. 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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LOMITAPIDE Edition 1	JUXTAPID	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

(Criteria continued on next page)

REQUIREMENTS: LOMITAPIDE (CONTINUED)

G. If you are statin intolerant, approval also requires ONE of the following:

1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy (drug used for cholesterol) such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant, or hypersensitivity (allergic) reaction
2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measurement of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.

References:

1. Juxtapid package insert. Cambridge, MA. Aegerion Pharmaceuticals, Inc. Revised December 2019. Accessed October 2021.
2. 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
LOMUSTINE Edition 1	GLEOSTINE	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

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

References:

1. Gleostine package insert. Miami, FL. NextSource Biotechnology. Revised January 2016. Accessed October 2021.
2. Nabors LB, Portnow J, Ahluwalia M, et al. Central Nervous System Cancers, Version 3.2020, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2020;18(11):1537-1570. Published 2020 Nov 2. doi:10.6004/jnccn.2020.0052

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LORLATINIB Edition 1	LORBRENA	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. Your tumors are anaplastic lymphoma kinase (ALK: type of enzyme)-positive which is shown by an FDA (Federal and Drug Administration) approved test

References:

1. Lorbrena package insert. New York, New York. Pfizer, Inc. Revised March 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LUMACAFTOR/IVACAFTOR Edition 2	ORKAMBI	4/29/2022	4/29/2022

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. You are 2 years of age or older
B. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
C. Documentation that you are homozygous (have 2 copies of the same gene) for the F508del- CFTR (type of gene: Cystic fibrosis transmembrane conductance regulator) mutation
D. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
E. If you are between 2 years and less than 6 years of age, Orkambi packets will be approved. Documentation of your weight is required

RENEWAL CRITERIA

Our guideline named **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

References:

1. Orkambi package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised August 2018. Accessed February 2022.
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
LUSUTROMBOPAG Edition 1	MULPLETA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Mulpleta package insert. Florham Park, NJ. Shionogi Inc. Revised July 2018. Accessed October 2021.
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
MEBENDAZOLE Edition 1	EMVERM	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. Emverm is being used for the treatment of *Enterobius vermicularis* (pinworm), *trichuris trichiura* (whipworm), *ascaris lumbricoides* (common roundworm), *ancylostoma duodenale* (common hookworm), or *necator americanus* (American hookworm)

B. You are 2 years of age or older

C. **If you have *enterobius vermicularis* (pinworm), approval also requires:**
   1. You previously had a trial of over-the-counter (OTC) pyrantel pamoate, unless there is a medical reason why you cannot (contraindication)

D. **If you have trichuris trichiura (whipworm) or ascaris lumbricoides (common roundworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *trichuris trichiura* (whipworm) or *ascaris lumbricoides* (common roundworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication)

E. **If you have ancylostoma duodenale (common hookworm) or necator americanus (American hookworm), approval also requires:**
   1. You have documentation confirming your diagnosis of *ancylostoma duodenale* (common hookworm) or *necator americanus* (American hookworm)
   2. You previously had a trial of albendazole (Albenza), unless there is a medical reason why you cannot (contraindication) OR you had a trial of over-the-counter (OTC) pyrantel pamoate

References:

1. Emverm package insert. Bridgewater, NJ. Amneal Pharmaceuticals LLC. Revised January 2019. Accessed October 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MECAMYLAMINE HCL Edition 1	VECAMYL	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. The requested medication will be used for the management of moderately severe to severe essential (or primary) hypertension or in uncomplicated cases of malignant hypertension

B. You have had a trial of at least three of the following, unless there is a medical reason why you cannot (contraindication): angiotensin converting enzyme inhibitor (ACE-I) or ACE-I combination, angiotensin receptor blocker (ARB) or ARB combination, Beta Blocker, or Calcium Channel Blocker, such as benazepril, benazepril-HCTZ, captopril, captopril-HCTZ, enalapril, enalapril-HCTZ, fosinopril, fosinopril-HCTZ, lisinopril, lisinopril-HCTZ, quinapril, ramipril, moexipril, moexipril-HCTZ, perindopril erbumine, quinapril, quinapril-HCTZ, trandolapril, trandolapril/verapamil, losartan, losartan-HCTZ, irbesartan, irbesartan-HCTZ, olmesartan, olmesartan-HCTZ, olmesartan-amlodipine-HCTZ, valsartan, valsartan-HCTZ, diltiazem HCL, diltiazem sustained release (generics only), verapamil, verapamil sustained release (generics only), atenolol, atenolol-chlorthalidone, bisoprolol, bisoprolol-HCTZ, carvedilol, metoprolol tartrate, nadolol, acebutolol, betaxolol, labetalol, metoprolol succinate, metoprolol-HCTZ, pindolol, propranolol, propranolol-HCTZ, sotalol, timolol maleate, or nebivolol.

References:

1. Vecamyl package insert. New York, NY. Vyera Pharmaceuticals, LLC. Revised July 2018. Accessed October 2021.
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
MECASERMIN Edition 1	INCRELEX	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
    1. Severe primary insulin growth-like factor 1 deficiency (IGF-1: hormone levels that promote normal bone and tissue growth and development are extremely low or undetectable in the blood)
    2. Growth hormone gene deletion (not growth hormone-deficient short stature) and developed neutralizing antibodies to growth hormone

B. You are 2 years to less than 18 years of age

C. The requested medication is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor) or pediatric nephrologist (kidney doctor)

D. You have a height standard deviation score less than or equal to -3.0, basal IGF-1 (insulin growth-like factor 1) standard deviation score less than or equal to -3.0, and normal or elevated growth hormone [serum growth hormone level of greater than or equal to 10ngm/mL to at least 2 stimuli (insulin, levodopa, arginine, clonidine or glucagon)]

E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)

RENEWAL CRITERIA

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

A. You have shown a response in the first 6 months of insulin growth-like factor-1 (IGF-1) therapy (increase in height, increase in height velocity)

References:

1. Increlex package insert. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. Revised December 2019. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

MECHLORETHAMINE GEL			
Generic	Brand	Reviewed	Effective Date
MECHLORETHAMINE HCL Edition 1	VALCHLOR	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Valchlor package insert. Iselin, NJ. Helsinn Therapeutics, (U.S.), Inc. Revised January 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MIDOSTAURIN Edition 1	RYDAPT	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

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

References:

1. Rydapt Package Insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised April 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MIFEPRISTONE Edition 1	KORLYM	10/29/2021	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. You have endogenous Cushing's syndrome (CS: condition that occurs after having high levels of cortisol hormone in the body for a long time)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. Your diagnosis has been confirmed by ONE of the following:
    1. 24-hour urine free cortisol test (at least 2 or more tests to confirm)
    2. Overnight 1mg dexamethasone test
    3. Late night salivary cortisol (at least 2 or more tests to confirm)
E. Your hypercortisolism (high levels of cortisol) is not a result of chronic glucocorticoids (class of drugs that consist of steroids)
F. You have type 2 diabetes mellitus (too much sugar in your blood) OR glucose intolerance (term for a group of conditions that result in elevated blood sugar)
G. You have failed surgical treatment for Cushing's syndrome OR you are not a candidate for surgery

RENEWAL CRITERIA

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

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

References:

1. Korlym package insert. Menlo Park, CA. Corcept Therapeutics Incorporated. Revised November 2019. Accessed October 2021.
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

Generic	Brand	Reviewed	Effective Date
MIGALASTAT Edition 1	GALAFOLD	10/29/2021	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. You have confirmed Fabry disease (rare genetic disease)
B. You are 18 years of age or older
C. You have an amenable (responsive) galactosidase alpha gene (GLA) variant based on in vitro assay data (data collected from lab test tubes or cultures) that is interpreted by clinical genetics professional as the cause of disease (pathogenic/likely pathogenic)
D. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist in genetics or inherited metabolic disorders
E. You are NOT concurrently using enzyme replacement therapy (Fabrazyme)
F. You are symptomatic OR have evidence of injury from GL-3 (a type of cell that builds up) to the kidney, heart, or central nervous system recognized by laboratory, histological, or imaging findings. Evidence of injury includes decreased GFR (measurement of how well your kidneys are working) for age, persistent albuminuria (buildup of a type of protein), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (scarring of the heart) on contrast cardiac MRI
G. You meet ONE of the following:
    1. If you are a female patient: Confirmation of Fabry disease (rare genetic disease) via genetic test documenting galactosidase alpha gene (GLA) mutation
    2. If you are a male patient: Confirmation of Fabry disease via enzyme assay (lab test) showing you have a low amount of alpha galactosidase A (a-Gal -A) OR genetic test documenting galactosidase alpha gene (GLA) mutation

(Criteria continued on next page)

REQUIREMENTS- MIGALAST (CONTINUED)

RENEWAL CRITERIA

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

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

References:

1. Galafold package insert. Cranbury, Nj. Amicus Therapeutics U.S., Inc. Revised September 2020. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MIGLUSTAT Edition 1	ZAVESCA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Zavesca package insert. South San Francisco, CA. Janssen Pharmaceutical. Revised December 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MILTEFOSINE Edition 1	IMPAVIDO	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Impavido Package insert. Orlando, FL. Profounda, Inc. Revised May 2021. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

MINOCYCLINE HCL MICROSPHERES			
Generic	Brand	Reviewed	Effective Date
MINOCYCLINE HCL MICROSPHERES Edition 1	ARESTIN	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: SEE RENEWAL CRITERIA BELOW)

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

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

(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. You have documentation of periodontitis (inflammation and infection of the gums)
B. The medication will be used as an adjunct (add-on therapy) to scaling and root 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 2017. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MIPOMERSEN SODIUM Edition 1	KYNAMRO	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

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

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

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

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

(Criteria continued on next page)

REQUIREMENTS- MIPOMERSEN SODIUM (CONTINUED)

F. If you are statin intolerant, approval also requires ONE of the following:

1. You have an absolute contraindication to (medical reason why you cannot use) statin therapy such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant or hypersensitivity reaction

2. You have complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation (a measure of how much muscle damage you have) greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (muscle breakdown), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

References:

1. Kynamro Package insert. Chicago, IL. Kastle Therapeutics. Revised March 2019. Accessed October 2021.
2. 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
3. Karr S. Epidemiology and management of hyperlipidemia. *Am J Manag Care*. 2017;23(9 Suppl):S139-S148.

WELLFLEET RX STUDENT FORMULARY

MOMETASONE SINUS IMPLANT			
Generic	Brand	Reviewed	Effective Date
MOMETASONE FUROATE Edition 1	SINUVA	10/29/2021	6/1/2021

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

RENEWAL CRITERIA

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

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

References:

1. Sinuva Package Insert. Menlo Park, CA. Intersect ENT, Inc. Revised April 2020. Accessed October 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NILOTINIB HCL Edition 1	TASIGNA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

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

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

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

References:

1. Tasigna Package Insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2020. Accessed April 2021.

WELLFLEET RX STUDENT FORMULARY

NIMODIPINE SOLUTION			
Generic	Brand	Reviewed	Effective Date
NIMODIPINE Edition 1	NYMALIZE	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **NIMODIPINE SOLUTION (Nymalize)** requires the following rule(s) be met for approval:

A. You have a history of subarachnoid hemorrhage (SAH: bleeding in the space surrounding your brain) from a ruptured intracranial berry aneurysm (an area of an artery wall in your brain ballooned and burst) within the past 21 days
B. You are 18 years of age or older
C. You are unable to swallow nimodipine oral capsules

References:

1. Nymalize Package Insert. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised December 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NIRAPARIB TOSYLATE Edition 1	ZEJULA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

B. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to your most recent platinum-based chemotherapy
   3. The requested medication will be used for maintenance treatment (*treatment* to prevent cancer from coming back after it has disappeared after initial *therapy)*
   4. The requested medication will be used as monotherapy (used by itself for treatment)
   5. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (treatment)
   6. You have completed at least 2 or more lines of platinum-based chemotherapy

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

(Criteria continued on next page)

REQUIREMENTS- NIRAPARIB (CONTINUED)

D. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
    1. You are 18 years of age or older
    2. You are in complete or partial response to first-line platinum based-chemotherapy
    3. The requested medication will be used for maintenance treatment

References:

1. Zejula package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised July 2021. Accessed October 2021.
2. Armstrong DK, Alvarez RD, Bakkum-Gamez JN, et al. Ovarian Cancer, Version 2.2020, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2021;19(2):191-226. Published 2021 Feb 2. doi:10.6004/jnccn.2021.0007

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OBETICHOLIC ACID Edition 1	OCALIVA	10/29/2021	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. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following criteria:
    1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
    2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
    3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age and older
C. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor) or hepatologist (liver doctor)
D. You meet ONE of the following:
    1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
    2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
E. You do not have complete biliary obstruction (blockage of bile ducts)

RENEWAL CRITERIA

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

A. You have primary biliary cholangitis (type of liver disease)
B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) are less than 1.67-times the upper limit of normal or have decreased by at least 15% from baseline while on treatment with obeticholic acid
C. You have not developed complete biliary obstruction (blockage of bile ducts)

References:

1. Ocaliva Package Insert. New York, NY. Intercept Pharmaceuticals. Revised May 2021. Accessed October 2021.
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

OCTREOTIDE - ORAL			
Generic	Brand	Reviewed	Effective Date
OCTREOTIDE Edition 1	MYCAPSSA	10/29/2021	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. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
B. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
C. You have responded to and are currently stable on an injectable somatostatin analog therapy (such as octreotide, lanreotide, or pasireotide)

RENEWAL CRITERIA

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

A. You have acromegaly (a hormonal disorder that develops when the pituitary gland produces too much growth hormone during adulthood)
B. You have had reduction, normalization, or maintenance of insulin-like growth factor 1 (IGF-1: a type of hormone) levels based on your age and gender
C. You have shown improvement or sustained remission (symptoms have gone away) of clinical symptoms of acromegaly

References:

1. Mycapssa package Insert. Cincinnati, OH. Chiasma Inc. Revised June 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

OCTREOTIDE - SQ			
Generic	Brand	Reviewed	Effective Date
OCTREOTIDE ACETATE Edition 1	BYNFEZIA	10/29/2021	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. You have ONE of the following diagnoses:
    1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
    2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
    3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)

B. **If you have acromegaly, approval also requires:**
    1. You are 18 years of age or older
    2. You had an inadequate response to or cannot be treated with **ALL** of the following:
        i. Surgical resection (removal by surgery)
        ii. Pituitary irradiation (radiation therapy directed at the pituitary)
        iii. Bromocriptine mesylate at maximally tolerated doses

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

D. **If you have profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas), approval also requires:**
    1. You are 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. You have ONE of the following diagnoses:
    1. Acromegaly (a disorder in which the pituitary gland produces too much growth hormone)
    2. Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors (a type of slow growing cancer that has spread to different parts of the body)
    3. Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas: a type of cancer that starts from hormone producing cells)
B. You have had improvement or sustained remission of your symptoms

References:

1. Bynfezia Package Insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised January 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OMACETAXINE MEPESUCCINATE Edition 1	SYNRIBO	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have chronic myeloid leukemia (CML: type of blood cell cancer)

B. **If the request is for induction therapy, approval also requires:**
   1. You have previously tried or have a contraindication (a medical reason why you cannot) to two of the following therapies: Gleevec, Sprycel, Tasigna, Bosulif, or Iclusig
   2. You have received less than 6 fills of Synribo

C. **If the request is NOT for induction therapy, approval also requires:**
   1. You have achieved a hematologic response (your blood tests show you have improvement), defined as an absolute neutrophil count [ANC] greater than or equal to 1.5 x 10(9)/L, AND platelets greater than or equal to 100 x 10(9)/L, AND no blood blasts; OR bone marrow blasts less than 5 percent)

References:

1. Synribo package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised January 2020. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OMADACYCLINE Edition 1	NUZYRA	10/29/2021	6/1/2021

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

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

B. **If you have community-acquired bacterial pneumonia, approval also requires:**
   1. You are 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
   3. You meet ONE of the following criteria:
      a. The requested medication is prescribed by or given in consultation with an Infectious Disease (ID) specialist
      b. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is available, and the infection site culture results indicate pathogenic (disease-causing) organism(s) with 1) resistance to at least TWO standard of care agents for community acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone), AND 2) Nuzyra will work against the bacteria
      c. Antimicrobial susceptibility test (lab test that shows what drugs may kill the bacteria) is unavailable, and you have had a trial of or contraindication (medical reason why you cannot use) to at least TWO standard of care agents for community-acquired bacterial pneumonia (such as azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)

(Criteria continued on next page)

REQUIREMENTS: OMADACYCLINE (CONTINUED)

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

References:

1. Nuzyra package insert. Boston, MA. Paratek Pharmaceuticals, Inc. Revised May 2021. Accessed October 2021.
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 STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OMBITASVIR/ PARITAPREVIR/ RITONAVIR Edition 1	TECHNIVIE	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have chronic hepatitis C, genotype 4 without cirrhosis (liver damage) or with compensated cirrhosis (you do not have symptoms related to liver damage; Child-Pugh A)
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. The requested medication will be used with ribavirin, unless you are treatment naïve without cirrhosis (you have never been previously treated and do not have liver damage) and you have an intolerance or contraindication to (medical reason why you cannot use) ribavirin
D. You are 18 years of age or older
E. You have previously failed a short trial of Harvoni or Epclusa. Reasons for failure may include adverse effect, intolerance to therapy, or contraindication to (medical reason why you cannot use) both drugs
F. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
G. You have evidence of current hepatitis C virus infection and chronic hepatitis C virus infection as documented by at least one detectable HCV RNA levels (amount of virus in your blood) within the past 6 months

A total of 12 weeks of therapy will be approved.

(Criteria continued on next page)

REQUIREMENTS: OMBITASVIR/PARITAPREVIR/RITONAVIR (CONTINUED)

The medication will NOT be approved for the following:

A. You are using any of the following medications at the same time while on Technivie: alfuzosin, carbamazepine, phenytoin, phenobarbital, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, NuvaRing, Ortho Evra or Xulane transdermal patch system), lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have moderate or severe liver impairment (Child Pugh B or Child Pugh C)
C. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
E. You have previously used (failed a full course of therapy) or are currently using any of the following regimens:
    1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
    2. A combination NS5B polymerase inhibitor/NS5A inhibitor (type of hepatitis C drug) including Harvoni (ledipasvir/sofosbuvir)
    3. Any HCV protease inhibitor including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)
    4. Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir) or Viekira XR

References:

1. Technivie package insert. North Chicago, IL. AbbVie Inc. Revised December 2019. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OSILODROSTAT Edition 1	ISTURISA	10/29/2021	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. You have Cushing's disease (CD: a condition due to a tumor in the pituitary gland causing an excess release of the hormone cortisol in the blood)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. Pituitary (major hormone gland) surgery is not an option or has not cured your condition
E. You previously had a trial of oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

RENEWAL CRITERIA

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

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

References:

1. Isturisa package insert. North Chicago, IL. AbbVie Inc. Revised December 2019. Accessed October 2021.
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

Generic	Brand	Reviewed	Effective Date
PALBOCICLIB Edition 1	IBRANCE	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced or metastatic breast cancer (cancer that is in the advanced stage or that has spread to other parts of the body)
B. You are 18 years of age or older
C. You meet ONE of the following:
    1. The requested medication will be used with an aromatase inhibitor (type of cancer drug such as anastrozole, letrozole, or exemestane) AND you meet ALL of the following:
        i. You are a postmenopausal female OR a male
        ii. You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        iii. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancer by preventing the cancer cells from multiplying)
    2. The requested medication will be used in combination with Faslodex (fulvestrant) AND you meet ALL of the following:
        i. Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        ii. Your disease has NOT worsened after previous cyclin-dependent kinase (CDK) inhibitor therapy (this type of therapy is used to treat cancers by preventing the cancer cells from multiplying)

References:

1. Ibrance package insert. New York, NY. Pfizer labs, Inc. Revised September 2019. Accessed October 2021.
2. Gradishar WJ, Anderson BO, Abraham J, et al. Breast Cancer, Version 3.2020, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2020;18(4):452-478. doi:10.6004/jnccn.2020.0016

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PANOBINOSTAT Edition 1	FARYDAK	10/29/2021	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. You have multiple myeloma (cancer that forms in a type of white blood cell)
B. You have been treated with at least 2 prior regimens including:
    1. Velcade (bortezomib)
    2. Immunomodulatory medication such as Thalomid, Revlimid, or Pomalyst. (These drugs adjust immune responses)
C. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone

RENEWAL CRITERIA

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

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

References:

1. Farydak package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised February 2015. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PARATHYROID HORMONE Edition 1	NATPARA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Natpara package insert. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. Revised June 2020. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PASIREOTIDE Edition 1	SIGNIFOR	10/29/2021	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. You have Cushing's disease (CD: a condition in which the pituitary gland releases too much of a hormone called adrenocorticotropic hormone [ACTH])
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an endocrinologist (doctor who specializes in hormones)
D. You have undergone pituitary (a major hormone gland) surgery OR pituitary surgery is not an option
E. You have previously tried oral ketoconazole, unless there is a medical reason you are cannot (contraindication)

RENEWAL CRITERIA

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

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

References:

1. Signifor package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised January 2020. Accessed October 2021.
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

PATIROMER			
Generic	Brand	Reviewed	Effective Date
PATIROMER CALCIUM SORBITEX Edition 1	VELTASSA	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Veltassa Package Insert. Redwood City, CA. Relypsa, Inc. Revised May 2021. Accessed April 2021.
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
PAZOPANIB Edition 1	VOTRIENT	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

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

References:

1. Votrient package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION Edition 1			
Generic	Brand	Reviewed	Effective Date
SILDENAFIL	REVATIO	10/29/2021	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. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group I: a way to classify the severity of disease)
B. The medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documentation showing you have pulmonary arterial hypertension based on the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
    1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
E. You are NOT concurrently or intermittently taking oral erectile dysfunction agents (such as Cialis, Viagra) or any organic nitrates in any form
F. You are NOT concurrently taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas)
G. In addition to the above requirements, the following criteria apply to the specific agents listed:
    1. Request for REVATIO (Sildenafil) ORAL SUSPENSION requires that you are unable to swallow pills and you have tried crushed sildenafil tablets

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

References:

1. Revatio package insert. New York, NY. Pfizer Inc. Revised February 2018. Accessed October 2021.
2. Adcirca package insert. Indianapolis, IN. Eli Lilly and Company. Revised September 2020. Accessed October 2021.
3. Alyq package insert. Parsippany, NJ. Teva Pharmaceuticals. Revised January 2019. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

PEANUT ALLERGEN POWDER-DNFP			
Generic	Brand	Reviewed	Effective Date
PEANUT (ARACHIS HYPOGAEA) ALLERGEN POWDER-DNFP Edition 1	PALFORZIA	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

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

References:

1. Palforzia Package Insert. Brisbane, CA. Aimmune Therapeutics, Inc. Revised January 2020. Accessed October 2021.
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
PEG-INTERFERON ALFA-2B Edition 1	SYLATRON, SYLATRON 4-PACK	10/29/2021	6/1/2021

REQUIREMENTS:

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

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

References:

1. Sylatron package Insert. Whitehouse Station, NJ. Merck & Co Inc. Revised August 2019. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON) Edition 1			
Generic	Brand	Reviewed	Effective Date
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	10/29/2021	6/1/2021
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. You have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 (type of liver inflammation caused by hepatitis C virus). Requests for Pegasys will also be approved for diagnosis of chronic hepatitis B.

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

(Criteria continued on next page)

REQUIREMENTS- PEGINTERFERON ALFA-2A or 2B (CONTINUED)

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

References:

1. Pegasys package insert. South San Francisco, CA. Genentech USA, Inc. Revised March 2021. Accessed October 2021.
2. Pegintron package insert. Whitehouse Station, NJ. Marck Shapr & Dohme Corp. Revised January 2019. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

PEGVALIASE			
Generic	Brand	Reviewed	Effective Date
PEGVALIASE-PQPZ Edition 1	PALYNZIQ	10/29/2021	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. You have phenylketonuria (PKU) (a type of birth defect that causes buildup of a chemical called phenylalanine)
B. You are 18 years of age or older
C. You have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management, as confirmed by a measurement in the last 30 days
D. You have previously tried Kuvan (sapropterin)
E. You are NOT receiving Kuvan (sapropterin) at the same time as Palynziq (pegvaliase)

RENEWAL CRITERIA

Our guideline named **PEGVALIASE (Palynziq)** requires the following rules be met for renewal:

A. You have a diagnosis of phenylketonuria (PKU: type of birth defect that causes buildup of a chemical called phenylalanine)
B. Your phenylalanine levels have dropped by at least 20% from baseline or to a level under 600 micromol/L.

References:

1. Palynziq package Insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised November 2020. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PEMIGATINIB Edition 1	PEMAZYRE	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have previously been treated
D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) fusion or other rearrangement as detected by a Food and Drug Administration (FDA)-approved test

References:

1. Pemazyre package insert. Wilmington, DE. Incyte Corporation. Revised February 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PENTOSAN POLYSULFATE SODIUM Edition 1	ELMIRON	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for approval:

A. You have a diagnosis of interstitial cystitis/bladder (painful bladder condition) pain syndrome ongoing for at least six weeks

RENEWAL CRITERIA

Our guideline named **PENTOSAN POLYSULFATE (Elmiron)** requires the following rule(s) be met for renewal:

A. You have experienced clinical improvement from baseline secondary to treatment

References:

1. Elmiron Package Insert. Titusville, New Jersey. Janssen Pharmaceuticals, Inc. Revised February 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PEXIDARTINIB Edition 1	TURALIO	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **PEXIDARTINIB (Turalio)** requires the following rules be met for approval:

A. You have symptomatic tenosynovial giant cell tumor (TGCT: type of non-cancerous growth in or around a joint causing tissue damage and reducing function)
B. TGCT is associated with severe morbidity (disease) or functional limitations
C. TGCT is NOT responsive to improvement with surgery
D. You are 18 years of age or older

References:

1. Turalio package insert. Basking Ridge, NJ. Daiichi Sankyo, Inc. Revised April 2020. Accessed October2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PHENOXYBENZAMINE Edition 1	DIBENZYLINE	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **PHENOXYBENZAMINE (Dibenzyline)** requires the following rules be met for approval:

A. You have pheochromocytoma (tumor in your adrenal gland)
B. The requested drug is used to treat pheochromocytoma before pheochromocytoma surgery to remove the tumor
C. The requested drug is prescribed by an endocrinologist (hormone doctor), an endocrine surgeon (surgeon specializing in removal of glands such as adrenal glands), or a hematologist/oncologist (cancer doctor)
D. You must have tried an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin), unless there is a medical reason why you cannot (contraindication)

References:

1. Dibenzyline package insert. Bradenton, FL. WellSpring Pharmaceutical. Revised March 2008. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PIMAVANSERIN Edition 1	NUPLAZID	10/29/2021	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. You have a diagnosis of psychosis associated with Parkinson's disease (a mental disorder that causes you to have false beliefs or to hear or see things that are not really there and is related to a movement disorder)
B. You are at least 18 years old; and
C. The drug is prescribed by a doctor specializing in one of the following areas: neurology (brain doctor), geriatric medicine (specialty that focuses on health care of elderly people), or behavioral health (such as a psychiatrist).

RENEWAL CRITERIA

Our guideline named **PIMAVANSERIN (Nuplazid)** requires that you have experienced an improvement in psychosis symptoms (mental issues such as false beliefs or hearing or seeing things that are not really there) from baseline during the past 12 months of therapy and you show a continued need for treatment.

References:

1. Nuplazid Package Insert. San Diego, CA. Acadia Pharmaceuticals Inc. Revised November 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PITOLISANT HCL Edition 1	WAKIX	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have one of the following:
   1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
   2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**
   1. You have narcolepsy that is confirmed by **ONE** of the following:
   2. A Multiple Sleep Latency Test showing a both an average sleep latency of 8 minutes or less **AND** 2 or more early-onset rapid eye movement (REM) sleep test periods
   3. A Multiple Sleep Latency Test (MSLT) showing both an average sleep latency of 8 minutes or less **AND** one early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** additionally one SOREMP (within approximately 15 minutes) on a polysomnography (type of sleep test) the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness
   4. You have low orexin/hypocretin levels on a cerebrospinal fluid (CSF) assay (test showing you have low levels of a chemical that helps with staying awake)
   5. You have excessive daytime sleepiness (EDS) lasting for at least 3 months and Epworth Sleepiness Scale (type of sleepiness test) score of more than 10
   6. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   7. You had a trial of one generic typical stimulant (such as amphetamine sulfate, methylphenidate, etc.) AND solriamfetol, armodafinil, or modafinil, unless there is a medical reason why you cannot (contraindication)

C. **If you have cataplexy with narcolepsy, approval also requires:**
   1. Wakix is prescribed by or given in consultation with a neurologist (nerve doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
   2. You have tried TWO of the following: venlafaxine, fluoxetine, or a TCA (tricyclic antidepressant such as clomipramine, imipramine)

(Criteria continued on next page)

REQUIREMENTS: PITOLISANT (CONTINUED)

RENEWAL CRITERIA

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

A. You have ONE of the following:
    1. Excessive daytime sleepiness (EDS) with narcolepsy (sleep disorder with extreme drowsiness)
    2. Narcolepsy as demonstrated by cataplexy (sleep disorder with extreme drowsiness with sudden and uncontrollable muscle weakness)
B. You meet ONE of the following:
    1. You have demonstrated 25% or more improvement in Epworth Sleepiness Scale (type of sleepiness test) scores compared to baseline
    2. You have shown improvement in cataplexy (sudden and uncontrollable muscle weakness) symptoms compared to baseline

References:

1. Wakix package Insert. Plymouth Meeting, PA. Harmony Biosciences, LLC. Revised March 2021. Accessed October 2021.
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

Generic	Brand	Reviewed	Effective Date
POMALIDOMIDE Edition 1	POMALYST	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Multiple myeloma (MM: cancer that forms in your white blood cells)
   2. Kaposi sarcoma (KS: cancer that forms from the cells in your lymph or blood vessels)

B. **If you have multiple myeloma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is used in combination with dexamethasone
   3. You have tried at least two drugs including Revlimid (lenalidomide) and a proteasome inhibitor (type of cancer drug such as Velcade [bortezomib], Kyprolis [carfilzomib], or Ninlaro [ixazomib])

C. **If you have Kaposi sarcoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
   3. You have acquired immunodeficiency syndrome (AIDS)-related Kaposi sarcoma after failing highly active antiretroviral therapy (HAART: medications used to treat human immunodeficiency virus [HIV])
   4. You are human immunodeficiency virus (HIV)-negative

References:

1. Pomalyst package inserts. Summit, NJ. Celgene Corporation. Revised November 2020. Accessed October 2021.
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
3. Reid E, Suneja G, Ambinder RF, et al. AIDS-Related Kaposi Sarcoma, Version 2.2019, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2019;17(2):171-189. doi:10.6004/jnccn.2019.0008.

WELLFLEET RX STUDENT FORMULARY

PREDNISONE DELAYED-RELEASE TABS			
Generic	Brand	Reviewed	Effective Date
PREDNISONE Edition 1	RAYOS	10/29/2021	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. You had a previous trial of **ONE** of the following, unless there is a medical reason why you cannot (contraindication): generic prednisone, prednisolone, or methylprednisolone
C. You have had a subclinical response (not a full response) or treatment failure of generic prednisone, prednisolone, or methylprednisolone

RENEWAL CRITERIA
Our guideline named **PREDNISONE DELAYED-RELEASE TABS (Rayos)** requires the following rule(s) be met for renewal approval:

A. The request is for a Food and Drug Administration-approved indication
B. You have had a clinical benefit from using Rayos (such as improvement in inflammatory condition from baseline)
C. You cannot be tapered off (slowly lowering the dose to stop use) corticosteroid (Rayos)

References:

1. Rayos package insert. Deerfield, IL Horizon. Therapeutics USA, Inc. Revised March 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PYRIMETHAMINE Edition 1	DARAPRIM	10/29/2021	6/1/2021

REQUIREMENTS:

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

Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for approval:

A. The request is ONE of the following:
   1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
   2. Chronic maintenance therapy for toxoplasmosis
   3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
   4. Congenital toxoplasmosis (the infection was passed on to you as a baby from your mother)

B. **If you are being treated for acute toxoplasmosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

C. **If you are being treated for chronic maintenance for toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
   2. You have successfully completed treatment for acute toxoplasmosis for at least 6 weeks treatment duration
   3. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)

D. **If you are being treated for primary prophylaxis of toxoplasmosis, approval also requires:**
   1. You are also infected with human immunodeficiency virus (HIV)
   2. The medication is prescribed by or given in consultation with an infectious disease specialist (doctor that specializes in treating infections)
   3. You had a previous trial of Bactrim (sulfamethoxazole and trimethoprim), unless there is a medication reason why cannot (contraindication)
   4. You tested positive for *Toxoplasma gondii* (a type of parasite) Immunoglobulins (IgG) (i.e., you had a current or past infection with *Toxoplasma gondii)*
   5. Your CD4 count (an indicator of how weak your immune system is) is less than 100 cells/mm^3

(Criteria continued on next page)

REQUIREMENTS: PYRIMETHAMINE (CONTINUED)

E. **If you have congenital toxoplasmosis, approval also requires:**
    1. The medication is prescribed by or given in consultation with a neonatologist (doctor that specializes in sick and premature newborn infants) or pediatric (children and adolescents) infectious disease specialist

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section. Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:

A. The request is ONE of the following:
    1. Acute treatment of toxoplasmosis (sudden and severe type of parasite infection)
    2. Chronic maintenance therapy for toxoplasmosis
    3. Primary prophylaxis of toxoplasmosis (prevention of a type of parasite infection)
B. **If you are being treated for acute toxoplasmosis, renewal also requires:**
    1. You have persistent clinical disease (headache, neurological symptoms, or fever) and persistent radiographic disease (one or more mass lesions on brain imaging)
C. **If you are being treated for chronic maintenance of toxoplasmosis OR primary prophylaxis for toxoplasmosis, renewal also requires:**
    1. You are also infected with human immunodeficiency virus (HIV: a virus that weakens your immune system with a parasite infection)
    2. Your CD4 count (an indicator of how weak your immune system is) is less than 200 cells/mm^3
    3. You are currently taking ART (anti-retroviral therapy)

References:

1. Daraprim package insert. New York, New York. Turing Pharmaceuticals LLC. Revised June 2017. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
REGORAFENIB Edition 1	STIVARGA	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have a diagnosis of metastatic colorectal cancer (colon cancer that has spread in the body), **OR** locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (type of growth in the digestive system tract, most commonly in the stomach or small intestine), OR hepatocellular carcinoma (type of liver cancer).

B. **If you have metastatic colorectal cancer (CRC), approval also requires:**
   1. If colorectal cancer is **wild type KRAS** (a type of unmutated gene), you must have tried an anti-EGFR therapy (treatment that stops a protein from helping cancer cells grow) such as Erbitux [cetuximab] or Vectibix [panitumumab], unless there is a medical reason why you cannot use these agents (contraindication).
   2. If colorectal cancer is **NOT wild type KRAS,** you must have tried **ALL** of the following preferred therapies unless there is a medical reason why you cannot (contraindication):
      i. An anti-VEGF therapy (group of medicines that reduce new blood vessel growth) such as Avastin [bevacizumab] or Zaltrap [ziv-aflibercept].
      ii. A fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy such as FOLFOX, FOLFIRI, FOLFOXIRI, CapeOx, or infusional 5-FU/LV or capecitabine.

C. **If you have locally advanced, unresectable, or metastatic gastrointestinal stromal tumor, approval also requires:**
   1. You had a trial with Gleevec (imatinib) and Sutent (sunitinib) unless there is a medical reason why you cannot use these agents (contraindication).

D. **If you have hepatocellular carcinoma (HCC), approval also requires:**
   1. You had a previous treatment with Nexavar (sorafenib).

These prior therapies may be covered under the medical benefit and/or may require prior authorization.

References:

1. Stivarga package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised February 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

RILUZOLE SUSPENSION			
Generic	Brand	Reviewed	Effective Date
RILUZOLE Edition 1	TIGLUTIK	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **RILUZOLE SUSPENSION (Tiglutik)** requires the following rule(s) be met for approval:

A. You have amyotrophic lateral sclerosis (ALS: nervous system disease that weakens muscles and affects physical function)
B. You are 18 years of age or older
C. You have tried riluzole tablets
D. You are unable to take riluzole tablet formulation

References:

1. Tiglutik package insert. Berwyn, PA. ITF Pharma, Inc. Revised March 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RIPRETINIB Edition 1	QINLOCK	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **RIPRETINIB (Qinlock)** requires ALL of the following rule(s) be met for approval:

A. You have advanced gastrointestinal stromal tumor (GIST: a type of cancer in your digestive tract)
B. You are 18 years of age or older
C. You have received prior treatment with 3 or more kinase inhibitors (class of drugs), including imatinib

References:

1. Qinlock package insert. Waltham, MA. Deciphera Pharmaceuticals, LLC. Revised June 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RISDIPLAM Edition 1	EVRYSDI	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])
C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. **If you are presymptomatic (symptoms have not yet appeared), approval also requires:**
    1. There is documentation showing you have up to three copies of survival motor neuron 2 (SMN2: type of protein in spinal cord) based on screening done when you were a newborn
E. **If you are symptomatic (symptoms have appeared), approval also requires:**
    1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
    2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
    3. If you previously had gene therapy, you had less than expected clinical benefit

(Criteria continued on next page)

REQUIREMENTS- RISDIPLAM (CONTINUED)

RENEWAL CRITERIA

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

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

References:

1. Evrysdi package insert. South San Francisco, CA. Genentech, Inc. Revised April 2021. Accessed October 2021.
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
SACROSIDASE Edition 1	SUCRAID	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **SACROSIDASE (Sucraid)** requires the following rule be met for approval:

A. You have a genetically determined sucrose deficiency (genetic disorder that will not allow your body to process a type of sugar), or congenital sucrase-isomaltase deficiency (CSID: disorder that affects your ability to digest certain sugars due to absent or low levels of two digestive enzymes).

References:

1. Sucraid package insert. Vero Beach, FL. QOL Medical, LLC. Revised June 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SAPROPTERIN DIHYDROCHLORIDE Edition 1	KUVAN	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SAPROPTERIN DIHYDROCHLORIDE (Kuvan)** requires the following rule(s) be met for approval:

A. You have hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You follow a phenylalanine-restricted diet

RENEWAL CRITERIA

Our guideline named **SAPROPTERIN DIHYDROCHLORIDE (Kuvan)** requires the following rule(s) be met for renewal:

A. You hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) (you have high levels of a type of amino acid phenylalanine and it can be lowered with a certain supplement tetrahydrobiopterin)
B. You experienced at least a 30% decrease in blood phenylalanine from baseline after taking Kuvan (sapropterin dihydrochloride)
C. You continue to follow a phenylalanine-restricted diet

References:

1. Kuvan package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised March 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SARGRAMOSTIM Edition 1	LEUKINE	10/29/2021	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 (blood specialist) or oncologist (cancer/tumor doctor), **OR** you meet **ONE** of the following:
   1. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer) and are using the requested medication to shorten time to neutrophil (a type of white blood cell) recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy AND you are 55 years of age or older
   2. You are undergoing autologous transplantation (your own blood-forming stem cells are collected) and using the requested medication for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis (to collect blood sample and separate white blood cells in a lab test) AND you are 18 years of age or older
   3. You have non-Hodgkin's lymphoma (NHL: type of cancer), acute lymphoblastic leukemia (ALL: type of white blood cell cancer) or Hodgkin's lymphoma (type of cancer) and are using the requested medication for the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation (to help your blood and bone marrow recover) AND you are 2 years of age or older
   4. The requested medication is being used for the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors (to help your blood and bone marrow recover after using a lab test to match you to the correct donors) AND you are 2 years of age or older
   5. The requested medication is being used for the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND you are 2 years of age or older
   6. You are acutely exposed to myelosuppressive doses (doses that suppress bone marrow activity) of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]) and using the requested medication to increase your survival

References:

1. Leukine package inserts. Bridgewater, NJ. Sanofi-aventis U.S. LLC. Revised March 2018. Accessed April 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SATRALIZUMA-MWGE Edition 1	ENSPRYNG	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for approval:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4:type of protein) antibodies
E. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (inflammation that damages an eye nerve)
    2. Acute myelitis (sudden and severe inflammation of the spinal cord)
    3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. You will NOT use rituximab, inebilizumab, or eculizumab together with Enspryng

RENEWAL CRITERIA

Our guideline named **SATRALIZUMAB-MWGE (ENSPRYNG)** requires the following rule(s) be met for renewal:

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You had a reduction in relapse frequency from baseline

References:

1. Enspryng package insert. South San Francisco, CA. Genentech, Inc. Revised May 2021. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SELPERCATINIB Edition 1	RETEVMO	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Metastatic (disease has spread to other parts of the body) *RET* (type of gene) fusion-positive non-small cell lung cancer (NSCLC: type of lung cancer)
   2. Advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC: type of thyroid cancer)
   3. Advanced or metastatic *RET* fusion-positive thyroid cancer

B. **If you have metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older

C. **If you have advanced or metastatic *RET*-mutant medullary thyroid cancer (MTC), approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy (treatment that travels through the bloodstream to the entire body)

D. **If you have advanced or metastatic *RET* fusion-positive thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You require systemic therapy
   3. You are radioactive iodine-refractory (your tumor is resistant to treatment with radioactive iodine), if radioactive iodine is appropriate

References:

1. Retevmo Package insert Indianapolis, IN. Lilly USA, LLC. Revised January 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SELUMETINIB Edition 1	KOSELUGO	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have neurofibromatosis type 1 (NF1: a genetic disorder that causes light brown skin spots and non-cancerous tumors to form on nerve tissue)
B. You are 2 to 17 years of age
C. You have symptomatic, inoperable (not treatable by surgery) plexiform neurofibromas (PN: tumors that grow from nerves anywhere in the body)

References:

1. Koselugo package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised April 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SIMEPREVIR Edition 1	OLYSIO	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have chronic hepatitis C, genotype 1 (type of liver inflammation)
B. You are 18 years of age or older
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. You must have documentation of a recent hepatitis c virus infection by at least one detectable HCV RNA level (amount of virus in your blood) within the past 6 months
E. You will be using Olysio with Sovaldi taken at the same time
F. You have previously failed a short trial of Harvoni or Epclusa and stopped due to reasons such as adverse effect or intolerance early in therapy, unless there is a medical reason why you cannot (contraindication) take both agents. The medication will not be approved for an individual who has completed a full course of therapy that did not achieve SVR (sustained virologic response)
G. You are treatment naïve (never previously treated) or treatment-experienced with prior treatment with peginterferon/ribavirin

Olysio will not be approved for the following patients:

A. You have failed a full course of treatment with 1) any HCV protease inhibitor (for example, simeprevir [Olysio], telaprevir [Incivek] or boceprevir [Victrelis]) **OR** 2) a regimen containing an NS5A inhibitor (e.g., Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
B. You have compensated cirrhosis (no symptoms related to liver damage) or decompensated cirrhosis (you have symptoms related to liver damage)
C. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
D. You are using Olysio with ribavirin and peginterferon alfa

(Criteria continued on next page)

REQUIREMENTS: SIMEPREVIR (CONTINUED)

E. You are taking any of the following medications that are not recommended for concurrent use with Olysio:
    1. Amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
    2. Any cobicistat-containing medication (e.g., Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost)
    3. Delavirdine, etravirine, nevirapine, or efavirenz
    4. Any HIV protease inhibitor (e.g., atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

References:

1. Olysio package insert. Titusville, NJ. Janssen Therapeutics. Revised November 2017. Accessed October 2021.
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.

WELLFLEET RX STUDENT FORMULARY

SIMVASTATIN ORAL SUSPENSION			
Generic	Brand	Reviewed	Effective Date
SIMVASTATIN Edition 1	FLOLIPID	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **SIMVASTATIN ORAL SUSPENSION (Flolipid)** requires the following rule(s) be met for approval:

A. You had a previous trial of simvastatin tablets, unless there is a medical reason why you cannot (contraindication)
B. Your prescriber provides documentation showing that you have dysphagia (general swallowing difficulties), difficulty swallowing tablets, or a feeding tube such as a G-tube or J-tube
C. Requests for zero dollar cost share also requires that you are between 40-75 years of age without a history of cardiovascular disease (relating to heart and blood vessels), and you have not used any of the following secondary prevention medications for cardiovascular disease within the past 120 days based on your prescription claims profile or medical records:
    1. Aspirin/dipyridamole (Aggrenox)
    2. Clopidogrel (Plavix)
    3. Dipyridamole
    4. Nitroglycerin (i.e., oral, sublingual, transdermal patch or ointment, translingual dosage forms)
    5. Prasugrel (Effient)
    6. Praluent Pen
    7. Repatha
    8. Ticagrelor (Brilinta)
    9. Ticlopidine
    10. Vorapaxar sulfate (Zontivity)

References:

1. Flolipid package Insert. Brooksville, FL. Salerno Pharmaceuticals LP. Revised June 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SODIUM PHENYLBUTYRATE Edition 1	BUPHENYL	10/29/2021	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. You have urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. There is documentation confirming you have urea cycle disorder via enzymatic, biochemical or genetic testing (types of lab tests)
C. Buphenyl will be used as adjunctive (add-on) therapy along with dietary protein restriction
D. Your condition cannot be managed by dietary protein restriction and/or amino acid supplementation alone

RENEWAL CRITERIA

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

A. You have a urea cycle disorder (a genetic disorder that causes high ammonia levels in the blood)
B. You have experienced clinical benefit from baseline (such as you are having normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity).

References:

1. Buphenyl package insert. Scottsdale, AZ. Ucyclyd Pharma, Inc. Revised April 2009. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR Edition 1	VOSEVI	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR** requires the following rule(s) be met for approval:

A. You are 18 years of age or older
B. You have a diagnosis of chronic hepatitis C (type of liver inflammation), genotype 1, 2, 3, 4, 5, or 6 infection
C. Documentation of hepatitis C virus infection with at least **ONE** detectable HCV RNA level (amount of virus in your blood) within the last 6 months
D. The medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (liver inflammation) such as a hepatologist, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. You have failed a full course of therapy with a DAA (direct-acting antiviral) regimen that includes NS5A inhibitor (class of hepatitis C drug such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination) OR you have genotype 1a or genotype 3 and previously failed a full course of therapy with DAA regimen that includes sofosbuvir without NS5A inhibitor (class of hepatitis C drug such as Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi (or other hepatitis c virus protease inhibitor in combination with Sovaldi))

The medication will not be approved for the following:

A. You are concurrently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV (human immunodeficiency virus) regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, or topotecan
B. You have moderate or severe hepatic (liver) impairment (Child-Pugh B or C)
C. You have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (other diseases)

References:

1. Vosevi package insert. Foster City, CA. Gilead Sciences, Inc. Revised November 2019. Accessed October 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOLRIAMFETOL Edition 1	SUNOSI	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).

B. **If you have excessive daytime sleepiness (EDS) with narcolepsy, approval also requires:**

1. Your diagnosis of narcolepsy is confirmed by **ONE** of the following:
    i. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** two (2) or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs)
    ii. You have a Multiple Sleep Latency Test (MSLT) showing an average sleep latency of 8 minutes or less **AND** one (1) early-onset rapid eye movement (REM) sleep test period (SOREMP) **AND** one (1) SOREMP (within about 15 minutes) on a sleep study(polysomnography) the night before the MSLT, with the sleep study ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS)
    iii. You have low orexin levels on a cerebrospinal fluid (CSF) assay (a test to determine the amount of a type of chemical for wakefulness in your brain)
2. You have had Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10
3. Therapy is prescribed by or given in consultation with a neurologist (brain doctor), psychiatrist (mental health doctor), or specialist in sleep medicine
4. You have tried one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) **AND** modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

REQUIREMENTS: SOLRIAMFETOL (CONTINUED)

C. **If you have excessive daytime sleepiness (EDS) with obstructive sleep apnea (OSA), approval also require:**
    1. Your diagnosis of OSA is confirmed by a sleep study (polysomnography), home sleep apnea testing devices, or hospital-based bedside monitoring
    2. You have had Excessive Daytime Sleepiness (EDS) for at least 3 months and your Epworth Sleepiness Scale (ESS) score is more than 10
    3. You have tried modafinil or armodafinil, unless there is a medical reason why you cannot (contraindication)
    4. You have been on a treatment for the obstructive causes of OSA, for at least one month since initiation, and you have been counseled on weight-loss intervention [if your BMI (Body Mass Index: a measure of body fat based on height and weight) is greater than 30]

RENEWAL CRITERIA

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

A. You have excessive daytime sleepiness (EDS) with narcolepsy (a sleep disorder); or obstructive sleep apnea (OSA: a disorder where airflow is blocked during sleep).
B. You have sustained improvement in Epworth Sleepiness Scale (ESS) scores by at least 25% compared to baseline

References:

1. Sunosi package Insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised June 2019. Accessed October 2021.
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

Generic	Brand	Reviewed	Effective Date
SONIDEGIB Edition 1	ODOMZO	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have a locally advanced basal cell carcinoma (BCC: type of skin cancer).
B. This is a recurrence (disease returns) of basal cell carcinoma (BCC: type of skin cancer) after surgery or radiation therapy OR you are not a candidate for surgery or radiation therapy
C. Baseline serum creatine kinase (CK: type of protein that helps determine muscle damage) and serum creatinine levels have been obtained before starting therapy
D. If you are a females of reproductive potential, you must verify your pregnancy status before starting therapy

References:

1. Odomzo package inserts. Cranbury, NJ. Sun Pharmaceutical Industries, Inc., Revised May 2019. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SORAFENIB TOSYLATE Edition 1	NEXAVAR	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline for **SORAFENIB (Nexavar)** requires that you have ONE of the following diagnoses for approval:

A. Advanced renal cell carcinoma (RCC: type of kidney cancer)
B. Unresectable hepatocellular carcinoma (liver cancer that cannot be removed with surgery))
C. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment (thyroid cancer that has returned, spread , is getting worse and is not responding to a type of treatment)

References:

1. Nexavar package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised July 2020. Accessed April 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
STIRIPENTOL Edition 1	DIACOMIT	10/29/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
B. You are 2 years of age or older
C. You are currently being treated with clobazam (a type of seizure drug)
D. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
E. You had a trial of valproic acid derivatives, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

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

A. You have seizures associated with Dravet syndrome (rare and severe type of seizure that begins in infancy)
B. You are currently being treated with clobazam (type of seizure drug)

References:

1. Diacomit package insert. Redwood City, CA. Biocodex. Revised August 2018. Accessed October 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SUNITINIB MALATE Edition 1	SUTENT	10/29/2021	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: type of kidney cancer)
   2. Gastrointestinal stromal tumor (GIST: type of growth in the digestive system)
   3. Unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET: type of pancreas cancer)
   4. Adjuvant (add-on) treatment of renal cell carcinoma.

B. **If you have gastrointestinal stromal tumor (GIST), approval also requires:**
   1. You had a previous trial of imatinib mesylate (Gleevec), unless there is a medical reason why you cannot (contraindication)

C. **If you have unresectable locally advanced or metastatic pancreatic neuroendocrine carcinoma (pNET), approval also requires:**
   1. Your tumor is progressive (getting worse) and well-differentiated

D. **If you have adjuvant treatment of renal cell carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You are at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy (surgical removal of kidney)

References:

1. Sutent package insert. New York, NY. Pfizer, Inc. Revised August 2020. Accessed April 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TADALAFIL Edition 1	CIALIS	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have benign prostatic hyperplasia (BPH: your prostate is too big causing difficulty urinating) OR erectile dysfunction (difficulty getting/keeping an erection)

B. **If you have benign prostatic hyperplasia (BPH), approval also requires:**
   1. You previously tried at least two preferred formulary alternatives, including one medication from each of the following classes:
      i. 5-alpha-reductase inhibitors: (such as finasteride or dutasteride)
      ii. Alpha blockers: (such as doxazosin, terazosin, tamsulosin, or alfuzosin)

C. **If you have erectile dysfunction, approval also requires**:
   1. You have previously tried generic sildenafil (Viagra)

References:

1. Cialis package insert. Indianapolis, IN. Lilly USA, LLC. Revised February 2018. Accessed October 2021.
2. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART I-Initial Work-up and Medical Management. *J Urol*. 2021;206(4):806-817. doi:10.1097/JU.0000000000002183
3. Lerner LB, McVary KT, Barry MJ, et al. Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA GUIDELINE PART II-Surgical Evaluation and Treatment. *J Urol*. 2021;206(4):818-826. doi:10.1097/JU.0000000000002184.

WELLFLEET RX STUDENT FORMULARY

TAFAMIDIS Edition 1			
Generic	Brand	Reviewed	Effective Date
TAFAMIDIS MEGLUMINE	VYNDAQEL	10/29/2021	6/1/2021
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. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein) which is confirmed by ONE of the following:
    1. Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mtcpyp/DPD (a type of test that shows your heart absorbs a chemical for imaging)(Note: Strongly positive define as heart to contralateral lung [H/Cl] ratio of at least 1.5 or grade 2 or greater localization to the heart using the Perugini grade 1-3 scoring system
    2. Biopsy of tissue of affected organ(s) (can be heart or non-heart related organs) to confirm amyloid (type of protein) presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

B. You are 18 years of age or older

C. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor), transthyretin amyloidosis (ATTR) specialist, or medical geneticist

D. You have New York Heart Association (NYHA) class I, II or III heart failure (classification of heart failure symptoms)

(Criteria continued on next page)

REQUIREMENTS: TAFAMIDIS (Vyndaqel, Vyndamax)

RENEWAL CRITERIA

Our guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires the following rule(s) be met for renewal:

A. You have cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM: heart disease caused by a build-up of a type of protein)
B. You have not progressed to (gotten worse to) New York Heart Association (NYHA) Class IV heart failure (classification of heart failure symptoms)

References:

1. Vyndaqel package insert. New York, NY. Pfizer labs. Revised June 2021. Accessed October 2021.
2. Vyndamax package insert. New York, NY. Pfizer labs. Revised June 2021. Accessed October 2021.
3. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Card Fail*. 2017;23(8):628-651. doi:10.1016/j.cardfail.2017.04.014.
4. O'Meara E, et al.,CCS/CHFS Heart Failure Guidelines: Clinical Trial Update on Functional Mitral Regurgitation, SGLT2 Inhibitors, ARNI in HFpEF, and Tafamidis in Amyloidosis. Can J Cardiol. 2020 Feb;36(2):159-169. doi: 10.1016/j.cjca.2019.11.036. PMID: 32036861.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TALAZOPARIB TOSYLATE Edition 1	TALZENNA	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (disease that is advanced or has spread throughout the body and does not have a type of protein)
B. You are 18 years of age or older
C. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by and Food and Drug Administration-approved test
D. You have been treated with chemotherapy in the neoadjuvant (before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
E. **If you have hormone receptor (HR)-positive breast cancer, approval also requires:**
    1. You have previously had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

References:

1. Talzenna package insert. New York, NY. Pfizer, Inc. Revised October 2020. Accessed October 2021.
2. Korde LA, Somerfield MR, Carey LA, et al. Neoadjuvant Chemotherapy, Endocrine Therapy, and Targeted Therapy for Breast Cancer: ASCO Guideline. J Clin Oncol. 2021;39(13):1485-1505. doi:10.1200/JCO.20.03399.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TAVABOROLE Edition 1	KERYDIN, TAVABOROLE	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have onychomycosis of the toenails (toenail fungus infection)
B. You have complicating factors such as diabetes, peripheral vascular disease (narrowed blood vessels cause low blood flow), a suppressed immune system, or pain surrounding the nail or soft tissue
C. You have previously tried the following agents, unless there is a medical reason why you cannot (contraindication):
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

References:

1. Kerydin package insert. New York, NY. Pfizer Labs. Revised July 2018. Accessed October 2021.
2. 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
TAZEMETOSTAT Edition 1	TAZVERIK	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Metastatic or locally advanced (cancer that has spread to other parts of the body or has grown outside the organ it started in, but has not yet spread to distant parts of the body) epithelioid sarcoma (rare type of soft tissue cancer)
   2. Relapsed or refractory follicular lymphoma (cancer of the white blood cells that has returned or is resistant to previous treatment)

B. **If you have metastatic or locally advanced epithelioid sarcoma, approval also requires:**
   1. You are 16 years of age or older
   2. You are not eligible for complete resection (surgically removing all of a tissue/organ)

C. **If you have relapsed or refractory follicular lymphoma, approval also requires:**
   1. You are 18 years or older
   2. You meet ONE of the following:
      i. Your tumors are positive for an EZH2 (type of gene) mutation as detected by a Food and Drug Administration (FDA)-approved test AND you have received at least 2 prior systemic therapies (medication/treatment that spreads throughout your body)
      ii. You have no satisfactory alternative treatment options

References:

1. Tazverik package Insert. Cambridge, MA. Epizyme, Inc. Revised January 2020. Accessed April 2021.
2. Zelenetz AD, Gordon LI, Abramson JS, et al. NCCN Guidelines Insights: B-Cell Lymphomas, Version 3.2019. J Natl Compr Canc Netw. 2019;17(6):650-661. doi:10.6004/jnccn.2019.0029.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEDUGLUTIDE Edition 1	GATTEX	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have short bowel syndrome (SBS; your body is unable to absorb nutrients from the foods you eat due to a lack of a functional small intestine)
B. You are 1 year of age or older
C. You are dependent on parenteral nutrition (administration of nutrition through a vein), defined as requiring parenteral nutrition at least three times per week

References:

1. Gattex package insert. Lexington, MA. Shire-NPS Pharmaceuticals, Inc. Revised January 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TELOTRISTAT Edition 1	XERMELO	10/29/2021	6/1/2021

REQUIREMENTS:

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

A. You have carcinoid syndrome diarrhea (diarrhea caused by a type of tumor affecting nerves/hormones)
B. The medication will be used in combination with a somatostatin analog such as octreotide
C. You are 18 years of age or older
D. The medication is being prescribed by or given in consultation with an oncologist (cancer/tumor doctor) or gastroenterologist (digestive system doctor)
E. There is documentation showing that you have been receiving a stable dose of long-acting somatostatin analog therapy such as Sandostatin LAR (octreotide) or Somatuline Depot (lanreotide) for a minimum of 3 months – unless there is a medical reason why you cannot (contraindication)
F. You have diarrhea that is inadequately controlled as defined by the presence of at least four bowel movements per day

References:

1. Xermelo package insert. Deerfield, IL. TerSera Therapeutics LLC. Revised October 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TERIPARATIDE Edition 1	FORTEO	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **TERIPARATIDE (Forteo, Teriparatide)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Postmenopausal osteoporosis (weak and brittle bones)
   2. Primary or hypogonadal (sex organs don't function properly) osteoporosis in a male patient
   3. Glucocorticoid (steroid)-induced osteoporosis

B. You have not received a total of 24 months or more cumulative treatment with any parathyroid hormone therapy (Forteo, Tymlos, Teriparatide)

C. You meet ONE of the following:
   1. You are at high risk for fractures defined as ONE of the following:
      i. History of osteoporotic (i.e., fragility, low trauma) fracture(s)
      ii. 2 or more risk factors for fracture (such as history of multiple recent low trauma fractures, bone marrow density (BMD) T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin, etc.)
      iii. No prior treatment for osteoporosis AND FRAX (test for your risk of fractures) score at least 20% for any major fracture OR at least 3% for hip fracture
   2. You are unable to use oral therapy due to reasons such as upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
   3. You had an adequate trial of or intolerance to bisphosphonates (such as alendronate, risedronate, ibandronate), unless there is a medical reason why you cannot (contraindication)

References:

1. Forteo package insert. Indianapolis, IN. Lilly USA, LLC. Revised November 2020. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TETRABENAZINE Edition 1	XENAZINE	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have chorea (involuntary movements) associated with Huntington's disease (type of inherited disease that causes nerve cells in brain to break down over time)
B. The medication has been prescribed or given in consultation with a neurologist (nerve doctor)
C. If your request is for a tetrabenazine dosage that exceeds 50mg, approval also requires:
    1. You have been genotyped for CYP2D6 (type of enzyme) and you are identified as an extensive (EM) or intermediate metabolizer (IM) of CYP2D6.

References:

1. Xenazine package insert. Deerfield, IL. Lundbeck. Revised September 2017. Accessed November 2021..
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
TOLVAPTAN Edition 1	JYNARQUE	01/28/2022	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. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
B. You are 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a nephrologist (kidney specialist)
D. You have confirmed polycystic kidney status via CT or MRI imaging (type of lab imaging tests) AND one of the following:
    1. You have a genotype that causes of autosomal dominant polycystic kidney disease (inherited disorder in which clusters of cysts develop in the kidneys) OR
    2. You have a family history of confirmed polycystic kidney disease in one or both parents
E. You do not have End-Stage Renal Disease (ESRD: advanced kidney disease) including no renal transplantation (kidney transplant) or dialysis
F. You are at high risk of rapidly progressing autosomal dominant polycystic kidney disease

RENEWAL CRITERIA

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

A. You have autosomal dominant polycystic kidney disease (ADPKD: inherited disorder in which clusters of cysts develop in the kidneys)
B. You have NOT progressed to end stage renal (kidney) disease (ESRD)

References:

1. Jynarque package insert. Rockville, MD. Otsuka America Pharmaceutical, Inc. Revised October 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TOREMIFENE CITRATE Edition 1	FARESTON	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic breast cancer (cancer has spread to other parts of body)
B. You are a postmenopausal female (already gone through menopause)
C. You have an estrogen-receptor positive or unknown tumor

References:

1. Fareston package insert. Bedminster, NJ. Kyowa Kirin Inc. Revised May 2017. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRAMETINIB DIMETHYL SULFOXIDE Edition 1	MEKINIST	01/28/2022	6/1/2021

REQUIREMENTS:
Our guideline named **TRAMETINIB DIMETHYL SULFOXIDE (Mekinist)** requires the following rule(s) be met for approval:

A. You have ONE of the following:
    1. Unresectable or metastatic melanoma (skin cancer that cannot be removed by surgery or has spread)
    2. Metastatic non-small cell lung cancer (NSCLC: lung cancer that has spread in body)
    3. Melanoma (skin cancer)
    4. Locally advanced or metastatic anaplastic thyroid cancer (ATC: thyroid cancer that has spread in body)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
    1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
    2. The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naïve patient (you have not been previously treated for this cancer)

C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
    1. You have BRAF V600E mutation (type of gene) as detected by an Food and Drug Administration -approved test
    2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **If you have melanoma, approval also requires:**
    1. You have BRAF V600E or V600K mutations (types of genes) as detected by a Food and Drug Administration (FDA)-approved test
    2. The requested medication will be used in combination with Tafinlar (dabrafenib)
    3. There is involvement of lymph node(s), following complete resection (surgical removal)

E. **If you have locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires:**
    1. You have BRAF V600E mutation (type of gene mutation)
    2. The requested medication will be used in combination with Tafinlar (dabrafenib)
    3. You do not have any satisfactory locoregional treatment options available (treatments that are focused on the affected area)

(Criteria continued on next page)

REQUIREMENTS- TRAMETINIB DIMETHYL SULFOXIDE (CONTINUED)

References:

1. Mekinist package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised May 2021. Accessed November 202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRIFLURIDINE/TIPIRACIL Edition 1	LONSURF	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have **ONE** of the following diagnoses:
   1. Metastatic (has spread in the body) colorectal cancer
   2. Metastatic gastric (stomach) or gastroesophageal junction adenocarcinoma (cancer of lower portion of the throat)

B. **If you have metastatic colorectal cancer, approval also requires:**
   1. You had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy such as Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)
   2. If you are negative for the RAS (type of gene) mutation (you are RAS wild-type), you had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)

C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
   1. You had previous treatment with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

References:

1. Lonsurf package insert. Princeton, NJ. Taiho Oncology, Inc. Revised December 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

T: SLIM/MINIMED INSULIN PUMPS Edition 1			
Generic	Brand	Reviewed	Effective Date
SUBCUTANEOUS INSULIN PUMP	T: SLIM X2, T:SLIM X2 CONTROL-IQ, T:SLIM X2 WITH BASAL-IQ, MINIMED 670G, MINIMED 770G	01/28/2022	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. You have completed a comprehensive diabetes education program within the previous 24 months
C. You follow a maintenance program of at least 3 injections of insulin per day and require frequent self-adjustments of your insulin dose for the past 6 months
D. You require glucose self-testing of at least 4 times per day on average in the previous 2 months
E. You have not received an insulin pump within the last 4 years (Exception: your pump is malfunctioning, not repairable, and not under warranty)
F. You are on a multiple daily insulin injection regimen and meet ONE of the following:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
G. If you are requesting the T: Slim X2 OR T: Slim X2 with Basal-IQ, approval also requires:
    1. You are 6 years of age or older
H. If you are requesting the T: Slim X2 with Control-IQ, approval also requires:
    1. You are 6 years of age or older

(Criteria continued on next page)

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

I. If you are requesting the MiniMed 670G, approval also requires:
1. You are 7 years of age or older

J. If you are requesting the MiniMed 770G, approval also requires:
1. You are 2 years of age or older

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 November 2021
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 November 2021.
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 2021
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 2021.
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 1	TUKYSA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have advanced unresectable (cannot be removed with surgery) or metastatic (disease that has spread to other parts of the body) human epidermal growth factor receptor 2 (HER2: type of protein)-positive breast cancer
B. You are 18 years of age or older
C. You have previously received one or more anti-HER2-based treatment for metastatic disease (specifically either trastuzumab or trastuzumab with pertuzumab)
D. The requested medication will be used in combination with trastuzumab and capecitabine

References:

1. Tukysa package insert. Bothell, WA. Seattle Genetics, Inc. Revised April 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
URIDINE TRIACETATE Edition 1	XURIDEN	01/28/2022	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. You have hereditary orotic aciduria (HOA: genetic disease where you do not have a type of protein to make a chemical)
B. Your diagnosis is confirmed by ALL of the following:
    a. Presence of a mutation in the uridine monophosphate synthase (UMPS) gene
    b. Elevated urinary orotic acid levels according to your age-specific reference range
C. Therapy is prescribed by or given in consultation with a doctor specializing in inherited metabolic diseases (genetic diseases that result in metabolism problems)

RENEWAL CRITERIA

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

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

References:

1. Xuriden package insert. Rockville, MD. Wellstat Therapeutics Corporation. Revised December 2019. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VALBENAZINE Edition 1	INGREZZA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have moderate to severe tardive dyskinesia (involuntary movements, usually due to certain drugs) and it has been present for at least 3 months
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor), movement disorder specialist, or psychiatrist (mental health doctor)
D. You have a history of using antipsychotic medications or metoclopramide for at least 3 months (or at least 1 month if you are 60 years of age or older) as documented in your prescription claims history

References:

1. Ingrezza package insert. San Diego, CA. Neurocrine Biosciences, Inc. Revised April 2021. Accessed November 2021
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VANDETANIB Edition 1	CAPRELSA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You are currently stable on the requested medication
B. You have symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease (advanced thyroid cancer that cannot be removed with surgery or has spread in body)

References:

1. Caprelsa package insert. Cambridge, MA. Genzyme Corporation. Revised June 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VENETOCLAX Edition 1	VENCLEXTA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have **ONE** of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer), small lymphocytic lymphoma (SLL: type of immune system cancer)
   2. Newly-diagnosed acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many undeveloped white blood cells)

B. **If you have chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
   1. You are 18 years of age or older

C. **If you have newly-diagnosed acute myeloid leukemia (AML), approval also requires:**
   1. You are 75 years of age or older, **OR** you are 18 years of age or older with comorbidities (additional diseases) that preclude (prevent) the use of intensive induction chemotherapy
   2. The requested medication will be used in combination with azacitidine or decitabine or low-dose cytarabine

References:

1. Venclexta package insert. North Chicago, IL. AbbVie Inc. Revised October 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

V-GO INSULIN DEVICES Edition 1			
Generic	Brand	Reviewed	Effective Date
SUB-Q INSULIN DEVICE, 20 UNIT	V-GO 20	01/28/2022	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. You are 18 years of age or older
B. The requested insulin pump is prescribed by or given in consultation with an endocrinologist (hormone doctor)
C. You follow a maintenance program of at least 3 injections of insulin per day
D. You have worked with your doctor to adjust your insulin dose for the past 6 months and still have not met your glucose (blood sugar) goals
E. You do not require regular adjustments to your basal rate during a 24-hour time period
F. You require bolus insulin dosing in increments of 2 units per bolus
G. You do not require a total daily insulin dose of more than 76 units
H. You meet ONE of the following criteria while on a multiple daily insulin injection regimen:
    1. You have a glycosylated hemoglobin level (HbA1c: measure of how well controlled your blood sugar has been over a period of about 3 months) greater than 7 percent
    2. You have a history of recurring hypoglycemia (low blood sugar)
    3. You have wide fluctuations in blood sugar before mealtime
    4. You experience the dawn phenomenon (abnormal early morning increase in blood sugar, usually between 2 a.m. and 8 a.m.) with fasting blood glucose levels frequently exceeding 200 mg/dL
    5. You have a history of severe glycemic excursions (sudden spikes in blood sugar levels)
I. You previously had a trial of the Omnipod or Omnipod Dash (type of insulin device)

(Criteria continued on next page)

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. You have shown a positive response to therapy AND are adherent to your doctor 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 November 2021.
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
VISMODEGIB Edition 1	ERIVEDGE	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic basal cell carcinoma.
B. You have locally advanced basal cell carcinoma (type of skin cancers that have spread in the body or is advanced but has not spread) that has returned after surgery or you are not a candidate for surgery or radiation.

References:

1. Erivedge package insert. South San Francisco, CA. Genentech USA, Inc. Revised July 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ADO-TRASTUZUMAB EMTANSINE Edition 1	KADCYLA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **ADO-TRASTUZUMAB EMTANSINE (Kadcyla)** requires the following rule(s) be met for approval:

A. You have metastatic breast cancer (cancer has spread to other parts of body) or early breast cancer

B. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (it has a protein that causes breast cancer cells to grow)
   2. You have previously received trastuzumab and a taxane (class of cancer medication), separately or in combination
   3. You have received prior therapy for metastatic disease (disease has spread) **OR** developed disease recurrence (disease returns) during or within six months of completing adjuvant (add-on) therapy

C. **If you have early breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (it has a protein that causes breast cancer cells to grow)
   2. You have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment (disease is still present after using certain types of cancer drugs)

References:

1. Kadcyla package insert. South San Francisco, CA. Genentech, Inc. Revised September 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AFAMELANOTIDE Edition 1	SCENESSE	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have erythropoietic protoporphyria (EPP: a rare disorder that makes exposure to light extremely painful)
B. You are 18 years of age or older
C. You have a history of phototoxic reactions (damage to the skin)
D. The requested medication will be used to increase pain free light exposure

References:

1. Scenesse package insert. West Menlo Park, CA. Clinuvel, Inc. Revised October 2019. Accessed November 2021.
2. National Institute of Health. Genetic and Rare Disease Information Center. Erythropoietic Protoporphyria. Accessed 11/17/2021. Available at: https://rarediseases.info.nih.gov/diseases/4527/erythropoieticprotoporphyria.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AFLIBERCEPT Edition 1	EYLEA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. Neovascular (wet) age-related macular degeneration (eye disease that causes vision loss)
    2. Macular edema following retinal vein occlusion (blood vessel in the retina is blocked by blood clot)
    3. Diabetic macular edema (build up of fluid in the part of the retina)
    4. Diabetic retinopathy with diabetic macular edema (eye nerve damage due to diabetes)

B. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina (back part inside the eye) specialist

References:

1. Eylea package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised March 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AGALSIDASE BETA Edition 1	FABRAZYME	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for approval:

A. You have Fabry disease (inherited disorder that causes buildup of a type of fat)
B. You are 2 years of age or older
C. Therapy is prescribed by or given in consultation with a nephrologist (kidney doctor), cardiologist (heart doctor), or specialist physician in genetics or inherited metabolic disorders
D. You are NOT concurrently using an alpha-galactosidase A (a-Gal A- a type of protein) pharmacological chaperone (a molecule that helps correct other bad proteins) such as migalastat
E. You are symptomatic **OR** have evidence of injury from GL-3 (Globotriaosylceramide – a type of fat) to the kidney, heart, or central nervous system recognized by laboratory, histological (viewed by microscope), or imaging findings. Evidence of injury would include decreased Glomerular filtration rate (GFR- a test to see how well kidneys function) for age, persistent albuminuria (protein in urine), cerebral white matter lesions on brain MRI (Magnetic resonance imaging), cardiac fibrosis (abnormal thickening of heart valves) on contrast cardiac MRI

RENEWAL CRITERIA

Our guideline named **AGALSIDASE BETA (Fabrazyme)** requires the following rule(s) be met for renewal approval:

A. You have a diagnosis of Fabry disease (inherited disorder that causes buildup of a type of fat)
B. You have demonstrated improvement or maintenance/stabilization while on Fabrazyme therapy in regard to at least ONE of the following:
    1. Symptoms which include pain, hyperhidrosis/anhidrosis (less sweating or no sweating), exercise intolerance, GI (gastrointestinal) symptoms, angiokeratomas (dark red/purple raised spots), abnormal cornea, tinnitus (ringing in the ears)/hearing loss
    2. Imaging such as brain/cardiac MRI (Magnetic resonance imaging), DEXA (test to measure bone density), renal (kidney) ultrasound
    3. Laboratory or histological (viewed by microscope) testing such as GL-3
    4. (Globotriaosylceramide – a type of fat) in plasma/urine, renal biopsy

(Criteria continued on next page)

REQUIREMENTS: AGALSIDASE BETA (CONTINUED)

References:

1. Fabrazyme package insert. Cambridge, MA. Genzyme Corporation. Revised March 2021. Accessed November 2021
2. Germain DP, Fouilhoux A, Decramer S, et al. Consensus recommendations for diagnosis, management and treatment of Fabry disease in paediatric patients. Clin Genet. 2019;96(2):107-117. doi:10.1111/cge.13546.
3. Wanner C, Germain DP, Hilz MJ, Spada M, Falissard B, Elliott PM. Therapeutic goals in Fabry disease: Recommendations of a European expert panel, based on current clinical evidence with enzyme replacement therapy. Mol Genet Metab. 2019;126(3):210-211. doi:10.1016/j.ymgme.2018.04.004.
4. Laney DA, Bennett RL, Clarke V, et al. Fabry disease practice guidelines: recommendations of the National Society of Genetic Counselors. J Genet Couns. 2013;22(5):555-564. doi:10.1007/s10897-013-9613-3.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALGLUCOSIDASE ALFA Edition 1	LUMIZYME	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have Pompe's disease (an inherited condition where complex sugar (glycogen) builds up in your body's cells because your body cannot make a type of enzyme called acid alpha glucosidase) for approval

References:

1. Lumizyme package insert. Cambridge, MA. Genzyme Corporation. Revised February 2020. Accessed November 2021.
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
AXICABTAGENE CILOLEUCEL Edition 1	YESCARTA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **AXICABTAGENE CILOLEUCEL (Yescarta)** requires the following rule(s) be met for approval:

A. You have a diagnosis of ANY of the following types of immune system cancers:
    1. Diffuse large B-cell lymphoma not otherwise specified
    2. Primary mediastinal large B-cell lymphoma
    3. High grade B-cell lymphoma (such as double-hit or triple-hit lymphoma)
    4. Diffuse large B-cell lymphoma arising from follicular lymphoma [such as transformed follicular lymphoma (TFL)]
    5. Relapsed or refractory (disease worsens after improving or no longer responds to treatment) follicular lymphoma (FL: type of cancer that affects your white blood cells)

B. You are 18 years of age or older

C. If you have diffused large B-cell lymphoma, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or diffuse large B-cell lymphoma arising from follicular lymphoma, approval also requires:
    1. Therapy is prescribed by a Yescarta-certified hematologist (blood doctor) or oncologist (cancer doctor)
    2. Yescarta will be administered at a treatment center that is certified to administer Yescarta
    3. You have not previously tried Yescarta
    4. Your disease has worsened or relapsed (worsens after improving) after two or more lines of systemic therapy (treatment that spreads through the bloodstream)

D. If you have relapsed or refractory follicular lymphoma (FL), approval also requires:
    1. You received two or more lines of systemic therapy

E. **Yescarta will not be approved for ANY of the following indications:**
    1. Primary Central Nervous System Lymphoma (PCNSL: disease where cancer cells form in the lymph tissue of the brain/spinal cord)
    2. Mantle Cell Lymphoma (MCL: type of cancer that affects your white blood cells
    3. Burkitt's lymphoma (type of cancer that affects your white blood cells)

References:

1. Yescarta package insert. Santa Monica, CA. Kite Pharma, Inc. Revised April 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BELINOSTAT Edition 1	BELEODAQ	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **BELINOSTAT (Beleodaq)** requires that the following rule be met for approval:

A. You have a diagnosis of relapsed or refractory (your condition has gotten worse after improving) peripheral T-cell lymphoma (PTCL; cancer that affects a type of immune system cells)
B. You are 18 years of age or older

References:

1. Beleodaq package insert. East Windsor, NJ. Acrotech Biopharma LLC. Revised January 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BLINATUMOMAB Edition 1	BLINCYTO	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)
    2. Minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)

B. If you have minimal residual disease (MRD) - positive B-cell precursor acute lymphoblastic leukemia (ALL), approval also requires:
    1. You are in first or second complete remission (no symptoms or signs of *disease)*
    2. You have minimal residual disease (small numbers cancer cells that remain in you after treatment) greater than or equal to 0.1%

RENEWAL CRITERIA
Our guideline named **BLINATUMOMAB (Blincyto)** requires the following rule(s) be met for renewal:

A. You have one of the following diagnoses:
    1. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)
    2. Minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL; cancer that attacks immune system B-cells)

B. **If you have relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), renewal also requires:**
    1. You have achieved complete remission (CR) (no symptoms or signs of *disease*) or CR with partial recovery of peripheral blood counts (CPh) after two cycles of induction (starter) treatment (cycle 1 and 2) with Blincyto
    2. You have NOT received allogeneic hematopoietic stem-cell transplant (stem cells from a genetically similar, but not identical, donor)

(Criteria continued on next page)

REQUIREMENTS- BLINATUMOMAB (CONTINUED)

C. **If you have minimal residual disease (MRD)-positive B-cell precursor acute lymphoblastic leukemia (ALL), renewal also requires:**
    1. You have no detectable level of minimal residual disease (small numbers cancer cells that remain in you after treatment) g) within one cycle of Blincyto treatment
    2. You are relapse-free (your disease does not come back after being gone) which includes hematological (relating to blood) or extramedullary relapse, or secondary leukemia (cancer)

References:

1. Blincyto package insert. Thousand Oaks, CA. Amgen Inc. Revised March 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BORTEZOMIB Edition 1	VELCADE, BORTEZOMIB	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have a diagnosis of multiple myeloma (plasma cell cancer) OR mantle cell lymphoma (white blood cell cancer)

B. **If you are requesting Bortezomib (manufactured by Fresenius Kabi), approval also requires:**

   1. You have previously received at least one therapy for mantle cell lymphoma (white blood cell cancer).

References:

1. Velcade package insert. Lexington, MA. Takeda Pharmaceuticals U.S.A., Inc. Revised November 2021. Accessed November 2021.
2. Bortezomib package insert. Lake Zurich, IL. Fresenius Kabi USA. Revised September 2021. Accessed November 2021 .

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BRENTUXIMAB VEDOTIN Edition 1	ADCETRIS	01/28/2022	6/1/2021

REQUIREMENTS:
Our guideline named **BRENTUXIMAB (Adcetris)** requires the following rule(s) be met for approval:

A. You have one of the following diagnoses:
    1. Classical Hodgkin lymphoma (cancer with large, abnormal cells in immune system)
    2. Systemic anaplastic large cell lymphoma (type of non-Hodgkin lymphoma that affects immune system), or other CD30-expressing peripheral T-cell lymphomas (type of immune system cancer)
    3. Primary cutaneous anaplastic large cell lymphoma (cancer that present in the skin affecting immune system cells), or CD30-expressing mycosis fungoides (rare form of immune system cancer affecting the skin)
    4. Stage III or IV classical Hodgkin lymphoma (cHL)

B. You are 18 years of age or older

C. **If you have classical Hodgkin lymphoma, approval also requires ONE of the following:**
    1. You have failed autologous hematopoietic stem cell transplant (auto-HSCT; transplant cells are from your own body)
    2. You have failed at least two multi-agent chemotherapy regimens, which include but are not limited to: ABVD [doxorubicin, bleomycin, vinblastine, dacarbazine], Stanford V [doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone], BEACOPP [bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone])
    3. You are considered high risk of relapse or disease progression (disease comes back or gets worse) after having auto-HSCT AND you have obtained complete/partial remission (little or no sign of cancer in your body), or stable disease to most recent pre-auto-HSCT salvage therapy

D. **If you have relapsed systemic anaplastic large cell lymphoma (ALCL), approval also requires:**
    1. You have failed at least one multi-agent chemotherapy regimen, which includes but are not limited to: CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone] or CHOEP [cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone]

(Criteria continued on next page)

REQUIREMENTS: BRENTUXIMAB (CONTINUED)

E. **If you have systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, approval also requires:**
    1. You have not received previous treatment for sALCL or other CD30-expressing PTCL
    2. The requested medication will be used in combination with cyclophosphamide, doxorubicin, and prednisone
F. **If you have primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF), approval also requires:**
    1. You have received prior systemic therapy (therapy that spreads throughout the body in the blood)
G. **If you have Stage III or IV classical Hodgkin lymphoma (cHL), approval also requires:**
    1. The requested medication will be used in combination with doxorubicin, vinblastine, and dacarbazine
    2. You have not received previous treatment for Stage III or IV classical Hodgkin Lymphoma (cHL)

References:

1. Adcetris package insert. Bothell, WA. Seattle Genetics, Inc. Revised October 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

BUPRENORPHINE EXTENDED-RELEASE			
Generic	Brand	Reviewed	Effective Date
BUPRENORPHINE EXTENDED-RELEASE Edition 1	SUBLOCADE	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have a diagnosis of moderate to severe opioid use disorder (mis-use of a type of pain medication)

B. You previously started treatment with a transmucosal (medication that enters body through a mucous layer like those in the mouth) buprenorphine-containing product, which was followed by dose adjustment for a minimum of 7 days

References:

1. Sublocade package insert. North Chesterfield, VA. Indivior Inc. Revised June 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BROLUCIZUMAB-DBLL Edition 1	BEOVU	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for approval:

A. You have a diagnosis of neovascular (wet) age-related macular degeneration (AMD: abnormal blood vessels grow in the eye which bleed and leak fluid, causing blurry vision)
B. Therapy is prescribed by or given in consultation with an ophthalmologist (eye doctor) or retina (area within the eye) specialist

References:

1. Beovu package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised June 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

BUPRENORPHINE IMPLANT			
Generic	Brand	Reviewed	Effective Date
BUPRENORPHINE Edition 1	PROBUPHINE	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have NOT previously received ONE Probuphine treatment course in EACH arm (for a maximum of TWO 6-month treatment courses)

B. You have achieved and continued to have clinical stability on low to moderate doses of transmucosal buprenorphine (such as Subutex, Suboxone, Bunavail, or Zubsolv) defined as 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

References:

1. Probuphine package insert. South San Francisco, CA. Titan Pharmaceuticals, Inc. Revised March 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BUROSUMAB-TWZA Edition 1	CRYSVITA	01/28/2022	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. You have ONE of the following diagnoses:
   1. X-linked hypophosphatemia (XLH: inherited disorder with low phosphate blood levels)
   2. Fibroblast growth factor 23 (FGF23)-related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)

B. **If you have X-linked hypophosphatemia (XLH), approval also requires:**
   1. Your diagnosis is confirmed by ONE of the following:
      i. You have XLH symptoms such as osteomalacia (bone softening), excessive fractures, bowed legs, impaired growth and ONE of the following:
         a. If you are less than 18 years of age, your serum phosphate level is less than 3.2mg/dL with normal vitamin D levels
         b. If you are 18 years of age or older, your serum phosphate level is less than 2.5mg/dL with normal vitamin D levels
         c. You have more than normal amount of FGF23 protein on assay (type of lab analysis)
         d. You have a family history of X-linked hypophosphatemia
      ii. You have a *PHEX* mutation (Phosphate-regulating neutral endopeptidase, X-linked) confirmed by a genotyping (type of test)
   2. You are 6 months of age or older
   3. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformities), or medical geneticist
   4. You will not be taking oral phosphate salt or active vitamin D analog supplementation with the requested medication
   5. You meet ONE of the following:
      i. You previously had a trial of or failure to phosphate/vitamin D analog therapy (such as calcitriol, paricalcitol)
      ii. Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

(Criteria continued on next page)

REQUIREMENTS: BUROSUMAB-TWZA (CONTINUED)

C. **If you have FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO), approval also requires:**
    1. Your diagnosis is confirmed by the following:
        i. You have symptoms of tumor-induced osteomalacia (such as osteomalacia [softening of the bones], excessive fractures, muscle weakness, fatigue, bone pain)
    2. You are 2 years of age or older
    3. Therapy is prescribed by or given in consultation with an endocrinologist (hormone doctor), nephrologist (kidney doctor), orthopedic surgeon (surgeon that deals with skeletal deformitis), or medical geneticist
    4. Your tumors cannot be curatively resected (surgically removed) or localized
    5. You have stopped oral phosphate and/or active vitamin D analogs (such as calcitriol, paricalcitol) at least 1 week prior to starting Crysvita
    6. You meet ONE of the following:
        i. You previously had a trial of or failure to phosphate/vitamin D analog therapy
        ii. Your disease condition, severity, and/or other factors indicate phosphate/vitamin D analog therapy is not preferable/advisable for you compared to anticipated outcomes with Crysvita

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. X-linked hypophosphatemia (XLH; inherited disorder with low phosphate blood levels)
    2. Fibroblast growth factor 23 (FGF23) -related hypophosphatemia in tumor-induced osteomalacia (TIO: a rare disease characterized by the development of tumors that cause weakened and softened bones. The tumors release hormones known as fibroblast growth factor 23 that lowers your phosphate levels)
B. **If you have X-linked hypophosphatemia (XLH), renewal also requires:**
    1. You have achieved normal blood phosphate levels as defined by the reference range for your age
C. **If you have Fibroblast growth factor 23 (FGF23) - related hypophosphatemia in tumor-induced osteomalacia, renewal also requires:**
    1. You have achieved normal fasting blood phosphate levels (around or above the lower end of the reference range for age and below 5 mg/dL)

(Criteria continued on next page)

REQUIREMENTS: BUROSUMAB-TWZA (CONTINUED)

References:

1. Crysvita package insert. Novato, CA. Ultragenyx Pharmaceutical Inc. Revised June 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

CALASPARGASE PEGOL			
Generic	Brand	Reviewed	Effective Date
CALASPARGASE PEGOL-MKNL Edition 1	ASPARLAS	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **CALASPARGASE PEGOL (Asparlas)** requires the following rule(s) be met for approval:

A. You have a diagnosis of acute lymphoblastic leukemia (type of blood and bone marrow cancer)
B. You are 1 month to 21 years of age
C. Asparlas will be used as a part of a chemotherapeutic treatment plan that contains multiple drugs

References:

1. Asparlas package insert. Boston, MA. Servier Pharmaceuticals LLC. Revised June 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CERLIPONASE ALFA Edition 1	BRINEURA	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2; group of severe diseases that affect the nervous system, including mental and movement skills), also known as tripeptidyl peptidase 1 (TPP1) deficiency
B. Your diagnosis is confirmed by TPP1 enzyme deficiency test or TPP1/CLN2 genotyping
C. You are ambulatory (able to walk) and experiencing symptoms such as instability, intermittent falls, requires assistance to walk, or can crawl only
D. You have a documented CLN2 Clinical Rating Scale Score (test to measure the severity of ceroid lipofuscinosis type 2) of 3 to 5, with a minimum score of 1 in each of the motor and language category
E. You are 3 years of age or older
F. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor) or pediatric ceroid lipofuscinosis type 2 specialist

RENEWAL CRITERIA

Our guideline named **CERLIPONASE ALFA (Brineura)** requires the following rule(s) be met for renewal:

A. You have improved or maintained baseline motor function (such as ambulation, walking, crawling) or demonstrated a less-than-expected decline in motor function (such as ambulation, walking or crawling) from baseline
B. You have a ceroid lipofuscinosis type 2 (CLN2) motor score of at least 1 (such as you are not bedridden or immobile)

References:

1. Brineura package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised March 2020. Accessed November 2021.
2. Mole SE, Schulz A, Badoe E, et al. Guidelines on the diagnosis, clinical assessments, treatment and management for CLN2 disease patients. Orphanet J Rare Dis. 2021;16(1):185. Published 2021 Apr 21. doi:10.1186/s13023-021-01813-5.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
COPANLISIB Edition 1	ALIQOPA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have relapsed follicular lymphoma (FL: a type of blood cancer)
B. You are 18 years of age or older
C. You have received at least two prior systemic therapies (therapy that travels through the blood) for follicular lymphoma

References:

1. Aliqopa package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised February 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DARATUMUMAB Edition 1	DARZALEX	01/28/2022	6/1/2021

REQUIREMENTS:
Our guideline named **DARATUMUMAB (Darzalex)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. You meet **ONE** of the following criteria:
    1. You have newly diagnosed multiple myeloma and are not eligible for autologous stem cell transplant (cells from your own body) and will receive daratumumab in combination with lenalidomide and dexamethasone
    2. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received at least one prior therapy **AND** will receive daratumumab in combination with lenalidomide and dexamethasone
    3. You are newly diagnosed with multiple myeloma, not eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, melphalan and prednisone
    4. You are newly diagnosed with multiple myeloma, are eligible for autologous stem cell transplant (cells from your own body), **AND** will receive daratumumab in combination with bortezomib, thalidomide and prednisone
    5. You have received at least one prior therapy **AND** will receive daratumumab in combination with bortezomib and dexamethasone
    6. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) and received one to three prior lines of therapy **AND** will receive daratumumab in combination with carfilzomib and dexamethasone
    7. You have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI: class of drug for myeloma cancer) **AND** will receive daratumumab in combination with pomalidomide and dexamethasone
    8. You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for myeloma) and an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) **AND** you will receive daratumumab as monotherapy (single drug to treat condition)
    9. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent **AND** will receive daratumumab as monotherapy

(Criteria continued on next page)

REQUIREMENTS- DARATUMUMAB (CONTINUED)

Note: Proteasome inhibitors examples include: bortezomib, carfilzomib, or ixazomib and Immunomodulatory agent examples include: lenalidomide, pomalidomide, or thalidomide.

References:

1. Darzalex package insert. Horsham, PA. Janssen Biotech, Inc. Revised July 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DAUNORUBICIN/ CYTARABINE LIPOSOME Edition 1	VYXEOS	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **DAUNORUBICIN/CYTARABINE LIPOSOME (Vyxeos)** requires the following rule(s) be met for approval:

A. You have a new diagnosis of therapy-related acute myeloid leukemia (type of white blood cell cancer) OR acute myeloid leukemia with myelodysplasia-related changes (type of blood and bone marrow cancer that affects production of blood cells)
B. You are 1 years of age or older

References

1. Vyxeos package insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised March 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

DENOSUMAB-PROLIA			
Generic	Brand	Reviewed	Effective Date
DENOSUMAB Edition 1	PROLIA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have postmenopausal osteoporosis (weak and brittle bones after menopause), osteoporosis in a male patient, glucocorticoid-induced osteoporosis (weak and brittle bones caused by steroids), bone loss in men receiving androgen deprivation therapy for non-metastatic prostate cancer (using the medication to lower hormone levels for prostate cancer that has not spread to other parts of the body), or bone loss in women receiving adjuvant aromatase inhibitor therapy (type of breast cancer drug) for breast cancer.

B. **If you have postmenopausal osteoporosis, approval also requires ONE of the following:**

1. You are at high risk for fracture defined as ONE of the following:
    i. History of osteoporotic (fragility, low trauma) fracture(s)
    ii. 2 or more risk factors for fracture. Some risk factors are history of multiple recent low trauma fractures, bone marrow density T-score (measurement of bone density) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone analogs such as nafarelin
    iii. No prior treatment for osteoporosis AND FRAX score (tool to measure your fracture risk) greater than or equal to 20% for any major fracture OR greater than or equal to 3% for hip fracture
2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)
3. You are unable to use oral therapy (for example, due to upper gastrointestinal [GI] problems- unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or your daily routine)

(Criteria continued on next page)

REQUIREMENTS: DENOSUMAB-PROLIA (CONTINUED)

C. **If you have glucocorticoid-induced osteoporosis OR are a male with osteoporosis, approval also requires:**
   1. You are at high risk for fractures defined as ONE of the following:
      i. History of osteoporotic (fragility, low trauma) fracture(s)
      ii. Two or more risk factors for fracture. Some risk factors are history of multiple recent low trauma fractures, bone marrow density T-score (measurement of bone density) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone analogs such as nafarelin
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)

D. **If you are a man with bone loss who is receiving androgen deprivation therapy for non-metastatic prostate cancer, OR you are a woman with bone loss who is receiving adjuvant aromatase inhibitor therapy for breast cancer, approval also requires:**
   1. You are at high risk for fracture. Some risk factors include history of osteoporotic fracture, history of multiple recent low trauma fractures, corticosteroid use, or use of gonadotropin releasing hormone analogs such as nafarelin
   2. You had a previous trial of bisphosphonates such as Fosamax, Actonel, Boniva, Reclast, unless there is a medical reason why you cannot (contraindication)

References:

1. Prolia package insert. Thousand Oaks, CA. Amgen Inc. Revised May 2021. Accessed November 2021.
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.
4. Michaud LB. Managing cancer treatment-induced bone loss and osteoporosis in patients with breast or prostate cancer. Am J Health Syst Pharm. 2010;67(7 Suppl 3):S20-S33. doi:10.2146/ajhp100078.

WELLFLEET RX STUDENT FORMULARY

DENOSUMAB-XGEVA			
Generic	Brand	Reviewed	Effective Date
DENOSUMAB Edition 1	XGEVA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **DENOSUMAB (Xgeva)** requires you meet ONE of the following criteria:

A. You have multiple myeloma (plasma cell cancer) OR bone metastases from solid tumors (cancer has spread to bones from solid tumors) AND the requested medication is being used to prevent skeletal-related events (such as bone fractures or bone pain requiring radiation)

B. You have giant cell tumor of bone that is unresectable (tumor cannot be removed completely through surgery) or where surgical resection is likely to result in severe morbidity (illness)

C. You have hypercalcemia (higher than normal levels of calcium in blood) of malignancy that does not respond to bisphosphonate therapy (such as Fosamax, Actonel, or Boniva)

References:

1. Xgeva package insert. Thousand Oaks, CA. Amgen Inc. Revised June 2020. Accessed November 2021.
2. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocrinol Metab. 2014;99(9):3144-3152. doi:10.1210/jc.2014-1001.
3. Hu MI, Glezerman I, Leboulleux S, et al. Denosumab for patients with persistent or relapsed hypercalcemia of malignancy despite recent bisphosphonate treatment. J Natl Cancer Inst. 2013;105(18):1417-1420. doi:10.1093/jnci/djt225.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DINUTUXIMAB Edition 1	UNITUXIN	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have high-risk neuroblastoma (a type of cancer that usually affects glands above the kidneys)
B. You are 17 years of age or younger
C. You have received an autologous (cells are from your own body) stem cell transplant
D. You had a partial response to chemotherapy given before you had an autologous stem cell transplant
E. You have not undergone 5 cycles of dinutuximab in the past
F. Dinutuximab will be used concurrently (at the same time) with isotretinoin and either Leukine or Proleukin

References:

1. Unituxin package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised September 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ECALLANTIDE Edition 1	KALBITOR	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have hereditary angioedema (a type of genetic disorder where you have extreme swelling in various parts of the body)
B. You are 12 years of age or older
C. Your diagnosis is confirmed by complement testing (measures the amount of certain types of proteins in the blood)
D. The medication is being used for treatment of acute (sudden and severe) attacks of hereditary angioedema
E. The medication is prescribed by or given in consultation with an allergist/immunologist (allergy/immune system doctor) or hematologist (blood specialty doctor)
F. The medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis (severe, possible life-threatening allergic reaction) and/or angioedema (extreme swelling/allergic reaction)

References:

1. Kalbitor package insert. Lexington, MA. Dyax Corp. Revised December 2020. Accessed November 2021
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

C1 ESTERASE INHIBITOR Edition 1			
Generic	Brand	Reviewed	Effective Date
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE HAEGARDA	01/28/2022	6/1/2021
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. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. You are 6 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Cinryze together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, danazol, berotralstat)

(Criteria continued on next page)

REQUIREMENTS: C1 ESTERASE INHIBITOR (CONTINUED)

HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. You are 6 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Haegarda together with an alternative preventive agent for HAE (such as Takhzyro, Cinryze, danazol, berotralstat)

BERINERT

Our guideline named **C1 ESTERASE INHIBITOR (Berinert)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

RUCONEST

Our guideline named **C1 ESTERASE INHIBITOR (Ruconest)** requires the following rule(s) be met for approval:

A. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by complement testing (blood *test* that measures the activity of a group of proteins in the bloodstream)
C. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
D. The requested medication is being used for acute (short term) attacks of hereditary angioedema

(Criteria continued on next page)

REQUIREMENTS: C1 ESTERASE INHIBITOR (CONTINUED)

RENEWAL CRITERIA

NOTE: For requests of Berinert or Ruconest, please refer to the initial criteria section.

CINRYZE

Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for renewal:

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

HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for renewal:

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

References:

1. Berinert package insert. Kankakee, IL. CSL Behring LLC. Revised September 2021. Accessed November 2021.
2. Cinryze package insert. Lexington, MA. ViroPharma Biologics LLC. Revised January 2021. Accessed November 2021.
3. Haegarda package insert. Kankakee, IL. CSL Behring LLC. Revised September 2020. Accessed November 2021.
4. Ruconest package insert. Warren, NJ. Pharming Healthcare Inc. Revised April 2020. Accessed November 2021.
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
LANADELUMAB-FLYO Edition 1	TAKHZYRO	01/28/2022	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. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Takhzyro together with an alternative preventive agent for HAE (such as Cinryze, Haegarda, danazol, berotralstat)

RENEWAL CRITERIA

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

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

References:

1. Takhzyro package insert. Lexington, MA. Dyax Corp. Revised November 2018. Accessed November 2021
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
BEROTRALSTAT HYDROCHLORIDE Edition 1	ORLADEYO	01/28/2022	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. You have hereditary angioedema (HAE: life-threatening genetic condition that causes severe swelling)
B. Your diagnosis is confirmed by documented complement testing (blood test that measures the activity of a group of proteins in the bloodstream)
C. You are 12 years of age or older
D. Therapy is prescribed by or given in consultation with an allergist, immunologist (allergy or immune system doctor) or hematologist (blood doctor)
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. You will not be using Orladeyo together with an alternative preventive agent for HAE (such as Takhzyro, Haegarda, Cinryze, danazol)

RENEWAL CRITERIA

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

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

References:

1. Orladeyo package insert. Durham, N.C. BioCryst Pharmaceuticals, Inc. Revised December 2020. Accessed November 2021.
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
ICATIBANT Edition 1	FIRAZYR	01/28/2022	6/1/2021

REQUIREMENTS:

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

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

References:

1. Firazyr package insert. Lexington, MA. Takeda Pharmaceutical Company. Revised April 2020. Accessed November 2021
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
ECULIZUMAB Edition 1	SOLIRIS	01/28/2022	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. You have ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: life-threatening condition with red blood cells being destroyed)
   2. Atypical hemolytic uremic syndrome (aHUS: condition where blood clots form in small blood vessels of kidneys)
   3. Generalized myasthenia gravis (gMG: disease that causes skeletal muscle weakness)
   4. Neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)

B. Eculizumab (Soliris) is NOT being used for hemolytic uremic syndrome related to Shiga toxin E.coli (small blood vessels in your kidneys become damaged and inflamed caused by a type of bacteria)

C. **If you have generalized myasthenia gravis (gMG), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a neurologist (nerve doctor)
   3. Your diagnosis is confirmed by a positive anti-acetylcholine receptor antibody test
   4. You have Myasthenia Gravis Foundation of America class II, III, or IV (types of severity of disease)
   5. You had a trial of corticosteroids, unless there is a medical reason why you cannot (contraindication)
   6. You meet ONE of the following:
      i. Failure of treatment with at least 2 immunosuppressive therapies (drugs that weaken your immune system such as azathioprine, cyclophosphamide, methotrexate)
      ii. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (types of blood therapy)

(Criteria continued on next page)

REQUIREMENTS: ECULIZUMAB (CONTINUED)

D. **If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   3. You have confirmed PNH as demonstrated by **ALL** of the following via flow cytometry:
      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. You meet **ONE** of the following:
      i. Transitioning from alternative complement inhibitor therapy (such as Ultomiris)
      ii. Documentation of evidence of intravascular hemolysis (blood cells being destroyed) such as lactate dehydrogenase [LDH] level greater than or equal to 1.5 times the upper limit of normal, hemoglobinuria (type of blood protein is in urine) OR you have a history of major adverse vascular event from thromboembolism (blood clot)

E. **If you have neuromyelitis optica spectrum disorder (NMOSD), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)
   3. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
   4. You have at least ONE of the following core clinical characteristics:
      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. You will NOT use rituximab, inebilizumab, or satralizumab together with Soliris

(Criteria continued on next page)

REQUIREMENTS: ECULIZUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. You have one of the following diagnoses:
    1. Paroxysmal nocturnal hemoglobinuria (PNH: life-threatening condition with red blood cells being destroyed)
    2. Atypical hemolytic uremic syndrome (aHUS: condition where blood clots form in small blood vessels of kidneys)
    3. Generalized myasthenia gravis (gMG: disease that causes skeletal muscle weakness)
    4. Neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)

B. **If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:**
    1. You have had clinical benefit compared to baseline such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (type of enzyme) and hemoglobin levels

C. **If you have generalized myasthenia gravis, renewal also requires:**
    1. You have had clinical benefit compared to baseline according to validated gMG instruments (such as Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool)

D. **If you have neuromyelitis optica spectrum disorder, renewal also requires:**
    1. You have had a reduction in relapse frequency compared to baseline

References:

1. Soliris package insert. Boston, MA. Alexion Pharmaceuticals, Inc. Revised November 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EDARAVONE Edition 1	RADICAVA	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have amyotrophic lateral sclerosis (ALS; a disease that causes brain and spinal cord nerve cells to break down)
B. You are currently taking or have previously tried riluzole (Rilutek)
C. The medication is prescribed by or given in consultation with a neurologist (doctor who specializes in disorders of the nervous system) or ALS specialist at an ALS Specialty Center or Care Clinic
D. You have the disease (from onset of symptoms) for less than 2 years
E. Your Normal Respiratory Function defined as a Forced Vital Capacity (FVC) is greater than 80%
F. You have mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS (Amyotrophic Lateral Sclerosis Functional Rating Scale; for example, speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, respiratory insufficiency)

RENEWAL CRITERIA

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

A. You have amyotrophic lateral sclerosis (ALS; a disease that causes brain and spinal cord nerve cells to break down)
B. You have improved or maintained baseline functional ability or demonstrated a less-than expected decline in functional ability from baseline as measured by functional assessments (such as Amyotrophic Lateral Sclerosis Functional Rating Scale)
C. You do not require invasive ventilation (such as inserting a breathing tube into your throat)
D. Patient has maintained a score of 2 or greater in all 12 items of the ALSFRS-R (Amyotrophic Lateral Sclerosis Functional Rating Scale Revised)

References:

1. Radicava package insert. Jersey City, NJ. Mitsubishi Tanabe Pharma America, Inc. Revised March 2021. Accessed November 2021.
2. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis:, Andersen PM, Abrahams S, et al. EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS)--revised report of an EFNS task force. Eur J Neurol. 2012;19(3):360-375. doi:10.1111/j.1468-1331.2011.03501.x.
3. Shoesmith C, Abrahao A, Benstead T, et al. Canadian best practice recommendations for the management of amyotrophic lateral sclerosis. CMAJ. 2020;192(46):E1453-E1468. doi:https://doi.org/ 10.1503/cmaj.191721.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELOSULFASE ALFA Edition 1	VIMIZIM	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **ELOSULFASE ALFA (Vimizim)** requires you have Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome - rare metabolic condition that mainly affects the skeleton).

References:

1. Vimizim package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised December 2019. Accessed November 2021.
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
ELOTUZUMAB Edition 1	EMPLICITI	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have multiple myeloma (plasma cell cancer)
B. You are 18 years of age or older
C. You meet ONE of the following criteria:
    1. Empliciti is used in combination with lenalidomide and dexamethasone if you have received one to three prior therapies such as bortezomib, thalidomide, lenalidomide, melphalan, or stem cell transplantation
    2. Empliciti is used in combination with pomalidomide and dexamethasone if you have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as bortezomib, carfilzomib, ixazomib)

References:

1. Empliciti package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised October 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EMAPALUMAB-LZSG Edition 1	GAMIFANT	01/28/2022	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. You have primary hemophagocytic lymphohistiocytosis (HLH; inherited condition where you have too much of certain types of immune cells, causing inflammation)
B. Your diagnosis is confirmed by ONE of the following:
    1. You have undergone a genetic test identifying HLH-associated gene mutation such as PRF1 (type of gene), UNC13D (type of gene)
    2. You have at least five of the following eight diagnostic criteria for HLH: fever; splenomegaly (enlarged spleen); cytopenias (low number of a type of blood cell affecting at least 2 of 3 cell lineages); hypertriglyceridemia (type of high cholesterol) and/or hypofibrinogenemia (type of genetic disorder); hemophagocytosis (destruction of certain types of cells) in bone marrow or spleen or lymph nodes, and no evidence of malignancy; low or absent natural killer-cell activity; ferritin level of at least 500 mcg/L; soluble CD25 level of at least 2,400 U/mL
C. You have refractory, recurrent, or progressive disease (disease returns or does not respond to treatment and gets worse); **OR** you had a trial or intolerance to conventional hemophagocytic lymphohistiocytosis therapy (such as chemotherapy, steroids, immunotherapy)
D. The requested medication will be used at the same time with dexamethasone
E. Therapy is prescribed by or given in consultation with an immunologist (doctor who specializes in immune disorders), hematologist (blood doctor), or oncologist (cancer doctor)

(Criteria continued on next page)

REQUIREMENTS- EMAPALUMAB-LZSG (CONTINUED)

RENEWAL CRITERIA

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

A. You have hemophagocytic lymphohistiocytosis (inherited condition where you have too much of certain types of immune cells, causing inflammation)
B. You have not received successful hematopoietic stem cell transplantation
C. You have demonstrated improved immune system response from baseline as shown by any of the following: your fever has gone away, decreased splenomegaly (spleen size has gotten smaller), improvement in central nervous system symptoms such as altered mental status, improved complete blood count, increased fibrinogen levels, reduced D-dimer, reduced ferritin, reduced soluble CD25 (type of protein) levels

References:

1. Gamifant package insert. Waltham, MA. Sobi Inc. Revised November 2018. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

ENZYME REPLACEMENT THERAPY: GAUCHER DISEASE Edition 1			
Generic	Brand	Reviewed	Effective Date
IMIGLUCERASE	CEREZYME	01/28/2022	6/1/2021
TALIGLUCERASE ALFA	ELELYSO		
VELAGLUCERASE ALFA	VPRIV		

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

REQUIREMENTS:

ELELYSO

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

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 4 years of age or older

VPRIV

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

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 4 years of age or older
C. You previously had a trial of Elelyso, unless there is a medical reason why you cannot (contraindication)

CEREZYME

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

A. You have type 1 Gaucher disease (genetic disorder where a type of fatty substance builds up in the body)
B. You are 18 years of age or older
C. You previously had a trial of Elelyso, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

REQUIREMENTS: ENZYME REPLACEMENT THERAPY - GAUCHER DISEASE (CONTINUED)

References:

1. Cerezyme package insert. Cambridge, MA. Genzyme Corporation. Revised April 2018. Accessed November 2021.
2. Elelyso package insert. New York, NY. Pfizer, Inc. Revised November 2020. Accessed November 2021.
3. Vpriv package insert. Lexington, MA. Shire Human Genetic Therapies, Inc. Revised December 2020. Accessed November 2021.
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
ERIBULIN MESYLATE Edition 1	HALAVEN	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Metastatic (cancer has spread) breast cancer
   2. Unresectable or metastatic liposarcoma (cancer that starts in fat cells that has spread or cannot be completely removed by surgery)

B. **If you have metastatic breast cancer, approval also requires:**
   1. You had previous treatment with an anthracycline (class of medication for cancer such as daunorubicin, doxorubicin, etc)
   2. You had previous treatment with a taxane (such as paclitaxel and docetaxel)

C. **If you have unresectable or metastatic liposarcoma, approval also requires:**
   1. You had previous treatment with an anthracycline (class of medication for cancer such as daunorubicin, doxorubicin, etc)

References:

1. Halaven package insert. Woodcliff Lake, NJ. Eisai Inc. Revised October 2016. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ETELCALCETIDE Edition 1	PARSABIV	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have secondary hyperparathyroidism (too much parathyroid hormone due to low blood calcium levels)
B. You are 18 years of age or older
C. You have chronic kidney disease
D. You are on hemodialysis (a way of removing toxins from your blood)
E. You are NOT taking another calcimimetic agent (a drug that acts like calcium in the body such as cinacalcet)

References:

1. Parsabiv package insert. Thousand Oaks, CA. KAI Pharmaceuticals, Inc. Revised March 2019. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FULVESTRANT Edition 1	FASLODEX	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative advanced breast cancer
   2. HR-positive advanced breast cancer
   3. HR-positive, HER2-negative advanced or metastatic breast cancer (cancer that has spread)

B. **If you have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer, approval also requires:**
   1. You are female and postmenopausal
   2. You have not previously been treated with endocrine (hormone) therapy
   3. The requested medication will be used as monotherapy (using a single drug to treat a condition)

C. **If you have hormone receptor (HR)-positive advanced breast cancer, approval also requires:**
   1. You are female and postmenopausal
   2. You have experienced disease progression (it has gotten worse) following endocrine (hormone) therapy
   3. The requested medication will be used as monotherapy (used alone)

D. **If you have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, approval also requires ONE of the following:**
   1. The requested medication will be used concurrently (at the same time) with Ibrance (palbociclib) or Verzenio (abemaciclib) and you are a female that has experienced disease progression (it has gotten worse) after endocrine (hormone) therapy
   2. The requested medication will be used in combination with Kisqali (ribociclib) and you meet ALL of the following:
      i. You are a female and postmenopausal
      ii. You have not received prior endocrine based therapy for metastatic breast cancer (such as letrozole, anastrozole, tamoxifen, exemestane) OR you have experienced disease progression on endocrine therapy

References:

1. Faslodex package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised January 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GEMTUZUMAB OZOGAMICIN Edition 1	MYLOTARG	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **GEMTUZUMAB OZOGAMICIN (Mylotarg)** requires that ONE of the following rule(s) be met for approval:

A. You have newly-diagnosed CD33 (type of molecule that is used as a marker to diagnose AML)–positive acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many immature white blood cells) AND you are 1 month of age or older
B. You have relapsed (returning) or refractory (resistant) CD33 (type of molecule that is used as a marker to diagnose AML) -positive acute myeloid leukemia (AML) AND you are 2 years of age or older

References:

1. Mylotarg package insert. Philadelphia, PA. Pfizer Inc. Revised June 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GIVOSIRAN Edition 1	GIVLAARI	01/28/2022	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. You have acute hepatic porphyria (enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP])
B. You are 18 years of age or older
C. You have genetic confirmation of AHP mutation (a change in your DNA that make up your gene), OR high (beyond reference range) urinary or plasma porphobilinogen (PBG), or aminolevulinic acid (ALA) (PBG and ALA: urine or blood tests that measure the level of porphyrins – a chemical that helps make hemoglobin in your body)
D. You have experienced two or more acute (sudden and severe) hepatic porphyria attacks in the past 12 months
E. The medication is prescribed by or given in consultation with a geneticist (doctor who specializes in conditions of gene disorders), hepatologist (doctor who specializes in treating the liver), hematologist (doctor who specializes in the study of blood, blood-forming organs and blood diseases), gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), neurologist (doctor who specializes in disorders of the nervous system), dermatologist (doctor who treats conditions of the skin, hair and nails), or a healthcare provider experienced in managing acute hepatic porphyria
F. Your doctor provided documentation of your weight

RENEWAL CRITERIA

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

A. You have acute hepatic porphyria (AHP: enzyme deficiency which leads to buildup of materials in the liver) (to include acute intermittent porphyria [AIP], variegate porphyria [VP], hereditary coproporphyria [HCP], ALA dehydratase-deficient porphyria [ADP])
B. You have achieved or maintained clinical (medical) benefit compared to baseline (such as lesshemin use, less AHP attacks, improvement of AHP symptoms, etc.)
C. You have not received a liver transplant (replaced your bad liver with a healthy liver from another person)
D. Your doctor provided documentation of your weight

(Criteria continued on next page)

REQUIREMENTS: GIVOSIRAN (CONTINUED)

References:

1. Givlaari package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised October 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST Edition 2			
Generic	Brand	Reviewed	Effective Date
TRIPTORELIN PAMOATE	TRIPTODUR, TRELSTAR	04/29/2022	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. You have or are using the requested drug for ONE of the following:
    1. Advanced prostate cancer
    2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
    3. Central precocious puberty (CPP; early sexual development in girls and boys)
    4. Gender dysphoria (you are distressed because your assigned sex/gender do not match your gender identity)
    5. As an endometrial-thinning agent prior to endometrial ablation (surgical removal of body tissue) for dysfunctional uterine bleeding
    6. Palliative treatment (treatment for pain or discomfort) of advanced breast cancer
    7. Management of locally confined carcinoma (cancer) of the prostate
    8. Anemia caused by uterine leiomyomata (fibroids; small muscle tumor)

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

(Criteria continued on next page)

REQUIREMENTS: GNRH AGONIST (CONTINUED)

B. **If you have advanced prostate cancer, approval also requires:**
    1. The request is for Eligard, Lupron Depot, Zoladex, Vantas, or Trelstar
C. **If you have moderate to severe pain from endometriosis, approval also requires:**
    1. The request is for Lupron Depot, Lupaneta, Synarel, or Zoladex
    2. You are 18 years of age or older
    3. Therapy is prescribed by or given in consultation with an obstetrician/gynecologist (doctor who specializes in women's health)
    4. You had a previous trial of a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation), unless there is a medical reason why you cannot (contraindication)
D. **If you are female and have central precocious puberty, approval also requires:**
    1. The request is for Triptodur, Supprelin LA, Synarel, leuprolide (generic), Lupron Depot-Ped, or Fensolvi
    2. You are 2 years of age or older
    3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
    4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
    5. You are/were younger than 8 years of age when your condition started
    6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)
E. **If you are male and have central precocious puberty, approval also requires:**
    1. The request is for Triptodur, Supprelin LA, Synarel, leuprolide (generic), Lupron Depot-Ped, or Fensolvi
    2. You are 2 years of age or older
    3. Therapy is prescribed by or given in consultation with a pediatric endocrinologist (hormone doctor)
    4. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
    5. You are/were younger than 9 years of age when your condition started
    6. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

(Criteria continued on next page)

REQUIREMENTS: GNRH AGONIST (CONTINUED)

F. **If you are using the requested medication as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding, approval also requires:**
    1. The request is for Zoladex
G. **If you are using the requested medication for palliative treatment of advanced breast cancer, approval also requires:**
    1. The request is for Zoladex
    2. You are a premenopausal or perimenopausal female
H. **If you are using the requested medication for the management of locally confined carcinoma of the prostate, approval also requires:**
    1. The request is for Zoladex
    2. The requested medication will be used in combination with flutamide
I. **If you have anemia caused by uterine leiomyomata, approval also requires:**
    1. The request is for Lupron Depot
    2. You are using the requested medication for preoperative hematologic (blood) improvement
    3. The requested medication will be used with iron therapy

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. You have or are using the requested drug for ONE of the following:
    1. Advanced prostate cancer
    2. Moderate to severe pain from endometriosis (tissue that is normally in the uterus grows outside the uterus)
    3. Central precocious puberty (CPP; early sexual development in girls and boys)
    4. Gender dysphoria (you are distressed because your assigned sex/gender do not match your gender identity)
B. **If you have moderate to severe pain associated with endometriosis, renewal also requires:**
    1. The request is for Lupron Depot, Lupaneta, Synarel, or Zoladex
    2. You experienced improvement of pain related to endometriosis while on therapy
    3. You are receiving add-back therapy at the same time (combination estrogen-progestin or progestin-only contraceptive preparation)
    4. You have NOT received a total course of therapy exceeding 12 months

(Criteria continued on next page)

REQUIREMENTS: GNRH AGONIST (CONTINUED)

C. **If you have 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 (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
   3. You have not reached actual age which corresponds to current pubertal age

D. **If you have advanced prostate cancer, renewal also requires:**
   1. The request is for Eligard, Lupron Depot, Zoladex, Vantas, or Trelstar

References:

1. Fensolvi package insert. Fort Collins, CO. Tolmar, Inc. Revised May 2020. Accessed March 2022.
2. Lupron Depot package insert. North Chicago, IL. AbbVie Inc. Revised March 2020. Accessed March 2022.
3. Lupron Depot-Ped Kit package insert. North Chicago, IL. AbbVie Inc. Revised March 2021. Accessed March 2022.
4. Lupaneta package insert. North Chicago, IL. AbbVie Inc. Revised June 2015. Accessed March 2022.
5. Supprelin LA package insert. Malvern, PA. Endo Pharmaceuticals Solutions, Inc. Revised November 2019. Accessed March 2022.
6. Trelstar package insert. Madison, NJ. Allergan USA, Inc. Revised December 2018. Accessed March 2022.
7. Triptodur package insert. Atlanta, GA. Arbor Pharmaceuticals, LLC. Revised June 2017. Accessed March 2022.
8. Vantas package insert. Malvern, PA. Endo Pharmaceuticals Solutions, Inc. Revised December 2020. Accessed March 2022.
9. Zoladex package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised February 2015. Accessed March 2022.
10. Eligard package insert. Fort Collins, CO. Tolmar Pharmaceuticals, Inc. Revised February 2019. Accessed March 2022.
11. Leuprolide acetate package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised January 2019. Accessed March 2022.
12. Synarel package insert. New York, NY. Pfizer Labs, Inc. Revised May 2017. Accessed March 2022.
13. World Professional Association for Transgender Health. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [7th 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

HYDROXYPROGESTERONE CAPROATE Edition 1			
Generic	Brand	Reviewed	Effective Date
HYDROXYPROGESTERONE CAPROATE	MAKENA	01/28/2022	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 woman with a history of singleton spontaneous preterm birth
B. You do **NOT** have multiple gestations (twins, triplets, etc.)
C. You are at least 16 weeks pregnant but less than 37 weeks pregnant with a single gestation (embryo/fetus)
D. You have a history of delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes

Our guideline named **HYDROXYPROGESTERONE CAPROATE (Generic Delalutin)** requires you are a non-pregnant female and are using the medication for **ONE** of the following:

A. For treatment of advanced adenocarcinoma of the uterine corpus (uterine cancer/tumor Stage III or IV)
B. For the management of primary/secondary amenorrhea (lack of normal menstruation) and abnormal uterine bleeding caused by hormonal imbalance with no organic pathology (no disease from body/organs), such as submucous fibroids or uterine cancer
C. As a test for endogenous (within the body) estrogen production
D. For the production of secretory endometrium and desquamation (shedding of the tissue lining of the uterus)

References:

1. Makena package insert. Waltham, MA. AMAG Pharmaceuticals, Inc. Revised February 2018. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IBALIZUMAB-UIYK Edition 1	TROGARZO	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have human immunodeficiency virus type 1 (HIV-1) infection (a virus that attacks the body's immune system and if untreated, can lead to AIDS [acquired immunodeficiency syndrome])
B. You are 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s) (class of medication used to treat HIV)
D. You are treatment experienced (previously treated)
E. You have multidrug-resistant HIV-1 infection (your virus is resistant to more than one HIV medication)
F. You are failing your current antiretroviral regimen

References:

1. Trogarzo package insert. Montréal, Québec Canada. Theratechnologies Inc. Revised April 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INEBILIZUMAB-CDON Edition 1	UPLIZNA	01/28/2022	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. You have neuromyelitis optica spectrum disorder (NMOSD: a rare immune system disease that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a neurologist (doctor who specializes in the brain, spinal cord, and nerves)
D. Your diagnosis is confirmed by a positive serologic (blood) test for anti-aquaporin-4 (AQP4: type of protein) antibodies
E. You have at least ONE of the following core clinical characteristics:
    1. Optic neuritis (inflammation that damages an eye nerve)
    2. Acute myelitis (sudden and severe inflammation of the spinal cord)
    3. Area postrema syndrome (attacks of uncontrollable nausea, vomiting, or hiccups)
    4. Acute brainstem syndrome (problems with vision, hearing, swallowing and muscle weakness in the head)
    5. Symptomatic narcolepsy (sudden attacks of sleep) or acute diencephalic clinical syndrome (rare disorder caused by a tumor above the brainstem) with NMOSD-typical diencephalic MRI lesions
    6. Symptomatic cerebral syndrome with NMOSD-typical brain lesions
F. You will NOT use rituximab, satrilizumab, or eculizumab together with Uplizna

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

A. You have neuromyelitis optica spectrum disorder (NMOSD: a rare disorder that affects the central nervous system and causes inflammation in the optic nerve and spinal cord)
B. You have shown clinical benefit (such as reduction in relapse frequency from baseline or a decrease in NMOSD-related hospitalizations) on therapy with Uplizna

(Criteria continued on next page)

REQUIREMENTS: INEBILIZUMAB-CDON (CONTINUED)

References:

1. Uplinza package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised July 2021. Accessed November 2021.
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
INOTUZUMAB OZOGAMICIN Edition 1	BESPONSA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **INOTUZUMAB OZOGAMICIN (Besponsa)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory B-cell pre-cursor acute lymphoblastic leukemia (ALL-type of blood and bone marrow cancer that affects white blood cells.)
B. You are 18 years of age or older
C. You have **NOT** received 6 cycles of Besponsa previously

References:

1. Besponsa package insert. Philadelphia, PA. Pfizer Inc. Revised March 2018. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

IOBENGUANE IODINE 131			
Generic	Brand	Reviewed	Effective Date
IOBENGUANE I 131 Edition 1	AZEDRA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **IOBENGUANE IODINE 131 (Azedra)** requires the following rule(s) be met for approval:

A. You have unresectable (cannot be removed completely through surgery), locally advanced or metastatic pheochromocytoma (type of tumor that releases hormones) or paraganglioma (type of tumors)
B. You are 12 years of age or older
C. You require systemic anticancer therapy (cancer treatment that travels in the blood throughout the entire body)
D. The tumors are iobenguane scan positive (type of test that detects a tumor)
E. You have **NOT** previously received 1 dosimetric dose (measurement of how much radiation dose is absorbed by the body) and 2 therapeutic doses of Azedra

References:

1. Azedra package insert. New York, NY. Progenics Pharmaceuticals, Inc. Revised March 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IPILIMUMAB Edition 1	YERVOY	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (skin cancer that cannot be completely removed with surgery or has spread)
   2. Cutaneous melanoma (type of skin cancer)
   3. Advanced renal cell carcinoma (type of kidney cancer)
   4. Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (types of colon cancer)
   5. Hepatocellular carcinoma (liver cancer)
   6. Metastatic or recurrent non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body or has returned)
   7. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (A tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs.)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
   1. You are 12 years of age or older

C. **If you have cutaneous melanoma, approval also requires:**
   1. The requested medication will be used for adjuvant (add-on) treatment
   2. There is pathologic (disease) involvement of regional lymph nodes of more than 1mm
   3. You have undergone complete resection (surgery to completely remove cancer), including total lymphadenectomy (lymph glands are surgically removed)

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. The requested medication will be used in combination with Opdivo (nivolumab)
   2. You have intermediate or poor risk disease
   3. You have not received prior treatment for advanced renal cell carcinoma

E. **If you have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval also requires:**
   1. You are 12 years of age or older
   2. The requested medication will be used in combination with Opdivo (nivolumab)
   3. You have disease progression (disease gets worse) following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

(Criteria continued on next page)

REQUIREMENTS: IPILIMUMAB (CONTINUED)

F. **If you have hepatocellular carcinoma, approval also requires:**
    1. The requested medication will be used in combination with Opdivo (nivolumab)
    2. You have previously been treated with Nexavar (sorafenib)
G. **If you have metastatic or recurrent non-small cell lung cancer (NSCLC), approval also requires:**
    1. You are 18 years of age or older
    2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (changes in your gene structure)
    3. The requested medication is used as first-line treatment
    4. You have NOT received Yervoy for more than 2 years
    5. You meet ONE of the following:
        i. **For metastatic NSCLC,** the requested medication will be used in combination with Opdivo (nivolumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) at greater than or equal to 1% as determined by an FDA (Food and Drug Administration)-approved test
        ii. **For metastatic or recurrent NSCLC,** the requested medication will be used in combination with Opdivo (nivolumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)
H. **If you have malignant pleural mesothelioma, approval also requires:**
    1. You are 18 years of age or older
    2. Yervoy will be used as first line treatment in combination with Opdivo (nivolumab)

RENEWAL CRITERIA

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

A. The request is for adjuvant (add-on) treatment of cutaneous melanoma (type of skin cancer)
B. You do not have any disease recurrence (defined as the appearance of one or more new melanoma lesions: local, regional or distant)
C. You have not been treated with Yervoy for more than 3 years

References:

1. Yervoy package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised May 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IRINOTECAN LIPOSOMAL Edition 1	ONIVYDE	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **IRINOTECAN LIPOSOMAL (Onivyde)** requires the following rule(s) be met for approval:

A. You have metastatic adenocarcinoma of the pancreas (type of pancreas cancer that has spread)
B. You have experienced disease progression (disease has worsened) despite a trial of gemcitabine-based therapy (type of cancer drug)
C. Onivyde (irinotecan liposomal) will be used in combination with fluorouracil and leucovorin

References:

1. Onivyde package insert. Cambridge, MA. Merrimack Pharmaceuticals, Inc. Revised October 2015. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ISATUXIMAB-IRFC Edition 1	SARCLISA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **ISATUXIMAB-IRFC (Sarclisa)** requires the following rule(s) be met for approval:

A. You have multiple myeloma (type of white blood cell cancer) OR relapsed or refractory multiple myeloma (type of white blood cell cancer that has returned or no longer responds to treatment)
B. You are 18 years of age or older
C. **If you have multiple myeloma, approval also requires:**
    a. The requested medication will be used in combination with pomalidomide and dexamethasone
    b. You have received at least two prior therapies including lenalidomide and a proteasome inhibitor (such as ixazomib, carfilzomib)
D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
    a. The requested medication will be used in combination with carfilzomib and dexamethasone
    b. You have received 1 to 3 prior lines of therapy

References

1. Sarclisa package insert. Bridgewater, NJ. Sanofi-Aventis US LLC. Revised March 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IXABEPILONE Edition 1	IXEMPRA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic (cancer that has spread to other parts of body) or locally advanced breast cancer
B. You meet **ONE** of the following:
    1. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), a taxane (paclitaxel or docetaxel), and Xeloda (capecitabine) **OR**
    2. You had a trial of a chemotherapy (drugs used to treat cancer) regimen containing an anthracycline (doxorubicin or epirubicin), and a taxane (paclitaxel or docetaxel) **AND** the requested medication is being used in combination with Xeloda (capecitabine)

References:

1. Ixempra package insert. Princeton, NJ. R-Pharm US LLC. Revised January 2016. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

LETERMOVIR IV			
Generic	Brand	Reviewed	Effective Date
LETERMOVIR IV Edition 1	PREVYMIS INJ	01/28/2022	6/1/2021
LETERMOVIR ORAL	PREVYMIS TABS		

REQUIREMENTS:

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

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

References:

1. Prevymis package insert. Whitehouse Station, NJ. Merck & Co.,Inc. Revised March 2020. Accessed November 2021.
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

Generic	Brand	Reviewed	Effective Date
LURBINECTEDIN Edition 1	ZEPZELCA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic small cell lung cancer (SCLC: type of lung cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You had disease progression (worsening) on or after platinum-based chemotherapy (such as carboplatin or cisplatin)

References:

1. Zepzelca package insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised June 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LUSPATERCEPT-AAMT Edition 1	REBLOZYL	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have anemia (low amount of healthy red blood cells)
B. You are 18 years of age or older
C. You have ONE of the following conditions:
    1. Beta thalassemia (blood disorder that reduces the production of hemoglobin) and you require regular red blood cell (RBC) transfusions
    2. Myelodysplastic syndromes (group of blood disorders caused when production of blood cells is disrupted) with ring sideroblasts (cells that contain rings of iron deposits) (MDS-RS)
    3. Myelodysplastic/myeloproliferative neoplasm (group of disorders in which the bone marrow makes too many white blood cells) with ring sideroblasts and thrombocytosis (excess of blood clotting cells (platelets)) (MDS/MPN-RS-T)
D. **If you have myelodysplastic syndromes with ring sideroblasts (MDS-RS) OR myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T), approval also requires:**
    1. You are failing an erythropoiesis (red blood cell production) stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks

References:

1. Reblozyl package insert. Summit, NJ. Celgene Corporation. Revised April 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LUTETIUM LU 177 DOTATATE Edition 1	LUTATHERA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs: type of hormone cancer in digestive tract)
B. You are 18 years of age or older
C. You will be treated with a long-acting octreotide (type of hormone) as maintenance therapy together with the requested medication
D. You have been previously treated with a long acting somatostatin analog (such as octreotide or lanreotide) before the request of this medication
E. You have **NOT** previously received 4 doses of Lutathera

References:

1. Lutathera package insert. Millburn, NJ. Advanced Accelerator Applications USA, Inc. Revised June 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MITOMYCIN Edition 1	JELMYTO	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with an oncologist (doctor who specializes in cancer) or urologist (doctor who specializes in the urinary tract and male reproductive organs)

RENEWAL CRITERIA

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

A. You have low grade Upper Tract Urothelial Cancer (LG-UTUC: type of cancer that grows in the upper part of the urinary system)
B. You were reassessed at no sooner than 3 months after initiation of Jelmyto
C. You showed complete response at the time of assessment

References:

1. Jelmyto package insert. Princeton, NJ. UroGen Pharma, Inc. Revised January 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MOGAMULIZUMAB-KPKC Edition 1	POTELIGEO	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **MOGAMULIZUMAB-KPKC (Poteligeo)** requires the following rule(s) be met for approval:

A. You have Mycosis Fungoides or Sezary syndrome (types of blood cancers that affect the skin)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or not responsive to therapy)
D. You have tried and failed at least one prior systemic therapy (treatment that travels in the blood throughout the body)

References:

1. Poteligeo package insert. Bedminster, NJ. Kyowa Kirin, Inc. Revised July 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MOXETUMOMAB PASUDOTOX-TDFK Edition 1	LUMOXITI	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **MOXETUMOMAB PASUDOTOX (Lumoxiti)** requires the following rule(s) be met for approval:

A. You have hairy cell leukemia (HCL: type of blood and bone marrow cancer)
B. You are 18 years of age or older
C. You have relapsed or refractory disease (disease has returned or is not responsive to therapy)
D. You have received at least two prior systemic therapies, including treatment with a purine nucleoside analog (type of drug that treats certain blood cancers)
E. You have NOT previously received 6 cycles of Lumoxiti

References:

1. Lumoxiti package insert. Rockville, MD. Innate Pharma Inc. Revised August 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NECITUMUMAB Edition 1	PORTRAZZA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. The medication will be used as a first-line treatment for metastatic squamous non-small cell lung cancer (NSCLC; type of lung cancer that has spread to other parts of the body) in combination with gemcitabine and cisplatin

References:

1. Portrazza package insert. Indianapolis, IN. Eli Lilly and Company. Revised November 2015. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NUSINERSEN Edition 1	SPINRAZA	01/28/2022	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. You have Spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)

B. Your diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1: type of protein in spinal cord) gene (such as homozygous deletions of SMN1, homozygous mutations of SMN1, compound heterozygous mutations in SMN1 [deletion of SMN1 on one allele and point mutation of SMN1 on the other allele])

C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center

D. If you are **pre-symptomatic (symptoms have not yet appeared), approval also requires:**
   1. There is documentation showing you have up to three copies of survival motor neuron 2 (*SMN2: type of protein in spinal cord*) based on screening done when you were a newborn)

E. **If you are symptomatic (symptoms have appeared), approval also requires:**
   1. The onset of spinal muscular atrophy (SMA) symptoms occurred before 20 years of age
   2. There is documentation showing you had a baseline motor function assessment by a neuromuscular (nerve and muscle) specialist or SMA specialist
   3. If you previously had gene therapy, you had less than expected clinical benefit with gene therapy

(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. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. You meet ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline. Some types of motor assessment tests include Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE) and Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
    2. You have improved, maintained, or demonstrated less than expected decline in other muscle function such as pulmonary (lung/breathing) function

References:

1. Spinraza package insert. Cambridge, MA. Biogen. Revised June 2020. Accessed November 2021.
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
OBINUTUZUMAB Edition 1	GAZYVA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)
   2. Follicular lymphoma (FL: type of cancer with abnormal immune cells)
   3. Stage II bulky, III or IV follicular lymphoma

B. **If you have chronic lymphocytic leukemia, approval also requires:**
   1. You have not received previous treatment for chronic lymphocytic leukemia
   2. The requested medication will be used in combination with chlorambucil

C. **If you have follicular lymphoma, approval also requires:**
   1. You have relapsed after or are refractory to (your disease has returned or is resistant to) a regimen containing Rituxan (rituximab)
   2. The requested medication will be used in combination with bendamustine for the initial six cycles OR as monotherapy (the only drug used in treatment) thereafter

D. **If you have stage II bulky, III or IV follicular lymphoma, approval also requires:**
   1. You are 18 years of age or older
   2. You have not received previous treatment for stage II bulky, III or IV follicular lymphoma
   3. The requested medication will be used in combination with chemotherapy for the initial six or eight cycles [bendamustine; CHOP (cyclophosphamide, daunorubicin, vincristine, prednisone or prednisolone); CVP (cyclophosphamide, vincristine, prednisone or prednisolone)] OR as monotherapy (the only drug used in treatment) thereafter

References:

1. Gazyva package insert. South San Francisco, CA. Genentech, Inc. Revised March 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OCRELIZUMAB Edition 1	OCREVUS	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Primary progressive multiple sclerosis (type of disease where body attacks its own nerves and it slowly gets worse)
   2. Relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) which includes clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)

B. **If you have primary progressive multiple sclerosis (PPMS), approval also requires:**
   1. You are 18 years of age or older

C. **If you have a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      i. You have previously tried any TWO agents indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)
      ii. You show signs of severe disease requiring high-efficacy disease modifying therapy (DMT) such as high lesion (affected areas) volume and/or count, walking disability, or rapid decline

References:

1. Ocrevus package insert. South San Francisco, CA. Genentech, Inc. Revised December 2020. Accessed November 2021.
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
DIROXIMEL FUMARATE Edition 1	VUMERITY	01/28/2022	6/1/2021

REQUIREMENTS:

The guideline named **DIROXIMEL FUMARATE (Vumerity)** requires a diagnosis of relapsing form of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. In addition, the following criteria must be met:

A. The patient is 18 years of age or older
B. 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 January 2021. Accessed November 2021.
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
MITOXANTRONE HCL Edition 1	NOVANTRONE	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **MITOXANTRONE** requires ONE of following rules be met for approval:

A. The medication is prescribed by or given in consultation with an oncologist (tumor/cancer doctor)
B. You have ONE of the following:
    1. Pain related to advanced refractory prostate cancer
    2. Acute nonlymphocytic leukemia (type of white blood cell cancer)
    3. Secondary progressive, progressive relapsing or worsening relapsing-remitting multiple sclerosis (disease where immune system attacks nerves)

References:

1. Mitoxantrone hydrochloride package insert. Lake Forest, IL. Hospira Inc. Revised May 2018. Accessed November 2021.
2. Mitoxantrone hydrochloride package insert. Schaumburg, IL. APP Pharmaceuticals, LLC. Revised January 2008. Accessed November 2021.
3. Mitoxantrone hydrochloride package insert. Irvine, CA. Teva Parenteral Medicines, Inc. Revised October 2021. Accessed November 2021.
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
OFATUMUMAB Edition 1	KESIMPTA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously trialed and failed generic dimethyl fumarate or glatiramer

References:

1. Kesimta package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2020. Accessed November 2021.
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
SIPONIMOD Edition 1	MAYZENT	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a diagnosis of relapsing forms of multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have trialed and failed either generic glatiramer or dimethyl fumarate
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

RENEWAL CRITERIA

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

A. You have a diagnosis of relapsing forms of secondary progressive multiple sclerosis (severe type of disease where immune system attacks nerves and returns after periods of no symptoms, and you continuously lose nerve function). This includes clinically isolated syndrome (occurs once), relapsing-remitting disease (symptoms return and go away), and active secondary progressive disease (advanced disease)
B. Your physician attests (confirms) you have demonstrated a clinical benefit compared to pre-treatment baseline
C. You do not have lymphopenia (low levels of a type of white blood cell)
D. You have CYP2C9 (type of enzyme) 1/1, 1/2, 2/2, 1/3, or 2/3 genotype

References:

1. Mayzent package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2021. Accessed November 2021.
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
OZANIMOD Edition 2	ZEPOSIA	01/28/2022	7/23/2021

REQUIREMENTS:

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

A. You are 18 years of age or older

B. You have one of the following diagnoses:

1. Relapsing form of multiple sclerosis (type of disease where body attacks its own nerves and symptoms return after treatment) to include clinically isolated syndrome (occurs once), relapsing-remitting disease (periods of symptoms and no symptoms), and active secondary progressive disease (advanced disease)
2. Moderately to severe active ulcerative colitis (UC)

C. If you have a Relapsing form of multiple sclerosis, approval also requires:

1.You had a previous trial of either generic glatiramer or dimethyl fumarate

D. If you have Moderate to severe UC approval also requires:

1. Therapy is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
2. You have previously tried at least ONE standard therapy such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine, unless there is a medical reason why you cannot (contraindication)
3. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Humira, Stelara SC

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

References:

1. Zeposia package insert. Summit, NJ. Celgene Corporation, Revised May 2021. Accessed November 2021.
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. 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 STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DIMETHYL FUMARATE Edition 1	TECFIDERA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), which includes clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have trialed and failed generic glatiramer

References:

1. Tecfidera package insert. Cambridge, MA. Biogen Inc. Revised January 2021. Accessed November 2021.
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
NATALIZUMAB Edition 1	TYSABRI	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for approval:

A. You have ONE of the following:
   1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract) OR
   2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return)and active secondary progressive disease (advanced disease)

B. **If you have moderate to severe Crohn's disease, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a gastroenterologist (digestive system doctor)
   3. You also tried or have a contraindication to (a medical reason why you cannot take a medication) at least one of the following conventional agents such as corticosteroids (for example, budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   4. You also tried or have a contraindication to (a medical reason why you cannot take a medication) one of the following formulary preferred immunomodulators: Humira **OR** Stelara (**NOTE:** Pharmaceutical samples from the prescriber or manufacturer assistance programs do not qualify.)

C. **If you have a relapsing form of multiple sclerosis (MS), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used as monotherapy (used by itself)
   3. You have previously tried **both** generic glatiramer and dimethyl fumarate

(Criteria continued on the next page)

REQUIREMENTS: NATALIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named **NATALIZUMAB (Tysabri)** requires the following rules be met for renewal:

A. You have ONE of the following:
    1. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects the lining of the digestive tract) OR
    2. A relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms goes away and returns), and active secondary progressive disease (advanced disease)

B. If you have moderate to severe Crohn's disease, approval also requires ONE of the following:
    1. **If you have received at least 12 months of Tysabri therapy, renewal also requires** that you have NOT received more than 3 months of corticosteroid within the past 12 months to control your Crohn's disease while on Tysabri
    2. **If you have only received 6 months of Tysabri therapy, renewal also requires** that you are NOT currently on corticosteroid therapy (you have slowly lowered the dose and stopped taking corticosteroids during the first 6 months of Tysabri therapy)

References:

1. Tysabri package insert. Cambridge, MA. Biogen Inc. Revised June 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ALEMTUZUMAB Edition 1	LEMTRADA	01/28/2022	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. You have a relapsing form of multiple sclerosis (MS: an illness where the immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have previously tried TWO drugs that have been FDA (Food and Drug Administration) approved for the treatment of relapsing forms of multiple sclerosis (MS) **(Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)

RENEWAL CRITERIA

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

A. You have a relapsing form of multiple sclerosis (MS: an illness where immune system eats away at the protective covering of the nerves), to include relapsing-remitting disease (symptoms go away and return) and active secondary progressive disease (advanced disease)
B. At least 12 months have passed since you received the most recent course of Lemtrada

References:

1. Lemtrada package insert. Cambridge, MA. Genzyme Corporation. Revised August 2021. Accessed November 2021.
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
TERIFLUNOMIDE Edition 1	AUBAGIO	01/28/2022	6/1/2021

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

A. You have a diagnosis of a relapsing form of multiple sclerosis (immune system eats away at protective covering of nerves and you have new or increasing symptoms), to include clinically isolated syndrome, relapsing-remitting disease (symptoms return and go away) and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have had a trial and failure of generic glatiramer or dimethyl fumarate

References:

1. Aubagio package insert. Cambridge, MA. Genzyme Corporation. Revised April 2021. Accessed November 2021.
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
CLADRIBINE Edition 1	MAVENCLAD	01/28/2022	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. You have a diagnosis of a relapsing form of multiple sclerosis (disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. You are 18 years of age or older
C. You have had a trial and failure of generic glatiramer or dimethyl fumarate

RENEWAL CRITERIA

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

A. You have a diagnosis of a relapsing form of multiple sclerosis (disease where body attacks its own nerves and returns after having no symptoms). This includes relapsing-remitting MS [RRMS], active secondary progressive MS [SPMS], etc.
B. Your physician attests/ confirms that you have demonstrated a clinical benefit compared to pre-treatment baseline (before you started therapy)
C. You do not have lymphopenia (low amount of a type of white blood cell called lymphocyte)
D. You have not received a total of two years of Mavenclad treatment

References:

1. Mavenclad package insert. Rockland, MA. EMD Serono, Inc. Revised March 2019. Accessed November 2021.
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

INTERFERONS FOR MULTIPLE SCLEROSIS Edition 1			
Generic	Brand	Reviewed	Effective Date
INTERFERON BETA-1A	AVONEX, AVONEX PEN	01/28/2022	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 a diagnosis of a relapsing form of multiple sclerosis to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease in patients 18 years of age or older disease AND meet the following criteria:

A. The patient is 18 years of age or older
B. The patient has trialed and failed either generic glatiramer or dimethyl fumarate.

References:

1. Avonex package insert. Cambridge, MA. Biogen Inc. Revised November 2021. Accessed November 2021.
2. Rebif package insert. Rockland, MA. EMD Serono, Inc. Revised November 2021. Accessed November 2021.
3. Betaseron package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised November 2021. Accessed November 2021.
4. Plegridy package insert. Cambridge, MA. Biogen Inc. Revised November 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FINGOLIMOD Edition 1	GILENYA	01/28/2022	6/1/2021

REQUIREMENTS:

The guideline named **FINGOLIMOD (Gilenya)** requires a diagnosis of a relapsing form of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in patients 10 years of age and older **AND** requires a trial of either generic glatiramer or dimethyl fumarate. In addition, approval requires the absence of medical history or cardiac events that are contraindicated with the use of Gilenya (those that may increase risk of cardiac events associated with Gilenya), which includes any of the following criteria:

A. A recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
B. A history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker
C. A baseline QTc interval 500ms or above
D. Concurrent treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)

References:

1. Gilenya package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2019. Accessed November 2021.
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
GLATIRAMER ACETATE Edition 1	COPAXONE, GLATOPA	01/28/2022	6/1/2021

REQUIREMENTS:

The guideline named **GLATIRAMER ACETATE (Copaxone)** requires a diagnosis of a relapsing form of multiple sclerosis.

References:

1. Copaxone package insert. Parsippany, NJ. Teva Neuroscience, Inc. Revised July 2020. Accessed November 2021.
2. Glatopa package insert. Princeton, NJ. Sandoz Inc. Revised July 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MONOMETHYL FUMARATE Edition 1	BAFIERTAM	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **MONOMETHYL FUMARATE (Bafiertam)** requires the following rule(s) be met for approval:

A. You have a relapsing form of multiple sclerosis (MS: immune system eats away at the protective covering of the nerves), to include clinically isolated syndrome (disease occurs once), relapsing-remitting disease (symptoms go away and return), and active secondary progressive disease (advanced disease)
B. You are 18 years of age or older
C. You have trialed and failed either generic glatiramer or dimethyl fumarate

References:

1. Bafiertam package insert. High Point, NC. Banner Life Sciences LLC. Revised April 2020. Accessed November 2021.
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
OFATUMUMAB Edition 1	ARZERRA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have chronic lymphocytic leukemia (CLL: type of blood and bone marrow cancer)

B. **If you have previously untreated chronic lymphocytic leukemia, approval also requires:**
   1. You have not received previous treatment for chronic lymphocytic leukemia
   2. Fludara (fludarabine)-based therapy is considered inappropriate for you
   3. The requested medication will be used in combination with chlorambucil

C. **If you have relapsed chronic lymphocytic leukemia (type of blood and bone marrow cancer that has returned), approval also requires:**
   1. The requested medication will be used in combination with Fludara (fludarabine) and cyclophosphamide

D. **If you are requesting extended treatment of chronic lymphocytic leukemia, approval also requires:**
   1. You are in complete or partial response
   2. You have received at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia

E. **If you have refractory chronic lymphocytic leukemia, approval also requires:**
   1. You are refractory (non-responsive) to Fludara (fludarabine) and Campath (alemtuzumab)

References:

1. Arzerra package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2016. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OLARATUMAB Edition 1	LARTRUVO	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have soft tissue sarcoma (STS: type of cancer that starts in soft tissues like muscles/tendons)
B. The request is for continuation of Lartruvo therapy (you are currently on Lartruvo)
C. The requested medication will be used in combination with doxorubicin for the first 8 cycles
D. The histologic subtype of sarcoma (the type of tissue cancer such as undifferentiated pleomorphic sarcoma, liposarcoma, leiomyosarcoma, synovial sarcoma, malignant peripheral nerve sheath tumors) may be appropriately treated with an anthracycline-containing regimen (a treatment plan that contains a specific type of cancer drug)
E. You are not responsive to curative treatment with radiotherapy or surgery

References:

1. Lartruvo package insert. Indianapolis, IN. Eli Lilly and Company. Revised October 2016. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ONASEMNOGENE ABEPARVOVEC-XIOI Edition 1	ZOLGENSMA	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have spinal muscular atrophy (SMA: genetic disorder where your muscles become weak and break down)
B. You are less than 2 years of age
C. The requested medication is prescribed by or given in consultation with a neuromuscular (nerve and muscle) specialist or spinal muscular atrophy (SMA) specialist at a SMA Specialty Center
D. You have documentation of gene mutation analysis with bi-allelic survival motor neuron 1 (SMN1: type of protein in spinal cord) mutations such as deletions and/or point mutations
E. You do NOT have anti-adeno-associated virus vector (anti-AAV9) antibody titers (amount of a type of immune system cells in blood) greater than 1:50 as determined by an enzyme linked immunosorbent assay (ELISA: type of lab test)
F. You do NOT have advanced spinal muscular atrophy (SMA) such as complete paralysis of the limbs or permanent ventilator dependence

References:

1. Zolgensma package insert. Bannockburn, IL. Novartis Gene Therapies, Inc. Revised October 2021. Accessed November 2021.
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
PANITUMUMAB Edition 1	VECTIBIX	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic colorectal cancer (mCRC: colon cancer that has spread to other parts of the body) with wild-type RAS gene (a gene called RAS when it is found in its natural, unchanged form). Wild-type RAS is defined as wild-type in both the KRAS gene and NRAS gene, as determined by a Food and Drug Administration (FDA)-approved test for this use

B. You must meet ONE of the following:
   1. Vectibix will be used as monotherapy (the only drug used to treat your cancer) AND you have been treated in the past with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing cancer treatment (chemotherapy)
   2. Vectibix will be used in combination with FOLFOX (regimen containing leucovorin calcium [folinic acid], fluorouracil, oxaliplatin)

References:

1. Vectibix package insert. Thousand Oaks, CA. Amgen Inc. Revised August 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PATISIRAN Edition 1	ONPATTRO	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: rare genetic disorder described by abnormal build-up of protein in the body's organs and tissues) with polyneuropathy (nerve damage/pain all over your body)
B. You are 18 years of age or older
C. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by ONE of the following:
    1. Biopsy (surgical removal of a sample) of tissue/organ to confirm amyloid (abnormal protein that can build up in any tissue or organ) presence AND chemical typing to confirm the presence of TTR protein
    2. DNA genetic sequencing (lab test for genes) to confirm hereditary transthyretin-mediated amyloidosis (hATTR)
D. The requested medication is prescribed by or given in consultation with a neurologist (nerve doctor), cardiologist (heart doctor), or a physician at an amyloidosis treatment center (center that treats a certain type of genetic disease), or medical geneticist
E. You have Stage 1 or 2 polyneuropathy (nerve damage/pain all over your body)

RENEWAL CRITERIA

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

A. You have hereditary transthyretin-mediated amyloidosis (hATTR: rare genetic disorder described by abnormal build-up of protein in the body's organs and tissues) with polyneuropathy (nerve damage/pain all over your body)
B. You have not progressed to stage 3 polyneuropathy as evidenced by functional decline such as being wheelchair-bound or bedridden

References:

1. Onpattro package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised May 2021. Accessed November 2021.
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
PEGAPTANIB SODIUM Edition 1	MACUGEN	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have neovascular (wet) age-related macular degeneration (a chronic eye disorder that causes blurred vision or a blind spot in your visual field)
B. The medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) and/or retina specialist

References:

1. Macugen package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised July 2016. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PEGLOTICASE Edition 1	KRYSTEXXA	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **PEGLOTICASE (Krystexxa)** requires the following rules be met for approval:

A. You have chronic gout that is refractory to conventional therapy (resistant to standard treatments)
B. You are 18 years of age or older
C. You have symptomatic gout as shown by **ONE** of the following:
    1. At least 3 or more gout flares in the previous 18 months
    2. History of at least 1 gout tophus (uric acid crystallizes in joints like hands/feet)
    3. Gouty arthritis (severe pain and inflammation in joints due to gout)
D. You had a baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications such as allopurinol, lesinurad
E. You do not have glucose-6-phosphate dehydrogenase (G6PD) deficiency (you are missing an enzyme that helps red blood cells work properly)
F. You will not be on urate-lowering therapy (such as xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad) at the same time as using pegloticase
G. You have experienced failure, contraindication (medical reason why you cannot use), intolerance or inadequate response to previous therapy with a maximum tolerated dose for TWO conventional gout medications for at least 3 months (such as allopurinol, probenecid, lesinurad)

RENEWAL CRITERIA

Our guideline named **PEGLOTICASE (Krystexxa)** requires a sustained serum uric level below 6 mg/dL for renewal.

References:

1. Krystexxa package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised March 2021. Accessed November 2021.
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
PEMETREXED DISODIUM Edition 1	ALIMTA	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **PEMETREXED (Alimta)** the following rules be met for approval:

A. You have one of the following diagnoses:
   1. Locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC)
   2. Metastatic, non-squamous, non-small cell lung cancer (NSCLC)
   3. Recurrent, metastatic non-squamous, non-small cell lung cancer (NSCLC)
   4. Malignant pleural mesothelioma (cancer of the protective lining of the lung)

B. **If you have locally advanced or metastatic, non-squamous, non-small cell lung cancer, approval also requires ONE of the following:**
   1. The requested medication is being used in combination with cisplatin for initial treatment
   2. The requested medication is being used as a single agent, maintenance therapy AND your disease has not progressed (gotten worse) after four cycles of platinum-based first-line chemotherapy

C. **If you have metastatic, non-squamous, non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used for initial (starting) treatment
   2. The requested medication is being used in combination with pembrolizumab and platinum chemotherapy
   3. You do NOT have EGFR (Epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic tumor aberrations (types of gene mutations)

D. **If you have recurrent, metastatic non-squamous, non-small cell lung cancer, approval also requires:**
   1. The requested medication is being used as a single agent
   2. You have received prior chemotherapy

E. **If you have malignant pleural mesothelioma (cancer of the protective lining of the lung), approval also requires:**
   1. The requested medication is being used in combination with cisplatin for initial (starting) treatment
   2. Your disease is unresectable (cannot be completely removed by surgery) OR you are not a candidate for curative surgery

References:

1. Alimta package insert. Indianapolis, IN. Eli Lilly and Company. Revised January 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PLERIXAFOR Edition 1	MOZOBIL	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have Non-Hodgkin's lymphoma (cancer of a part of the immune system called the lymph system) or multiple myeloma (cancer that forms in a type of white blood cell called a plasma cell)

B. The medication is prescribed by or given in consultation with a hematologist or oncologist (blood or cancer doctor)

References:

1. Mozobil package insert. Cambridge, MA. Genzyme Corporation. Revised August 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
POLATUZUMAB VEDOTIN-PIIQ Edition 1	POLIVY	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **POLATUZUMAB VEDOTIN (Polivy)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (a type of cancer that affects your white blood cells and returns or resistant to treatment)
B. You are at least 18 years old
C. The requested drug will be used in combination with bendamustine and a rituximab product (type of cancer drug)
D. You have had at least two prior therapies.
E. You are not a candidate for autologous hematopoietic stem cell transplant (cells transferred from your own body)

References:

1. Polivy package insert. South San Francisco, CA. Genentech, Inc. Revised September 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PORFIMER SODIUM Edition 1	PHOTOFRIN	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **PORFIMER (Photofrin)** requires that the drug is being used for one of the following conditions:

A. The reduction of blockage and palliation of symptoms (treatment focused on relief from the symptoms and stress of a serious illness) in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC) or,
B. Treatment of microinvasive endobronchial non-small cell lung cancer (a type of lung cancer that involves airway blockage) where surgery and radiation therapy cannot be used; or
C. Helping to lessen your symptoms with completely obstructing or partially obstructing esophageal cancer, where in the opinion of your physician, you cannot be treated with Nd:YAG laser therapy (a high intensity laser that can be used to remove cancer) or,
D. The ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy (removal of precancerous cells of the esophagus and you did not have surgical treatment for esophageal cancer)

References:

1. Photofrin package insert. Bannockburn, IL. Pinnacle Biologics, Inc. Revised December 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PRALATREXATE Edition 1	FOLOTYN	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **PRALATREXATE (Folotyn)** requires a diagnosis of relapsed or refractory peripheral T-cell lymphoma (a type of white blood cell cancer that returns or does not fully respond to treatment).

References:

1. Folotyn package insert. East Windsor, NJ. Acrotech Biopharma LLC. Revised September 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RAMUCIRUMAB Edition 1	CYRAMZA	01/28/2022	6/1/2021

REQUIREMENTS:
Our guideline named **RAMUCIRUMAB (Cyramza)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Advanced or metastatic (cancer that has spread to other parts of the body), gastric cancer or gastro-esophageal junction adenocarcinoma (cancer of the stomach or caner of the esophagus [tube that connects mouth and stomach])
    2. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of your body)
    3. Metastatic colorectal cancer (type of colon or rectum cancer that has spread to other parts of the body)
    4. Hepatocellular carcinoma (type of liver cancer)

B. **If you have advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, approval also requires:**
    1. The requested medication will be used as a single agent or in combination with paclitaxel
    2. You have experienced disease progression (disease has worsened) on or after prior fluoropyrimidine-containing chemotherapy (examples include fluorouracil [5-FU], capecitabine, floxuridine) OR platinum-containing chemotherapy (examples include cisplatin, oxaliplatin, carboplatin)

C. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires ONE of the following:**
    1. The requested medication will be used in combination with docetaxel, and you meet ONE of the following:
        i. You have experienced disease progression (disease has worsened) on or after platinum-based chemotherapy (cisplatin, oxaliplatin, carboplatin)
        ii. You have an epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK : type of enzyme) genomic tumor abnormality AND your disease has gotten worse on a Food and Drug Administration (FDA)-approved therapy (examples include Tarceva, Gilotrif, Xalkori, or Zykadia) prior to receiving Cyramza
    2. The requested medication will be used in combination with erlotinib as first-line treatment AND your tumors have epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 (L858R) substitution mutations

(Criteria continued on next page)

REQUIREMENTS: RAMUCIRUMAB (CONTINUED)

D. **If you have metastatic colorectal cancer, approval also requires:**
    1. The requested medication will be used in combination with FOLFIRI (drug combination of irinotecan, folinic acid, and 5-fluorouracil)
    2. You have experienced disease progression (disease has worsened) on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine (such as 5-fluorouracil or capecitabine)
E. **If you have hepatocellular carcinoma, approval also requires:**
    1. The requested medication will be used as a single agent
    2. You have an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL
    3. You have been treated with sorafenib (Nexavar)

References:

1. Cyramza package insert. Indianapolis, IN. Eli Lilly and Company. Revised June 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RANIBIZUMAB Edition 1	LUCENTIS	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have a diagnosis of neovascular (wet) age-related macular degeneration (abnormal blood vessels form in your eye causing vision loss), diabetic macular edema (buildup of fluid in the eye affecting vision), diabetic retinopathy (damage to blood vessels in the eye due to high blood sugar), macular edema following retinal vein occlusion (buildup of fluid in eye due to vein blockage), or myopic choroidal neovascularization (abnormal blood vessels grow in the back of the eye).

B. The medication is prescribed by an ophthalmologist (doctor who specializes in medical and surgical eye disease) or retina specialist.

References:

1. Lucentis package insert. South San Francisco, CA. Genentech, Inc. Revised March 2018. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RESLIZUMAB Edition 1	CINQAIR	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You are 18 years of age or older
C. Cinqair is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
D. Cinqair will be used as add-on maintenance treatment
E. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
F. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
G. You have experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
H. You are not being treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (such as Nucala, Fasenra) at the same time with requested medication

RENEWAL CRITERIA

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

A. You have severe asthma with an eosinophilic phenotype (inflammatory type of asthma where there is a high number of a type of white blood cell)
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV_1 (type of lung test) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms such as wheezing, shortness of breath, coughing, etc.

(Criteria continued on next page)

REQUIREMENTS: RESLIZUMAB (CONTINUED)

References:

1. Cinqair package insert. Frazer, PA. Teva Respiratory, LLC. Revised January 2019. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

ROMOSOZUMAB			
Generic	Brand	Reviewed	Effective Date
ROMOSOZUMAB-AQQG Edition 1	EVENITY	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have postmenopausal osteoporosis (weak and brittle bones)
B. You have not received a total of 12 months or more of Evenity therapy.
C. You meet **ONE** of the following criteria:
    1. You are at high risk for fractures defined as **ONE** of the following:
        i. History of osteoporotic (fragility, low trauma) fracture(s)
        ii. 2 or more risk factors for fracture such as history of multiple recent low trauma fractures, bone marrow density [BMD] T-score (measurement of how high your risk for osteoporosis is) less than or equal to -2.5, corticosteroid use, or use of gonadotropin-releasing hormone [GnRH] analogs such as nafarelin, etc.
        iii. No prior treatment for osteoporosis **AND** FRAX score (test for your risk of fractures) greater than or equal to 20% for any major fracture **OR** greater than or equal to 3% for hip fracture
    2. You are unable to use oral therapy. Reasons include upper gastrointestinal [GI] problems -unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine
    3. You had an adequate trial of, intolerance to, or a contraindication to (medical reason why you cannot use) bisphosphonates such as Fosamax, Actonel, Boniva

References:

1. Evenity package insert. Thousand Oaks, CA. Amgen Inc. Revised December 2019. Accessed November 2021
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
SEBELIPASE ALFA Edition 1	KANUMA	01/28/2022	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. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol), as confirmed by the presence of clinical features such as hepatomegaly (enlarged liver), elevated serum transaminases (types of enzymes), dyslipidemia (abnormal levels of fats), splenomegaly (enlarge spleen)

B. The medication is prescribed by or given in consultation with an endocrinologist (hormone doctor), hepatologist (liver specialist), gastroenterologist (digestive system doctor), medical geneticist, or lipidologist (cholesterol management specialist)

C. You meet ONE of the following:
   1. A blood test indicating low or absent levels of lysosomal acid lipase enzyme activity
   2. A dried blood spot test indicating low or absent lysosomal acid lipase enzyme activity
   3. A genetic test indicating the bi-allelic presence of altered LIPA gene(s) (you have a change in a gene that provides instructions for producing an enzyme called lysosomal acid lipase)

RENEWAL CRITERIA

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

A. You have lysosomal acid lipase (LAL) deficiency (inherited condition where your body cannot breakdown and use fats and cholesterol) presenting after the first 6 months of life and not considered rapidly progressive (getting worse)

B. You have documented improvement in ONE of the following clinical parameters associated with lysosomal acid lipase (LAL) deficiency during the past 6 months:
   1. A relative reduction from baseline in any one of the following lipid levels (fat lab measurements such as LDL-c, Non-HDL-c, or triglycerides)
   2. Normalization of aspartate aminotransferase (AST: type of liver enzyme) based on age- and gender-specific normal ranges
   3. A decrease in liver fat content compared to baseline assessed by abdominal imaging such as multi-echo gradient echo [MEGE] MRI

(Criteria continued on next page)

REQUIREMENTS: SEBELIPASE ALFA (CONTINUED)

References:

1. Kanuma package insert. Boston MA. Alexion Pharmaceuticals, Inc. Revised November 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SILTUXIMAB Edition 1	SYLVANT	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have multi-centric Castleman's disease (MCD: disease that affects the lymph nodes and related tissues)
B. You are negative for both human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8)

References:

1. Sylvant package insert. Hemel Hempstead, Hertfordshire, U.K. EUSA Pharma (UK), Ltd. Revised December 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TAGRAXOFUSP-ERZS Edition 1	ELZONRIS	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **TAGRAXOFUSP-ERZS (Elzonris)** requires the following rule(s) be met for approval:

A. You have blastic plasmacytoid dendritic cell neoplasm (BPDCN: aggressive and rare disease of the bone marrow and blood that can affect multiple organs)
B. You are 2 years of age or older

References:

1. Elzonris package insert. New York, NY. Stemline Therapeutics, Inc. Revised December 2018. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TALIMOGENE LAHERPAREPVEC Edition 1	IMLYGIC	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline for **TALIMOGENE LAHERPAREPVEC (Imlygic)** requires the following rule(s) be met for approval:

A. You have unresectable melanoma (type of skin cancer that cannot be removed with surgery)
B. Your melanoma lesions are recurrent after initial surgery (cancer returns after surgery)
C. You do not have a history of primary or acquired immunodeficient states (conditions that weaken your immune system), leukemia (type of white blood cell cancer), lymphoma (type of cancer affecting immune system), or Acquired Immunodeficiency Syndrome (AIDS)
D. You are not currently receiving immunosuppressive therapy (treatment that weakens your immune system)
E. You are not receiving concurrent medical therapy for the treatment of melanoma including pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), dabrafenib (Tafinlar), trametinib (Mekinist), vemurafenib (Zelboraf), interleukin-2, interferon, dacarbazine, temozolomide (Temodar), paclitaxel, carboplatin, imatinib (Gleevec), melphalan (Alkeran), imiquimod, or radiation therapy
F. The request is for Imlygic to be injected into cutaneous, subcutaneous, and/or nodal lesions (injected into the skin layers) that are visible, palpable (can be felt), or detectable by ultrasound guidance

References:

1. Imlygic package insert. Thousand Oaks, CA. BioVex, Inc. Revised October 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEMOZOLOMIDE – IV Edition 1	TEMODAR - IV	01/28/2022	6/1/2021
TEMOZOLOMIDE – ORAL	TEMODAR - ORAL		

REQUIREMENTS:

Our guideline named **TEMOZOLOMIDE (Temodar)** requires you have one of the following diagnoses for approval:

A. Metastatic melanoma (type of skin cancer)
B. Anaplastic astrocytoma (type of brain tumor)
C. Glioblastoma multiforme (type of tumor affecting brain or spine)
D. Small cell lung cancer (SCLC)

References:

1. Temodar package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised November 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

TEMSIROLIMUS			
Generic	Brand	Reviewed	Effective Date
TEMSIROLIMUS Edition 1	TORISEL	01/28/2022	6/1/2021

REQUIREMENTS:

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

A. You have advanced renal cell carcinoma (RCC: type of kidney cancer).

References:

1. Torisel package insert. Philadelphia, PA. Pfizer Inc. Revised March 2018. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

THYROTROPIN ALFA FOR INJECTION			
Generic	Brand	Reviewed	Effective Date
THYROTROPIN ALFA Edition 1	THYROGEN	01/28/2022	6/1/2021

REQUIREMENTS:

Our guideline named **THYROTROPIN ALFA FOR INJECTION (Thyrogen)** requires that the requested product is being used as adjunctive (add-on) treatment for radioiodine ablation of thyroid tissue remnants for thyroid cancer without evidence of metastatic disease (used to destroy thyroid tissue that is left over after using another treatment and you have no signs of the disease spreading in body)

References:

1. Thyrogen package insert. Cambridge, MA. Genzyme Corporation. Revised March 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRASTUZUMAB Edition 1	HERCEPTIN	01/28/2022	6/1/2021
TRASTUZUMAB HYALURONIDASE-OYSK	HERCEPTIN HYLECTA		
TRASTUZUMAB-PKRB	HERZUMA		
TRASTUZUMAB-ANNS	KANJINTI		
TRASTUZUMAB-DKST	OGIVRI		
TRASTUZUMAB-DTTB	ONTRUZANT		
TRASTUZUMAB-QYYP	TRAZIMERA		

REQUIREMENTS:

Our guideline named **TRASTUZUMAB (Herceptin, Herceptin Hylecta, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   2. Breast cancer
   3. Metastatic gastric or gastroesophageal junction adenocarcinoma (cancer in the stomach and/or lower throat that has spread to other parts of the body)

B. If you have metastatic breast cancer, approval also requires:
   1. You have HER2-positive tumor (type of protein found in breast cancer) as detected by a Food and Drug Administration (FDA)-approved test
   2. You meet ONE of the following:
      i. The requested medication is being used in combination with paclitaxel for first-line treatment
      ii. The requested medication is being used as a single agent if you have previously tried chemotherapy for metastatic disease (disease has spread to other areas of body)
   3. If you are requesting Herceptin Hylecta, you must be 18 years of age or older
   4. If you are requesting Herceptin, Herceptin Hylecta, Herzuma, Ontruzant**,** you previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri

(Criteria continued on next page)

REQUIREMENTS: TRASTUZUMAB (CONTINUED)

C. If you have breast cancer, approval also requires:
1. The request is for adjuvant therapy (add-on therapy to main treatment)
2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) tumor as detected by a Food and Drug Administration (FDA)-approved test
3. You meet ONE of the following:
    i. The requested medication is being used as part of a treatment plan that includes doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
    ii. The requested medication is being used as part of a treatment plan with docetaxel and carboplatin
    iii. The requested medication is being used as a single agent following multi-modality anthracycline based therapy (therapy using a class of cancer drug that combines more than one method of treatment) such as daunorubicin, doxorubicin, idarubicin, epirubicin, or valrubicin
4. If you are requesting Herceptin, Herceptin Hylecta, Herzuma, Ontruzant, you previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Kanjinti, Trazimera, or Ogivri
5. If you are requesting Herceptin Hylecta, you must be 18 years of age or older

D. If you have metastatic gastric or gastroesophageal junction adenocarcinoma (stomach throat cancer that has spread), approval also requires:
1. The request is for Herceptin (not Herceptin Hylecta)
2. You have HER2-overexpressing (HER2-positive: a type of breast cancer gene) metastatic breast cancer as detected by a Food and Drug Administration (FDA)-approved test
3. The requested medication is being used in combination with cisplatin and capecitabine or 5- fluorouracil
4. You have not received prior treatment for metastatic disease (disease has spread to other parts of the body)

References:

1. Herceptin package insert. South San Francisco, CA. Genentech, Inc. Revised February 2021. Accessed November 2021.
2. Herceptin Hylecta package insert. South San Francisco, CA. Genentech, Inc. Revised February 2019. Accessed November 2021.
3. Herzuma package insert. North Wales, PA. Teva Pharmaceuticals USA, Inc. Revised May 2019. Accessed November 2021
4. Ontruzant package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised January 2019. Accessed November 2021.
5. Kanjinti package insert. Thousand Oaks, CA. Amgen Inc. Revised October 2019. Accessed November 2021.
6. Trazimera package insert. New York, NY. Pfizer Inc. Revised March 2019. Accessed November 2021.
7. Ogivri package insert. Steinhausen, Switzerland. Mylan GmbH. Revised April 2019. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BARICITINIB Edition 1	OLUMIANT	01/28/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **BARICITINIB (Olumiant)** requires a diagnosis of moderate to severe rheumatoid arthritis. In addition, the following criteria must also be met:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **BARICITINIB (Olumiant)** requires a diagnosis of moderate to severe rheumatoid arthritis and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

References:

1. Olumiant package insert. Indianapolis, IN. Lilly USA, LLC, Revised December 2021. Accessed December 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEPROTUMUMAB-TRBW Edition 1	TEPEZZA	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have thyroid eye disease (a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards)

References:

1. Tepezza package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised October 2021. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TISAGENLECLEUCEL Edition 1	KYMRIAH	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. B-cell precursor acute lymphoblastic leukemia (ALL: type of immune system cancer)
    2. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of immune system cancer that has returned or did not fully respond to previous treatment) not otherwise specified, high grade B-cell lymphoma (type of white blood cell cancer), or DLBCL arising from follicular lymphoma (FL: type of white blood cell cancer) such as transformed follicular lymphoma

B. Treatment is prescribed by a Kymriah-certified hematologist (blood specialist) or oncologist (tumor/ cancer doctor)

C. Kymriah will be administered at a treatment center that is certified to administer Kymriah

D. You have not had a previous trial of Kymriah

E. **If you have B-cell precursor acute lymphoblastic leukemia (ALL), approval also requires:**
    1. You are 25 years of age or younger
    2. You have **ONE** of the following criteria:
        i. You are in second or greater bone marrow relapse (disease returns)
        ii. You are currently in bone marrow relapse after having undergone allogeneic stem cell transplantation (SCT: donor cells are from another person)
        iii. You have not achieved minimal residual disease (MRD) negative complete remission after two cycles of a standard chemotherapy regimen (you have primary refractory disease)
        iv. You have not achieved complete remission after one cycle of standard chemotherapy for relapsed leukemia (i.e., chemorefractory relapsed leukemia)
        v. You have Philadelphia chromosome positive (Ph+; type of gene mutation) acute lymphoblastic leukemia and meets at least **ONE** of the following:
            1. You had a previous trial of 2 or more tyrosine kinase inhibitors (TKIs)
            2. You are unable to tolerate TKI therapy
            3. You have a medical reason why you cannot take TKI therapy (contraindication)
        vi. You are not eligible for allogeneic stem cell transplantation (SCT)

(Criteria continued on next page)

REQUIREMENTS: TISANGENLECLEUCEL (CONTINUED)

F. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma (FL) [i.e., transformed follicular lymphoma (TFL)], approval also requires:**
    1. You are 18 years of age or older
    2. You meet **ALL** of the following criteria:
        i. You are refractory (disease does not fully respond to treatment) or have had disease progression (gotten worse) after two or more lines of systemic therapy including rituximab and an anthracycline
        ii. You had disease progression or relapsed (disease worsens or returns) after autologous hematopoietic stem cell transplantation (ASCT) **OR** you are not eligible for ASCT

References:

1. Kymriah package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRABECTEDIN Edition 1	YONDELIS	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have unresectable or metastatic liposarcoma or leiomyosarcoma (cancer of the fat cells or muscles that cannot be removed with surgery or has spread to other parts of body).

B. You have previously received therapy with an anthracycline-containing regimen such as doxorubicin.

References:

1. Yondelis package insert. Horsham, PA. Janssen Products, LP. Revised June 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VESTRONIDASE ALFA-VJBK Edition 1	MEPSEVII	4/29/2022	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. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
B. The requested medication is prescribed by or given in consultation with a physician specializing in genetic or metabolic disorders
C. You have a documented urinary GAG (glycosaminoglycan: type of chemical that builds up when your body cannot break it down) level of greater than three times the upper level of normal based on the laboratory test
D. Your diagnosis of Mucopolysaccharidosis VII is confirmed by documentation of betaglucuronidase enzyme activity deficiency (you don't have a protein that breaks down a chemical) or genetic testing
E. You have at least ONE of the following clinical signs of Mucopolysaccharidosis VII:
    1. Enlarged liver and spleen
    2. Joint limitations
    3. Airway obstructions or pulmonary (lung/breathing) dysfunction
F. You have not undergone successful bone marrow or stem cell treatment for Mucopolysaccharidosis VII
G. You have limitation in mobility, but you still have ambulatory (walking) capacity for the six-minute walk test (6MWT) to be measured and evaluated

RENEWAL CRITERIA

Our guideline named **VESTRONIDASE ALFA-VJBK (Mepsevii)** requires the following rule(s) be met for renewal:

A. You have Mucopolysaccharidosis VII (MPS VII, Sly syndrome: genetic metabolism disorder that does not allow the body to break down a certain chemical)
B. You have improved, maintained, or demonstrated less than expected decline in ambulatory (walking) ability based on a six-minute walk test compared to baseline

References:

1. Mepsevii package insert. Novato, CA. Ultragenyx Pharmaceutical Inc. Revised December 2020. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VINCRISTINE SULFATE LIPOSOMAL Edition 1	MARQIBO	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **VINCRISTINE SULFATE LIPOSOMAL (Marqibo)** requires the following rule(s) be met for approval:

A. You have Philadelphia chromosome-negative (Ph-) acute lymphoblastic leukemia (a type of cancer that does not have a certain gene mutation)
B. You meet ONE of the following criteria:
    1. You have experienced a relapse (disease returns) two or more times
    2. You have experienced disease progression after treatment with two or more anti-leukemia therapies

References:

1. Marqibo package insert. East Windsor, NJ. Acrotech Biopharma LLC. Revised June 2020. Accessed March 2022..

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VORETIGENE NEPARVOVEC-RZYL Edition 1	LUXTURNA	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have confirmed biallelic RPE65 mutation-associated retinal dystrophy (loss of vision in one or both eyes due to a gene mutation)
B. You are 3 years of age or older
C. Your diagnosis of biallelic RPE65 (type of gene) mutation-associated retinal dystrophy is confirmed by documentation of genetic testing
D. The requested medication is prescribed by or given in consultation with an ophthalmologist (eye doctor) or retinal specialist
E. You have a visual acuity of 20/60 or worse or a visual field less than 20 degrees in any meridian in both eyes
F. You have enough retinal cells as demonstrated by sufficient retinal thickness
G. You do **NOT** have pre-existing eye conditions that may lead to blindness independently of RPE65 (type of gene) -mutation associated retinal dystrophy. Pre-existing eye conditions may include leukemia (type of cancer) with Central Nervous System/optic nerve involvement, macular edema (fluid buildup in the eye) or cytomegalovirus retinitis (inflammation of the retina of the eye that can lead to blindness)
H. You have **NOT** previously received gene therapy (including Luxturna) for the treatment of vision loss
I. The procedure and administration of Luxturna will be completed at a designated specialty Luxturna treatment center

References:

1. Luxturna package insert. Philadelphia, PA. Spark Therapeutics, Inc. Revised June 2020. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ZIV-AFLIBERCEPT Edition 1	ZALTRAP	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic colorectal cancer (cancer has spread in body)
B. You previously had a trial of an oxaliplatin-containing regimen (such as FOLFOX)
C. You will be using the requested medication with fluorouracil, leucovorin, irinotecan (FOLFIRI) at the same time

References:

1. Zaltrap package insert. Bridgewater, NJ. sanofi-aventis U.S. LLC. Revised June 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

ANTIMIGRAINE AGENTS Edition 1			
Generic	Brand	Reviewed	Effective Date
ALMOTRIPTAN	AXERT	4/29/2022	6/1/2021
ELETRIPTAN HBR	RELPAX		
FROVATRIPTAN SUCCINATE	FROVA		
NARATRIPTAN HCL	AMERGE		
RIZATRIPTAN BENZOATE	MAXALT, MAXALT MLT		
SUMATRIPTAN	IMITREX NASAL SPRAY		
SUMATRIPTAN SUCCINATE	ALSUMA, IMITREX, SUMAVEL DOSEPRO		
SUMATRIPTAN SUCC/ NAPROXEN SOD	TREXIMET		
ZOLMITRIPTAN	ZOMIG, ZOMIG ZMT		

REQUIREMENTS:

Our guideline for **ANTIMIGRAINE AGENTS** requires a trial of a formulary prophylactic migraine agent such as calcium channel blockers, beta blockers, tricyclic antidepressants, or anticonvulsants.

References:

1. Axert package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised May 2017. Accessed February 2022.
2. Relpax package insert. New York, NY. Pfizer Inc. Revised March 2020. Accessed February 2022.
3. Frova package insert. Malvern, PA. Endo Pharmaceuticals Inc. Revised August 2018. Accessed February 2022.
4. Amerge package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised November 2016. Accessed February 2022.
5. Maxalt package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised October 2019. Accessed February 2022.
6. Imitrex package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised December 2017. Accessed February 2022.
7. Alsuma package insert. New York, NY. Pfizer Inc. Revised April 2014. Accessed February 2022.
8. Sumavel package insert. Malvern, PA. Endo Pharmaceuticals Inc. Revised January 2020. Accessed February 2022.
9. Treximet package insert. Morristown, NJ. Currax Pharmaceuticals LLC. Revised April 2021. Accessed February 2022.
10. Zomig package insert. Hayward, CA. Impax Specialty Pharma. Revised December 2018. Accessed February 2022.
11. Oskoui M, Pringsheim T, Holler-Managan Y, et al. Practice guideline update summary: Acute treatment of migraine in children and adolescents: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society [published correction appears in Neurology. 2020 Jan 7;94(1):50]. Neurology. 2019;93(11):487-499. doi:10.1212/WNL.0000000000008095.

12. 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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEMPEDOIC ACID Edition 1	NEXLETOL	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have **ONE** of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])

B. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

(Criteria continued on next page)

REQUIREMENTS: BEMPEDOIC ACID (CONTINUED)

RENEWAL CRITERIA

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

A. You have **ONE** of the following diagnoses:
    1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
    2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)
B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering
C. You meet **ONE** of the following:
    1. You have continued therapy with a maximally tolerated dose of any statin
    2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
    3. You have complete statin intolerance

References:

1. Nexletol package insert. Ann Arbor, MI. Esperion Therapeutics, Inc. Revised February 2020. Accessed February 2022.
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 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
BEMPEDOIC ACID AND EZETIMIBE Edition 1	NEXLIZET	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol]

B. You are 18 years of age or older

C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You previously had a trial of ezetimibe

E. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL

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

(Criteria continued on next page)

REQUIREMENTS: BEMPEDOIC ACID AND EZETIMIBE (CONTINUED)

G. If you are statin intolerant, approval also requires ONE of the following:

1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
   2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)

B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering

C. You meet **ONE** of the following:
   1. You have continued therapy with a maximally tolerated dose of any statin
   2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   3. You have complete statin intolerance

References:

1. Nexlizet package insert. Ann Arbor, MI. Esperion Therapeutics, Inc. Revised February 2020. Accessed February 2022.
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 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
CINACALCET Edition 1	SENISPAR	4/29/2022	6/1/2021

REQUIREMENTS:

The guideline named **CINACALCET (SENSIPAR)** requires that the patient is 18 years of age or older and has one of the following diagnoses. Additional guideline requirements may apply.

A. Parathyroid carcinoma.
B. Primary hyperparathyroidism and is unable to undergo parathyroidectomy.
C. Secondary hyperparathyroidism
    1. Has chronic kidney disease (CKD) and is on dialysis.
    2. Has an intact parathyroid hormone (iPTH) level that was at least 2 times the upper limit of normal as defined by the laboratory reference values measured on TWO separate occasions.
    3. Has tried and had an inadequate response to, intolerance to, or has a contraindication to one phosphate binder (e.g. PhosLo, Fosrenol, Renvela, Renagel, etc.) AND one vitamin analog (e.g., calcitriol, doxercalciferol, paricalcitol, etc.)

The medication will not be approved if the patient has hypocalcemia (serum calcium less than the lower limit of the normal laboratory reference range).

Renewal of therapy requires the patient experience a reduction in serum calcium from baseline with cinacalcet (Sensipar) therapy.

References:

1. Sensipar package insert. Thousand Oaks, CA. Amgen Inc. Revised December 2019. Accessed February 2022
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

CONTINUOUS GLUCOSE MONITORS Edition 1			
Generic	Brand	Reviewed	Effective Date
BLOOD-GLUCOSE METER, CONTINUOUS	DEXCOM, DEXCOM G4, DEXCOM G5, DEXCOM G6	4/29/2022	4/29/2022
BLOOD-GLUCOSE TRANSMITTER	DEXCOM G4, DEXCOM G5, DEXCOM G6		
BLOOD-GLUCOSE SENSOR	DEXCOM G6, DEXCOM G5-G4 SENSOR		
FLASH GLUCOSE SCANNING READER	FREESTYLE LIBRE READER FREESTYLE LIBRE 2 READER		
FLASH GLUCOSE SENSOR	FREESTYLE LIBRE SENSOR FREESTYLE LIBRE 2 SENSOR		

REQUIREMENTS:
The guideline named **Continuous Glucose Monitors** requires a diagnosis of type 1 diabetes or type 2 diabetes and insulin dependent. In addition, the following must be met:

For request of FreeStyle Libre System (i.e., Reader, Sensor), approval requires:
A. Patient is 18 years of age or above
B. The patient is currently performing at least 4 finger-stick glucose tests daily
C. The patient's insulin treatment plan requires frequent adjustment of insulin dosing

For request of FreeStyle Libre 2 System (i.e., Reader, Sensor), approval requires:
A. Patient is 4 years of age or above
B. The patient is currently performing at least 4 finger-stick glucose tests daily
C. The patient's insulin treatment plan requires frequent adjustment of insulin dosing

For request of Dexcom continuous glucose monitoring system (i.e., Meter, Transmitter, Sensor), approval requires:
A. Patient is 2 years of age or above
B. The patient is currently performing at least 4 finger-stick glucose tests daily
C. The patient's insulin treatment plan requires frequent adjustment of insulin dosing

(Criteria continued on next page)

REQUIREMENTS: CONTINUOUS GLUCOSE MONITORS (CONTINUED)

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

CONTOUR TEST STRIPS (INSULIN PUMP) Edition 1			
Generic	Brand	Reviewed	Effective Date
BLOOD SUGAR DIAGNOSTIC BLOOD SUGAR DIAGNOSTIC, DISC BLOOD SUGAR DIAGNOSTIC, DRUM	CONTOUR TEST STRIPS	4/29/2022	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

CYCLOSPORINE OPHTHALMIC Edition 2			
Generic	Brand	Reviewed	Effective Date
CYCLOSPORINE OPHTHALMIC	RESTASIS	4/29/2022	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. 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. 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 February 2022.
2. Cequa package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised September 2019. Accessed February 2022
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EMTRICITABINE/ TENOFOVIR ALAFENAMIDE Edition 2	DESCOVY	4/29/2022	4/29/2022

REQUIREMENTS:
Our guideline named **EMTRICITABINE-TENOFOVIR ALAFENAMIDE (Descovy)** requires (Descovy) the following rules be met for approval (select only one of the following):

HIV Infection

A. You have a have a diagnosis of HIV infection
B. You are being prescribed other antiretroviral medications in addition to Descovy
C. You weigh greater than or equal to 14 kg
D. If you weigh at least 14kg and less than 35kg, then Descovy must NOT be used in combination with any protease inhibitor (i.e., atazanavir, darunavir, lopinavir) which is required to be administered along with a CYP3A inhibitor (i.e., cobicistat, ritonavir).
E. If you recently started HIV treatment, you must first use emtricitabine-tenofovir disoproxil fumarate (generic Truvada), unless there is medical justification supporting why you cannot use that product

PrEP

A. You do NOT have a diagnosis of HIV and you have no signs or symptoms of active HIV infection
B. You are considered high risk for acquiring HIV infection
C. You weigh greater than or equal to 35 kg
D. You must first use emtricitabine-tenofovir disoproxil fumarate (generic Truvada), unless there is medical justification supporting why you cannot use that product

References:

1. Descovy package insert. Foster City, CA. Gilead Sciences, Inc. Revised January 2022. Accessed February 2022.
2. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021.

WELLFLEET RX STUDENT FORMULARY

ENDOTHELIN RECEPTOR ANTAGONISTS Edition 2			
Generic	Brand	Reviewed	Effective Date
BOSENTAN	TRACLEER	4/29/2022	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 ≥ 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    3. Pulmonary vascular resistance (PVR) > 3 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 ≥ 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    3. Pulmonary vascular resistance (PVR) > 3 Wood units
D. The patient has NYHA-WHO Functional Class II to IV symptoms
E. The patient does not have idiopathic pulmonary fibrosis (IPF)
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)

(Criteria continued on next page)

REQUIREMENTS: ENDOTHELIN RECEPTOR ANTAGONISTS (CONTINUED)

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 ≥ 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    3. Pulmonary vascular resistance (PVR) > 3 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 July 2021. Accessed February 2022.
2. Letairis package insert. Foster City, CA. Gilead Sciences, Inc. Revised August 2019. Accessed February 2022.
3. Opsumit package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised October 2021. Accessed February 2022.
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
EVOLOCUMAB Edition 1	REPATHA SYRINGE REPATHA SURECLICK REPATHA PUSHTRONEX	4/30/2021	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a diagnosis of established cardiovascular disease (health issues related to heart and blood vessels) such as: history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of the aorta), carotid plaque with 50% or more stenosis (narrowing of blood vessel), **OR** primary hyperlipidemia (high cholesterol) such as heterozygous familial hypercholesterolemia (HeFH, type of inherited high cholesterol), **OR** homozygous familial hypercholesterolemia (HoFH, type of inherited high cholesterol)

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

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

D. **If you are statin tolerant, approval also requires** you will continue statin treatment in combination with Repatha. You must also meet **ONE** of the following criteria:

   1. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for at least 8 weeks
   2. You have been taking a maximally tolerated dose of any statin for at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: EVOLOCUMAB (CONTINUED)

E. **If you are statin intolerant, approval also requires ONE of the following:**
    1. You have an absolute contraindication (medical reason why you cannot use) to statin therapy such as active decompensated liver disease (you have symptoms related to liver damage), nursing female, pregnancy or plans to become pregnant, hypersensitivity (allergic) reaction
    2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group
F. **If you have established cardiovascular disease, approval also requires you are** 18 years of age or older
G. **If you have primary hyperlipidemia (e.g., heterozygous familial hypercholesterolemia (HeFH)), approval also requires:**
    1. You are 18 years of age or older
    2. The diagnosis is determined by Simon Broome diagnostic criteria (definite) **OR** Dutch Lipid Network criteria with a score of 6 or greater
H. **For patients with homozygous familial hypercholesterolemia (HoFH), the diagnosis must be determined by meeting ONE of the following criteria:**
    1. Simon Broome diagnostic criteria (definite)
    2. Dutch Lipid Network criteria with a score of 8 or greater
    3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein)-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

RENEWAL CRITERIA

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rules be met for renewal:

A. You have a diagnosis of established cardiovascular disease (health issues related to heart and blood vessels), primary hyperlipidemia (high cholesterol such heterozygous familial hypercholesterolemia), or homozygous familial hypercholesterolemia (type of inherited high cholesterol)
B. You meet **ONE** of the following:
    1. You have continued to take a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) with the requested medication
    2. You have continued therapy with a maximally tolerated dose of any statin with the requested medication
    3. You have an absolute contraindication (medical reason why you cannot use) to statin therapy
    4. You have complete statin intolerance

(Criteria continued on next page)

REQUIREMENTS: EVOLOCUMAB (CONTINUED)

References:

1. U.S. Food & Drug Administration. Package Inserts. Drugs@FDA: FDA-Approved Drugs website. https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm. Accessed April 2021.

WELLFLEET RX STUDENT FORMULARY

HYALURONATE Edition 1			
Generic	Brand	Reviewed	Effective Date
HYALURONATE SODIUM	EUFLEXXA, ORTHOVISC	4/29/2022	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 Othovisc:

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 February 2022.
2. Orthovisc package insert. Raynham, MA. DePuy Mitek. Revised July 2016. Accessed February 2022.
3. Monovisc package insert. Bedford, MA. Anika Therapeutics, Inc. Revised March 2014. Accessed February 2022.
4. Synvisc package insert. Ridgefield, NJ. Genzyme Biosurgery. Revised September 2014. Accessed February 2022.
5. Synvisc One package insert. Ridgefield, NJ. Genzyme Biosurgery. Revised September 2014. Accessed February 2022.
6. Hyalgan package insert. Parsippany, NJ. Fidia Pharma USA, Inc. Revised May 2014. Accessed February 2022.
7. Supartz package insert. Tokyo, Japan. Seigaku Corporation. Revised February 2001. Accessed February 2022.
8. Gel-One package insert. Warsaw, IN. Zimmer. Revised May 2011. Accessed February 2022.
9. Hymovis package insert. Parsippany, NJ. Fidia Pharma USA, Inc. Revised October 2015. Accessed February 2022.
10. Gelsyn-3 package insert. Durham, NC. Bioventus LLC. Revised December 2017. Accessed February 2022.
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
LEDIPASVIR/SOFOSBUVIR Edition 1	HARVONI	4/29/2022	6/1/2021

REQUIREMENTS:

The guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires a diagnosis of hepatitis C. Please note that the preferred formulary product for patients weighing at least 45 kg (99 pounds) is Mavyret. The following criteria must also be met:

A. Has genotype 1, genotype 4, genotype 5, or 6 hepatitis C
B. The request is for ONE of the following:
    1. A pediatric patient age 3 to 17 years who is treatment naive with no or compensated cirrhosis or is treatment experienced with no cirrhosis
    2. A pediatric patient age 3 to 17 years with genotype 4, 5, or 6 who is treatment experienced with compensated cirrhosis
    3. A pediatric patient age 3 to 17 years with genotype 1 who is treatment experienced with compensated cirrhosis and the requested medication will be taken in combination with ribavirin
    4. A pediatric patient age 3 to 17 years with genotype 1 who has decompensated cirrhosis and the requested medication will be taken in combination with ribavirin
    5. A pediatric patient age 3 to 17 years with genotype 1 or 4 who is status post liver transplant with no or compensated cirrhosis and the requested medication will be taken in combination with ribavirin
    6. A pediatric patient weighing between 35 kg to 44 kg who is treatment naive or treatment experienced with an interferon-containing regimen without cirrhosis or with compensated cirrhosis
    7. An adult with hepatitis C post-liver transplant with cirrhosis and the requested medication will be taken in combination with ribavirin
C. Patient is currently supervised by a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. Documentation of HCV infection at least **ONE** detectable HCV RNA level within the last 6 months

(Criteria continued on next page)

REQUIREMENTS: LEDIPASVIR/SOFOSBUVIR CONTINUED)

Harvoni will not be approved for the following patients:

A. Patient using any of the following medications concurrently while on Harvoni: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, sofosbuvir, Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), or tipranavir/ritonavir
B. Patient with limited life expectancy (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 March 2022 .
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LIFITEGRAST Edition 2	XIIDRA	4/29/2022	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. 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 February 2022.
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
METHYLNALTREXONE BROMIDE Edition 1	RELISTOR	4/29/2022	6/1/2021

REQUIREMENTS:

The guideline for **METHYLNALTREXONE (Relistor)** requires that the patient have a diagnosis of opioid-induced constipation with chronic non-cancer pain, **OR** with advanced (terminal) illness or pain caused by active cancer who require opioid dosage escalation for palliative care. The patient must also be 18 years of age or older. For patients with advanced (terminal) illness, or pain caused by active cancer who require opioid dosage escalation for palliative care, only Relistor injection may be approved. The following criteria must also be met:

A. **For patients with chronic non-cancer pain, approval requires all of the following:**
    a. 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 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OMALIZUMAB Edition 2	XOLAIR	4/29/2022	04/29/2022

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **OMALIZUMAB (Xolair)** requires a diagnosis of nasal polyps, chronic idiopathic urticaria or moderate to severe persistent asthma. In addition, the following criteria must also be met:

For patients with nasal polyps, approval also requires:

A. The patient is 18 years of age or older
B. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
C. You have inadequately controlled disease as determined by ONE of the following:
    1. Use of systemic steroids in the past 2 years
    2. Endoscopic sinus surgery (using a small camera to help in surgery)
D. Xolair will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
E. The medication is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist

For patients with chronic idiopathic urticaria (CIU), approval requires:

A. The patient is 12 years of age or older
B. The patient still experiences hives on most days of the week for at least 6 weeks
C. Patient remains symptomatic despite second generation H1 antihistamine therapy with maximized dosing used continuously for at least 2 weeks (see Appendix)
D. Patient remains symptomatic despite a two week continuous trial of at least one of the following:
    1. Higher dose (up to four times the recommended dose) of second generation H1 antihistamine therapy
    2. Addition of another second generation antihistamine to existing therapy
    3. Addition of a leukotriene receptor antagonist (LTRA) to existing therapy
    4. Addition of a H2-antagonist to existing therapy
    5. Addition of a first generation antihistamine taken at bedtime
E. Patient remains symptomatic despite the addition of a potent antihistamine (e.g., hydroxyzine or doxepin) used continuously for at least two weeks
F. Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

(Criteria continued on next page)

REQUIREMENTS: OMALIZUMAB (CONTINUED)

For patients with moderate to severe persistent asthma, approval requires:

A. The patient is 6 years of age or older
B. The patient has a positive skin prick or RAST test to a perennial aeroallergen
C. The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
D. The patient is currently adherent to a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
E. The patient has experienced at least 2 asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
F. The patient has **ONE** of the following:
    1. Asthma Control Test (ACT) score of less than 20
    2. Asthma Control Questionnaire (ACQ) score of at least 1.5
    3. Asthma Therapy Assessment Questionnaire (ATAQ) score of at least 1
G. Xolair will be used as add-on maintenance treatment
H. The patient is not being concurrently treated with Dupixent or anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
I. Xolair is prescribed by or given in consultation with a physician specializing in allergy or pulmonary medicine

RENEWAL CRITERIA

The guideline named **OMALIZUMAB (Xolair)** renewal requires a diagnosis of moderate to severe persistent asthma or chronic idiopathic urticaria. In addition, the following criteria must also be met:

For patients with moderate to severe persistent asthma, approval requires:

A. The patient has experienced a reduction in asthma exacerbations (defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days) from baseline during the past 12 months of therapy
B. The patient has experienced an improvement in the Asthma Control Test (ACT), Asthma Control Questionnaire (ACQ), or Asthma Therapy Assessment Questionnaire (ATAQ) score from baseline
C. The patient has decreased their total daily oral corticosteroid dose from baseline if the patient was on a maintenance regimen of oral corticosteroids prior to initiation of Xolair

References:

1. Xolair package insert. South San Francisco, CA. Genentech, Inc. Revised April 2021. Accessed March 2022.
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. 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.
4. 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
RIFAMYCIN Edition 1	AEMCOLO	4/29/2022	6/1/2021

REQUIREMENTS:

The guideline named **RIFAMYCIN (AEMCOLO)** requires a diagnosis of traveler's diarrhea (TD). The patient must also have a contraindication to **BOTH** azithromycin and ciprofloxacin. Aemcolo will not be approved if the patient has diarrhea complicated by fever or bloody stool.

References:

1. Aemcolo package insert. Lainate, Milan, Italy. Cosmo S.p.A. Revised November 2018. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

RIFAXIMIN			
Generic	Brand	Reviewed	Effective Date
RIFAXIMIN 200 MG RIFAXIMIN 550 MG Edition 1	XIFAXAN	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **RIFAXIMIN 200 mg (Xifaxan)** requires a diagnosis of traveler's diarrhea caused by non-invasive strains of E.coli. Additional guideline requirements apply.

A. For the treatment of traveler's diarrhea (TD), the following criteria must be met:
    1. Age at least 12 years old
    2. TD is caused by non-invasive strains of E.coli
    3. Patient has a contraindication to **BOTH** azithromycin and ciprofloxacin

Our guideline for **RIFAXIMIN 550mg (Xifaxan)** requires a diagnosis of hepatic encephalopathy (HE) or irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply.

A. **For the treatment of hepatic encephalopathy (HE),** the following criteria must be met:
    1. Age at least 18 years old
    2. Trial of lactulose or currently on lactulose monotherapy
    3. Prescriber is a hepatologist.
B. **For the treatment of irritable bowel syndrome with diarrhea (IBS-D),** the following criteria must be met:
    1. Age at least 18 years old
    2. Trial of or contraindication to tricyclic anti-depressants or dicyclomine
    3. Prescriber is a gastroenterologist.

(Criteria continued on next page)

REQUIREMENTS: RIFAXIMIN (CONTINUED)

RENEWAL CRITERIA

Our guideline for **RIFAXIMIN 550mg** (Xifaxan) renewal requires a diagnosis of hepatic encephalopathy (HE) or irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply.

A. **For the treatment of irritable bowel syndrome with diarrhea (IBS-D),** the following criteria must be met:
    1. At least 10 weeks have passed since the last treatment course of rifaximin
    2. Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale)
    3. 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. Xifaxan package insert. Morrisville, NC. Salix Pharmaceuticals, Inc. Revised October 2020. Accessed March 2022.
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.
3. Rogal, S., Hansen, L., Patel, A., Ufere, N.N., Verma, M., Woodrell, C. and Kanwal, F. (2022), AASLD Practice Guidance: Palliative care and symptom-based management in decompensated cirrhosis. Hepatology. Accepted Author Manuscript. https://doi.org/10.1002/hep.32378.
4. Weinberg DS, Smalley W, Heidelbaugh JJ, Sultan S; Amercian Gastroenterological Association. American Gastroenterological Association Institute Guideline on the pharmacological management of irritable bowel syndrome [published correction appears in Gastroenterology. 2015 Feb;148(2):455. multiple investigator names added]. Gastroenterology. 2014;147(5):1146-1148. doi:10.1053/j.gastro.2014.09.001.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SODIUM ZIRCONIUM CYCLOSILICATE Edition 1	LOKELMA	4/29/2022	6/1/2021

REQUIREMENTS:

The guideline named **SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma)** requires a diagnosis of hyperkalemia. In addition, the following criteria must also be met:

A. The patient is 18 years of age or older
B. The requested drug is not being used as an emergency treatment for life-threatening hyperkalemia
C. The requested drug will not be used in a patient currently receiving dialysis
D. The requested drug is being prescribed by or in consultation with a nephrologist or cardiologist
E. 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:
        i. Angiotensin converting enzyme inhibitor (ACE-I)
        ii. Angiotensin receptor blocker (ARB)
F. Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)
G. 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 October 2021. Accessed March 2022.
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

SOMATROPIN Edition 1			
Generic	Brand	Reviewed	Effective Date
SOMATROPIN	GENOTROPIN	4/29/2022	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)

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 2022.
2. Norditropin Flexpro package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised February 2018. Accessed March 2022.
3. Serostim package insert. Rockland, MA. EMDSerono, Inc. Revised May 2017. Accessed March 2022.
4. Zorbtive package insert. Rockland, MA. EMDSerono, Inc. Revised May 2017. Accessed March 2022.
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 STUDENT FORMULARY

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

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)

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/m2
B. 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 February 2022.
2. Androgel package insert. North Chicago, IL. Abbvie Inc. Revised February 2019. Accessed February 2022.
3. Axiron package insert. Indianapolis, IN. Lilly USA, LLC. Revised July 2017. Accessed February 2022.
4. Testim package insert. Malvern, PA. Endo Pharmaceuticals, Inc. Revised August 2021. Accessed February 2022.
5. Vogelxo package insert. Maple Grove, MN. Upsher-Smith Laboratories. Revised April 2020. Accessed February 2022.
6. Depo-testosterone package insert. New York, NY. Pfizer, Inc. Revised August 2018. Accessed February 2022.
7. Delatestryl package insert. Malvern, PA. Endo Pharmaceuticals, Inc. Revised October 2016. Accessed February 2022.
8. Striant package insert. Malvern, PA. Actient Pharmaceuticals LLC. Revised October 2016. Accessed February 2022.
9. Testopel package insert. Malvern, PA. Endo Pharmaceuticals Inc. Revised August 2018. Accessed February 2022.
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WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VEDOLIZUMAB Edition 1	ENTYVIO	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe Crohn's disease, approval requires ALL of the following:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 18 years of age or older

For patients with moderate to severe ulcerative colitis, approval requires ALL of the following:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 18 years of age or older

RENEWAL CRITERIA
The guideline named **VEDOLIZUMAB (Entyvio)** requires a diagnosis of moderate to severe Crohn's disease or moderate to severe ulcerative colitis for renewal.

References:

1. Entyvio package insert. Lexington, MA. Takeda Pharmaceuticals U.S.A., Inc. Revised August 2021. Accessed March 2022.
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.
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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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LIRAGLUTIDE Edition 1	SAXENDA	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **Saxenda (liraglutide)** requires an indication of weight loss or weight management. In addition, the following criteria must be met:

A. The patient has **ONE** of the following:
    1. Body mass index (BMI) of 30 kg/m^2 or greater **OR**
    2. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or hyperlipidemia)
B. Evidence of active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
C. The patient is **NOT** currently taking a GLP-1 receptor agonist (e.g., Victoza, Byetta, Bydureon, Tanzeum)
D. The patient is 18 years of age or older

RENEWAL CRITERIA

The guideline named **Saxenda (liraglutide)** requires an indication of weight loss or weight management. In addition, the following criteria must be met:

A. The patient lost at least 4% of baseline body weight after 4 months of treatment

References:

1. Saxenda package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised December 2020. Accessed March 2022.
2. 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.

WELLFLEET RX STUDENT FORMULARY

AMINO ACID BASED AND ENTERAL FORMULAS Edition 1			
Generic	Brand	Reviewed	Effective Date
ENTERAL FORMULAS	VARIOUS	4/29/2022	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.2016.01.020.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELUXADOLINE Edition 1	VIBERZI	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **ELUXADOLINE (Viberzi)** requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply. The following criteria must also be met:

A. The patient is at least 18 years old
B. The medication is being prescribed by or in consultation with a gastroenterologist
C. The patient has had a trial of or contraindication to either tricyclic anti-depressants (e.g., amitriptyline, desipramine) **OR** gastrointestinal anti-spasmodics (e.g., dicyclomine or hyoscyamine)

RENEWAL CRITERIA

Our guideline for **ELUXADOLINE (Viberzi)** renewal requires a diagnosis of irritable bowel syndrome with diarrhea (IBS-D). Additional guideline requirements apply. The following criteria must also be met:

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 February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

IMMUNE GLOBULIN Edition 1			
Generic	Brand	Reviewed	Effective Date
IMMUNE GLOBULIN	BIVIGAM, FLEBOGAMMA DIF GAMASTAN S-D, GAMMAGARD S-D, GAMMAPLEX, PRIVIGEN, GAMMAGARD LIQUID, HIZENTRA	4/29/2022	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 you to have ONE of the following diagnoses:

1. Primary Immunodeficiency Disease (genetic disease where your immune system is weak)
2. Idiopathic Thrombocytopenic Purpura (Low levels of the blood cells that prevent bleeding)
3. Chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)
4. Dermatomyositis: For Octagam only

(Criteria continued on next page)

REQUIREMENTS: IMMUNE GLOBULIN (CONTINUED)

5. Multifocal Motor Neuropathy (nerve disorder with increasing muscle weakness and wasting)
6. Kawasaki Syndrome (inflammation in the walls of blood vessels in the body)
7. B-cell Chronic Lymphocytic Leukemia (blood and bone marrow cancer of immune cells) with Autoimmune Hemolytic Anemia (body destroys red blood cells more rapidly than it produces them), Immune Thrombocytopenic Purpura (decreased number of blood cells that prevent bleeding with increased easy bruising) OR Pure Red Cell Blood Aplasia (bone marrow stops making red blood cells)
8. Guillain-Barre Syndrome (immune system attacks the nerves)
9. Myasthenia Gravis (weakness and rapid fatigue of muscles under voluntary control)
10. Autoimmune Graves' Ophthalmopathy (type of eye disease from having little to no thyroid)
11. Cytomegalovirus-induced Pneumonitis related to a solid organ transplant (lung tissue inflammation)
12. Prevention of bacterial infection in an HIV-infected child (human immunodeficiency virus)- infected child
13. Reduction of secondary infections in pediatric HIV infections
14. Dermatomyositis (inflammatory disease with muscle weakness and skin rash) or polymyositis (type of inflammatory muscle disease)
15. Autoimmune uveitis (Birdshot retinochoroidopathy; inflammation of the middle layer of the eye)
16. Lambert-Eaton myasthenic syndrome (nerve disease in which the immune system attacks the body's own tissues)
17. IgM (Immunoglobulin M) anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathy (type of nerve damage)
18. Stiff-man syndrome (nerve disorder with increasing muscle stiffness (rigidity) and repeated episodes of painful muscle spasms)
19. Neonatal sepsis (blood infection in infants)
20. Rotaviral enterocolitis (severe diarrhea among infants and young children)
21. Toxic shock syndrome (life-threatening complication of certain bacterial infections)
22. Enteroviral meningoencephalitis (Inflammation of the brain and surrounding tissues caused by a virus)
23. Toxic Epidermal Necrolysis or Stevens-Johnson syndrome (both are types of serious skin bacterial infections)
24. Autoimmune Mucocutaneous Blistering Disease (group of serious skin conditions that start with blisters on the skin) such as pemphigus vulgaris, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita
25. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
26. Pediatric acute-onset neuropsychiatric syndrome (PANS)

(Criteria continued on next page)

REQUIREMENTS: IMMUNE GLOBULIN (CONTINUED)

B. **For Gamastan S-D, approval requires:**

1. You are using the requested drug for prophylaxis (prevention) or passive immunization (immune response where antibodies are obtained from outside the body) of hepatitis A, measles, varicella, or rubella

C. **For Hizentra, approval requires:**

1. The medication is only for subcutaneous (under the skin) use
2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak) OR chronic Inflammatory Demyelinating Polyneuropathy (a nerve disorder with increasing weakness and loss of sensory function in the legs and arms)

D. **For Cuvitru, Hyqvia, Cutaquig, or Xembify, approval requires:**

1. The medication is only for subcutaneous (under the skin) use
2. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

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

1. You have a diagnosis of primary immunodeficiency disease (genetic disease where your immune system is weak)

References:

1. Bivigam package insert. Boca Raton, FL. Biotest Pharmaceuticals Corporation, Revised June 2013. Accessed February 2022.
2. Flebogamma DIF package insert. Los Angeles, CA. Grifols Biologicals, Inc. Revised October 2018. Accessed February 2022.
3. GamaSTAN S/D package insert. Research Triangle Park, NC. Grifolis Therapeutics, Inc. Revised February 2013. Accessed February 2022.
4. Gammagard S/D package insert. Westlake Village, CA. Baxalta US Inc. Revised June 2014. Accessed February 2022.
5. Gammaplex package insert. Durham, NC. BPL Inc. Revised July 2015. Accessed February 2022.
6. Privigen package insertn. Kankakee, IL. CSL Behring, LLC. Revised September 2017. Accessed February 2022.
7. Gammagard Liquid package insert. Westlake Village, CA. Baxalta US Inc. Revised June 2012. Accessed February 2022.
8. Hizentra package insert. Kankakee, IL. CSL Behring LLC. Revised April 2021. Accessed February 2022.
9. Gamunex-C package insert. Research Triangle Park, NC. Grifols Therapeutics, Inc. Revised December 2015. Accessed February 2022.
10. Gammaked package insert. Research Triangle Park, NC. Grifols Therapeutics Inc. Revised June 2018. Accessed February 2022.
11. Octagam package insert. Hoboken, NJ. Octapharma USA, Inc.Revised June 2021. Accessed February 2022.
12. HyQvia package insert. Westlake Village, CA. Baxalta US Inc. Revised September 2014. Accessed February 2022.
13. Cuvitru package insert. Westlake Village, CA. Baxalta US, Inc. Revised September 2021. Accessed February 2022.
14. Panzyga package insert. Hoboken, NJ. Octapharma. Revised January 2021. Accessed February 2022.
15. Cutaquig package insert. Hoboken, NJ. Octapharma USA, Inc. Revised October 2021. Accessed February 2022.
16. Xembify package insert. Research Triangle Park, NC. Grifols Therapeutics LLC. Revised July 2019. Accessed February 2022.
17. Martin JM, Danziger-Isakov LA. Cytomegalovirus risk, prevention, and management in pediatric solid organ transplantation. Pediatr Transplant. 2011;15(3):229-236. doi:10.1111/j.1399-3046.2010.01454.x.
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19. Lunn MP, Nobile-Orazio E. Immunotherapy for IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathies. Cochrane Database Syst Rev. 2016;10(10):CD002827. Published 2016 Oct 4. doi:10.1002/14651858.CD002827.pub4.
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21. Alsaleem M. Intravenous Immune Globulin Uses in the Fetus and Neonate: A Review. Antibodies (Basel). 2020;9(4):60. Published 2020 Nov 4. doi:10.3390/antib9040060.
22. Agrawal RV, Murthy S, Sangwan V, Biswas J. Current approach in diagnosis and management of anterior uveitis. Indian J Ophthalmol. 2010;58(1):11-19. doi:10.4103/0301-4738.58468.
23. Mofenson LM, Brady MT, Danner SP, et al. Guidelines for the Prevention and Treatment of Opportunistic Infections among HIV-exposed and HIV-infected children: recommendations from CDC, the National Institutes of Health, the HIV Medicine Association of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, and the American Academy of Pediatrics. MMWR Recomm Rep. 2009;58(RR-11):1-166.
24. Keogh M, Sedehizadeh S, Maddison P. Treatment for Lambert-Eaton myasthenic syndrome. Cochrane Database Syst Rev. 2011;2011(2):CD003279. Published 2011 Feb 16. doi:10.1002/14651858.CD003279.pub3.
25. 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.
26. Olney RK, Lewis RA, Putnam TD, Campellone JV Jr; American Association of Electrodiagnostic Medicine. Consensus criteria for the diagnosis of multifocal motor neuropathy. Muscle Nerve. 2003;27(1):117-121. doi:10.1002/mus.10317.
27. 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.
28. McCrindle BW, Rowley AH, Newburger JW, et al. Diagnosis, Treatment, and Long-Term Management of Kawasaki Disease: A Scientific Statement for Health Professionals From the American Heart Association [published correction appears in Circulation. 2019 Jul 30;140(5):e181-e184]. Circulation. 2017;135(17):e927-e999. doi:10.1161/CIR.0000000000000484.
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34. Khanlou H, Eiger G. Long-term remission of refractory stiff-man syndrome after treatment with intravenous immunoglobulin. Mayo Clin Proc. 1999;74(12):1231-1232. doi:10.4065/74.12.1231.
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39. Carapetis JR, Jacoby P, Carville K, Ang SJ, Curtis N, Andrews R. Effectiveness of clindamycin and intravenous immunoglobulin, and risk of disease in contacts, in invasive group a streptococcal infections. Clin Infect Dis. 2014;59(3):358-365. doi:10.1093/cid/ciu304.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ESKETAMINE Edition 1	SPRAVATO	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. Treatment-resistant depression (TRD: no improvement in depression symptoms after treatment within a certain amount of time)
    2. Major depressive disorder (MDD: clinical depression or low mood)

B. **If you have treatment-resistant depression (TRD), approval also requires:**
    1. You are 18 years of age or older
    2. The requested medication will be used in combination with an oral antidepressant
    3. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
    4. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
    5. You do NOT have active substance abuse
    6. You had a trial of **TWO** oral anti-depressants from different classes for the treatment of depression. Classes of anti-depressants include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), bupropion, mirtazapine, serotonin modulator, tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs) are optional. You must have used the drugs for an adequate time period defined as at least 6 weeks (unless the patient has shown little to no improvement after 4 weeks)

C. **If you have major depressive disorder (MDD), approval also requires:**
    1. You are 18 years of age or older
    2. Therapy is prescribed by or given in consultation with a psychiatrist (mental health doctor)
    3. You have acute suicidal ideation or behavior (thoughts of killing yourself)
    4. The requested medication will be used in combination with an oral antidepressant
    5. You have non-psychotic, unipolar depression (you have no other mental health conditions except depression)
    6. You do NOT have active substance abuse

(Criteria continued on next page)

REQUIREMENTS: ESKETAMINE (CONTINUED)

RENEWAL CRITERIA

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

A. You have treatment-resistant depression (TRD: no improvement in depression symptoms after treatment within a certain amount of time) OR major depressive disorder (MDD: clinical depression or low mood)
B. You have demonstrated clinical benefit (improvement in depression) compared to baseline

References:

1. Spravato package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised July 2020. Accessed February 2022.
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
ETEPLIRSEN Edition 2	EXONDYS 51	4/29/2022	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **ETEPLIRSEN (Exondys-51)** requires the following rule(s) be met for approval:

A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 51 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)
F. Requested medication is not concurrently prescribed with other exon-skipping therapies (e.g., Amondys 45, Vyondys 53, Viltepso)

RENEWAL CRITERIA

Our guideline named **ETEPLIRSEN (Exondys-51)** requires ONE of the following rule(s) be met for renewal:

A. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

References:

1. Exondys 51 package insert. Cambridge, MA. Sarepta Therapeutics, Inc. Revised January 2022. Accessed February 2022.
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
GALCANEZUMAB-GNLM Edition 1	EMGALITY	4/29/2022	6/1/2021

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. You have migraines or episodic cluster headaches (very painful headaches that occur in patterns)

B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol

C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
   1. You are 18 years of age or older
   2. Emgality is prescribed for the preventive treatment of migraines
   3. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]

D. **If you have episodic cluster headaches, approval also requires:**
   1. You are 18 years of age or older

(Criteria continued on next page)

REQUIREMENTS: GALCANEZUMAB-GNLM (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. Emgality is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headache (very painful headaches that occur in patterns)
B. **If you have migraines, renewal also requires ONE of the following:**
    1. You have experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy
    2. You have experienced a reduction in migraine severity with Emgality therapy
    3. You have experienced a reduction in migraine duration with Emgality therapy
C. **If you have episodic cluster headaches, renewal also requires:**
    1. You had improvement in episodic cluster headache frequency as compared to baseline

References:

1. Emgality package insert. Indianapolis, IN. Eli Lilly and Company. Revised December 2019. Accessed February 2022.
2. Loder, E. , Burch, R. and Rizzoli, P. (2012), The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. Headache: The Journal of Head and Face Pain, 52: 930-945. doi:10.1111/j.1526-4610.2012.02185.x.
3. 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. Neurology. 2012;78(17):1337-45.
4. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the differences between episodic migraine and chronic migraine. Curr Pain Headache Rep. 2011;16(1):86-92.
5. Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, Schwedt TJ. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016;56(7):1093-1106. doi:10.1111/head.12866.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GOLODIRSEN Edition 2	VYONDYS-53	4/29/2022	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. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)
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. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

References:

1. Vyondys 53 package insert. Cambridge, MA. Sarepta Therapeutics, Inc. Revised February 2021. Accessed February 2022.
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
IMATINIB MESYLATE Edition 1	GLEEVEC, IMATINIB MESYLATE	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia positive chronic myeloid leukemia (type of blood cell cancer that begins in bone marrow with an abnormal gene) in chronic phase
   2. Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy
   3. Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer that has returned or did not respond to treatment)
   4. Newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   5. Myelodysplastic/myeloproliferative disease (a group of diseases where the bone marrow makes too many white blood cells) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
   6. Aggressive systemic mastocytosis (a type of cell accumulates in internal tissues and organs) without D816V c-Kit mutation or with c-Kit mutational status unknownI
   7. Hypereosinophilic syndrome and/or chronic eosinophilic leukemia (type of inflammatory cancer)
   8. Unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans (type of rare skin tumor that cannot be completely removed by surgery or returns/spreads)
   9. Unresectable and/or metastatic malignant gastrointestinal stromal tumor (tumor in stomach/intestines that spreads or cannot be removed by surgery) with a Kit (CD117) positive
   10. Adjuvant (add-on) treatment after complete gross resection (surgical removal) of Kit (CD117) positive gastrointestinal stromal tumor

B. **If you are newly diagnosed with Philadelphia positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)

(Criteria continued on next page)

REQUIREMENTS: IMATINIB (CONTINUED)

C. **If you have Philadelphia chromosome positive chronic myeloid leukemia in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy, approval also requires:**
    1. You have NOT received previous treatment with another tyrosine kinase inhibitor such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Iclusig (ponatinib)
D. **If you have relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
    1. You are 18 years of age or older
E. **If you have newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
    1. The requested medication will be used in combination with chemotherapy
F. **If you have myelodysplastic/myeloproliferative disease associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements, approval also requires:**
    1. You are 18 years of age or older
G. **If you have aggressive systemic mastocytosis without D816V c-Kit mutation or with c-Kit mutational status unknown, approval also requires:**
    1. You are 18 years of age or older
H. **If you have hypereosinophilic syndrome and/or chronic eosinophilic leukemia, approval also requires:**
    1. You are 18 years of age or older
I. **If you have unresectable, recurrent, and/or metastatic dermatofibrosarcoma protuberans, approval also requires:**
    1. You are 18 years of age or older
J. **If the request is for adjuvant treatment following complete gross resection of Kit (CD117) positive gastrointestinal stromal tumor (GIST), approval also requires:**
    1. You are 18 years of age or older
K. **If you have gastrointestinal stromal tumor, approval also requires:**
    1. For request of Gleevec 400mg twice daily, approval requires a trial of Gleevec 400mg once daily OR a GIST tumor expressing a KIT exon 9 (type of gene) mutation (a permanent change in your DNA that make up your gene)

References:

1. Gleevec package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised August 2020. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IVACAFTOR Edition 1	KALYDECO	4/29/2022	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. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You are 4 months of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert
D. You are NOT homozygous (have 2 copies of the same gene) for the F508del mutation in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
E. If you are between 4 months and less than 6 years of age, **Ivacaftor packets** will be approved. Documentation of your weight is required
F. You have documentation of ONE of the following mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene

Table 3: List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDECO				
711+3A→G *	*F311del*	*I148T*	*R75Q*	*S589N*
2789+5G→A *	*F311L*	*I175V*	*R117C* *	*S737F*
3272-26A→G *	*F508C*	*I807M*	*R117G*	*S945L* *
3849+10kbC→T *	*F508C;S1251N* †	*I1027T*	*R117H* *	*S977F* *
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W* *	*R170H*	*S1251N* *
A455E *	*G178R* *	*L320V*	*R347H* *	*S1255P* *
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q* *	*T1053I*
D110H	*G551D* *	*L1480P*	*R553Q*	*V232D*
D192G	*G551S* *	*M152V*	*R668C*	*V562I*
D579G *	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
D1152H *	*G1069R*	*P67L* *	*R1070Q*	*W1282R*
D1270N	*G1244E* *	*Q237E*	*R1070W* *	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D* *	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N* *	
E831X *	*H1375P*	*R74W*	*S549R* *	

(Criteria continued on next page)

REQUIREMENTS: IVACAFTOR (CONTINUED)

RENEWAL CRITERIA

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

A. You have cystic fibrosis (CF: life-threatening disorder that damages lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have maintained, or demonstrated less than expected decline in FEV_1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

References:

1. Kalydeco package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised December 2020. Accessed February 2022.
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
BELANTAMAB MAFODOTIN-BLMF Edition 1	BLENREP	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **BELANTAMAB MAFODOTIN-BLMF (Blenrep)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (type of blood cancer that has returned or did not respond to previous treatment)
B. You are 18 years of age or older
C. You have received at least four prior therapies, including an anti-CD38 monoclonal antibody (such as daratumumab, isatuximab), a proteasome inhibitor (such as ixazomib, carfilzomib), and an immunomodulatory agent (such as lenalidomide, pomalidomide)

References:

1. Blenrep package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised August 2020. Accessed February 2022..

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BUDESONIDE Edition 1	ORTIKOS	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have mild to moderate Crohn's Disease (inflammation of the digestive tract that affects a part of your small intestines and/or the beginning of the colon which can lead to stomach pain, diarrhea, weight loss, or malnutrition)

B. **If you have mild to moderate ACTIVE Crohn's Disease, approval also requires:**
   1. You are 8 years of age or older
   2. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

C. **If you have mild to moderate Crohn's Disease in clinical remission, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is being used for the maintenance of clinical remission (signs and symptoms of disease have either improved or disappeared)
   3. You have previously tried generic budesonide 3mg capsules OR you cannot tolerate the pill burden associated with the generic product

References:

1. Ortikos package insert. Cranbury, NJ. Sun Pharmaceutical Industries, Inc. Revised June 2019. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CANNABIDIOL Edition 2	EPIDIOLEX	4/29/2022	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. You have ONE of the following diagnoses:
   1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
   2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
   3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)

B. You are 1 year of age or older

C. Therapy is prescribed by or given in consultation with a neurologist (nerve doctor)

D. **If you have seizures associated with Dravet syndrome, approval also requires:**
   1. You have previously tried clobazam AND valproic acid derivative, unless there is a medical reason why you cannot (contraindication)

E. **If you have seizures associated with Lennox-Gastaut syndrome, approval also requires:**
   1. You have previously tried TWO of the following, unless there is a medical reason why you cannot (contraindication): clobazam, valproic acid derivative, topiramate, lamotrigine

F. **If you have seizures associated with tuberous sclerosis complex, approval also requires:**
   1. You have previously tried TWO anti-epileptic medications (drugs to treat seizures) such as clobazam, valproic acid derivative, topiramate, lamotrigine, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

REQUIREMENTS: CANNABIDIOL (CONTINUED)

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. Seizures associated with Dravet syndrome (type of seizures that are hard to control starting in infants)
    2. Seizures associated Lennox-Gastaut syndrome (condition where you keep getting seizures starting in childhood)
    3. Seizures associated tuberous sclerosis complex (a genetic disorder which causes the growth of numerous noncancerous (benign) tumors in many parts of the body)
B. You have experienced positive response to therapy as evidenced by clinical improvement from baseline

References:

1. Epidiolex package insert. Carlsbad, CA. Greenwich Biosciences, Inc. Revised September 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DECITABINE/ CEDAZURIDINE Edition 1	INQOVI	4/29/2022	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: type of blood cancer)
    b. Chronic myelomonocytic leukemia (CMML: rare form of blood cancer)
B. You are 18 years of age or older
C. **If you have myelodysplastic syndromes (MDS), approval also requires:**
    a. You meet ONE of the following International Prognostic Scoring System groups (scoring system used to predict the course of a patient's disease):
        i. Intermediate-1
        ii. Intermediate-2
        iii. High-risk

References:

1. Inqovi package insert. Princeton, NJ. Taiho Oncology, Inc. Revised July 2020. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELAGOLIX AND ESTRADIOL AND NORETHINDRONE Edition 1	ORIAHNN	4/29/2022	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: non-cancerous growths in the uterus)
B. You are 18 years of age or older
C. You are a premenopausal woman
D. Therapy is prescribed by or given in consultation with an obstetrician or gynecologist (OB/GYN: doctor who specializes in women's reproductive system)
E. You have not received a total of 24 months cumulative treatment with Oriahnn

RENEWAL CRITERIA
Our guideline named **ELAGOLIX/ESTRADIOL/NORETHISTERONE (Oriahnn)** requires the following rule(s) be met for renewal:

A. The request is for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids: non-cancerous growths in the uterus)
B. You had improvement of heavy menstrual bleeding on therapy
C. You have not received a total of 24 months cumulative treatment with Oriahnn

References:

1. Oriahnn package insert. North Chicago, IL. AbbVie Inc. Revised August 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR Edition 2	TRIKAFTA	4/29/2022	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. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You are 6 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert
D. You meet ONE of the following:
    1. Documentation that you have at least one *F508del* mutation (a permanent change in your DNA that make up your gene) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
    2. Documentation that you have at least one of the following mutations in the CFTR gene:

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)

REQUIREMENTS: ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV_1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

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References:

1. Trikafta package insert. Boston, Ma. Vertex Pharmaceuticals Incorporated. Revised October 2021. Accessed February 2022.
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

EPOPROSTENOL IV Edition 2			
Generic	Brand	Reviewed	Effective Date
EPOPROSTENOL SODIUM (GLYCINE)	FLOLAN	4/29/2022	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. You have pulmonary arterial hypertension (type of high blood pressure in the arteries of the lungs, World Health Organization Group 1)
B. Therapy is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
C. You are 18 years of age or older
D. You have documentation confirming your diagnosis of pulmonary arterial hypertension based on right heart catheterization (a test using a thin tube that is placed into the right side of your heart) with the following values:
    1. Mean pulmonary artery pressure greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure less than or equal to 15 mmHg
    3. Pulmonary vascular resistance greater than 3 Wood units
E. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms (a system to classify how severely limited you are in daily activities due to heart failure symptoms)

RENEWAL CRITERIA

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

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

(Criteria continued on next page)

REQUIREMENTS: EPOPROSTENOL (CONTINUED)

References:

1. Flolan package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised August 2021. Accessed February 2022.
2. Veletri package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised October 2020. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TAFASITAMAB-CXIX Edition 1	MONJUVI	4/29/2021	6/1/2021

REQUIREMENTS:

Our guideline named **TAFASITAMAB-CXIX (Monjuvi)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of white blood cancer that has returned or did not respond to previous treatment)
B. You are 18 years of age or older
C. The requested medication will be used in combination with lenalidomide
D. You are not eligible for autologous stem cell transplant (ASCT: stem cell transplant transferred from your own body)

References:

1. Monjuvi package insert. Boston, MA. Morphosys US Inc. Revised June 2021. Accessed March 2022..

WELLFLEET RX STUDENT FORMULARY

TEPOTINIB			
Generic	Brand	Reviewed	Effective Date
TEPOTINIB HCL Edition 1	TEPMETKO	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have metastatic non-small cell lung cancer (NSCLC)
B. You are 18 years of age or older
C. Mesenchymal-epithelial transition (MET) exon 14 skipping alterations (abnormal change in a gene that makes MET protein) are present

References:

1. Tepmetko package insert. Rockland, MA. EMDSerono, Inc. Revised February 2021. Accessed March 2022..

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TEZACAFTOR/IVACAFTOR Edition 1	SYMDEKO	4/29/2022	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. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
B. You are 6 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
D. You have documentation that you are either homozygous (you have 2 copies of the same gene) for the F508del-CFTR (Cystic fibrosis transmembrane conductance regulator) gene mutation; **OR** you have documentation that you have at least one of the following mutations in the CFTR gene:

Table 6: List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to SYMDEKO

546insCTA	*E92K*	*G576A*	*L346P*	*R117G*	*S589N*
711+3A→G *	*E116K*	*G576A;R668C* †	*L967S*	*R117H*	*S737F*
2789+5G→A *	*E193K*	*G622D*	*L997F*	*R117L*	*S912L*
3272-26A→G *	*E403D*	*G970D*	*L1324P*	*R117P*	*S945L* *
3849+10kbC→T *	*E588V*	*G1069R*	*L1335P*	*R170H*	*S977F* *
A120T	*E822K*	*G1244E*	*L1480P*	*R258G*	*S1159F*
A234D	*E831X*	*G1249R*	*M152V*	*R334L*	*S1159P*
A349V	*F191V*	*G1349D*	*M265R*	*R334Q*	*S1251N*
A455E *	*F311del*	*H939R*	*M952I*	*R347H* *	*S1255P*
A554E	*F311L*	*H1054D*	*M952T*	*R347L*	*T338I*
A1006E	*F508C*	*H1375P*	*P5L*	*R347P*	*T1036N*
A1067T	*F508C;S1251N* †	*I148T*	*P67L* *	*R352Q* *	*T1053I*
D110E	*F508del* ^	*I175V*	*P205S*	*R352W*	*V201M*
D110H *	*F575Y*	*I336K*	*Q98R*	*R553Q*	*V232D*
D192G	*F1016S*	*I601F*	*Q237E*	*R668C*	*V562I*
D443Y	*F1052V*	*I618T*	*Q237H*	*R751L*	*V754M*
D443Y;G576A;R668C †	*F1074L*	*I807M*	*Q359R*	*R792G*	*V1153E*
D579G *	*F1099L*	*I980K*	*Q1291R*	*R933G*	*V1240G*
D614G	*G126D*	*I1027T*	*R31L*	*R1066H*	*V1293G*
D836Y	*G178E*	*I1139V*	*R74Q*	*R1070Q*	*W1282R*
D924N	*G178R*	*I1269N*	*R74W*	*R1070W* *	*Y109N*
D979V	*G194R*	*I1366N*	*R74W;D1270N* †	*R1162L*	*Y161S*
D1152H *	*G194V*	*K1060T*	*R74W;V201M* †	*R1283M*	*Y1014C*
D1270N	*G314E*	*L15P*	*R74W;V201M;D1270N* †	*R1283S*	*Y1032C*
E56K	*G551D*	*L206W* *	*R75Q*	*S549N*	
E60K	*G551S*	*L320V*	*R117C* *	*S549R*	

(Criteria continued on next page)

REQUIREMENTS: TEZACAFTOR/IVACAFTOR (CONTINUED)

RENEWAL CRITERIA

Our guideline named **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (CF: inherited life-threatening disorder that damages the lungs and digestive system)
B. You have shown improvement in clinical (medical) status compared to baseline as shown by ONE of the following:
    1. You have improved, maintained, or demonstrated less than expected decline in FEV_1 (forced expiratory volume: amount of air you can exhale in 1 second)
    2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
    3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

References:

1. Symdeco package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised December 2020. Accessed February 2022.
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
TRIHEPTANOIN Edition 1	DOJOLVI	4/29/2022	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. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. Your diagnosis is confirmed by documentation of at least TWO of the following:
    1. Disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma
    2. Low enzyme activity in cultured fibroblasts
    3. One or more known pathogenic mutations in *CPT2, ACADVL, HADHA, or HADHB*
C. You are symptomatic for LC-FAOD (for example you have rhabdomyolysis [break down of muscle tissue] or cardiomyopathy [disease of the heart muscle])
D. Therapy is prescribed by or given in consultation with a gastroenterologist (digestive tract doctor) or physician specialist in medical genetics/inherited metabolic disorders
E. You have previously tried commercial MCT oil (a medical food product) unless there is a medical reason you are unable to (contraindication)

RENEWAL CRITERIA

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

A. You have a long-chain fatty acid oxidation disorder (LC-FAOD: rare, genetic disorder that affects how the body breaks down fat)
B. You had a positive clinical response (such as improved exercise tolerance) or stabilization of clinical status compared to baseline

References:

1. Dojolvi package insert. Novato, CA. Ultragenyx Pharmaceutical Inc. Revised June 2020. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
UBROGEPANT Edition 1	UBRELVY	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

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

A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
    1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINEACT])
    2. You have experienced clinical improvement as defined by ONE of the following:
        i. Ability to function normally within 2 hours of dose
        ii. Headache pain disappears within 2 hours of dose
        iii. Treatment works consistently in majority of migraine attacks

References:

1. Ubrelvy package insert. Madison, NJ. Allergan, Inc. Revised December 2019. Accessed February 2022.
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
VERICIGUAT Edition 1	VERQUVO	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA

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

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You are 18 years of age or older
D. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)
E. You have previously tried ONE of the following sodium-glucose transporter-2 inhibitors (SGLT-2 inhibitors: class of drugs) unless there is a medical reason why you cannot (contraindication): Farxiga, Xigduo XR, Jardiance, Synjardy
F. You have previously tried ONE agent from EACH of the following classes unless there is a medical reason why you cannot (contraindication):
    1. Angiotensin converting enzyme (ACE) inhibitors (such as enalapril, lisinopril), angiotensin II receptor blockers (ARB: such as valsartan, candesartan), or angiotensin receptor-neprilysin inhibitor (ARNI: such as sacubitril/valsartan)
    2. Beta-blocker (bisoprolol, carvedilol, metoprolol succinate)
    3. Aldosterone antagonists (spironolactone or eplerenone)

RENEWAL CRITERIA

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

A. You have chronic heart failure
B. You have an ejection fraction (measurement of how well your heart pumps out blood with each heartbeat) of less than 45%
C. You will not be taking Verquvo together with long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil, tadalafil)

(Criteria continued on next page)

REQUIREMENTS: VERICIGUAT (CONTINUED)

References:

1. Verquvo package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised January 2021. Accessed March 2022
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VILTOLARSEN Edition 2	VILTEPSO	4/29/2022	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. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have documented genetic testing that confirms you have a mutation (change in DNA that make up your gene) in the DMD gene that is responsive to exon 53 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)
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. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

References:

1. Viltepso package insert. Paramus, NJ. NS Pharma, Inc. Revised March 2021. Accessed February 2022.
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
VOCLOSPORIN Edition 1	LUPKYNIS	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA

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

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints) or nephrologist (doctor who specializes in the kidney)
D. The requested medication will be used in combination with a background immunosuppressive therapy regimen (such as mycophenolate mofetil, corticosteroids)

RENEWAL CRITERIA

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

A. You have active lupus nephritis (LN: inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)
B. You have improvement in renal response from baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]) and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid use)

References:

1. Lupkynis package insert. Rockville, MD. Aurinia Pharma U.S., Inc. Revised January 2021. Accessed March 2022
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LASMIDITAN SUCCINATE Edition 1	REYVOW	4/29/2022	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. You are being treated for acute (quick onset) migraine
B. You are 18 years of age or older
C. You have previously tried ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

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

A. You are being treated for acute (quick onset) migraine
B. You meet ONE of the following:
    1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as Migraine Assessment of Current Therapy [MIGRAINE-ACT])
    2. You have experienced clinical improvement as defined by ONE of the following:
        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 January 2021. Accessed February 2022.
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
LEVAMLODIPINE MALEATE Edition 1	CONJUPRI	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have hypertension (high blood pressure)
B. You are 6 years of age or older
C. You have tried and failed BOTH of the following unless there is a medical reason you are unable to (contraindication):
    1. TWO generic dihydropyridine calcium channel blockers (such as amlodipine, felodipine, nicardipine, nifedipine)
    2. TWO other antihypertensive agents from any of the following classes:
        i. Thiazides (such as hydrochlorothiazide, chlorothiazide)
        ii. Angiotensin-converting enzyme inhibitors (such as lisinopril, enalapril)
        iii. Angiotensin II receptor blockers (such as losartan, irbesartan)

References:

1. Conjupri package insert. Shijiazhuang, China. CSPC Ouyi Pharmaceutical Co., Ltd. Revised December 2019. Accessed February 2022.
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: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018;138(17):e426-e483. doi:10.1161/CIR.0000000000000597.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
METOCLOPRAMIDE Edition 1	GIMOTI	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have acute (short duration) and recurrent (occurring repeatedly) diabetic gastroparesis (disorder that causes delayed emptying of food from the stomach)
B. You are 18 years of age or older
C. You have previously tried or have a contraindication (medical reason why you cannot take) to metoclopramide ODT (orally disintegrating tablet)

References:

1. Gimoti package insert. Solana Beach, CA. Evoke Pharma, Inc. Revised January 2021. Accessed March 2022.
2. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L; American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013;108(1):18-38. doi:10.1038/ajg.2012.373.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NINTEDANIB Edition 1	OFEV	4/29/2022	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. You have ONE of the following diagnoses:
   1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
   2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
   3. Chronic fibrosing interstitial lung disease (ILDs) with a progressive phenotype (PFILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. **If you have idiopathic pulmonary fibrosis (IPF), approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
   3. You have a usual interstitial pneumonia pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
   4. You do NOT have other known causes of interstitial lung disease, such as connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (lung inflammation from inhaled substances), systemic sclerosis (an immune system disorder), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (growth of inflammatory cells in the body), bronchiolitis obliterans organizing pneumonia (type of lung infection), human immunodeficiency virus infection, viral hepatitis (type of liver inflammation), or cancer
   5. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline

(Criteria continued on next page)

REQUIREMENTS: NINTEDANIB (CONTINUED)

C. **If you have systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval also requires:**
   1. You have Systemic Sclerosis (SSc) according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 40% of predicted value
   6. Other causes of interstitial lung disease are ruled out. Other causes may include heart failure/fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease (MCTD)

D. **If you have chronic fibrosing interstitial lung disease with progressive phenotype (PF-ILD), approval also requires:**
   1. Your lung function and respiratory (breathing) symptoms OR chest imaging have worsened/progressed despite treatment with medications used in clinical practice for interstitial lung disease (ILD) (not caused by comorbidities such as infection, heart failure)
   2. You are 18 years of age or older
   3. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
   4. You have at least 10% fibrosis (tissue scarring) on a chest high resolution computed tomography (HRCT: type of imaging testing)
   5. You have a baseline forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 45% of predicted value

(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. You have ONE of the following diagnoses:
    1. Idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
    2. Systemic sclerosis-associated interstitial lung disease (SSc-ILD: disorder that causes hardening of lung tissue)
    3. Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (PF-ILD: scarring of the lungs caused by different underlying diseases or conditions that worsens over time)

B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

References:

1. Ofev package insert. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Revised January 2022. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NITISINONE Edition 1	ORFADIN, NITYR	4/29/2022	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. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your diagnosis is confirmed by elevated urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) OR a mutation in the fumarylacetoacetate hydrolase gene
C. Therapy is prescribed by or given in consultation with a prescriber specializing in inherited metabolic diseases
D. You have been counseled on maintaining dietary restriction of tyrosine and phenylalanine
E. **If you are requesting Nityr tablets; brand Orfadin 2mg, 5mg, 10mg capsules; or Orfadin oral suspension, approval also requires:**
    1. You have previously tried generic nitisinone capsules unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

Our guideline named **NITISINONE (Orfadin, Nityr)** requires the following rule(s) be met for renewal:

A. You have hereditary tyrosinemia type 1 (HT-1: a type of genetic disorder where you cannot breakdown an important component in proteins)
B. Your urinary or plasma succinylacetone levels (a chemical that is present in hereditary tyrosinemia) have decreased from baseline while on treatment with nitisinone

References:

1. Nityr package insert. Manno, Switzerland. Rivopharm SA. Revised September 2020. Accessed March 2022.
2. Orfadin package insert. Sweden. Apotek Produktion & Laboratorier AB. Revised May 2019. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OPICAPONE Edition 1	ONGENTYS	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have Parkinson's disease (PD: a nerve system disorder that affects movement)
B. You are 18 years of age or older
C. You are experiencing 'OFF' episodes (times when you have symptoms return due to medication wearing off)
D. You are currently being treated with carbidopa/levodopa
E. You have tried or failed or have a contraindication (medical reason why you cannot use) to TWO Parkinson's disease medications from TWO different classes of medications:
    1. Dopamine agonist (such as ropinirole, pramipexole, rotigotine)
    2. Monoamine oxidase-inhibitors (MAO-I) (such as selegiline, rasagiline)
    3. Adenosine receptor antagonist A2A (such as istradefylline)
    4. Catechol-O-methyltransferase (COMT) inhibitors (such as entacapone, tolcapone)

References:

1. Ongentys package insert. San Diego, CA. Neurocrine Biosciences, Inc. Revised April 2020. Accessed March 2022.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidence-based medicine review: Update on treatments for the motor symptoms of Parkinson's disease [published correction appears in Mov Disord. 2018 Dec;33(12):1992]. Mov Disord. 2018;33(8):1248-1266. doi:10.1002/mds.27372.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OSIMERTINIB MESYLATE Edition 1	TAGRISSO	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have non-small cell lung cancer (type of lung cancer)
B. You are 18 years of age or older
C. **If you have metastatic non-small cell lung cancer (lung cancer that has spread throughout the body), approval also requires you meet ONE of the following:**
    1. You are positive for an epidermal growth factor receptor (EGFR) T790M (type of gene) mutation as confirmed by an FDA (Food and Drug Administration)-approved test AND meet all of the following:
        i. You have progressed (your condition has worsened) while on or after EGFR tyrosine kinase-inhibitor therapy. Examples of EGFR tyrosine kinase-inhibitor therapy include Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
        ii. You are not currently receiving therapy with an EGFR tyrosine kinase-inhibitor such as Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
    2. You are positive for epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (types of genes) mutations as confirmed by an FDA-approved test AND you have not received prior systemic treatment (therapy that travels through the blood) for metastatic non-small cell lung cancer
D. **If you have non-small cell lung cancer, approval also requires ALL of the following:**
    1. The requested medication is being used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor)
    2. You are positive for an epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (type of genes) mutations as confirmed by a FDA-approved test

References:

1. Tagrisso package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised January 2022. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PERTUZUMAB-TRASTUZUMAB-HY-ZZXF Edition 1	PHESGO	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **PERTUZUMAB-TRASTUZUMAB-HY-ZZXF (Phesgo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Locally advanced, inflammatory, or early breast cancer (tumor is greater than 2 cm in diameter or node positive)
   2. Early breast cancer at high risk of recurrence (returning)
   3. Metastatic breast cancer (breast cancer has spread to other parts of the body)

B. **If you have locally advanced, inflammatory or early breast cancer (tumor is greater than 2 cm in diameter or node positive), approval also requires:**
   1. Your breast cancer is HER2-positive
   2. The requested medication will be used in combination with chemotherapy as part of a complete treatment regimen for early breast cancer in the neoadjuvant setting (given before surgery)

C. **If you have early breast cancer at high risk of recurrence, approval also requires:**
   1. Your breast cancer is HER2-positive
   2. The requested medication will be used in combination with chemotherapy in the adjuvant setting (given as add-on treatment)

D. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive
   2. You have not previously received anti-HER2 therapy or chemotherapy for metastatic disease
   3. The requested medication is being used in combination with docetaxel

References:

1. Phesgo package insert. South San Francisco, CA. Genentech, Inc. Revised June 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PIRFENIDONE Edition 1	ESBRIET	4/29/2022	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. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You are 18 years of age or older
C. Therapy is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor)
D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (joint pain and inflammation), radiation, sarcoidosis (an inflammatory disease that affects multiple organs in the body, but mostly the lungs and lymph glands), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (condition that weakens your immune system), viral hepatitis (liver inflammation), or cancer
E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy and HRCT
F. You have a predicted forced vital capacity (FVC: amount of air that can be forcefully exhaled) of at least 50% at baseline
G. You do NOT currently smoke cigarettes

RENEWAL CRITERIA

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

A. You have idiopathic pulmonary fibrosis (IPF: scarring of the lungs with an unknown cause)
B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

References:

1. Esbriet package insert. South San Francisco, CA. Genentech, Inc. Revised February 2022. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PONATINIB HCL Edition 1	ICLUSIG	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Chronic Phase (CP) Chronic Myeloid Leukemia (CML: type of blood-cell cancer that begins in the bone marrow)
   2. Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)
   3. T315I-positive (a genetic mutation) chronic myeloid leukemia (CML: type of blood-cell cancer that begins in the bone marrow) OR T315I-positive (a genetic mutation) Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) (type of white blood cell cancer)

B. **If you have Chronic Phase (CP) Chronic Myeloid Leukemia (CML), approval also requires:**
   1. You are 18 years of older
   2. You are resistant or not able to safely use at least two prior kinase inhibitor treatments such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib)

C. **If you have Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML), OR Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of older
   2. No other kinase inhibitors treatment, such as Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imantinib), can be used for your disease

D. **If you have T315I-positive chronic myeloid leukemia (CML), OR T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), approval also requires:**
   1. You are 18 years of older

References:

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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PRALSETINIB Edition 1	GAVRETO	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following:
   1. Metastatic non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)
   2. Advanced or metastatic medullary thyroid cancer (MTC: thyroid cancer that started in the center of the thyroid and has spread to other parts of the body)
   3. Advanced or metastatic thyroid cancer (thyroid cancer that has spread to other parts of the body)

B. **If you have metastatic non-small cell lung cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor that has been detected by a Food and Drug Administration (FDA)-approved test

C. **If you have advanced or metastatic medullary thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) mutant tumor
   3. You need systemic therapy (medicine that goes into the entire body)

D. **If you have advanced or metastatic thyroid cancer, approval also requires:**
   1. You are 12 years of age or older
   2. You have a rearranged during transfection (*RET:* type of gene) fusion-positive tumor
   3. You need systemic therapy (medicine that goes into the entire body)
   4. You have received treatment with radioactive iodine, and it did not work or is no longer working (if radioactive iodine is appropriate)

References:

1. Gavreto package insert. Cambridge, MA. Blueprint Medicines Corporation. Revised December 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SELINEXOR Edition 1	XPOVIO	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Multiple myeloma (MM: cancer of a type of white blood cells called plasma cells)
   2. Relapsed or refractory multiple myeloma (RRMM: cancer of a type of white blood cells called plasma cells, that has return or did not respond to treatment)
   3. Relapsed or refractory diffuse large B-cell lymphoma (DLBCL: type of cancer that starts in the immune system), including DLBCL arising from follicular lymphoma

B. You are 18 years of age or older

C. **If you have multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with Velcade (bortezomib) and dexamethasone
   2. You have received at least one therapy before Xpovio

D. **If you have relapsed or refractory multiple myeloma, approval also requires:**
   1. The requested medication will be used in combination with dexamethasone
   2. You have received at least four prior therapies for the treatment of RRMM)
   3. Your RRMM is refractory (non-responsive) to **ALL** of the following:
      i. Two proteasome inhibitors (such as bortezomib, carfilzomib)
      ii. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
      iii. One anti-CD38 monoclonal antibody (such as daratumumab)

E. **If you have relapsed or refractory diffuse large B-cell lymphoma (DLBCL), approval also requires:**
   1. You have received at least two lines of systemic therapy (treatment that spreads throughout the body)

References:

1. Xpovio package insert. Newton, MA. Karyopharm Therapeutics Inc. Revised December 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
APALUTAMIDE Edition 1	ERLEADA	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
    2. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

B. You meet ONE of the following:
    1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
    2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
    3. Your blood testosterone levels are less than 50 ng/dL

C. **If you have a non-metastatic castration-resistant prostate cancer, approval also requires:**
    1. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA] levels)

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. Non-metastatic castration-resistant prostate cancer (prostate cancer that does not respond to hormone reduction therapy but has not spread)
    2. Metastatic castration-sensitive prostate cancer (cancer that has spread and responds to hormone therapy)

References:

1. Erleada package insert. Horsham, PA. Janssen Products, LP. Revised September 2021. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AZACITIDINE Edition 1	ONUREG	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have acute myeloid leukemia (AML: type of blood and bone marrow cancer with too many white blood cells)
B. You are 18 years of age or older
C. You have achieved first complete remission (CR: signs or symptoms of cancer have disappeared) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy (medications for cancer)
D. You are not able to complete intensive curative therapy (treatment to cure the disease)

References:

1. Onureg package insert. Summit, NJ. Bristol Myers Squibb. Revised May 2021. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

AMANTADINE EXTENDED RELEASE Edition 2			
Generic	Brand	Reviewed	Effective Date
AMANTADINE EXTENDED RELEASE	GOCOVRI	4/29/2022	4/29/2022
AMANTADINE HCL	OSMOLEX ER		

REQUIREMENTS:

Our guideline named **AMANTADINE EXTENDED RELEASE** requires the following rule(s) be met for approval:

A. You have Parkinson's disease (nervous system disorder that affects movement) or drug induced extrapyramidal reactions

B. You are 18 years of age or older**If you have dyskinesia (abnormal involuntary movements), approval also requires:**
   1. You are receiving levodopa-based therapy

C. **If you are experiencing 'off' episodes (when the medication stops working), approval also requires:**
   1. Your request is for Gocovri
   2. You are also receiving levodopa-carbidopa therapy

D. **If you are being treated for drug-induced extrapyramidal symptoms (group of movement disorders), approval also requires:**
   1. Your request is for Osmolex ER

E. You have a previous trial and failure with generic amantadine immediate-release capsules, tablets or solution

References:

1. Gocovri package insert. Emeryville, CA. Adamas Pharma, LLC. Revised January 2021. Accessed February 2022.
2. Osmolex ER package insert. Emeryville, CA. Adamas Pharma, LLC. Revised March 2021. Accessed February 2022.
3. Inzelberg R, Nisipeanu P, Schechtman E. Practice parameter: initiation of treatment for Parkinson's disease: an evidence-based review. Neurology. 2002;59(8):1292. doi:10.1212/wnl.59.8.1292.

WELLFLEET RX STUDENT FORMULARY

BOTULINUM NEUROTOXIN Edition 1			
Generic	Brand	Reviewed	Effective Date
ONABOTULINUM TOXIN A	BOTOX	4/29/2022	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. You are using the requested medication for ONE of the following non-cosmetic (not for appearance) conditions:
   1. Overactive bladder (OAB: problem with the bladder function that causes the sudden need to urinate)
   2. Urinary incontinence (uncontrolled leakage of urine)
   3. Neurogenic detrusor overactivity (NDO: nerve related bladder dysfunction)
   4. Prevention of chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer)
   5. Spasticity (stiffness or tightness of your muscles)
   6. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
   7. Severe axillary hyperhidrosis (excessive underarm sweating)
   8. Blepharospasm (involuntary forcible closure of the eyelid)
   9. Strabismus (cross-eyed).

B. **If you have overactive bladder (OAB), approval also requires:**
   1. You are 18 years of age or older.
   2. You previously tried an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

REQUIREMENTS: BOTOX (CONTINUED)

C. **If you have urinary incontinence, approval also requires:**
    1. You are 18 years of age or older.
    2. You have detrusor (bladder muscle) overactivity associated with a neurologic (nervous system) condition such as: spinal cord injury (SCI) or multiple sclerosis (MS).
    3. You previously tried an anticholinergic medication such as oxybutynin, Ditropan XL, Detrol, Detrol LA, Enablex, Toviaz, Vesicare, or Sanctura, unless there is a medical reason why you cannot
D. **If you have neurogenic detrusor overactivity (NDO), approval also requires:**
    1. You are 5 years of age or older
    2. You did not have an adequate response or are not able to take anticholinergic medications
E. **If you have chronic migraine headaches (at least 15 days per month with headache lasting 4 hours a day or longer), approval also requires:**
    1. You are 18 years of age or older.
    2. You previously tried any **TWO** (2) of the following migraine prevention treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol.
F. **If you have cervical dystonia and severe axillary hyperhidrosis, approval also requires:**
    1. You are 18 years of age or older.
G. **If you have spasticity, approval also requires:**
    1. You are 2 years of age or older.
H. **If you have blepharospasm and strabismus, approval also requires:**
    1. You are 12 years of age or older.

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

DYSPORT

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

A. You have cervical dystonia also called spasmodic torticollis (involuntary contracting of the neck muscles) AND you are 18 years of age or older
B. You have spasticity (stiffness or tightness of your muscles) AND you are 2 years of age or older

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

(Criteria continued on next page)

REQUIREMENTS: BOTULINUM NEUROTOXIN (CONTINUED)

MYOBLOC

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

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
    1. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
    2. Chronic sialorrhea (drooling or excessive salivation)
B. You are 18 years of age or older

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

XEOMIN

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

A. You have ONE of the following non-cosmetic (not for appearance) conditions:
    1. Chronic sialorrhea (drooling or excessive salivation)
    2. Cervical dystonia (spasmodic torticollis or involuntary contracting of the neck muscles)
    3. Blepharospasm (involuntary forcible closure of the eyelid)
    4. Upper limb spasticity (stiffness or tightness of your muscles)
B. **If you have cervical dystonia or blepharospasm, approval also requires:**
    1. You are 18 years of age or older
C. **If you have chronic sialorrhea, approval also requires:**
    1. You are 2 years of age or older
D. **If you have upper limb spasticity, approval also requires ONE of the following:**
    1. You are 18 years of age or older
    2. You are 2 to 17 years of age and do not have spasticity caused by cerebral palsy (an illness that affects movement, muscle tone or posture)

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

(Criteria continued on next page)

REQUIREMENTS: BOTULINUM NEUROTOXIN (CONTINUED)

References:

1. Botox package insert. Madison, NJ. Allergan USA, Inc. Revised July 2021. Accessed February 2022.
2. Dysport package insert. Cambridge, MA. Ipsen Biopharmaceuticals, Inc. Revised July 2020. Accessed February 2022.
3. Myobloc package insert. Rockville, MD. Solstice Neurosciences, LLC. Revised Sepetmber 2020. Accessed February 2022.
4. Xeomin package insert. Raleigh, NC. Merz Pharmaceuticals, LLC. Revised August 2021. Accessed February 2022.
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

LISOCABTAGENE MARALEUCEL			
Generic	Brand	Reviewed	Effective Date
LISOCABTAGENE MARALEUCEL Edition 1	BREYANZI	04/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **LISOCABTAGENE MARALEUCEL (Breyanzi)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory large B-cell lymphoma (type of immune system cancer that has returned or is not responding to treatment, including diffuse large B-cell lymphoma [DLBCL] not otherwise specified [including DLBCL arising from indolent lymphoma], high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B)
B. You are 18 years of age or older
C. You have previously received 2 or more lines of systemic therapy (treatment that travels throughout the body)

References:

1. Breyanzi package insert. Bothell, WA. Juno Therapeutics Inc. Revised February 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CEMIPLIMAB-RWLC Edition 2	LIBTAYO	4/29/2022	04/29/2022

REQUIREMENTS:

Our guideline named **CEMIPLIMAB-RWLC (Libtayo)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC: type of skin cancer that has spread or has highly developed)
   2. Metastatic or locally advanced basal cell carcinoma (BCC: type of skin cancer that has spread or has highly developed)
   3. Metastatic or locally advanced non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body)

B. **If you have metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC), approval also requires:**
   1. You are not a candidate for curative surgery or curative radiation.

C. **If you have metastatic or locally advanced basal cell carcinoma (BCC), approval also requires:**
   1. You have previously been treated with a hedgehog pathway inhibitor (such as Erivedge, Odomzo) or a hedgehog pathway inhibitor is not appropriate for you

D. **If you have metastatic or locally advanced non-small cell lung cancer (NSCLC), approval also requires:**
   1. Your disease is locally advanced and you are not a candidate for surgical resection or definitive chemoradiation OR your disease is metastatic
   2. You are using the requested medication as first-line treatment
   3. Your tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations

References:

1. Libtayo package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised February 2021. Accessed February 2022..

WELLFLEET RX STUDENT FORMULARY

OPIOID NAIVE FILL LIMIT Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/23/2021	7/23/2021

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.

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 you meet at least **ONE** of the following conditions:

A. You have active cancer
B. You are enrolled in hospice
C. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of blood disorder)
F. You are NOT opioid naïve (you have been consistently using opioid pain medications)
G. Your doctor confirms that the additional fill of the requested opioid analgesic (pain-relieving) medication is intended and clinically appropriate for you

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

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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 7/30/19]
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-durofr- master-webposting-508.pdf [Accessed 2/1/21].
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
UMBRALISIB TOSYLATE Edition 1	UKONIQ	4/29/2022	6/1/2021

REQUIREMENTS:

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

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

References:

1. Ukoniq package insert. Edison, NJ. TG Therapeutics, Inc. Revised February 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DROXIDOPA Edition 1	NORTHERA	4/29/2022	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. You have neurogenic orthostatic hypotension (a type of low blood pressure)
B. You are 18 years of age or older
C. You have a documented diagnosis of neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency (you are missing a type of enzyme), or nondiabetic autonomic neuropathy (nerve pain/damage)
D. You have previously tried midodrine OR fludrocortisone, unless there is a medical reason why you cannot (contraindication)
E. The medication was prescribed or given in consultation with a neurologist (nerve doctor) or cardiologist (heart doctor)
F. Your doctor performed baseline blood pressure readings while you are sitting and also within 3 minutes of standing from a supine (lying face up) position
G. You have a documented decrease of at least 20mmHg in systolic blood pressure or 10mmHg diastolic blood pressure within 3 minutes after standing from a sitting position
H. You have persistent symptoms of neurogenic orthostatic hypotension which includes dizziness, lightheadedness, and the feeling of 'blacking out'

RENEWAL CRITERIA

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

A. You have neurogenic orthostatic hypotension (NOH)
B. You have demonstrated improvement in severity from baseline symptoms of dizziness, lightheadedness, feeling faint, or feeling like you may black out
C. You had an increase in systolic blood pressure from baseline of at least 10mmHg upon standing from a supine (lying face up) position

References:

1. Northera package insert. Deerfield, IL. Lundbeck. Revised February 2017. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NIVOLUMAB Edition 3	OPDIVO	4/29/2022	4/29/2022

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma (type of skin cancer that has spread or cannot be completely removed with surgery)
   2. Melanoma with lymph node involvement or metastatic (cancer that has spread to other parts of the body) disease
   3. Resectable non-small cell lung cancer (NSCLC) as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) disease
   4. Metastatic or recurrent non-small cell lung cancer (NSCLC: type of lung cancer that has spread to other parts of the body or has returned)
   5. Unresectable (cannot be removed by surgery) malignant pleural mesothelioma (A tumor of the tissue that has spread and lines the lungs, stomach, heart, and other organs.)
   6. Advanced renal cell carcinoma (RCC: type of kidney cancer)
   7. Classical Hodgkin lymphoma (cHL: a type of immune system cancer)
   8. Recurrent (returning) or metastatic squamous cell carcinoma of the head and neck (SCCHN: type of head/neck cancer that has spread to other parts of the body)
   9. Urothelial carcinoma (urinary system cancer)
   10. Locally advanced, or metastatic urothelial carcinoma (urinary system cancer)
   11. Microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer
   12. Hepatocellular carcinoma (HCC: liver cancer)
   13. Unresectable (cannot be removed by surgery) advanced, recurrent (returning) or metastatic esophageal squamous cell carcinoma (ESCC: type of cancer that affects the esophagus [tube that runs from the throat to the stomach] and has spread to other parts of the body)
   12. Metastatic Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma
   13. Completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease

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REQUIREMENTS: NIVOLUMAB (CONTINUED)

B. **If you have unresectable or metastatic melanoma, approval also requires:**
    1. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
    2. You will not be using the requested medication with Tafinlar (dabrafenib), Mekinist (trametinib), Zelboraf (vemurafenib) or Cotellic (cobimetinib)
C. **If you have melanoma with lymph node involvement or metastatic disease, approval also requires:**
    1. You have undergone complete resection (completely removed by surgery)
    2. The requested medication will be used as an adjuvant (add-on) treatment
D. **If you have resectable non-small cell lung cancer, approval also requires:**
    1. You are 18 years of age or older
    2. Your tumors are resectable (tumors ≥4 cm or node positive)
    3. The requested medication is used as neoadjuvant treatment
    4. The requested medication will be used in combination with platinum-doublet chemotherapy
E. **If you have metastatic or recurrent non-small cell lung cancer, approval also requires:**
    1. You are 18 years of age or older
    2. Your tumor does NOT have epidermal growth factor receptor (EGFR: type of protein) or anaplastic lymphoma kinase (ALK: type of protein) genomic tumor aberrations (changes in your gene structure)
    3. The requested medication is used as first-line treatment
    4. You meet ONE of the following:
        i. **For metastatic NSCLC:** the requested medication will be used in combination with Yervoy (ipilimumab) AND your tumor expresses programmed death-ligand 1 (PD-L1: type of protein) at greater than or equal to 1% as determined by an FDA (Food and Drug Administration)-approved test
        ii. **For metastatic or recurrent NSCLC:** the requested medication will be used in combination with Yervoy (ipilimumab) and 2 cycles of platinum-doublet chemotherapy (type of cancer medication)
F. **If you have metastatic non-small cell lung cancer, approval also requires:**
    1. Your disease has worsened while on or after platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. If you have ALK mutations (type of gene mutation), your disease must have worsened after using an FDA-approved ALK-directed therapy (such as crizotinib, ceritinib)
    3. If you have EGFR mutations (type of gene mutation), your disease must have worsened after using an FDA-approved EGFR-directed therapy (such as erlotinib, gefitinib, afatinib)

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REQUIREMENTS: NIVOLUMAB (CONTINUED)

G. **If you have malignant pleural mesothelioma, approval also requires:**
    1. You are 18 years of age or older
    2. Opdivo will be used as first line treatment in combination with Yervoy (ipilimumab)

H. **If you have advanced renal cell carcinoma (RCC), approval also requires ONE of the following:**
    1. Opdivo will be used in combination with Yervoy (ipilimumab) AND meet the following:
        i. You have intermediate or poor risk disease
        ii. You have not received prior treatment for advanced renal cell carcinoma
    2. Opdivo will be used in combination with Cabometyx (cabozanitib) AND meet the following:
        i. You have not received prior treatment for renal cell carcinoma
    3. Opdivo will be used alone, and you have previously received one prior antiangiogenic therapy (drugs that stop tumors from growing their own blood vessels such as Sutent (sunitinib), Votrient (pazopanib), Cabometyx (cabozantinib), Inlyta (axitinib), Nexavar (sorafenib)

I. **If you have classical Hodgkin lymphoma (cHL), approval also requires:**
    1. You are 18 years of age or older
    2. Your disease has relapsed or worsened after ONE of the following:
        i. Autologous hematopoietic stem cell transplantation (cells from your own body are used) and Adcetris (brentuximab vedotin)
        ii. Three or more lines of systemic therapy that includes autologous hematopoietic stem cell transplantation

J. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck (HNSCC), approval also requires:**
    1. You are 18 years of age or older
    2. Your disease has worsened on or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

K. **If you have urothelial carcinoma, approval also requires the following:**
    1. You are 18 years of age or older
    2. You have undergone radical resection of tumor and your disease is considered high risk for recurrence
    3. The requested medication is used as adjuvant treatment

L. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
    1. Your disease has worsened during or following platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. Your disease has worsened within 12 months of neoadjuvant or adjuvant (add-on) treatment with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

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REQUIREMENTS: NIVOLUMAB (CONTINUED)

M. **If you have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, approval also requires:**
    1. You are 12 years of age or older
    2. You will be using Opdivo alone OR in combination with Yervoy (ipilimumab)
    3. Your disease has worsened after treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

N. **If you have hepatocellular carcinoma (HCC), approval also requires:**
    1. You are 18 years of age or older
    2. You will be using Opdivo in combination with Yervoy (ipilimumab)
    3. You have been previously treated with Nexavar (sorafenib)

O. **If you have unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC), approval also requires:**
    1. You are 18 years of age or older
    2. You have previously received treatment with fluoropyrimidine and platinum-based chemotherapy (type of cancer medications)

P. **If you have advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma**
    1. You are 18 years of age or older
    2. You will be using Opdivo in combination with fluoropyrimidine- and platinum-containing chemotherapy

Q. **If you have completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease**
    1. You are 18 years of age or older
    2. The requested medication is used as adjuvant treatment
    3. You have previously received neoadjuvant chemoradiotherapy

References:

1. Opdivo Package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised March 2022. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

EVINACUMAB-DGNB			
Generic	Brand	Reviewed	Effective Date
EVINACUMAB-DGNB Edition 2	EVKEEZA	4/29/2022	04/29/2022

REQUIREMENTS:

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for approval:

A. You have homozygous familial hypercholesterolemia as determined by ONE of the following:
   1. genetic testing
   2. history of an untreated total cholesterol (TC) >500 mg/dL and either xanthoma before 10 years of age or evidence of TC >250 mg/dL in both parents

B. You are 12 years of age or older

C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You have an LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL

E. If you are statin tolerant, approval also requires:
   1. You will continue statin treatment in combination with Evkeeza
   2. You meet ONE of the following:
      i. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
      ii. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

F. If you are statin intolerant, approval also requires ONE of the following:
   1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

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REQUIREMENTS: EVINACUMAB-DGNB (CONTINUED)

G. If you are statin intolerant, approval also requires Evkeeza will be used as an adjunct (add-on) to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (such as PCSK9 inhibitors, ezetimibe, lomitapide, lipoprotein apheresis)

RENEWAL CRITERIA

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for renewal:

A. If statin tolerant, you continue with statin treatment in combination with the Evkeeza
B. If you are statin intolerant, you continue with other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (such as PCSK9 inhibitors, ezetimibe, lomitapide, lipoprotein apheresis) in combination with the Evkeeza
C. You are responding positively to therapy as evidenced by lab results within the last 3 months showing an LDL-C reduction since initiation of Evkeeza therapy

References:

1. Evkeeza package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised February 2021. Accessed February 2022.
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 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

TRILACICLIB			
Generic	Brand	Reviewed	Effective Date
TRILACICLIB DIHYDROCHLORIDE Edition 1	COSELA	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have extensive-stage small cell lung cancer
B. You are 18 years of age or older
C. Cosela is being used to decrease the incidence of chemotherapy-induced myelosuppression (decreased bone marrow activity causing fewer red blood cells, white blood cells, and platelets)
D. Cosela will be given prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

References:

1. Cosela package insert. Durham, NC. G1 Therapeutics, Inc. Revised February 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NERATINIB Edition 1	NERLYNX	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Early stage (stage I-III) breast cancer
   2. Advanced or metastatic breast cancer

B. **If you have early stage (stage I-III) breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
   3. The tumor is hormone-receptor positive
   4. The requested medication will be used as extended adjuvant therapy following Herceptin- (trastuzumab-) based therapy
   5. The medication is being requested within 2 years of completing the last trastuzumab dose

C. **If you have advanced or metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a HER2-overexpressed/amplified (HER2-positive) tumor
   3. The requested medication will be used in combination with capecitabine
   4. You have received two or more prior anti-HER2 based regimens in the metastatic setting

References:

1. Nerlynx package insert. Los Angeles, CA. Puma Biotechnology, Inc. Revised June 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

OPIOID-BENZODIAZEPINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/23/2021	7/23/2021

REQUIREMENTS:

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of use of an opioid with a benzodiazepine together when ONE of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of red blood cell disorder)
F. Your doctor confirms (attests) to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019."*CMS 2019 Call Letter, page 251*
The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.
This guideline allows an approval for patients with one of the following conditions:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease

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REQUIREMENTS: OPIOID-BENZODIAZEPINE CONCURRENT USE (CONTINUED)

- Physician attestation that the prescriber is aware that the patient is concurrently receiving a
- benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine

References:

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 4/2/18].
2. Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at https://www.cms.gov/Medicare/Prescription-Drug Coverage/PrescriptionDrugCovContra/Downloads/Frequently-Asked-Questions-about-Contract-Year-2019-Formulary-Level-Opioid-Point-of-Sale-Safety-Edits.pdf [Accessed 5/13/19].
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-durofr-master-webposting-508.pdf [Accessed 2/1/21].
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-BUPRENORPHINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/23/2021	7/23/2021

REQUIREMENTS:

Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid with buprenorphine or a buprenorphine-containing agent together when ONE of the following rule(s) is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. Your doctor confirms (attests) that you have discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and you need to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. Your doctor is aware that you are currently receiving buprenorphine or a buprenorphine containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from CMS guidance. For further information, please refer to the Drug Monograph for Opioid-Buprenorphine Concurrent Use.

References:

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 4/2/18].
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-durofr-master-webposting-508.pdf [Accessed 2/1/21].
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.

WELLFLEET RX STUDENT FORMULARY

OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/23/2021	7/23/2021

REQUIREMENTS:

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together when one of the following criteria is met:

A. You have active cancer
B. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
C. You are enrolled in a hospice
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. Your doctor confirms that the use of an opioid with Soma (carisoprodol) and a benzodiazepine medication together is intended and clinically appropriate for you

Please consult your physician if you have any questions about this prescription medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To mitigate the risk of the overdose from dangerous combinations of CNS depressants while preserving patient access to drug regimens if deemed medically necessary.

The Opioid-Benzodiazepine-Soma Concurrent Use at POS edit will identify and deny concurrent use of opioids, benzodiazepines, and carisoprodol when there is an overlap in day supply (for at least one drug from each 'class'). This edit will reject the claim that creates the three-drug overlap. The edit will have internal reject codes REJ- 433- 1204, and the following parameters:

1. Triple drug overlap = 1 day
2. Prescriber threshold = 1 prescriber
3. Exceptions =
    a. Cancer diagnosis (edit will lookback for presence of claims related to these diseases in the past 180 days to automatically exclude from the edit)
    b. Hospice or palliative care (edit will look for hospice attribute on claims to automatically exclude from the edit)
    c. Long Term Care residence (edit will look for patient residence code to automatically exclude from the edit)

Please note that sickle cell disease will not be included in the exception criteria. Although opioids and benzodiazepines can be used in managing pain crises, treatment guidelines do not mention skeletal muscle relaxants such as carisoprodol as a typical treatment modality.

(Continued on next page)

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

Generic	Brand	Reviewed	Effective Date
PERTUZUMAB Edition 1	PERJETA	4/29/2022	6/1/2021

REQUIREMENTS:
Our guideline named **PERTUZUMAB (Perjeta)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other body parts)
   2. Locally advanced, inflammatory, or early stage breast cancer (breast cancer defined as either greater than 2cm in diameter or node positive)
   3. Early breast cancer at high risk of recurrence (returning)

B. **If you have metastatic breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (higher than normal levels of a protein called human epidermal growth factor receptor 2)
   2. You have not received prior therapy with an anti-HER2 agent (drug that works against a protein called human epidermal growth factor receptor 2) or chemotherapy for metastatic disease (cancer treatment for disease that has spread to other parts of the body)
   3. The requested medication will be used in combination with trastuzumab and docetaxel

C. **If you have locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive), you must also meet ALL of the below:**
   1. Your breast cancer is HER2-positive (higher than normal levels of a protein called human epidermal growth factor receptor 2)
   2. The requested drug will be used in the neoadjuvant setting (given before surgery); and
   3. The requested drug will be used in combination with trastuzumab and chemotherapy (cancer drug treatment such as paclitaxel, carboplatin, or cyclophosphamide) as part of a complete drug regimen for early breast cancer

D. **If you have early breast cancer, approval also requires:**
   1. Your breast cancer is HER2-positive (higher than normal levels of a protein called human epidermal growth factor receptor 2)
   2. The requested drug will be used in the adjuvant setting (given as an add-on treatment)
   3. The requested drug will be used in combination with trastuzumab and chemotherapy (cancer drug treatment such as paclitaxel, carboplatin, or cyclophosphamide)

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REQUIREMENTS: PERTUZUMAB (CONTINUED)

References:

1. Perjeta package insert. South San Francisco, CA. Genentech, Inc. Revised January 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ROMIPLOSTIM Edition 1	NPLATE	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. Immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding)
    2. Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS: you have been acutely exposed to myelosuppressive doses of radiation)

B. If you have immune thrombocytopenia (ITP), approval also requires:
    1. You are 1 year of age or older
    2. You have previously tried or have a contraindication to (medical reason why you cannot use) corticosteroids or immunoglobulins, OR you had an insufficient response to a splenectomy (surgical removal of spleen)
    3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist) or immunologist (allergy/immune system doctor)
    4. **If you are between 1 and 17 years old, approval also requires:**
        i. You had immune thrombocytopenia (ITP) for at least 6 months

RENEWAL CRITERIA

NOTE: For the diagnoses of Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS), please refer to the Initial Criteria section.

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

A. You have immune thrombocytopenia (ITP: your immune system attacks blood cells that prevent bleeding)
B. You had a clinical response, as defined by an increase in platelet count to at least 50 X 10^9/L (at least 50,000 per microliter)

(Continued on next page)

REQUIREMENTS: ROMIPLOSTIM (CONTINUED)

References:

1. Nplate package insert. Thousand Oaks, CA. Amgen Inc. Revised February 2022. Accessed March 2022.
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. Waselenko JK, MacVittie TJ, Blakely WF, et al. Medical management of the acute radiation syndrome: recommendations of the Strategic National Stockpile Radiation Working Group. Ann Intern Med. 2004;140(12):1037-1051. doi:10.7326/0003-4819-140-12-200406150-00015.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
URSODIOL Edition 1	RELTONE	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have radiolucent (barely visible on x-ray), non-calcified gallbladder stones (hardened deposits formed in gallbladder that do not contain calcium)
B. Your gallbladder stones are less than 20mm in diameter
C. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, **OR** you refuse surgery
D. You have tried generic ursodiol or are unable to take generic ursodiol formulations

References:

1. Reltone package insert. Las Vegas, NV. Intra-Sana Laboratories LLC. Revised January 2020. Accessed March 2022.
2. 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
ALIROCUMAB Edition 2	PRALUENT PEN, PRALUENT SYRINGE	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
    1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
    2. Primary hyperlipidemia (high cholesterol such as heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol])
    3. Homozygous familial hypercholesterolemia (HoFH)
B. You are 18 years of age or older
C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)
D. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70mg/dL
E. **If you are statin tolerant, approval also requires:**
    1. You will continue statin treatment in combination with Praluent
    2. You meet ONE of the following:
        i. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
        ii. You have been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: ALIROCUMAB (CONTINUED)

F. **If you are statin intolerant, approval also requires ONE of the following:**
    1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
    2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group
G. **If you have primary hyperlipidemia (such as heterozygous familial hypercholesterolemia [HeFH]), approval also requires the diagnosis is determined by meeting ONE of the following:**
    1. Simon Broome diagnostic criteria (definite)
    2. Dutch Lipid Network criteria with a score of at least 6
H. **For patients with homozygous familial hypercholesterolemia (HoFH), the diagnosis must be determined by meeting ONE of the following criteria:**
    1. Simon Broome diagnostic criteria (definite)
    2. Dutch Lipid Network criteria with a score of 8 or greater
    3. A clinical diagnosis based on a history of an untreated LDL (low density lipoprotein)-cholesterol level greater than 500 mg/dL, in combination with either (1) xanthoma before 10 years of age **OR** (2) evidence of heterozygous familial hypercholesterolemia (type of inherited high cholesterol) in both parents

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
    2. Primary hyperlipidemia (high cholesterol such as heterozygous familial hypercholesterolemia [HeFH]: type of inherited high cholesterol)
    3. Homozygous familial hypercholesterolemia [(HoFH) type of inherited high cholesterol]

(Criteria continued on next page)

REQUIREMENTS: ALIROCUMAB (CONTINUED)

B. You also meet ONE of the following:
    1. You have continued to take a high intensity statin atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with the requested medication
    2. You have continued therapy with a maximally tolerated dose of any statin along with the requested medication
    3. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
    4. You have complete statin intolerance

References:

1. Praulent package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised April 2021. Accessed July 2021.
2. 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

GRANULOCYTE COLONY-STIMULATING FACTORS Edition 2			
Generic	Brand	Reviewed	Effective Date
FILGRASTIM-AAFI	NIVESTYM	4/29/2022	4/29/2022
FILGRASTIM-SNDZ	ZARXIO		
PEGFILGRASTIM	NEULASTA		
PEGFILGRASTIM-JMDB	FULPHILA		
PEGFILGRASTIM-BMEZ	ZIEXTENZO		
PEGFILGRASTIM-CBQV	UDENYCA		

REQUIREMENTS:
The guideline named **GRANULOCYTE COLONY-STIMULATING FACTORS (GCSF)** requires that the requested medication is prescribed by or given in consultation with a hematologist or oncologist. In addition, the following criteria must be met:

Requests for Nivestym or Zarxio require ONE of the following indications:

A. Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
B. Patients with acute myeloid leukemia (AML) undergoing induction or consolidation chemotherapy treatment
C. Patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) who are experiencing neutropenia and/or neutropenia-related clinical sequelae (e.g., febrile neutropenia)
D. Mobilization of autologous hematopoietic progenitor cells into peripheral blood for collection by leukapheresis
E. Patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Requests for Neulasta requires the following indication:

A. Increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)

Requests for Fulphila, Udencya, or Ziextenzo require the following indication:

A. Patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

(Continued on next page)

REQUIREMENTS: GRANULOCYTE COLONY-STIMULATING FACTORS (CONTINUED)

References:

1. Nivestym package insert. Lake Forest, IL. Hospira, Inc. Revised April 2021. Accessed February 2022.
2. Zarxio package insert. Princeton, NJ. Sandoz Inc. Revised March 2021. Accessed February 2022
3. Neulasta package insert. Thousand Oaks, CA. Amgen Inc. Revised February 2021. Accessed February 2022.
4. Fulphila package insert. Morgantown, WV. Mylan Pharmaceuticals Inc. Revised March 2021. Accessed February 2022.
5. Udencya package insert. Redwood City, CA. Coherus BioSciences, Inc. Revised June 2021. Accessed February 2022.
6. Ziextenzo package insert. Princeton, NJ. Sandoz Inc. Revised March 2021. Accessed February 2022.
7. 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.
8. 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 STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AMIFAMPRIDINE Edition 2	FIRDAPSE, RUZURGI	4/29/2022	4/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for approval:

A. You have Lambert-Eaton myasthenic syndrome (LEMS)
B. Therapy is prescribed by or given in consultation with a neurologist or hematologist-oncologist (blood-cancer doctor)
C. 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
D. Your 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.]
E. If you are requesting Firdapse, approval also requires:
    1. You are 18 years of age or older
F. If you are requesting Ruzurgi, approval also requires:
    1. Documentation of your weight

RENEWAL CRITERIA

Our guideline named **AMIFAMPRIDINE (Firdapse, Ruzurgi)** requires the following rule(s) be met for renewal:

A. You have Lambert-Eaton myasthenic syndrome (LEMS)
B. Submitted documentation shows you have experienced or maintained improvement in disease activity from baseline 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 February 2021. Accessed February 2022.
2. Ruzurgi package insert. Princeton, NJ. Jacobus Pharmaceutical Company, Inc. Revised April 2020. Accessed February 2022.
3. 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.

WELLFLEET RX STUDENT FORMULARY

RIBOCICLIB Edition 2			
Generic	Brand	Reviewed	Effective Date
RIBOCICLIB SUCCINATE	KISQALI	4/29/2022	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. You have advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (cancer that has spread throughout the body and has a type of hormone with no gene mutation).

B. **For Kisqali-Femara Co-Pack, approval also requires:**
   1. You have **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 you have **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 meet **ONE** of the following:
      i. You have **NOT** received prior endocrine-based therapy for advanced or metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
      ii. You have experienced disease progression on endocrine therapy **AND** had a trial of Ibrance (palbociclib) or Verzenio (abemaciclib)

References:

1. Kisqali package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2021. Accessed March 2022.
2. Kisqali Femara co-pack package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Date Revised	Effective Date
SODIUM OXYBATE Edition 1	XYREM	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline for **SODIUM OXYBATE (XYREM)** requires a diagnosis of cataplexy in narcolepsy OR excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2). Additional guideline requirements apply.

For the diagnosis of cataplexy in narcolepsy, the following criteria must be met:

A. The patient is 7 years of age or older
B. Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
C. Both the patient and physician are registered in the "Xyrem REMS Program" provided by the manufacturer
D. The patient has tried **TWO** of the following: venlafaxine, fluoxetine, or a tricyclic antidepressant (e.g., amitriptyline, clomipramine, imipramine)
E. 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.**
F. Provide clinical documentation of functional impairment due to narcolepsy with cataplexy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
G. 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)

(Criteria continued on next page)

REQUIREMENTS: SODIUM OXYBATE (XYREM) (CONTINUED)

For the diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2), the following criteria must be met:

A. The patient is 7 years of age or older
B. Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
C. Both the patient and physician are registered in the "Xyrem REMS Program" provided by the manufacturer
D. Diagnosis of narcolepsy, after evaluation including a sleep study which excludes other causes of chronic daytime sleepiness (unless the prescriber provides documentation that a sleep study would not be clinically appropriate)
E. Modafinil in doses up to 400 mg daily, OR armodafinil in doses up to 250 mg daily, has been ineffective, not tolerated, or contraindicated
F. At least one generic stimulant (e.g., methylphenidate, dextroamphetamine, or amphetamine) has been ineffective, not tolerated, or contraindicated
G. Provide clinical documentation of narcolepsy symptoms occurring for at least 3 months with ESS (Epworth Sleepiness Scale) scores > 10 confirmed by one of the following: **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
    a. MSLT mean sleep latency 8 minutes or less, including REM sleep episodes during 2* or more test periods (aka SOREMPs)
        i. *Polysomnography demonstrating early-onset REM sleep of approximately 15 minutes the night before the MSLT may replace one mid-MSLT SOREMP but should rule out non-narcolepsy causes of EDS
    b. Alternately, low CSF orexin/hypocretin levels per assay
H. Provide clinical documentation of functional impairment due to narcolepsy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
I. Patient is not currently on a sedative hypnotic agent (e.g., Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), estazolam, Restoril (temazepam), Halcion (triazolam), flurazepam, quazepam, Belsomra)

RENEWAL CRITERIA

Our guideline for **SODIUM OXYBATE (XYREM)** requires a diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2) for renewal. In addition, one of the following criteria must also be met:

(Criteria continued on next page)

REQUIREMENTS: SODIUM OXYBATE (XYREM) (CONTINUED)

A. Provide documentation of sustained improvement of cataplexy symptoms compared to baseline. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met**

B. Provide documentation of sustained EDS improvement as shown by sustained ESS improvement of at least 25% over baseline since initial authorization. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**

References:

1. Xyrem package insert. Palo Alto, CA. Jazz Pharmaceuticals, Inc. Revised September 2020. Accessed March 2022.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders, 3rd ed, American Academy of Sleep Medicine, Darien, IL 2014.

WELLFLEET RX STUDENT FORMULARY

DEFERASIROX			
Generic	Brand	Reviewed	Effective Date
DEFERASIROX Edition 1	EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for approval:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)

B. The medication is prescribed by or given in consultation with a hematologist (blood specialty doctor) or hematologist/oncologist (tumor/cancer doctor)

C. **If you have chronic iron overload due to blood transfusions, approval also requires:**
   1. You are 2 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 1000mcg/L (we need at least 2 lab values taken within the previous 3 months)

D. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), approval also requires:**
   1. You are 10 years of age or older
   2. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
   3. Your liver iron concentration (LIC) is at least 5mg Fe/g dry weight or greater

E. Requests for Jadenu sprinkle packets, Jadenu, and Exjade require a trial and failure of at least **ONE** of the following Preferred Products: generic deferasirox tablets, generic deferasirox tablets for suspension, or generic deferasirox granules

(Criteria continued on next page)

REQUIREMENTS: DEFERASIROX (CONTINUED)

RENEWAL CRITERIA

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

A. You have chronic iron overload due to blood transfusions (you have too much iron from blood transfers) or non-transfusion dependent thalassemia (a blood disorder involving less than normal amounts of an oxygen-carrying protein)

B. **If you have chronic Iron overload due to blood transfusions, renewal also requires:**
    1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 500 mcg/L (we need at least 2 lab values taken within the previous 3 months)

C. **If you have chronic iron overload resulting from non-transfusion dependent thalassemia (NTDT), renewal also requires ONE of the following:**
    1. Your serum ferritin levels (amount of iron-containing blood cell proteins) are regularly greater than 300mcg/L (we need at least 2 lab values taken within the previous 3 months)
    2. Your liver iron concentration (LIC) is at least 3mg Fe/g dry weight or greater

References:

1. Exjade package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2020. Accessed February 2022.
2. Jadenu package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2020. Accessed February 2022.
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
BRODALUMAB Edition 2	SILIQ	4/29/2022	7/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **BRODALUMAB (Siliq)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

A. Therapy is prescribed by or given in consultation with a dermatologist
B. The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
C. The patient had a previous trial of or contraindication to at least ONE or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
D. The patient is 18 years of age or older
E. The patient has been counseled on and expresses understanding of the risk of suicidal ideation and behavior
F. The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Otezla, Enbrel, Skyrizi, Stelara SC, Taltz, or Tremfya.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **BRODALUMAB (Siliq)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) for renewal. The following criteria must also be met:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more
B. The patient has NOT developed or reported worsening depressive symptoms or suicidal ideation and behaviors while on treatment with Siliq

References:

1. Siliq package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised February 2017. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
USTEKINUMAB Edition 1	STELARA	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of moderate to severe plaque psoriasis, **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, **OR** psoriatic arthritis without co-existent plaque psoriasis, **OR** moderately to severely active Crohn's disease **OR** moderately to severely active ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe plaque psoriasis (PsO) OR moderate to severe plaque psoriasis (PsO) with co-existent psoriatic arthritis (PsA), approval requires all of the following criteria:

A. Therapy is prescribed by or given in consultation with a dermatologist
B. The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
C. The patient has had a previous trial of at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
D. The patient is 6 years of age or older
E. Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA) without co-existent plaque psoriasis (PsO), approval requires all of the following criteria:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older

(Criteria continued on next page)

REQUIREMENTS: USTEKINUMAB (CONTINUED)

For patients with moderately to severely active Crohn's disease (CD), approval requires all of the following criteria:
Therapy is prescribed by or given in consultation with a gastroenterologist

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 is 18 years of age or older
C. Documentation of the patient's current weight

For patients with moderately to severely active ulcerative colitis (UC), approval requires all the following criteria:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 18 years of age or older

RENEWAL CRITERIA
The guideline named **USTEKINUMAB (Stelara)** requires a diagnosis of psoriatic arthritis without co-existent plaque psoriasis, **OR** moderate to severe plaque psoriasis **OR** moderate to severe plaque psoriasis with co-existent psoriatic arthritis, **OR** moderately to severely active Crohn's disease, **OR** moderately to severely active ulcerative colitis (UC). The following criteria must also be met:

Renewal for the diagnosis of psoriatic arthritis without co-existent plaque psoriasis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of moderate to severe plaque psoriasis OR moderate to severe plaque psoriasis with co-existent psoriatic arthritis requires that the patient has achieved or maintained clear or minimal disease **OR** a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more **AND** documentation of the patient's current weight.

(Criteria continued on next page)

REQUIREMENTS: USTEKINUMAB (CONTINUED)

References:

1. Stelara package insert. Horsham, PA. Janssen Biotech, Inc. Revised December 2020. Accessed March 2022.
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.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.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ADALIMUMAB Edition 2	HUMIRA	4/29/2022	4/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, or moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis. The following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older
C. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

For patients with moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older
D. Documentation of the patient's current weight

For patients with psoriatic arthritis (PsA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 of years of age or older

(Criteria continued on next page)

REQUIREMENTS: ADALIMUMAB (CONTINUED)

For patients with ankylosing spondylitis (AS), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

A. Therapy is prescribed by or given in consultation with a dermatologist
B. The patient has plaque psoriasis involving at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face
C. The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
D. The patient is 18 years of age or older

For patients with moderate to severe Crohn's disease (CD), approval requires:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 6 years of age or older

For patients with moderate to severe ulcerative colitis (UC), approval requires:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 5 years of age or older

For patients with moderate to severe hidradenitis suppurativa (HS), approval requires:

A. The patient is 12 years of age or older

For patients with non-infectious intermediate, posterior and panuveitis, approval requires:

A. Therapy is prescribed by or given in consultation with an ophthalmologist
B. The patient is 2 years of age or older
C. The patient does not have isolated anterior uveitis
D. Documentation of the patient's current weight if between 2 to 17 years of age

(Criteria continued on next page)

REQUIREMENTS: ADALIMUMAB (CONTINUED)

RENEWAL CRITERIA

The guideline named **ADALIMUMAB (Humira)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, moderate to severe hidradenitis suppurativa, or non-infectious intermediate, posterior and panuveitis for renewal. The following criteria must also be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
B. Requests for Humira weekly dosing requires that the patient has had a trial of at least a 3-month regimen of Humira 40mg every other week

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of psoriatic arthritis requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of ankylosing spondylitis requires:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

Renewal for the diagnosis of moderate to severe plaque psoriasis requires:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

Renewal for the diagnosis of non-infectious intermediate, posterior and panuveitis requires:

A. The patient has not experienced treatment failure, defined as **ONE** of the following criteria:
    1. Development of new inflammatory chorioretinal or retinal vascular lesions
    2. A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade
    3. A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved

(Criteria continued on next page)

REQUIREMENTS: ADALIMUMAB (CONTINUED)

References:

1. Humira package insert. North Chicago, IL. Abbott Laboratories. Revised February 2021. Accessed February 2022.
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. enre.
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.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ANAKINRA Edition 1	KINERET	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis, Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS), or Deficiency of Interleukin-1 Receptor Antagonist (DIRA). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **ANAKINRA (Kineret)** requires a diagnosis of moderate to severe rheumatoid arthritis, Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Cryopyrin-Associated Periodic Syndromes (CAPS), or Deficiency of Interleukin-1 Receptor Antagonist (DIRA) for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Criteria continued on next page)

REQUIREMENTS: ANAKINRA (CONTINUED)

References:

1. Kineret package insert. Stockholm, Sweden. Swedish Orphan Biovitrum AB. Revised December 2020. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ETANERCEPT Edition 1	ENBREL	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **ETANERCEPT (Enbrel)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis. In addition, the following criteria must be met.

For patients with moderate to severe rheumatoid arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older
C. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older

For patients with psoriatic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older

For patients with ankylosing spondylitis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older

(Criteria continued on next page)

REQUIREMENTS: ETANERCEPT (CONTINUED)

For patients with moderate to severe plaque psoriasis, approval requires:

A. Therapy is prescribed by or given in consultation with a dermatologist
B. 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
C. The patient has had a previous trial of at least one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
D. The patient is 4 years of age or older

RENEWAL CRITERIA

The guideline named **ETANERCEPT (Enbrel)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe juvenile polyarticular idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, or moderate to severe plaque psoriasis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis, approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of psoriatic arthritis, approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of ankylosing spondylitis, approval requires:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

Renewal for the diagnosis of moderate to severe plaque psoriasis, approval requires:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

(Criteria continued on next page)

REQUIREMENTS: ETANERCEPT (CONTINUED)

References:

1. Enbrel package insert. Thousand Oaks, CA. Amgen. Revised April 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CERTOLIZUMAB PEGOL Edition 2	CIMZIA	4/29/2022	7/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe Crohn's disease, non-radiographic axial spondyloarthritis, or moderate to severe psoriasis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient meets **ONE** of the following:
    1. The patient is pregnant or breastfeeding
    2. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, Rinvoq, or Xeljanz/XR

For patients with psoriatic arthritis (PsA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient meets **ONE** of the following:
    1. The patient is pregnant or breastfeeding
    2. The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Stelara, Xeljanz/XR, Otezla, Taltz or Tremfya.

For patients with ankylosing spondylitis (AS), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older
C. The patient meets **ONE** of the following:
    1. The patient is pregnant or breastfeeding
    2. The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, or Taltz

(Criteria continued on next page)

REQUIREMENTS: CERTOLIZUMAB PEGOL (CONTINUED)

For patients with moderate to severe Crohn's disease (CD), approval requires:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 18 years of age or older
D. The patient meets **ONE** of the following:
    1. The patient is pregnant or breastfeeding
    2. The patient has had a previous trial of **ONE** of the formulary preferred immunomodulators: Humira

For patients with non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist
C. The patient had a previous trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.)
D. The patient meets ONE of the following objective signs of inflammation:
    1. C-reactive protein (CRP) levels above the upper limit of normal
    2. Sacroiliitis on magnetic resonance imaging (MRI)
E. The patient is pregnant, breastfeeding, or trying to become pregnant

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

A. The patient is 18 years of age or older
B. Documentation of the patient's current weight
C. Therapy is prescribed by or given in consultation with a dermatologist
D. The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
E. The patient has had a previous trial of one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
F. The patient meets **ONE** of the following:
    1. The patient is pregnant or breastfeeding
    2. The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Humira, Enbrel, Otezla, Skyrizi, Stelara, Taltz or Tremfya.

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

(Criteria continued on next page)

REQUIREMENTS: CERTOLIZUMAB PEGOL (CONTINUED)

RENEWAL CRITERIA

The guideline named **CERTOLIZUMAB PEGOL (Cimzia)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe Crohn's disease, non-radiographic axial spondyloarthritis, or moderate to severe plaque psoriasis for renewal. In addition, the following criteria must be met:

Renewal for the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of psoriatic arthritis (PsA), approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

Renewal for the diagnosis of ankylosing spondylitis (AS), approval requires:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

Renewal for the diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

Renewal for the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

(Criteria continued on next page)

REQUIREMENTS: CERTOLIZUMAB PEGOL (CONTINUED)

References:

1. Cimzia package insert, UCB Inc, Smyrna, GA. Revised September 2019. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GOLIMUMAB – IV Edition 2	SIMPONI ARIA – IV	4/29/2022	7/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or polyarticular juvenile idiopathic arthritis. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient meets ONE of the following:
    1. Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
    2. For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
    3. Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
C. The patient is concurrently using or has a contraindication to methotrexate
D. The patient is 18 years of age or older
E. The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz/XR

For the diagnosis of psoriatic arthritis (PsA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older
D. The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Stelara, Taltz, Otezla, Tremfya, or Xeljanz/XR

For the diagnosis of ankylosing spondylitis (AS), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older
C. The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, or Taltz

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-IV (CONTINUED)

For the diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), approval requires:

A. The patient is 2 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

NOTE: For the diagnosis of polyarticular juvenile idiopathic arthritis (PJIA), please refer to the initial criteria section.

The guideline named **GOLIMUMAB - IV (Simponi Aria - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
B. The patient is concurrently using or has a contraindication to methotrexate

For the diagnosis of psoriatic arthritis (PsA), approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

For the diagnosis of ankylosing spondylitis (AS), approval requires:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-IV (CONTINUED)

References:

1. Simponi package insert. Horsham, PA. Janssen Biotech, Inc. Revised February 2021. Accessed February 2022.
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.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GOLIMUMAB – SQ Edition 2	SIMPONI – SQ	4/29/2022	7/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **GOLIMUMAB - SQ (Simponi - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis. In addition, the following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
C. Concurrent use of methotrexate (unless contraindicated)
D. The patient is 18 years of age or older
E. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, Rinvoq, or Xeljanz/XR

For patients with psoriatic arthritis (PsA), approval requires all of the following:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient has had a previous trial of any **TWO** of the following preferred formulary immunomodulators: Enbrel, Humira, Stelara, Otezla, Tremfya, Taltz, or Xeljanz/XR.

For patients with moderate to severe ankylosing spondylitis (AS), approval requires all of the following:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older
C. The patient has had a previous trial of any **TWO** of the following preferred immunomodulators: Enbrel, Humira, or Taltz.

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-SQ (CONTINUED)

For patients with moderate to severe ulcerative colitis (UC), approval requires all of the following:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. 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
C. The patient is 18 years of age or older
D. The patient has had a previous trial of the formulary preferred immunomodulator: Humira

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **GOLIMUMAB - SQ (Simponi - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ankylosing spondylitis, or moderate to severe ulcerative colitis for renewal. In addition, the following criteria must also be met.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis (RA), approval requires all of the following:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
B. Concurrent use of methotrexate (unless contraindicated)

Renewal for the diagnosis of psoriatic arthritis (PsA), approval requires all of the following:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

Renewal for the diagnosis of moderate to severe ankylosing spondylitis (AS), approval requires the following:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-SQ (CONTINUED)

References:

1. Simponi package insert. Horsham, PA. Janssen Biotech, Inc. Revised September 2019. Accessed February 2022.
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. 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. 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.
5. 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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GUSELKUMAB Edition 1	TREMFYA	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **GUSELKUMAB (Tremfya)** requires a diagnosis of moderate to severe psoriasis or psoriatic arthritis. In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

A. Therapy is prescribed by or given in consultation with a dermatologist
B. The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, or genital area
C. The patient has had a previous trial of at least one or more forms of preferred therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
D. The patient is 18 years of age or older

For patients with psoriatic arthritis (PsA), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
C. The patient had a previous trial of or contraindication to at least **ONE** DMARDs (disease modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA
Our guideline named **GUSELKUMAB (Tremfya)** requires the following rule(s) be met for renewal:

A. You have **ONE** of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO; dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA; joint pain and swelling)

B. **If you have moderate to severe plaque psoriasis, renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Criteria continued on next page)

REQUIREMENTS: GUSELKUMAB (CONTINUED)

References:

1. Tremfya package insert. Horsham, PA. Janssen Biotech, Inc. Revised July 2020. Accessed February 2022.
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
IXEKIZUMAB Edition 2	TALTZ	4/29/2022	7/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA). In addition, the following criteria must be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:

A. The patient is 6 years of age or older
B. Therapy is prescribed by or given in consultation with a dermatologist
C. The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
D. The patient had a previous trial of or contraindication to at least one or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

For the diagnosis of psoriatic arthritis (PsA), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
C. The patient had a previous trial of or contraindication to at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

For the diagnosis of ankylosing spondylitis (AS), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist

(Criteria continued on next page)

REQUIREMENTS: IXEKIZUMAB (CONTINUED)

For the diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:

A. You are 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
C. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
D. You have ONE of the following signs of inflammation:
    1. C-reactive protein (CRP; a measure of how much inflammation you have) levels above the upper limit of normal
    2. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **IXEKIZUMAB (Taltz)** requires a diagnosis of moderate to severe plaque psoriasis (PsO), psoriatic arthritis (PsA), or ankylosing spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA) for renewal. In addition, the following criteria must be met:

For the diagnosis of moderate to severe plaque psoriasis (PsO), approval requires:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

For the diagnosis of psoriatic arthritis (PsA), approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

For the diagnosis of ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA), approval requires:

A. The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

(Criteria continued on next page)

REQUIREMENTS: IXEKIZUMAB (CONTINUED)

References:

1. Taltz package insert. Indianapolis, IN. Eli Lilly and Company. Revised March 2021. Accessed February 2022.
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
RISANKIZUMAB-RZAA Edition 2	SKYRIZI	4/29/2022	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) or psoriatic arthritis (PsA). In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a dermatologist
C. The patient has psoriatic lesions involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
D. The patient had a previous trial of or contraindication to one or more forms of conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

For patients with psoriatic arthritis (PsA), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
C. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

The guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) or psoriatic arthritis (PsA). In addition, the following criteria must be met:

For patients with moderate to severe plaque psoriasis (PsO), renewal also requires:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

If you have psoriatic arthritis (PsA), renewal also requires:

A. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Criteria continued on next page)

REQUIREMENTS: RISANKIZUMAB-RZAA (CONTINUED)

References

1. Skyrizi package insert. North Chicago, IL. AbbVie Inc. Revised January 2022. Accessed March 2022.
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
SARILUMAB Edition 1	KEVZARA	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **SARILUMAB (Kevzara)** requires a diagnosis of moderate to severe rheumatoid arthritis. The following criteria must also be met:

A. **For patients with moderate to severe rheumatoid arthritis, approval requires:**
   1. Therapy initiated by or given in consultation with a rheumatologist
   2. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   3. Patient is 18 years of age or older
   4. Previous trial of **TWO** formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **SARILUMAB (Kevzara)** requires a diagnosis of moderate to severe rheumatoid arthritis for renewal. The following criteria must also be met:

A. **Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:**
   1. Documentation that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

References:

1. Kevzara package insert. Bridgewater, NJ. Sanofi-Aventis. Revised April 2018. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TILDRAKIZUMAB-ASMN Edition 2	ILUMYA	4/29/2022	7/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO). In addition, the following criteria must be met:

A. Therapy is prescribed by or given in consultation with a dermatologist
B. The patient has psoriatic lesions involving at least 10% of body surface area (BSA) **OR** psoriatic lesions affecting the hands, feet, genital area, or face
C. The patient had a previous trial of or contraindication to at least ONE or more forms of preferred conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
D. The patient is 18 years of age or older
E. The patient had a previous trial of or contraindication to any **TWO** of the following formulary preferred immunomodulators: Humira, Otezla, Renflexis, Skyrizi, Stelara SC, Taltz, or Tremfya

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **TILDRAKIZUMAB-ASMN (Ilumya)** requires a diagnosis of moderate to severe plaque psoriasis (PsO) for renewal. The following criterion must also be met:

A. The patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

References:

1. Ilumya package insert. Whitehouse Station, NJ. Merck & Co, INC., Revised March 2018. Accessed March 2022.
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
TOCILIZUMAB - IV Edition 3	ACTEMRA - IV	4/29/2022	4/29/2022

REQUIREMENTS:

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

The guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA), systemic juvenile idiopathic arthritis (SJIA), giant cell arteritis (GCA), or chimeric antigen receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (CRS). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient meets ONE of the following:
    1. Therapeutic failure of a 3-month trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
    2. For patients who cannot tolerate oral methotrexate: therapeutic failure of 3-month trial of dual therapy with non-biologic DMARDs (injectable methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
    3. Contraindication to non-biologic DMARDs that would prevent a trial of dual therapy with non-biologic DMARDs (methotrexate, hydroxychloroquine, sulfasalazine, or leflunomide)
C. The patient is 18 years of age or older
D. The patient has had a previous trial of ONE of the preferred immunomodulators: Humira

For patients with polyarticular juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older
D. The patient has had a previous trial of **ONE** of the formulary preferred immunomodulators: Humira or Enbrel

(Criteria continued next page)

REQUIREMENTS: TOCILIZUMAB - IV (CONTINUED)

For patients with systemic juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older

For the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS), approval requires all:

A. The patient is 2 years of age or older

For the treatment of Giant Cell Arteritis (GCA), approval requires:

A. The patient is 18 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **TOCILIZUMAB - IV (Actemra - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis and that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy for renewal.

References:

1. Actemra package insert. South San Francisco, CA. Genentech, Inc.. Revised February 2022. Accessed March 2022.
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. 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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ELBASVIR/GRAZOPREVIR Edition 2	ZEPATIER	4/29/2022	4/29/2022

REQUIREMENTS:

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. You have hepatitis C (type of liver inflammation caused by a virus)
B. You have genotype 1 or genotype 4 hepatitis C
C. You are 12 years of age or older
D. You are currently supervised by a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs), infectious disease specialist, physician specializing in the treatment of hepatitis (such as a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. You have documentation of HCV (hepatitis C virus) infection that shows at least one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
F. You have previously tried Epclusa or Harvoni unless you have a contraindication (medical reason why you cannot try) to both. Patient with previous failure of a full treatment of Epclusa or Harvoni will not be approved.
G. If you have genotype 1a infection, we require testing for baseline NS5A (nonstructural protein 5A) polymorphisms (variations of a type of protein)
H. Ribavirin use is required if you meet ANY of the following:
    1. You have genotype 1a or 1b infection and were previously treated with HCV protease inhibitor triple therapy (HCV protease inhibitor (such as Victrelis, Incivek, Olysio) plus peginterferon/ribavirin
    2. You have genotype 1a infection, are treatment-naïve, and have baseline NS5A polymorphisms
    3. You have genotype 1a infection, were previously treated, and have baseline NS5A polymorphisms (variations of a type of protein)
    4. You have genotype 4 infection and were previously treated
I. Treatment experienced patients will be approved per product labeling (previous failure of peginterferon/ribavirin for genotype 1a, 1b or 4; previous failure of HCV protease inhibitor triple therapy regimen for genotype 1a or 1b infection)

(Continued on next page)

REQUIREMENTS: ELBASVIR/GRAZOPREVIR (CONTINUED)

Zepatier will not be approved if you meet any of the following:

A. You are using any of the following interacting medications at the same time while on elbasvir/grazoprevir: phenytoin, carbamazepine, rifampin, efavirenz (such as Atripla, Sustiva), atazanavir (such as Evotaz, Reyataz), darunavir (such as Prezcobix, Prezista), lopinavir, saquinavir, tipranavir, cyclosporine, nafcillin, ketoconazole, modafinil, bosentan, etravirine, elvitegravir/cobicistat/emtricitabine/tenofovir (such as Stribild, Genvoya), atorvastatin at doses higher than 20mg daily, or rosuvastatin at doses greater than 10mg daily
B. You are taking Sovaldi (sofosbuvir) with Zepatier
C. You have moderate or severe hepatic impairment (Child-Pugh B or C)
D. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (having two or more diseases at the same time)

References

1. Zepatier package insert. Whitehouse Station, NJ. Merck & Co. Revised December 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BELIMUMAB Edition 2	BENLYSTA	4/29/2022	4/29/2022

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

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

A. You have ONE of the following diagnoses:
    1. Autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
    2. Lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody positive systemic lupus erythematosus (SLE), approval also requires:**
    1. You are 5 years of age or older
    2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
    3. You are currently using corticosteroids, antimalarials (drugs that treat parasites), non-steroidal anti-inflammatory drugs (NSAIDS), or immunosuppressives (drugs that weaken your immune system)

C. **If you have lupus nephritis, approval also requires:**
    1. You are 18 years of age or older
    2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or nephrologist (kidney doctor)
    3. You are receiving standard treatment (such as steroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDs), or immunosuppressives (drugs that weaken your immune system)

D. **If your request is for SUBCUTANEOUS Benlysta, approval also requires:**
    1. You are 18 years of age or older

(Criteria continued on next page)

REQUIREMENTS: BELIMUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. You have autoantibody positive systemic lupus erythematosus (SLE: inflammatory disease caused when the immune system attacks its own tissues)
    2. Active lupus nephritis (inflammation of the kidneys caused by lupus when the immune system attacks its own tissues)

B. **If you have autoantibody-positive systemic lupus erythematosus (SLE), renewal also requires:**
    1. You had clinical improvement while on Benlysta

C. **If you have active lupus nephritis, renewal also requires:**
    1. You have had clinical improvement in renal response as compared to baseline laboratory values (eGFR [measurement of kidney function] or proteinuria [level of protein in urine]), and/or clinical parameters (such as fluid retention, use of rescue drugs, glucocorticoid dose)

D. **If your request is for SUBCUTANEOUS Benlysta, approval also requires:**
    1. You are 18 years of age or older

References:

1. Benlysta package insert. Rockville, MD. Human Genome Sciences, Inc. Revised December 2020. Accessed February 2022.
2. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis. 2019;78(6):736-745. doi:10.1136/annrheumdis-2019-215089.
3. Fanouriakis A, Kostopoulou M, Cheema K, et al. 2019 Update of the Joint European League Against Rheumatism and European Renal Association-European Dialysis and Transplant Association (EULAR/ERA-EDTA) recommendations for the management of lupus nephritis. Ann Rheum Dis. 2020;79(6):713-723. doi:10.1136/annrheumdis-2020-216924.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FOSDENOPTERIN HYDROBROMIDE Edition 1	NULIBRY	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have molybdenum cofactor deficiency (MoCD) Type A (rare condition characterized by brain dysfunction)

References:

1. Nulibry package insert. Boston, MA. Origin Biosciences, Inc. Revised February 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CANAKINUMAB/PF Edition 1	ILARIS	4/29/2022	6/1/2021

REQUIREMENTS:

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

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

A. You have ONE of the following diagnoses:
   1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle- Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
   2. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS: genetic disease that causes recurrent episodes of fever)
   3. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) (genetic *disorders* that have recurrent fever episodes and inflammation)
   4. Familial Mediterranean Fever (FMF: genetic disorder that causes recurrent episodes of fever and pain in the abdomen, chest, or joints)
   5. Systemic Juvenile Idiopathic Arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   6. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. **If you have Cryopyrin-Associated Periodic Syndromes (CAPS) such as Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS), approval also requires:**
   1. You are 4 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)

C. **If you have Systemic Juvenile Idiopathic Arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints), dermatologist (skin doctor), or immunologist (immune system doctor)
   3. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
   4. You had a previous trial of the preferred immunomodulator: Actemra, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

REQUIREMENTS: CANAKINUMAB (CONTINUED)

D. **If you have Adult-Onset Still's Disease (AOSD), approval also requires:**
    1. Therapy is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) dermatologist (skin doctor), or immunologist (immune system doctor)
    2. You had a previous trial of ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. Cryopyrin-Associated Periodic Syndromes such as Familial Cold Autoinflammatory Syndrome (FCAS: inherited inflammatory disorder that is triggered with cold) or Muckle- Wells Syndrome (MWS: disorder characterized by periodic episodes of skin rash, fever, and joint pain)
    2. Systemic Juvenile Idiopathic Arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
    3. Adult-Onset Still's Disease (AOSD: rare autoinflammatory disease caused by abnormalities of the immune system)

B. If you have Systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD), renewal also requires ONE of the following:
    1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
    2. You have shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

(Criteria continued on next page)

REQUIREMENTS: CANAKINUMAB (CONTINUED)

References:

1. Ilaris package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised September 2020. Accessed February 2022.
2. 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.
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. 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
6. 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 STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CASIMERSEN Edition 2	AMONDYS-45	4/29/2022	04/29/2021

REQUIREMENTS:

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

A. You have Duchenne muscular dystrophy (DMD: inherited disorder where your muscles get weaker over time)
B. You have a confirmed mutation in the DMD gene that is responsive to exon 45 skipping (a process that allows a protein to still function with sections of faulty genetic code)
C. Therapy is prescribed by or given in consultation with a neurologist (brain, spinal cord, nervous system doctor) specializing in treatment of Duchenne muscular dystrophy at a DMD treatment center
D. You are ambulatory (able to move and walk)
E. You are currently receiving treatment with corticosteroids (such as prednisone or prednisolone) unless there is a medical reason why you cannot (contraindication)
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. You have maintained or demonstrated less than expected decline in ambulatory ability (ability to move and walk) based on muscle function assessments (such as the 6-minute walk test)
B. You have maintained or demonstrated less than expected decline in other muscle function (such as pulmonary [lung] or cardiac [heart] function)

References:

1. Amondys 45 package insert. Cambridge, MA. Sarepta Therapeutics, Inc. Revised February 2021. Accessed February 2022.
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
ENZALUTAMIDE Edition 1	XTANDI	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

B. You meet ONE of the following:
   1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
   2. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
   3. Your blood testosterone levels are less than 50 ng/dL

C. **If you have non-metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have a high-risk prostate cancer (rapidly increasing prostate specific antigen levels)

D. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You have previously tried Zytiga (abiraterone acetate) unless there is a medical reason why you cannot take it (contraindication)

E. **If you have metastatic castration-sensitive prostate cancer, approval also requires:**
   1. You have trialed and failed or have a contraindication to generic Zytiga (abiraterone) 250mg.

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Metastatic or non-metastatic castration-resistant prostate cancer (cancer that does or does not spread after being treated with hormone therapy)
   2. Metastatic castration-sensitive prostate cancer (cancer that has spread beyond the prostate and responds to hormone therapy)

References:

1. Xtandi package insert. Northbrook, IL. Astellas Pharma US, Inc. Revised January 2022. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DAROLUTAMIDE Edition 1	NUBEQA	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)
B. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)
C. You meet ONE of the following:
    1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
    2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
    3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

RENEWAL CRITERIA

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

A. You have non-metastatic castration resistant prostate cancer (cancer that has not spread to other parts of the body and does not respond to hormone therapy)

References:

1. Nubeqa package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised January 2021. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
HYDROCORTISONE Edition 1	ALKINDI SPRINKLE	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **HYDROCORTISONE (Alkindi Sprinkle)** requires the following rule(s) be met for approval:

A. You have adrenocortical insufficiency (your body does not produce enough of certain hormones)
B. You are less than 18 years of age
C. You are unable to take the tablet form of hydrocortisone (for example you need a lower strength, or you have difficulty swallowing)

References:

1. Alkindi package insert. Binzen, BadenWuerttemberg, Germany. Eton Pharmaceuticals, Inc. Revised February 2022. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LONAFARIB Edition 1	ZOKINVY	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have Hutchinson-Gilford progeria syndrome (HGPS) OR processing-deficient progeroid laminopathies (rare genetic disorders that cause premature aging in children)
B. You are 1 year of age or older
C. You have a body surface area (BSA) of 0.39 meters squared or more
D. **If you have processing-deficient progeroid laminopathies, approval also requires you have ONE of the following:**
    1. Heterozygous LMNA (type of gene) mutation with progerin-like protein accumulation
    2. Homozygous or compound heterozygous ZMPSTE24 (type of gene) mutations

References:

1. Zokinvy package insert. Palo Alto, CA. Eiger BioPharmaceuticals, Inc. Revised November 2020. Accessed March 2022.
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
LOTEPREDNOL ETABONATE Edition 1	EYSUVIS	4/29/2022	4/29/2022

REQUIREMENTS:

The guideline named **LOTEPREDNOL (Eysuvis)** 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. You are aged 18 years or older.
B. You will be using for short term (up to two weeks) treatment of signs and symptoms of dry eye disease.
C. You had a previous trial of or contraindication to at least 4 weeks of treatment with an artificial tears product.
D. You previously tried one generic loteprednol ophthalmic product **AND** one non-loteprednol ophthalmic (eye) corticosteroid (such as fluorometholone, dexamethasone, prednisolone) unless there is a medical reason why you cannot (contraindication).
E. You will not be using concurrently with Restasis, Cequa, Tyrvaya or Xiidra.

References:

1. Eysuvis package insert. Watertown, MA. Kala Pharmaceuticals, Inc. Revised October 2020. Accessed March 2022.
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.2018.10.02.

WELLFLEET RX STUDENT FORMULARY

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

REQUIREMENTS:

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

A. You have primary hyperoxaluria type 1 (PH1: a rare disorder in which buildup of a substance called oxalate is deposited in the kidneys and urinary tract) 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. Prescribed by or in consultation with an endocrinologist, hepatologist, or nephrologist
C. You have 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. Documentation of estimated glomerular filtration rate (eGFR) greater than 30 mL/min/1.73m2
E. You 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. You have 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. 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 November 2020. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RELUGOLIX Edition 1	ORGOVYX	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have advanced prostate cancer
B. You are 18 years of age or older

References:

1. Orgovyx package insert. Kawagoe, Saitama, Japan. Bushu Pharmaceuticals, Ltd. Revised December 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MARGETUXIMAB-CMKB Edition 1	MARGENZA	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **MARGETUXIMAB-CMKB (Margenza)** requires the following rule(s) be met for approval:

A. You have metastatic HER2 (human epidermal growth factor receptor 2)-positive breast cancer (cancer has spread to other parts of the body)
B. Margenza will be used in combination with chemotherapy (such as Xeloda, Halaven, gemcitabine, Navelbine)
C. You have received two or more prior anti-HER2 regimens (such as Herceptin, Perjeta), at least one of which was for metastatic disease

References:

1. Margenza package insert. Rockville, MD. MacroGenics, Inc. Revised December 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MELPHALAN FLUFENAMIDE HCL Edition 1	PEPAXTO	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **MELPHALAN FLUFENAMIDE (Pepaxto)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not responsive to treatment)
B. You are 18 years of age or older
C. Pepaxto will be used in combination with dexamethasone
D. You have received at least four prior lines of therapy
E. Your disease is refractory to at least one proteasome inhibitor (such as Velcade, Kyprolis), one immunomodulatory agent (such as Revlimid, Pomalyst), AND one CD38-directed monoclonal antibody (such as Darzalex)

References:

1. Pepaxto package insert. Waltham, MA. Oncopeptides Inc. Revised February 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
NAXITAMAB-GQGK Edition 1	DANYELZA	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **NAXITAMAB-GQGK (Danyelza)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory high-risk neuroblastoma (cancer that starts in early nerve cells that has returned or no longer responds to treatment) in the bone or bone marrow
B. You are 1 year of age or older
C. The requested medication will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)
D. You have demonstrated a partial response, minor response, or stable disease to prior therapy

References:

1. Danyelza package insert. New York, NY. Y-mAbs Therapeutics, Inc. Revised November 2020. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
OLAPARIB Edition 2	LYNPARZA	4/29/2022	04/29/2022

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Advanced ovarian cancer
   2. Recurrent or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal (abdomen) cancer
   3. HER2-negative (you do not have a certain gene mutation) metastatic breast cancer (breast cancer that has spread to other parts of the body)
   4. HER2-negative high risk early breast cancer
   5. Metastatic pancreatic adenocarcinoma (cancer of the pancreas that has spread to other parts of the body)
   6. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have advanced ovarian cancer, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as monotherapy (used alone for treatment)
   3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with at least three prior lines of chemotherapy (such as, paclitaxel, docetaxel, cisplatin, carboplatin)

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to your most recent platinum-based chemotherapy
   3. You have completed at least two or more lines of platinum-based chemotherapy
   4. The requested medication will be used alone for maintenance treatment

(Criteria continued on next page)

REQUIREMENTS: OLAPARIB (CONTINUED)

D. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
    1. You are 18 years of age or older
    2. The requested medication will be used for maintenance treatment
    3. You are in complete or partial response to first-line platinum-based chemotherapy
    4. You meet ONE of the following:
        i. You 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
        ii. Your cancer is homologous recombination deficiency (HRD: type of gene mutation) positive
            1. HRD status is defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
            2. Lynparza will be used in combination with bevacizumab

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
    1. You are 18 years of age or older
    2. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    3. You have been treated with chemotherapy in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (disease that has spread to other parts of the body)
    4. If you have hormone receptor (HR)-positive breast cancer, you must have had prior treatment with endocrine (hormone) therapy or be considered inappropriate for endocrine therapy

F. **If you have HER2-negative high risk early breast cancer, approval also requires:**
    1. You are 18 years of age or older
    2. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
    3. You have been treated with chemotherapy in the neoadjuvant (given before main treatment) or adjuvant (add-on to main treatment) setting

(Criteria continued on next page)

REQUIREMENTS: OLAPARIB (CONTINUED)

G. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used for maintenance treatment
   3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

H. **If you have metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation that causes a change in your DNA that make up your gene) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide or abiraterone
   4. You meet ONE of the following:
      i. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      ii. You have a castrate level of testosterone (your blood testosterone levels are 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. Lynparza package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised March 2022. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR Edition 1			
Generic	Brand	Reviewed	Effective Date
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA PAK	4/29/2022	6/1/2021
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA XR		

REQUIREMENTS:

Our guideline named **OMBITASVIR/PARITAPREVIR/RITONAVIR/ DASABUVIR (Viekira Pak or Viekira XR)** requires the following rule(s) be met for approval:

A. You have chronic hepatitis C, genotype 1
B. You are treatment naïve (never previously treated) or treatment experienced (previous treatment with peginterferon/ribavirin)
C. You will be using ribavirin with the requested medication, unless you have genotype 1b
D. You are 18 years of age or older
E. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
F. You have previously failed a short trial with Epclusa or Harvoni. Reasons for failure include adverse effect early in therapy, intolerance to therapy, or if you have a medical reason why you cannot use (contraindication) both drugs. (**NOTE:** If you completed a full course of therapy with Epclusa or Harvoni and you did not achieve sustained virologic response [no virus can be detected in blood], the request will not be approved)
G. You have documentation of a recent hepatitis C virus infection shown by at least one HCV RNA level (amount of virus in the blood) within the past 6 months

(Criteria continued on next page)

REQUIREMENTS: OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR (CONTINUED)

The medication will not be approved for the following patients:

A. You are using any of the following medications at the same time while on Viekira: alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergotamine dihydroergotamine, ergonovine, methylergonovine, ethinyl estradiol containing medications (such as combined oral contraceptives, Nuvaring, Ortho Evra or Xulane transdermal patch system), St. John's Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio, triazolam, oral midazolam, darunavir/ritonavir, lopinavir/ritonavir, rilpivirine, or salmeterol
B. You have decompensated cirrhosis (symptoms related to liver damage)
C. You have moderate liver impairment (Child Pugh B) or severe liver impairment (Child Pugh C)
D. You are on hemodialysis (process of purifying the blood of a person whose kidneys are not working normally)
E. You have a limited life expectancy (less than 12 months) due to other conditions not related to the liver
F. You have previously used/failed a full course of therapy, or currently using any of the following regimens:
    1. A nucleotide NS5B polymerase inhibitor (type of hepatitis C drug) including Sovaldi (sofosbuvir)
    2. A combination NS5B polymerase inhibitor/NS5A inhibitor including Harvoni (ledipasvir/sofosbuvir)
    3. A hepatitis C virus protease inhibitor (type of hepatitis drug) including Olysio (simeprevir), Victrelis (boceprevir), and Incivek (telaprevir)

A total of 12 weeks of therapy will be approved except 24 weeks of therapy for 1) genotype 1a with cirrhosis if patient is treatment experienced, previous null responder or 2) a liver transplant recipient.

References

1. Viekira Pak/Viekira Pak XR package insert. North Chicago, IL. AbbVie Inc. Revised November 2019. Accessed March 2022.
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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RAVULIZUMAB-CWVZ Edition 2	ULTOMIRIS	7/23/2021	7/23/2021

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. You have ONE of the following diagnoses:
    1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely)
    2. Atypical hemolytic uremic syndrome (aHUS: a rare disorder that causes abnormal blood clots to form in small vessels in the kidneys)

B. **If you have paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
    1. You are 1 month of age or older weighing 5kg or greater
    2. There is documentation of your current weight
    3. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
    4. You have confirmed paroxysmal nocturnal hemoglobinuria as supported by **ALL** of the following via flow cytometry (type of measurement of physical and chemical qualities of cells):
        i. At least 2 different GPI-protein deficiencies (you're missing a certain type of protein such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes, granulocytes)
        ii. Paroxysmal nocturnal hemoglobinuria granulocyte clone size of 10% or greater
    5. You meet **ONE** of the following:
        i. You are transitioning from alternative complement inhibitor therapy (such as Soliris)
        ii. You have evidence of intravascular hemolysis (blood cells break down within your blood stream) such as lactate dehydrogenase level of at least 1.5 times the upper limit of normal or hemoglobinuria (urine has substance called hemoglobin)
        iii. You have history of major adverse vascular event from thromboembolism (blood clot)

(Criteria continued on next page)

REQUIREMENTS: RAVULIZUMAB-CWVZ (CONTINUED)

C. **If you have atypical hemolytic uremic syndrome, approval also requires:**
    1. You are one month of age or older weighing 5kg or greater
    2. There is documentation of your current weight

RENEWAL CRITERIA

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely) or atypical hemolytic uremic syndrome
B. If you have paroxysmal nocturnal hemoglobinuria, renewal also requires:
    a. You have shown clinical benefit (such as reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (an enzyme) and hemoglobin levels) compared to baseline (before you started treatment)
    b. There is documentation of your current weight
C. **If you have atypical hemolytic uremic syndrome, renewal also requires:**
    a. There is documentation of your current weight
D. You weigh 5kg or greater

References:

1. Ultomiris package insert. Boston, Ma. Alexion Pharmaceuticals, Inc. Reviewed June 2021. Accessed July 2021.
2. Bar M, Ott SM, Lewiecki EM, et al. Bone Health Management After Hematopoietic Cell Transplantation: An Expert Panel Opinion from the American Society for Transplantation and Cellular Therapy. *Biol Blood Marrow Transplant*. 2020;26(10):1784-1802. doi:10.1016/j.bbmt.2020.07.001

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRAMADOL Edition 2	QDOLO	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have ONE of the following:
   a. The request is for the management of pain severe enough to require an opioid analgesic (type of pain medication) for which alternative treatments are inadequate
   b. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
   c. You are enrolled in hospice
B. You are 18 years of age or older
C. You previously tried generic tramadol or a generic tramadol with acetaminophen product unless there is a medical reason why you cannot (contraindication)
D. You are unable to take oral solid formulations of tramadol or tramadol with acetaminophen (such as with difficulty swallowing)

References:

1. Qdolo package insert. Athens, GA. Athena Bioscience, LLC. Revised September 2020. Accessed July 2021.
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
RIOCIGUAT Edition 1	ADEMPAS	4/29/2022	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. You have a diagnosis of a persistent/recurrent chronic thromboembolic pulmonary hypertension World Health Organization Group 4 (CTEPH: form of high blood pressure affecting the lungs caused by blood clots) or a diagnosis of pulmonary arterial hypertension World Health Organization Group 1 (PAH: type of high blood pressure affecting lungs and arteries)

B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/ breathing doctor)

C. **If you have pulmonary arterial hypertension, approval also requires:**
   1. You have a documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
      a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 3 Wood units
   2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   3. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

D. **If you have chronic thromboembolic pulmonary hypertension, approval also requires:**
   1. You have persistent or recurrent disease after surgical treatment (it continues to exist or returns after surgery) OR you are not a candidate for surgery or have inoperable chronic thromboembolic pulmonary hypertension
   2. You have NYHA-WHO Functional Class II to IV symptoms (a way to classify how limited you are during physical activity)
   3. You are not concurrently taking nitrates or nitric oxide donors (such as amyl nitrate), phosphodiesterase inhibitors (such as sildenafil, tadalafil, or vardenafil), or non-specific phosphodiesterase inhibitors (such as dipyridamole, theophylline)

(Criteria continued on next page)

REQUIREMENTS: RIOCIGUAT (CONTINUED)

RENEWAL CRITERIA

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

A. You have one of the following diagnoses:
    1. Persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO [World Health Organization] Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class
    2. Pulmonary arterial hypertension (PAH) (WHO Group 1)
B. You show improvement from baseline in the 6-minute walk distance **OR** have a stable 6-minute walk distance with a stable or improved World Health Organization (WHO) functional class.

References:

1. Adempas package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Revised September 2021. Accessed March 2022.
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
RUCAPARIB Edition 1	RUBRACA	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer that affects the abdomen or a woman's sex organs)
   2. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (cancer returns and affects the abdomen or a woman's sex organs)
   3. Metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)

B. **If you have epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic) confirmed by Food and Drug Administration (FDA)-approved test for Rubraca
   3. You have been treated with two or more chemotherapies such as paclitaxel, docetaxel, cisplatin, carboplatin

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in a complete or partial response to platinum based-chemotherapy
   3. The requested medication will be used for maintenance treatment

(Criteria continued on next page)

REQUIREMENTS: RUCAPARIB (CONTINUED)

D. **If you have metastatic castration-resistant prostate cancer (mCRPC), approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious BRCA mutation (gene mutation such as germline and/or somatic)
   3. You have been treated with androgen receptor-directed therapy AND a taxane-based chemotherapy
   4. You meet ONE of the following:
      i. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
      ii. You have a castrate level of testosterone (your 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 September 2021. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SETMELANOTIDE ACETATE Edition 1	IMCIVREE	4/29/2022	4/29/2022

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. You are 6 years of age or older
C. You meet ONE of the following criteria:
    1. If you are at least 18 years of age, then you currently have body mass index (BMI) ≥ 30 kg/m2
    2. If you are 6 to 17 years of age, then you currently have a BMI ≥ 95th percentile for age and sex
D. Your obesity is confirmed by ONE of the following deficiencies:
    1. Proopiomelanocortin (POMC: type of gene)
    2. Proprotein convertase subtilisin/kexin type 1 (PCSK1: type of gene)
    3. Leptin receptor (LEPR: type of gene)
E. Confirmed genetic testing shows variants (changes) in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic (causing disease), likely pathogenic, or of uncertain significance (VUS)
F. Medication is prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders

RENEWAL CRITERIA

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

A. You have lost at least 5% of your baseline body weight or 5% of your baseline body mass index (BMI: a measure of body fat based on your height and weight)

References:

1. Imcivree package insert. Boston, MA. Rhythm Pharmaceuticals Inc. Revised November 2020. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR Edition 1	SOVALDI	4/29/2022	6/1/2021

REQUIREMENTS:

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

A. You have chronic hepatitis C (long term type of liver inflammation)
B. You are 18 years of age or older with genotype 1 or 3, **OR** you are 3 to 17 years old with genotype 2 or 3
C. You are currently supervised by a gastroenterologist (digestive system doctor), infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. There is evidence showing you have current and chronic hepatitis c virus infection documented by one detectable HCV RNA level (amount of virus in your blood) within the last 6 months
E. **If you are an adult patient (18 years of age or older), approval also requires:**
    1. You are treatment naive (never previously treated) or treatment experienced (prior treatment with peginterferon/ribavirin)
    2. You will be using Sovaldi with Olysio (genotype 1 only) or Daklinza (genotype 1 or 3 only)
    3. You had a short trial of the preferred formulary agent (you stopped because of intolerance or adverse effect early in therapy) or have a contraindication (medical reason why you cannot use) to therapy with the preferred formulary agents as specified below. An individual who has completed a full course of therapy that did not achieve a sustained virologic response (SVR) will not be approved
        i. If you have genotype 1 infection, you had a short trial of Epclusa or Harvoni or you have a contraindication to BOTH agents
        ii. If you have genotype 3 infection, you had a short trial of Epclusa or you have a contraindication to this agent
F. **If you are a pediatric patient (under age 18) approval also requires:**
    1. The request must meet the Food and Drug Administration (FDA)-approved indication [treatment naive (never previously treated) or treatment experienced patient with compensated cirrhosis (no symptoms related to liver damage) (Child-Pugh A) or without cirrhosis (liver scarring)]
    2. You will be using Sovaldi together with ribavirin (genotypes 2 and 3)

(Criteria continued on next page)

REQUIREMENTS: SOFOSBUVIR (CONTINUED)

The medication will not be approved for the following:

A. You have severe renal (kidney) impairment (Glomerular filtration rate less than 30 mL/min/1.73m^2), end stage renal disease and/or those requiring dialysis
B. You have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (additional diseases)
C. You are an adult with compensated cirrhosis (no symptoms related to liver damage)
D. You are using any of the following medications concurrently while on Sovaldi: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, or tipranavir/ritonavir
E. You are using Sovaldi with another direct acting antiviral (e.g., Olysio or Daklinza) AND are on concurrent amiodarone
F. You are an adult who is taking Sovaldi with ribavirin OR peginterferon alfa and ribavirin

For requests for Sovaldi/Olysio regimen for genotype 1, the following must also be met:

A. You are 18 years of age or older
B. You do not have cirrhosis (liver scarring)
C. You have not previously failed a full course of therapy with 1) any hepatitis c virus protease inhibitor (type of Hep C drug such as Incivek [telaprevir], Olysio [simeprevir], or Victrelis [boceprevir) **OR** 2) a regimen containing NS5A inhibitor (type of hepatitis medication such as Harvoni, Epclusa, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza-containing regimen)
D. You will not be using the requested medication together with any of the following medications as they are contraindicated (there is a medical reason why you cannot use the drug) or not recommended by the manufacturer:
    1. Carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, erythromycin (does not include topical formulations), clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole (does not include topical formulations), voriconazole, dexamethasone, cisapride, cyclosporine, rosuvastatin (dose above 10mg), or atorvastatin (dose above 40mg)
    2. Any of the following human immunodeficiency virus (HIV) medications: delavirdine, etravirine, nevirapine, or efavirenz
    3. A cobicistat-containing medication such as Stribild or Genvoya [elvitegravir/cobicistat/emtricitabine/tenofovir], Evotaz, Prezcobix, or Tybost
    4. A human immunodeficiency virus (HIV) protease inhibitor such as atazanavir, fosamprenavir, lopinavir, indinavir, nelfinavir, saquinavir, tipranavir, ritonavir, or darunavir/ritonavir)

(Criteria continued on next page)

REQUIREMENTS: SOFOSBUVIR (CONTINUED)

For patients using Sovaldi with Daklinza, the following must also be met:

A. You are 18 years of age or older
B. You have genotype 1 or 3 hepatitis C (type of liver inflammation)
C. You will not be using the requested medication together with any of the following medications because they are contraindicated (medical reason why you cannot use a drug) or not recommended by the manufacturer): amiodarone, carbamazepine, phenytoin, rifampin, or rifapentine
D. You will be taking ribavirin together with Sovaldi and Daklinza if you have decompensated cirrhosis (you have symptoms related to liver damage) or you are post-liver transplant

References:

1. Sovaldi package insert. Foster City, CA. Gilead Sciences, Inc. Revised March 2020. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TASIMELTEON Edition 1	HETLIOZ	4/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **TASIMELTEON (HETLIOZ)** requires a diagnosis of Non-24 Hour Sleep Wake Disorder (N24HSWD). In addition, ALL the following criteria must be met:

For Non-24 Hour Sleep Wake Disorder:

A. The medication is prescribed by or in consultation with a physician who specializes in the treatment of sleep disorders.
B. The patient is not receiving concomitant therapy with a sedative hypnotic (e.g., zolpidem, zaleplon) or other medications for insomnia or other sleep disorders.
C. The diagnosis of Non-24 has been confirmed by ONE of the following:
    1. A history of insomnia, excessive daytime sleepiness, or both, that alternates with time periods of being asymptomatic, as the individual rotates between alignment and misalignment with the environmental light-dark schedule
    2. Symptoms must be present for at least three months
    3. Daily sleep logs and/or actigraphy for at least 14 days (though preferably longer) demonstrate a gradual daily drift (typically later) in rest-activity patterns
    4. The symptoms are not better explained by another current sleep, medical, neurologic, mental, or substance abuse disorder, or medication use
D. The patient has had a trial of melatonin with inadequate results.

For Smith-Magenis Syndrome:

A. The patient had a trial and failure of maximally-tolerated melatonin therapy

RENEWAL CRITERIA

Renewal of Hetlioz requires the patient has achieved adequate results with Hetlioz therapy as documented by entrainment, clinically meaningful or significant increases in nighttime sleep, or clinically meaningful or significant decreases in daytime sleep.

References:

1. Hetlioz package insert. Washington, D.C. Vanda Pharmaceuticals Inc. Revised December 2020. Accessed March 2022.
2. Auger RR, Burgess HJ, Emens JS, Deriy LV, Thomas SM, Sharkey KM. Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders: Advanced Sleep-Wake Phase Disorder (ASWPD), Delayed Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD). An Update for 2015: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2015;11(10):1199-1236. Published 2015 Oct 15. doi:10.5664/jcsm.5100.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
IDECABTAGENE VICLUECEL Edition 1	ABECMA	4/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **IDECABTAGENE VICLEUCEL (Abecma)** requires the following rule(s) be met for approval:

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not responsive to treatment)
B. You are 18 years of age or older
C. The medication is being prescribed by or given in consultation with a hematologist/oncologist
D. You have received four or more prior lines of therapy, including an immunomodulatory agent (such as Revlimid, Pomalyst), a proteasome inhibitor (such as Velcade, Kyprolis), and an anti CD38 monoclonal antibody (such as Darzalex)
E. Patient is registered to the Risk Evaluation and Mitigation Strategy (REMS) Program
F. Abecma is administered in a certified REMS facility

References

1. Abecma package insert. Summit, NJ. Celgene Corporation. Revised March 2021. Accessed February 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TIVOZANIB HCL Edition 1	FOTIVDA	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have relapsed or refractory advanced renal cell carcinoma (type of kidney cancer that returns or has not responded to treatment)
B. You are 18 years of age or older
C. The medication is being prescribed by or given in consultation with a hematologist/oncologist
D. You previously had two or more prior systemic therapies

References

1. Fotivda package insert. Boston, MA. AVEO Pharmaceuticals, Inc. Revised March 2021. Accessed July 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SOTORASIB Edition 1	LUMAKRAS	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You are 18 years or older
B. Prescribed by or in consultation with a hematologist/oncologist
C. You have locally or advanced metastatic non-small cell lung cancer (NSCLC) (type of cancer that has spread to other parts of the body) non-small cell lung cancer (NSCLC)
D. Your tumor has an abnormal KRAS G12C gene mutation as determined by an FDA-approved test
E. You have received at least ONE prior systemic therapy

References:

1. Lumakras package insert. Thousand Oaks, CA. Amgen Inc. Revised May 2021. Accessed July 2021.
2. Lindeman NI, Cagle PT, Beasley MB, et al. Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology. Arch Pathol Lab Med 2013; 137:828.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INFIGRATINIB Edition 1	TRUSELTIQ	7/23/2021	7/23/2021

REQUIREMENTS:

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

A. You have previously treated, unresectable locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has grown outside the organ but has not yet spread to other parts of the body and cannot be removed by surgery, or bile duct cancer that has spread to other parts of the body)
B. Prescribed by or in consultation with a hematologist/oncologist
C. You are 18 years of age or older
D. You have a fibroblast growth factor receptor 2 (FGFR2: type of protein) 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 July 2021.
2. Lindeman NI, Cagle PT, Beasley MB, et al. Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology. Arch Pathol Lab Med 2013; 137:828.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ERENUMAB-AOOE Edition 1	AIMOVIG	10/29/2021	6/1/2021

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. You have migraines
B. **If you have episodic migraines (0-14 headache days per month), approval also requires:**
    a. You are 18 years of age or older
    b. Aimovig is prescribed for the preventive treatment of migraines
    c. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol
C. **If you have chronic migraines (15 or more headache days per month), approval also requires:**
    a. You are 18 years of age or older
    b. Aimovig is prescribed for the preventive treatment of migraines
    c. You have previously tried ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]

RENEWAL CRITERIA

Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:

A. Aimovig is being prescribed for preventive treatment of migraines.
B. You meet **ONE** of the following criteria:
    a. You have experienced less migraines or headache attacks by at least 2 days per month with Aimovig therapy
    b. You have experienced a lessening in migraine severity with Aimovig therapy
    c. You have experienced a lessening in migraine duration with Aimovig therapy

(Criteria continued on next page)

REQUIREMENTS: ERENUMAB-AOOE (CONTINUED)

References:

1. Aimovig package insert. Thousand Oaks, CA. Amgen Inc. Revised May 2021. Accessed October 2021.
2. Loder, E. , Burch, R. and Rizzoli, P. (2012), The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. Headache: The Journal of Head and Face Pain, 52: 930-945. doi:10.1111/j.1526-4610.2012.02185.x
3. 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. Neurology. 2012;78(17):1337-45.
4. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the differences between episodic migraine and chronic migraine. *Curr Pain Headache Rep*. 2011;16(1):86-92.
5. International Headache Society Classification ICHD-II. Available at: http://www.ihs-klassifikation.de/en/02_klassifikation/05_anhang/01.05.01_anhang.html. Accessed 12/14/2018

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MEPOLIZUMAB Edition 2	NUCALA	10/29/2021	10/29/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have ONE of the following diagnoses:
   1. Severe asthma with an eosinophilic phenotype (inflammatory type)
   2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
   3. Hypereosinophilic syndrome (HES) (a rare blood disorder)
   4. Chronic rhinosinusitis with nasal polyps (CRSwNP)

B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/ breathing) medicine or allergy medicine
   3. Nucala will be used as add-on maintenance treatment
   4. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
   5. You had prior therapy with medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid plus at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as tiotropium), a leukotriene receptor antagonist (such as montelukast), theophylline, or oral corticosteroid
   6. You have experienced at least ONE asthma exacerbation (worsening of symptoms) within the past 12 months. Exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days
   7. You are not being treated on the requested medication concurrently (at the same time) with Xolair, Dupixent, or another anti-IL-5 asthma biologic (such as Cinqair, Fasenra)

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

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

D. **If you have hypereosinophilic syndrome (HES), approval also requires:**
    1. You are 12 years of age or older
    2. You had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause
E. **If you have chronic rhinosinusitis with nasal polyps (CRSwNP), approval also requires:**
    1. You are 18 years of age or older
    2. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
    3. You have inadequately controlled disease as determined by **ONE** of the following:
        a. Use of systemic steroids in the past 2 years
        b. Endoscopic sinus surgery (using a small camera to help in surgery)
    4. Nucala will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
    5. The medication is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist

RENEWAL CRITERIA

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

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

A. You have severe asthma with an eosinophilic phenotype
B. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
C. You have shown a clinical response as evidenced by ONE of the following:
    1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV_1 (amount of air you can forcefully exhale) from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing, etc.)
D. If you have chronic rhinosinusitis with nasal polyps, approval also requires**:**
    1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

References:

1. Nucala package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised July 2021. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

ASPARAGINASE Edition 2			
Generic	Brand	Reviewed	Effective Date
ASPARAGINASE (ERWINIA CHRYSAN)	ERWINAZE	10/29/2021	10/29/2021
ASPARAGINASE (ERWINIA CHRYSAN) RECOMBINANT	RYLAZE		
PEGASPARGASE	ONCASPAR		

REQUIREMENTS:

Our guideline named **ASPARAGINASE (Erwinaze, Oncaspar)** requires the following rule(s) be met for approval:

A. The requested medication will be used as a part of a chemotherapeutic treatment plan with multiple drugs

B. **If you are requesting Oncaspar, approval also requires ONE of the following:**
   1. You have a diagnosis of acute lymphoblastic leukemia (ALL: type of blood and bone marrow cancer)
   2. Oncaspar will be used as a first-line therapy
   3. You have hypersensitivity to native forms of L-asparaginase (you are allergic to natural forms of a type of enzyme/protein)

C. **If you are requesting Erwinaze, approval also requires:**
   1. You have a diagnosis of acute lymphoblastic leukemia (ALL: type of blood and bone marrow cancer)
   2. You have developed a hypersensitivity to a E. Coli-derived asparaginase (you are allergic to an enzyme/protein that is from a type of bacteria)

D. **If you are requesting Rylaze, approval also requires:**
   1. You have a diagnosis of acute lymphoblastic leukemia (ALL) or lymphoblastic (LBL)
   2. You are 1 month of age or older
   3. You have developed hypersensitivity to E.coli-derived asparaginase

References:

1. Erwinaze package insert. Langhorne, PA. EUSA Pharma (USA), Inc. Revised November 2011. Accessed October 2021.
2. Rylaze package insert. Palo Alto, CA. Jazz Pharmaceuticals. Revised June 2021. Accessed October 2021.
3. Oncaspar package insert. Gaithersburg, MD. Sigma-Tau Pharmaceuticals, Inc. Revised March 2011. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
FREMANEZUMAB-VFRM Edition 2	AJOVY	10/29/2021	10/29/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires a diagnosis of migraines. The following criteria must also be met:

For episodic migraines, approval requires:

A. The patient is 18 years of age or older
B. Ajovy is prescribed for the preventive treatment of migraines
C. The patient has had a previous trial of any 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

For chronic migraines, approval requires:

A. The patient is 18 years of age or older
B. Ajovy is prescribed for the preventive treatment of migraines
C. The patient has had a previous trial of any **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 that Ajovy is being prescribed for preventive treatment of migraines. At least **ONE** of the following criteria must also be met:

A. The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Ajovy therapy
B. The patient has experienced a reduction in migraine severity with Ajovy therapy
C. The patient has experienced a reduction in migraine duration with Ajovy therapy

(Criteria continued on next page)

REQUIREMENTS: FREMANEZUMAB-VFRM (CONTINUED)

References:

1. Ajovy package insert. North Wales, PA. Teva Pharmaceuticals USA, Inc. Revised January 2020. Accessed October 2021.
2. Oskoui M, Pringsheim T, Holler-Managan Y, et al. Practice guideline update summary: Acute treatment of migraine in children and adolescents: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society [published correction appears in 3. Neurology. 2020 Jan 7;94(1):50]. *Neurology*. 2019;93(11):487-499. doi:10.1212/WNL.0000000000008095
3. Loder, E. , Burch, R. and Rizzoli, P. (2012), The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. Headache: The Journal of Head and Face Pain, 52: 930-945. doi:10.1111/j.1526-4610.2012.02185.x
4. 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. Neurology. 2012;78(17):1337-45.
5. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the differences between episodic migraine and chronic migraine. Curr Pain Headache Rep. 2011;16(1):86-92.
6. International Headache Society Classification ICHD-II. Available at: http://www.ihs-klassifikation.de/en/02_klassifikation/05_anhang/01.05.01_anhang.html. Accessed 12/14/2018

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RIMEGEPANT Edition 3	NURTEC ODT	10/29/2021	10/29/2021

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. You are being treated for acute (quick onset) migraine
    1. You are 18 years of age or older
    2. You had a trial of ONE triptan (such as sumatriptan, rizatriptan), unless there is a medical reason why you cannot (contraindication)

B. **If you have episodic migraines (0-14 headache days per month), approval also requires**
    1. You have had a previous trial of ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
    2. You have had a previous trial of TWO of the following preferred prevention medications: Aimovig, Emgality, Ajovy

RENEWAL CRITERIA

Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

A. You are being treated for acute (quick onset) migraine or for the prevention of treatment of episodic migraines in adults

B. If you have migraines **renewal also requires ONE of the following:**
    1. You have experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINEACT])
    2. You have experienced clinical improvement as defined by ONE of the following:
        i. Ability to function normally within 2 hours of dose
        ii. Headache pain disappears within 2 hours of dose
        iii. Treatment works consistently in majority of migraine attacks

C. If you have episodic migraines
    1. You had improvement in episodic cluster headache frequency compared to baseline

(Criteria continued on next page)

REQUIREMENTS: RIMEGEPANT CONTINUED)

References:

1. Nurtec ODT package insert. New Haven, CT. Biohaven Pharmaceuticals, Inc. Reviewed May 2021. Accessed October 2021.
2. Oskoui M, Pringsheim T, Holler-Managan Y, et al. Practice guideline update summary: Acute treatment of migraine in children and adolescents: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society [published correction appears in Neurology. 2020 Jan 7;94(1):50]. *Neurology*. 2019;93(11):487-499. doi:10.1212/WNL.0000000000008095.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
LENVATINIB MESYLATE Edition 2	LENVIMA	10/29/2021	10/29/2021

REQUIREMENTS:

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

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

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

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

D. **If you have advanced endometrial carcinoma, approval also requires:**
   1. Lenvima is used in combination with pembrolizumab (Keytruda)
   2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
   3. You have experienced disease progression following prior systemic therapy (disease has worsened after previous therapy) in any setting
   4. You are not a candidate for curative surgery or radiation

References:

1. Lenvima package insert. Woodcliff Lake, NJ. Eisai Inc., Revised August 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ENFORTUMAB VEDOTIN-EJFV Edition 2	PADCEV	10/29/2021	10/29/2021

REQUIREMENTS:

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

A. You have locally advanced or metastatic urothelial cancer (type of urinary system cancer that has spread to other parts of the body)
B. You are 18 years of age or older
C. You have ONE of the following:
    1. You have previously received a medication that works against a type of protein called programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and you have previously received a platinum-containing chemotherapy (type of cancer medication) in the neoadjuvant/adjuvant (given before surgery or as an add-on), locally advanced or metastatic setting (cancer has spread to other parts of the body)
    2. You are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy

References:

1. Padcev package insert. Northbrook, IL. Astellas Pharma US, Inc. Revised July 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

PENICILLAMINE Edition 2			
Generic	Brand	Reviewed	Effective Date
PENICILLAMINE	CUPRIMINE	10/29/2021	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. You have a known family history of Wilson's disease (a genetic disorder in which copper builds up in the body) or physical examination consistent with Wilson's disease, cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)

B. **If you have Wilson's disease, approval also requires:**
    1. The drug is prescribed by or given in consultation with a hepatologist (a liver doctor); and
    2. You have maintained a low copper diet (less than 2mg copper per day); and
    3. If you are requesting Cuprimine, you must have tried to Depen (penicillamine)unless there is a medical reason why you cannot take it (contraindication)
    4. You meet ONE of the following:
        1. You have blood levels of the copper-protein ceruloplasmin less than 20mg/dL; or
        2. Your liver biopsy (sample cells taken from your liver) shows you have an abnormally high amount of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (rings around the iris of your eye); or
        3. Your diagnosis has been confirmed by genetic testing for ATP7B (type of gene) mutations

(Criteria continued in next page)

REQUIREMENTS: PENICILLAMINE (CONTINUED)

C. **If you have cystinuria, approval also requires:**
   1. You have nephrolithiasis (kidney stones) and one (1) or more of the following:
      1. Kidney stone analysis shows that there is cystine (an amino acid);
      2. Urine analysis shows there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      3. You have a family history of cystinuria with positive tests results in the cyanidenitroprusside screen (a test to determine the amount of cysteine in your body);
   2. You have a daily cystine output greater than 300mg per 24 hours after a urine cystine excretion testing
   3. You have failed to respond to an adequate trial of conventional therapy which includes **ALL** of the following, unless there is a medical reason why you cannot (contraindicated):
      1. Increased fluid intake
      2. Modest reductions in sodium and protein intake
      3. Urinary alkalinization (a process that makes urine basic)
   4. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor)
   5. For Cuprimine requests, you must have a previous trial of Depen (penicillamine) **AND** Thiola (tiopronin), unless there is a medical reason why you cannot (contraindication)

D. **If you have active rheumatoid arthritis, approval requires:**
   1. The medication is prescribed by or given in consultation with a rheumatologist (joint disease doctor)
   2. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   3. You have failed to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. If you are requesting Cuprimine, you must have tried Depen (penicillamine) or D-Penamine (penicillamine), unless there is a medical reason why you cannot take it (contraindication)

(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. You have a diagnosis of Wilson's disease (a genetic disorder in which copper builds up in the body), cystinuria (high concentrations of the amino acid cysteine in the urine), or active rheumatoid arthritis (chronic inflammatory disorder affecting many joints)

B. **If you have Wilson's disease, approval also requires:**
   1. You have achieved free serum copper of less than 10 mcg/dL

C. **If you have cystinuria, approval also requires:**
   1. You have achieved cystine excretion of less than 200 mg/day

D. **If you have active rheumatoid arthritis, approval also requires:**
   1. You do not have a history of or other evidence of renal insufficiency (kidney problems)
   2. You have experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

References:

1. Cuprimine package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised October 2004. Accessed October 2021.
2. Depen package insert. Somerset, NJ. Meda Pharmaceuticals Inc. Revised July 2018. Accessed October 2021.
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

WELLFLEET RX STUDENT FORMULARY

SELEXIPAG Edition 2			
Generic	Brand	Reviewed	Effective Date
SELEXIPAG Tablets	UPTRAVI	10/29/2021	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. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. The medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have documented confirmatory pulmonary arterial hypertension diagnosis based on right heart catheterization (placing a small tube into right side of heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) of 25 mmHg or greater
    2. Pulmonary capillary wedge pressure (PCWP) of 15 mmHg or less
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have New York Heart Association-World Health Organization (NYHA-WHO) Functional Class II-IV symptoms (a way to classify how limited you are during physical activity)

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects the lungs)
B. You meet ONE of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance
    2. You have a stable 6-minute walk distance from baseline AND your World Health Organization (WHO) functional class (way to classify how limited you are during physical activity) has remained stable or improved

References:

1. Uptravi package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised July 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
EPTINEZUMAB-JJMR Edition 2	VYEPTI	10/29/2021	10/29/2021

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. You have migraines

B. **If you have episodic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines
   3. You have had a previous trial of 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. You have had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, and Emgality

C. **If you have chronic migraines, approval also requires:**
   1. You are 18 years of age or older
   2. Vyepti is prescribed for the preventive treatment of migraines
   3. You have had a previous trial of ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox [**Note**: For Botox, previous trial of only NDCs 00023-1145-01 or 00023-3921-02 are allowable]
   4. You have had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, and Emgality

RENEWAL CRITERIA

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:

A. Vyepti is being prescribed for preventive treatment of migraines

B. You also meet **ONE** of the following:
   a. You have experienced a reduction in migraine or headache frequency by at least 2 days per month with Vyepti therapy
   b. You have experienced a reduction in migraine severity with Vyepti therapy
   c. You have experienced a reduction in migraine duration (length of time) with Vyepti therapy

(Criteria continued on next page)

REQUIREMENTS: EPTINEZUMAB-JJMR (CONTINUED)

References:

1. Vyepti package insert. Bothell, WA. Lundbeck Seattle BioPharmaceuticals, Inc. Revised September 2021. Accessed October 2021.
2. Loder, E. , Burch, R. and Rizzoli, P. (2012), The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. Headache: The Journal of Head and Face Pain, 52: 930-945. doi:10.1111/j.1526-4610.2012.02185.x
3. 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. Neurology. 2012;78(17):1337-45.
4. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the differences between episodic migraine and chronic migraine. *Curr Pain Headache Rep*. 2011;16(1):86-92.
5. International Headache Society Classification ICHD-II. Available at: http://www.ihs-klassifikation.de/en/02_klassifikation/05_anhang/01.05.01_anhang.html. Accessed 12/14/2018

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Date Reviewed	Effective Date
SODIUM, CALCIUM, MAG, POT OXYBATE Edition 2	XYWAV	10/29/2021	10/29/2021

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

Our guideline for **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires a diagnosis of cataplexy in narcolepsy OR excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2), OR idiopathic hypersomnia in adults. Additional guideline requirements apply.

For the diagnosis of cataplexy in narcolepsy, the following criteria must be met:

A. The patient is 7 years of age or older
B. Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
C. Both the patient and physician are registered in the "Xywav REMS Program" provided by the manufacturer
D. The patient has tried **TWO** of the following: venlafaxine, fluoxetine, or a tricyclic antidepressant (e.g., amitriptyline, clomipramine, imipramine)
E. 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.**
F. Provide clinical documentation of functional impairment due to narcolepsy with cataplexy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
G. 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)

(Criteria continued on next page)

REQUIREMENTS: SODIUM/CALCIUM/MAG/POT OXYBATE (XYWAV) (CONTINUED)

For the diagnosis of excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2), the following criteria must be met:

A. The patient is 7 years of age or older
B. Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
C. Both the patient and physician are registered in the "Xywav REMS Program" provided by the manufacturer
D. Diagnosis of narcolepsy, after evaluation including a sleep study which excludes other causes of chronic daytime sleepiness (unless the prescriber provides documentation that a sleep study would not be clinically appropriate)
E. Modafinil in doses up to 400 mg daily, OR armodafinil in doses up to 250 mg daily, has been ineffective, not tolerated, or contraindicated
F. At least one generic stimulant (e.g., methylphenidate, dextroamphetamine, or amphetamine) has been ineffective, not tolerated, or contraindicated
G. Provide clinical documentation of narcolepsy symptoms occurring for at least 3 months with ESS (Epworth Sleepiness Scale) scores > 10 confirmed by one of the following: **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
    a. MSLT mean sleep latency 8 minutes or less, including REM sleep episodes during 2* or more test periods (aka SOREMPs)
        i. *Polysomnography demonstrating early-onset REM sleep of approximately 15 minutes the night before the MSLT may replace one mid-MSLT SOREMP but should rule out non-narcolepsy causes of EDS
    b. Alternately, low CSF orexin/hypocretin levels per assay
H. Provide clinical documentation of functional impairment due to narcolepsy, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
I. 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)

(Criteria continued on next page)

REQUIREMENTS: SODIUM/CALCIUM/MAG/POT OXYBATE (XYWAV) (CONTINUED)

For the diagnosis of idiopathic hypersomnia (IH), the following criteria must be met:

A. The patient is 18 years of age or older
B. Patient has diagnosis of idiopathic hypersomnia (IH)
C. Prescribed by or in consultation with one of the following specialists: neurologist or specialist in sleep medicine
D. Both the patient and physician are registered in the "Xywav REMS Program" provided by the manufacturer
E. Diagnosis of idiopathic hypersomnia, after evaluation including a sleep study which excludes other causes of chronic daytime sleepiness (unless the prescriber provides documentation that a sleep study would not be clinically appropriate)
F. Cataplexy is not present.
G. Modafinil in doses up to 400 mg daily, OR armodafinil in doses up to 250 mg daily, has been ineffective, not tolerated, or contraindicated
H. At least one generic stimulant (e.g., methylphenidate, dextroamphetamine, or amphetamine) has been ineffective, not tolerated, or contraindicated
I. Provide clinical documentation of idiopathic hypersomnia symptoms occurring for at least 3 months with ESS (Epworth Sleepiness Scale) scores > 10 confirmed by both of the following: **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
    a. MSLT documents less than 2 sleep-onset rapid eye movement periods (SOREMPs) or no SOREMPSs if the REM sleep latency on the preceding polysomnogram was less than or equal to 15 minutes.
    b. The presence of at least one of the following:
        i. MSLT shows mean sleep latency 8 minutes or less
        ii. Total 24-hour sleep time is less than or equal to 660 minutes on 24-hour polysomnography or by wrist actigraphy in association with a sleep log.
J. Provide clinical documentation of functional impairment due to idiopathic hypersomnia, which may include (but is not limited to) documentation of limitation of activities of daily living (ADLs), such as missing school/work, inability to drive/exercise safely, or inability to care for self/family. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
K. 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).

(Criteria continued on next page)

REQUIREMENTS: SODIUM/CALCIUM/MAG/POT OXYBATE (XYWAV) (CONTINUED)

RENEWAL CRITERIA

Our guideline for **SODIUM/CALCIUM/MAG/POT OXYBATE (Xywav)** requires a diagnosis of cataplexy in narcolepsy, excessive daytime sleepiness associated with narcolepsy without cataplexy (narcolepsy type 2) or idiopathic hypersomnia for renewal. In addition, one of the following criteria must also be met:

A. For diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness associated with narcolepsy, provide documentation of sustained improvement of cataplexy symptoms compared to baseline. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
B. For diagnosis of cataplexy in narcolepsy or excessive daytime sleepiness associated with narcolepsy, provide documentation of sustained EDS improvement as shown by sustained ESS improvement of at least 25% over baseline since initial authorization. **PLEASE NOTE: verbal responses are not accepted to confirm the criteria has been met.**
C. For diagnosis of idiopathic hypersomnia, documentation of sustained EDS improvement as shown by sustained ESS improvement or Idiopathic Hypersomnia Severity Scale (IHSS) improvement of at least 25% over 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 August 2021. Accessed October 2021.
2. American Academy of Sleep Medicine. International Classification of Sleep Disorders, 3rd ed, American Academy of Sleep Medicine, Darien, IL 2014.
3. 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
IVOSIDENIB Edition 2	TIBSOVO	10/29/2021	10/29/2021

REQUIREMENTS:

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

A. You have acute myeloid leukemia (AML: blood and bone marrow cancer with too many white blood cells) OR locally advanced or metastatic cholangiocarcinoma (cancer formed in the slender tubes which connect your gall bladder, liver, and small intestine)

B. **If you have relapsed or refractory acute myeloid leukemia (AML: type of blood and bone marrow cancer that returns after treatment), approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. You are 18 years of age or older

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

A. **If you have a diagnosis of locally advanced or metastatic cholangiocarcinoma, approval also requires:**
   1. You have a susceptible isocitrate dehydrogenase-1 (IDH1; type of enzyme) mutation as detected by an FDA (Food and Drug Administration)-approved diagnostic test
   2. Your locally advanced or metastatic cholangiocarcinoma has been previously treated with at least one treatment regimen for cholangiocarcinoma (e.g. gemcitabine/cisplatin, FOLFOX, FOLFIRI, etc.)
   3. You are 18 years of age or older

References:

1. Tibsovo package insert. Cambridge, MA. Agios Pharmaceuticals, Inc. Revised August 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ZANUBRUTINIB Edition 2	BRUKINSA	10/29/2021	10/29/2021

REQUIREMENTS:

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

A. You have a diagnosis of mantle cell lymphoma (type of white blood cell cancer) OR Waldenström's macroglobulinemia (WM) OR relapsed or refractory marginal zone lymphoma (MZL).
B. You are 18 years of age or older
C. If you have mantle cell lymphoma, you have previously received at least ONE prior therapy for mantle cell lymphoma
D. If you have relapsed or refractory marginal zone lymphoma (MZL), you have previously received at least one anti-CD20-based regimen for marginal zone lymphoma

References:

1. Brukinsa package insert. San Mateo, CA. BeiGene USA, Inc. Revised September 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CABOZANTINIB S-MALATE Edition 2	COMETRIQ, CABOMETYX	10/29/2021	10/29/2021

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

REQUIREMENTS:

COMETRIQ

Our guideline named **CABOZANTINIB S-MALATE (Cometriq)** requires the following rule be met for approval:

A. You have a diagnosis of progressive, metastatic medullary thyroid cancer (MTC; type of thyroid cancer that has spread).

CABOMETYX

Our guideline named **CABOZANTINIB S-MALATE (Cabometyx)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
    1. Advanced renal cell carcinoma (type of kidney cancer)
    2. Hepatocellular carcinoma (type of liver cancer)
    3. Locally advanced or metastatic differentiated thyroid cancer (DTC)

B. **If Cabometyx will be used in combination with Opdivo, approval also requires:**
    1. You have advanced renal cell carcinoma (type of kidney cancer)
    2. You have not received prior treatment for advanced renal cell carcinoma

C. **If you have hepatocellular carcinoma (type of kidney cancer), approval also requires:**
    1. You have previously been treated with Nexavar (sorafenib)

D. **If you have Locally advanced or metastatic differentiated thyroid cancer (DTC), approval also requires:**
    1. You are 12 years of age or older
    2. Your disease has progressed following prior VEGFR-targeted therapy
    3. You are radioactive iodine-refractory or ineligible

References:

1. Cabometyx package insert. Alameda, CA. Exelixis, Inc. Revised September 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RUXOLITINIB PHOSPHATE Edition 3	JAKAFI	4/29/202	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. You have ONE of the following diagnoses:
   1. Intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis)
   2. Polycythemia vera
   3. Steroid -refractory acute graft-versus-host disease
   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. You have a 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. You had a trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)

D. **If you have steroid -refractory acute graft-versus-host disease, approval also requires:**
   1. You are 12 years of age or older
   2. Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist
   3. You had a trial and failure of a systemic corticosteroid (e.g., prednisone, methylprednisolone, etc.)

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. You have 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 you have intermediate or high-risk myelofibrosis, (type of bone marrow cancer such as primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis), renewal requires you have experienced or maintained symptom improvement as evidenced by one of the following:
    1. 50 percent or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0]
    2. 50 percent or greater reduction in palpable spleen length
    3. Spleen reduction of 35 percent or greater from baseline spleen volume after 6 months of therapy
B. If you have polycythemia vera, renewal requires documentation you 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. Not eligible for therapeutic phlebotomy (Hematocrit (Hct) of 48% or less)
C. If you have chronic graft-versus-host disease, renewal requires documentation you 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 September 2021. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

OPIOID-NAÏVE DAY SUPPLY LIMITATION Edition 3			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	10/29/2021	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 you are opioid-naïve and meet at least **ONE** of the following conditions:

A. You have active cancer
B. You are enrolled in hospice
C. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of blood disorder)
F. You are NOT opioid naïve (you have been consistently using opioid pain medications)
G. Your doctor confirms (attests) that the prescribed dose of opioids with the requested day supply is intended and medically necessary

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens.

(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 4/2/18]
2. The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service- Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
3. Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].
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-durofr- master-webposting-508.pdf [Accessed 2/1/21].
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.

WELLFLEET RX STUDENT FORMULARY

OPIOID CUMULATIVE DOSING OVERRIDE Edition 3			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	10/29/2021	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 you to receive a higher quantity of an opioid medication if ONE of the following rules (A or B) is met:

A. You have ONE of the following conditions:
    1. You have active cancer
    2. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
    3. You are enrolled in hospice
    4. You are a resident of a long-term care facility or intermediate care for intellectually disabled
    5. You have sickle cell disease (type of blood disorder)
B. Your prescriber is aware that there is more than one provider prescribing opiates for the patient, and you meet **TWO** of the following:
    1. You have documentation showing your current level of opioid use is necessary and required for the level of pain management needed
    2. You have been evaluated by a pain specialist, and/or the request is based on the recommendation of a pain specialist
    3. You have a pain contract in place
    4. You do not have a history of substance abuse or addiction
    5. Your provider has committed to monitoring the state's Prescription Monitoring Program to ensure controlled substance history is consistent with prescribing record.

This safety edit allows for an override for an opioid product equal to or exceeding the soft-stop threshold (90 mg morphine milligram equivalent (MME)) or hard-stop threshold (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. Please consult your physician if you have any questions about this safety edit on prescription opioid medications and the requirements needed for you to obtain an approval for higher quantities of these agents.

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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 4/2/18]
2. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.
3. Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.
4. 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 8/11/16].
5. Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed 8/11/16].
6. CMS Medicare Benefit Policy Manual Chapter 9 – Coverage of Hospice Services Under Hospital Insurance. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c09.pdf [Accessed 1/2/17].
7. 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.
8. The Social Security Act: Title XVIII: Section 1861(t), Center for Medicare and Medicaid Service. March 23, 2012. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DME_SSAct.html [Accessed 9/28/18].
9. Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point of Sale Safety Edits. Available at https://mopa.memberclicks.net/assets/docs/Opioid_SafetyEdit_Memo_10232018%20%28002%29.pdf [Accessed 11/20/18].

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REQUIREMENTS- OPIOID CUMULATIVE DOSING OVERRIDE (CONTINUED)

10. 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-durofr-master-webposting-508.pdf [Accessed 2/1/21].
11. 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.
12. 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 NAIVE FILL LIMIT Edition 3			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	10/29/2021	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 you meet at least **ONE** of the following conditions:

A. You have active cancer
B. You are enrolled in hospice
C. You are receiving palliative care (treatment for comfort from symptoms) or end-of-life care
D. You are a resident of a long-term care facility or intermediate care for intellectually disabled
E. You have sickle cell disease (type of blood disorder)
F. You are NOT opioid naïve (you have been consistently using opioid pain medications)
G. Your doctor confirms that the additional fill of the requested opioid analgesic (pain-relieving) medication is intended and clinically appropriate for you

Please consult your physician if you have any questions about this prescription pain medication and the requirements needed for you to obtain an approval for this agent.
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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 7/30/19]
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-durofr- master-webposting-508.pdf [Accessed 2/1/21].
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MOBOCERTINIB Edition 1	EXKIVITY	10/29/2021	10/29/2021

REQUIREMENTS:

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

A. Prescribed by or in consultation with an oncologist/hematologist, and
B. You have a diagnosis of non-small cell lung cancer (NSCLC)
C. You are 18 years of age or older
D. You have locally advanced or metastatic disease
E. Your tumors have epidermal growth factor receptor (EGFR; type of protein) exon 20 insertion mutations as shown by an FDA (Food and Drug Administration)-approved test
F. Your 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 2021. Accessed October 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TESAMORELIN Edition 2	EGRIFTA	01/28/2022	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 (human immunodeficiency virus)-infected patients who have lipodystrophy syndrome (abnormal distribution of fat in the body)

B. You 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 November 2021.
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).

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
THALIDOMIDE Edition 2	THALOMID	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have one of the following diagnoses:
    1. Multiple myeloma (plasma cell cancer)
    2. Erythema nodosum leprosum (ENL: type of inflammatory disease that causes skin lesions and nerve damage)

B. **If you have 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 February 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

TOBRAMYCIN INHALED			
Generic	Brand	Reviewed	Effective Date
TOBRAMYCIN Edition 2	BETHKIS, TOBRAMYCIN	01/28/2022	01/28/2022
TOBRAMYCIN IN 0.225% NACL	TOBI		
TOBRAMYCIN	TOBI PODHALER		
TOBRAMYCIN/NEBULIZER	KITABIS PAK		

REQUIREMENTS:

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)

B. You have a lung infection per culture of the airway demonstrating a gram-negative species (type of bacteria that does not stain a purple color), *Pseudomonas aeruginosa.*

References:

1. TOBI Inhalation Solution package insert. East Hanover, NJ. Novartis Pharmaceuticals. Revised October 2018. Accessed November 2021.
2. TOBI Podhaler [package insert]. East Hanover, NJ. Novartis Pharmaceuticals; Revised July 2020. Accessed November 2021.
3. Bethkis package insert. Woodstock, IL. Catalent Pharma Solutions, LLC. Revised December 2019. Accessed November 2021.
4. Kitabis Pak package insert. Woodstock, IL. Catalent Pharma Solutions, LLC. Revised December 2019. Accessed November 2021.
5. Tobramycin Inhalation Solution package insert. Parsippany, NJ. Teva Pharmaceuticals USA. Revised February 2020. Accessed November 2021. 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.
6. 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

TREPROSTINIL			
Generic	Brand	Reviewed	Effective Date
TREPROSTINIL SODIUM Edition 2	REMODULIN	01/28/2022	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. You have pulmonary arterial hypertension (PAH: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. **For continuation of current therapy**, you must have NYHA-WHO Functional Class II, III, or IV symptoms (a way to classify how limited you are during physical activity)
E. **For new start requests**, approval also requires **ONE** of the following:
    1. You have NYHA-WHO Functional Class III or IV symptoms
    2. You have NYHA-WHO Functional Class II symptoms **AND** had a previous trial of or a medical reason why you cannot use (contraindication to) a phosphodiesterase-5 inhibitor (such as Adcirca [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. You have ONE of the following diagnoses:
    1. Pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
    2. Pulmonary hypertension (PH-: form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group 3 (type of classification of the disease)

B. If you have PAH (WHO Group 1), approval also requires:
    1. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
    2. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
        i. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
        ii. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
        iii. Pulmonary vascular resistance (PVR) greater than 3 Wood units
    3. You have NYHA-WHO Functional Class III or IV symptoms (a way to classify how limited you are during physical activity)
    4. Documentation of baseline 6-minute walk distance test

C. If you have PH (WHO Group 3), approval also requires:
    1. Your PAH must be associated with interstitial lung disease (PH-ILD; scarring and inflammation of the tissues in the lungs which makes it difficult to breath)
    2. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor).
    3. Documentation of baseline 6-minute walk distance test

(Criteria continued on next page)

REQUIREMENTS: TREPROSTINIL- ORENITRAM (CONTINUED)

ORENITRAM

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

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease)
B. The requested medication is prescribed by or given in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
C. You have a documented confirmed diagnosis of pulmonary arterial hypertension based on right heart catheterization (placing a small tube into the right side of the heart) with the following lab values:
    1. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. You have NYHA-WHO Functional Class II, III or IV symptoms (a way to classify how limited you are during physical activity)
E. Documentation of baseline 6-minute walk distance test
F. You do not have severe hepatic (liver) impairment
G. You meet **ONE** of the following:
    1. Your request is for continuation of current Orenitram therapy
    2. You have tried a preferred formulary phosphodiesterase-5 inhibitor (such as sildenafil [Revatio] or tadalafil [Adcirca]) **OR** an endothelin receptor antagonist (such as Tracleer [bosentan], Letairis [ambrisentan], or Opsumit [macitentan])

RENEWAL CRITERIA

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

A. You have pulmonary arterial hypertension (form of high blood pressure that affects blood vessels in lungs and heart) World Health Organization (WHO) Group I (type of classification of the disease) OR pulmonary hypertension associated with interstitial lung disease WHO Group 3 (**Orenitram ONLY).**
B. You meet **ONE** of the following:
    1. You have shown improvement from baseline in the 6-minute walk distance test
    2. You have remained stable from baseline in the 6-minute walk distance test **AND** your World Health Organization (WHO) functional class (a way to classify how limited you are during physical activity) has improved or remained stable

(Criteria continued on next page)

REQUIREMENTS: TREPROSTINIL (CONTINUED)

References:

1. Remodulin package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised July 2021. Accessed November 2021.
2. Tyvaso package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised March 2021. Accessed November 2021.
3. Orenitram package insert. Research Triangle Park, NC. United Therapeutics Corp. Revised November 2020. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TRIENTINE Edition 1	SYPRINE	01/28/2022	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. You have a known family history of Wilson's disease (a genetic disorder that leads to copper accumulation in the organs) or physical examination consistent with Wilson's disease
B. You meet **ONE** of the following criteria:
    1. Your plasma copper-protein ceruloplasmin (amount of copper-carrying protein in your blood) is less than 20mg/Dl
    2. You had a liver biopsy (sample) positive for an abnormally high concentration of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (brownish-yellow ring around the iris of the eye)
    3. Your diagnosis has been confirmed by genetic testing for ATP7B mutations (mutation in the Wilson disease protein)
C. You have maintained a reduced copper dietary intake (less than 2mg copper per day)
D. The medication is prescribed by or given in consultation with a hepatologist (a doctor who specialize in the liver, biliary tree, gallbladder, and the pancreas)
E. You have had a previous trial of or contraindication to (medical reason why you cannot take) Depen (penicillamine)

RENEWAL CRITERIA

Our guideline named **TRIENTINE (Syprine)** requires the following rules be met for renewal:

A. You have Wilson's disease (a genetic disorder that leads to copper accumulation in the organs)
B. You have achieved a free serum copper (amount of copper in your blood) of less than 10 mcg/dL

References:

1. Syprine package insert. Bridgewater, NJ. Bausch Health US, LLC. Revised September 2020. Accessed November 2021.
2. Saroli Palumbo C, Schilsky ML. Clinical practice guidelines in Wilson disease. Ann Transl Med. 2019;7(Suppl 2):S65. doi:10.21037/atm.2018.12.53.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VEMURAFENIB Edition 2	ZELBORAF	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have unresectable or metastatic melanoma with a BRAF V600E mutation (you have skin cancer with a certain type of gene mutation, and it cannot be removed with surgery or it has spread in the body) as detected by an Food and Drug Administration-approved test

B. You have Erdheim-Chester Disease with a BRAF V600 mutation (rare type of slow growing blood cancer that has a type of gene mutation)

References:

1. Zelboraf package insert. South San Francisco, CA. Genentech USA, Inc. Revised May 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VOXELOTOR Edition 3	OXBRYTA	04/29/2022	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. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
B. You are 4 years of age or older
C. Your hemoglobin (a protein that carries oxygen in the blood) is less than or equal to 10.5 g/dL
D. The medication is prescribed by or given in consultation with a hematologist (a doctor who specializes in the study of blood, blood-forming organs and blood diseases) or other specialist with expertise in the diagnosis and management of sickle cell disease.
E. You meet **ONE** of the following:
    1. Your baseline hemoglobin (Hb) is less than or equal to 10.5 g/dL (must be within past 30 days)
    2. You have 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 (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
F. You had a previous trial of hydroxyurea, unless there is a medical reason why you cannot (contraindication)
G. You are not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)
H. You are not receiving concomitant chronic, prophylactic red-cell transfusion therapy.
I. You will be receiving Oxbryta concurrently with hydroxyurea, unless there is a medical reason why you cannot (contraindication)

(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. You have sickle cell disease (disorder that causes red blood cells to become twisted and break down)
B. You have maintained an improvement in symptoms associated with sickle cell anemia (condition where the blood doesn't have enough healthy red blood cells) as evidenced by **ONE** of the following:
    a. You have an increase in Hb level from baseline of at least 1 g/dL
    b. You have a reduction in the number of sickle cell-related vaso-occlusive crises (VOC) from pre-treatment baseline.
C. You are not receiving Oxbryta in combination with Adakveo (crizanlizumab-tmca)
D. You are not receiving concomitant chronic, prophylactic red-cell transfusion therapy.
E. You are receiving Oxbryta concurrently with hydroxyurea, unless there is a medical reason why you cannot (contraindication)

References:

1. Oxbryta package insert. South San Francisco, CA. Global Blood Therapeutics, Inc. Revised December 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CRIZANLIZUMAB-TMCA Edition 2	ADAKVEO	01/28/2022	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. You have sickle cell disease (type of red blood cell disorder)
B. You are at least 16 years old
C. The medication is prescribed by or given in consultation with a hematologist (blood doctor specialist) or other specialist with expertise in the diagnosis and management of sickle cell disease.
D. You have previously tried hydroxyurea, unless there is a medical reason why you cannot (contraindication)
E. You have 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 (given into the vein) narcotic or parenterally administered ketorolac, the occurrence of acute chest syndrome, priapism (prolonged erection of penis), or splenic sequestration [suppressing of spleen])
F. You are not receiving Adakveo in combination with Oxbryta (voxelotor)
G. You are not receiving concomitant chronic, prophylactic red-cell transfusion therapy.
H. You will be receiving Adakveo concurrently with hydroxyurea, unless there is a medical reason why you cannot (contraindication)

(Criteria continued on next page)

REQUIREMENTS: CRIZANLIZUMAB-TMCA (CONTINUED)

RENEWAL CRITERIA

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

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

References:

1. Adakveo package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2021. Accessed November 2021.
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

Generic	Brand	Reviewed	Effective Date
PALIVIZUMAB Edition 2	SYNAGIS	01/28/2022	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. You are less than 24 months at the start of respiratory syncytial virus (RSV: type of lung and respiratory tract infection) season (mid-September to mid-May)

B. Your 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 you are LESS THAN 12 months old at the start of the RSV season, you must meet ONE of the following**:

1. You were born premature at less than 29 weeks (gestational age)
2. You have chronic lung disease (CLD) of prematurity AND you were born at less than 32 weeks AND required more than 21% of additional oxygen for at least the first 28 days after birth
3. You are profoundly immunocompromised during RSV season with ONE of the following:
    i. Severe combined immunodeficiency (SCID)
    ii. Acquired immunodeficiency syndrome (AIDS)
    iii. Chemotherapy recipient
    iv. Solid organ or stem cell transplant
4. You are receiving a heart transplant during RSV season
5. You have congenital (starting from birth) abnormalities of the lung airways or a neuromuscular (nerve-muscle) disorder that impairs your ability to clear respiratory (lung/breathing) secretions
6. You have cystic fibrosis (CF) with clinical evidence of ONE of the following
    i. Chronic lung disease (respiratory distress and/or the need for positive pressure respiratory support or oxygen)
    ii. Nutritional compromise (poor growth and poor weight gain)

(Criteria continued on next page)

REQUIREMENTS: PALIVIZUMAB (CONTINUED)

D. **If you are 12 months old or less at the start of the RSV season, you must meet ONE of the following**
    1. You have ONE of the following hemodynamically significant heart conditions at birth:
        i. Acyanotic heart disease (blood from the left side to the right side of the heart due to a hole in the heart walls) with ONE of the following:
            a) You need medication to control chronic heart failure and will require heart surgical procedures
            b) You have moderate to severe pulmonary hypertension (high blood pressure in the lungs)
        ii. Cyanotic heart defect (low blood oxygen level) and the requested medication is prescribed by or given in consultation with a pediatric cardiologist (a heart doctor for children)
    2. You are an American Navajo, American White Mountain Apache, or Alaska Native infant born prematurely

E. If you are at least 12 months old AND less than 24 months old at the start of the RSV season, you must meet ONE of the following:
    1. You are profoundly immunocompromised during RSV season with ONE of the following:
        i. Severe combined immunodeficiency (SCID)
        ii. Acquired immunodeficiency syndrome (AIDS)
        iii. Chemotherapy recipient
        iv. Solid organ or stem cell transplant
    2. You have chronic lung disease of prematurity AND you were born at less than 32 weeks AND required more than 21% of additional oxygen for at least the first 28 days after birth 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:
        i. Supplemental oxygen
        ii. Diuretic (drug that makes you urinate)
        iii. Chronic systemic corticosteroid therapy
    3. You are receiving a heart transplant during RSV season

(Criteria continued on next page)

REQUIREMENTS: PALIVIZUMAB (CONTINUED)

4. You have cystic fibrosis and at least ONE of the following:
    i. Previous hospitalization for pulmonary exacerbation in the first year of life
    ii. Abnormalities on chest radiography, or chest computed tomography that persist when stable
    iii. Weight for length is less than the 10th percentile.

RENEWAL CRITERIA

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

A. You are under 24 months old
B. You will undergo a surgery requiring cardiopulmonary bypass (a machine temporarily takes over the function of the heart and lungs during surgery) during respiratory syncytial virus (RSV) season (mid-September to mid-May)
C. You have 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 November 2021.
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/ .

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ATEZOLIZUMAB Edition 2	TECENTRIQ	01/28/2022	01/28/2022

REQUIREMENTS:
Our guideline named **ATEZOLIZUMAB (Tecentriq)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Locally advanced or metastatic (disease has spread to other parts of the body) urothelial carcinoma (cancer that occurs in the urinary system)
   2. Non-small cell lung cancer (NSCLC: a type of lung cancer that has spread to other parts of the body)
   3. Extensive-stage small cell lung cancer (ES-SCLC: type of lung cancer)
   4. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be removed by surgery or has spread to other parts of the body)
   5. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)

B. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. You meet ONE of the following:
      i. You are not eligible to receive cisplatin-containing chemotherapy **AND** has a tumor that expresses PD-L1 (Programmed death-ligand 1 sustained tumor-infiltrating immune cells [IC] covering 5% or more of the tumor area), as determined by a Food and Drug Administration approved test
      ii. You are not eligible to receive any platinum containing chemotherapy regardless of PDL1 status

C. **If you have metastatic non-squamous non-small cell lung cancer (NSq NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. You do not have EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) genomic tumor abnormalities
   3. The requested medication will be given in combination with ONE of the following regimens as a first-line treatment:
      i. Bevacizumab, paclitaxel, and carboplatin, OR
      ii. Paclitaxel protein-bound and carboplatin

(Criteria continued on next page)

REQUIREMENTS: ATEZOLIZUMAB (CONTINUED)

D. **If you have stage II to IIIA non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as a single-agent
   3. You have tumors that have PD-L1 (programmed death-ligand 1: type of protein) expression (PD-L1 expression on at least 1% of tumor cells) as determined by a Food and Drug Administration (FDA) approved test
   4. The requested medication is being used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor) AND after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

E. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication will be used as a single-agent
   3. You meet ONE of the following:
      i. You do not have an EGFR (*epidermal growth factor receptor- a type of protein)* or ALK *(anaplastic lymphoma kinase- a type of protein)* mutation AND your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
      ii. You do not have an EGFR (epidermal growth factor receptor- a type of protein) or ALK (anaplastic lymphoma kinase- a type of protein) mutation, the requested medication will be used as first line treatment, AND you have tumors that have high PD-L1 (programmed death-ligand 1: type of protein) expression (PD-L1 stained 50% or more of tumor cells, or PD-L1 stained tumor infiltrating immune cells covering 10% or more of the tumor area) as determined by an Food and Drug Administration (FDA) approved test
      iii. You have an ALK mutation and your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) **AND** ALK-directed therapy [such as Xalkori (crizotinib), Zykadia (ceritinib)]
      iv. You have an EGFR mutation and your disease has gotten worse during or after treatment with a platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin) **AND** EGFR-directed therapy [such as Tarceva (erlotinib), Iressa (gefitinib), Gilotrif (afatinib)]

(Criteria continued on next page)

REQUIREMENTS: ATEZOLIZUMAB (CONTINUED)

F. **If you have extensive-stage small cell lung cancer (ES-SCLC), approval also requires:**
    1. You are 18 years of age or older
    2. The requested medication will be used in combination with carboplatin and etoposide as a first-line treatment
G. **If you have unresectable or metastatic hepatocellular carcinoma (HCC), approval also requires:**
    1. You have not previously been treated with systemic therapy
    2. The requested medication will be used in combination with bevacizumab
H. **If you have unresectable or metastatic melanoma, approval also requires:**
    1. The requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf)
    2. You have a BRAF V600 mutation (type of gene mutation)

References:

1. Tecentriq package insert. South San Francisco, CA. Genentech, Inc. Revised October 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AVELUMAB Edition 2	BAVENCIO	01/28/2022	01/28/2022

REQUIREMENTS:

Our guideline named **AVELUMAB (Bavencio)** requires the following rules be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic Merkel cell carcinoma (MCC: a type of skin cancer)
   2. Locally advanced or metastatic (disease that has spread) urothelial carcinoma (UC: type of urinary system cancer)
   3. Advanced renal cell carcinoma (RCC: type of kidney cancer)

B. **If you have metastatic Merkel Cell Carcinoma, approval also requires:**
   1. You are 12 years of age or older

C. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
   1. Your disease has worsened during or after platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   2. Your disease has worsened within 12 months of neoadjuvant (treatment given before a main treatment) or adjuvant treatment (add-on to a main treatment) with platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
   3. Your disease has not worsened with first-line platinum-containing chemotherapy (such as cisplatin, carboplatin, oxalipatin) AND the requested medication will be used as first-line maintenance treatment

D. **If you have advanced renal cell carcinoma, approval also requires:**
   1. The requested medication will be used as first-line treatment
   2. The requested medication will be used in combination with axitinib

References:

1. Bavencio package insert. Rockland, MA. EMD Serono, Inc. Revised November 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BEVACIZUMAB Edition 2	AVASTIN	01/28/2022	01/28/2022
BEVACIZUMAB-BVZR	MVASI		
BEVACIZUMAB-BVZR	ZIRABEV		

REQUIREMENTS:
Our guideline named **BEVACIZUMAB (Avastin, Mvasi, Zirabev)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon cancer that has spread in the body)
   2. Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC: type of lung cancer that cannot be completely removed with surgery or has spread/returned)
   3. Recurrent glioblastoma (GBM: type of brain tumor)
   4. Metastatic renal cell carcinoma (mRCC: type of kidney cancer)
   5. An ophthalmic (eye) indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb
   6. Persistent, recurrent, or metastatic cervical cancer (type of uterus cancer)
   7. Platinum-resistant recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   8. Platinum-sensitive recurrent epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   9. Stage III or IV epithelial ovarian/fallopian tube (female sex organs) or primary peritoneal (abdomen) cancer
   10. Unresectable or metastatic hepatocellular carcinoma (HCC: type of liver cancer that cannot be completely removed with surgery or has spread to other parts of the body)

(Criteria continued on next page)

REQUIREMENTS: BEVACIZUMAB (CONTINUED)

B. **If you have metastatic colorectal cancer, approval also requires:**
    1. You meet ONE of the following:
        i. The requested medication is being used in combination with intravenous (given into the vein) 5-fluorouracil based chemotherapy for first or second-line treatment
        ii. Your disease has progressed (gotten worse) on a first-line Avastin product-containing regimen AND the requested medication is being used in combination with fluoropyrimidine- irinotecan- (for example FOLFIRI) or fluoropyrimidine-oxaliplatin- (for example FOLFOX, CapeOx) based chemotherapy as a second-line treatment
    2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
C. **If you have unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, approval also requires:**
    1. The requested medication is being used in combination with carboplatin and paclitaxel for first-line treatment
    2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
D. **If you have recurrent glioblastoma, approval also requires:**
    1. You are 18 years of age or older
    2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
E. **If you have metastatic renal cell carcinoma, approval also requires:**
    1. The requested medication is being used in combination with interferon-alfa
    2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
F. **If you have any ophthalmic indication as listed by Micromedex/Drugdex strength of recommendation Class I, IIa, or IIb, approval also requires:**
    1. The requested medication is prescribed by an ophthalmologist (eye doctor) and/or retina specialist (a special type of eye doctor)
G. **If you have persistent, recurrent, or metastatic cervical cancer, approval also requires:**
    1. The requested medication is being used in combination with paclitaxel and cisplatin OR paclitaxel and topotecan
    2. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev
H. **If you have platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires:**
    1. The requested medication is being used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan
    2. You have received no more than two prior chemotherapy regimens
    3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

(Criteria continued on next page)

REQUIREMENTS: BEVACIZUMAB (CONTINUED)

I. **If you have platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, approval also requires ONE of the following:**
   1. The requested medication is being used in combination with carboplatin and paclitaxel, OR with carboplatin and gemcitabine
   2. The requested medication is being used as a single agent after previous use in combination with one of the carboplatin-containing chemotherapy regimens listed above
   3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

J. **If you have Stage III or IV epithelial ovarian/fallopian tube or primary peritoneal cancer, approval also requires:**
   1. The requested medication is being used following initial surgical resection (removal)
   2. The requested medication is being used in combination with carboplatin and paclitaxel, OR as a single agent after previous use in combination with carboplatin and paclitaxel
   3. You previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Mvasi or Zirabev

K. **If you have unresectable or metastatic hepatocellular carcinoma, approval also requires:**
   1. The requested medication will be used in combination with atezolizumab
   2. You have not received prior systemic therapy (treatment that spreads throughout the body)

References:

1. Avastin package insert. South San Francisco, CA. Genentech, Inc. Revised December 2020. Accessed November 2021.
2. Mvasi package insert. Thousand Oaks, CA. Amgen, Inc. Revised November 2021. Accessed November 2021.
3. Zirabev package insert. New York, NY. Pfizer, Inc. Revised February 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
CETUXIMAB Edition 2	ERBITUX	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Metastatic colorectal cancer (mCRC: colon/rectum cancer that has spread)
   2. Locally or regionally advanced squamous cell carcinoma (type of skin cancer) of the head and neck
   3. Recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck
   4. Recurrent or metastatic squamous cell carcinoma of the head and neck.

B. **If you have metastatic colorectal cancer (mCRC), approval also requires ONE of the following:**
   1. Your cancer is KRAS wild-type (a type of gene with no mutation) as determined by an FDA (Food and Drug Administration)-approved test, and ALL of the following:
      i. Your cancer is epidermal growth factor receptor (EGFR)-expressing as determined by an FDA-approved test
      ii. You meet also ONE of the following:
         a) The requested medication is being used in combination with FOLFIRI (irinotecan, 5- fluorouracil, leucovorin) for first-line treatment
         b) The requested medication is being used in combination with irinotecan and you are refractory (resistant) to irinotecan-based chemotherapy
         c) The requested medication is being used as a single agent AND you have failed oxaliplatin-based and irinotecan-based chemotherapy unless you are intolerant to irinotecan
   2. Your cancer is positive for BRAF V600E mutation (a type of gene mutation) as determined by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used in combination with encorafenib (Braftovi)

C. **If you have locally or regionally advanced squamous cell carcinoma of the head and neck, approval also requires:**
   1. The requested medication will be used in combination with radiation therapy

(Criteria continued on next page)

REQUIREMENTS- CETUXIMAB (CONTINUED)

D. **If you have recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
    1. The requested medication will be used in combination with platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin) and 5-fluorouracil (5-FU) as first-line treatment

E. **If you have recurrent or metastatic squamous cell carcinoma of the head and neck, approval also requires:**
    1. The requested medication will be used as a single agent
    2. You have previously failed platinum-based therapy (such as cisplatin, carboplatin, or oxaliplatin)

References:

1. Erbitux package insert. Indianapolis, IN. Eli Lilly and Company. Revised September 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DURVALUMAB Edition 1	IMFINZI	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have unresectable (cannot be completely removed with surgery) Stage III non-small cell lung cancer (NSCLC), or extensive-stage small cell lung cancer (ES-SCLC)
B. You are 18 years of age or older
C. **If you have unresectable Stage III non-small cell lung cancer (NSCLC), approval also requires:**
    1. Your disease has not worsened after using concurrent platinum-based chemotherapy (such as cisplatin, carboplatin, oxaliplatin) and radiation therapy (you used chemotherapy and radiation therapy at the same time)
D. **If you have extensive-stage small cell lung cancer (ES-SCLC), approval also requires:**
    1. The requested medication is being used as first line of therapy
    2. The requested medication will be used in combination with etoposide and either carboplatin or cisplatin

References:

1. Imfinzi package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised July 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

FAM-TRASTUZUMAB			
Generic	Brand	Reviewed	Effective Date
FAM-TRASTUZUMAB DERUXTECAN-NXKI Edition 2	ENHERTU	01/28/2022	01/28/2022

REQUIREMENTS:

Our guideline named **FAM-TRASTUZUMAB (Enhertu)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   a. Unresectable or metastatic HER2-positive breast cancer
   b. Locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma

B. You are 18 years of age or older

C. **If you have unresectable or metastatic HER2-positive breast cancer, approval also requires**
   a. You have received two or more prior anti-HER2-based regimens in the metastatic setting

D. **If you have locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma, approval also requires**
   a. You have received a prior trastuzumab-based regimen

References:

1. Enhertu package insert. Basking Ridge, NJ. Daiichi Sankyo, Inc. Revised January 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PACLITAXEL PROTEIN-BOUND Edition 1	ABRAXANE	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have ONE of the following diagnoses:
   1. Metastatic breast cancer (breast cancer that has spread to other parts of the body)
   2. Locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC: cancer that is in the advanced stage or that has spread to other parts of the body)
   3. Metastatic adenocarcinoma of the pancreas (pancreas cancer that has spread to other parts of the body)

B. **If you have metastatic breast cancer, approval also requires:**
   1. You have tried a chemotherapy regimen (cancer-treating medications) containing an anthracycline (cancer drug such as doxorubicin or epirubicin) or paclitaxel

C. **If you have metastatic adenocarcinoma of the pancreas, approval also requires:**
   1. The requested medication will be used in combination with gemcitabine

References:

1. Abraxane package insert. Summit, NJ. Celgene Corporation. Revised August 2020. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ROMIDEPSIN Edition 2	ISTODAX	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have a diagnosis of cutaneous T-cell lymphoma

B. **If you have cutaneous T-cell lymphoma, approval also requires the following:**

1. You had a trial of Zolinza (vorinostat), unless there is a medical reason why you cannot (contraindication) AND you are not able to tolerate oral medications.
2. You have tried at least one form of systemic therapy (such as retinoids, interferon, denileukin diftitox, methotrexate, liposomal doxorubicin, gemcitabine, chlorambucil) AND you are able to tolerate oral medications.
3.

References:

1. Istodax package insert. Summit, NJ. Celgene Corporation. Revised July 2021. Accessed November 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BREXUCABTAGENE AUTOLEUCEL Edition 2	TECARTUS	01/28/2022	01/28/2022

REQUIREMENTS:

Our guideline named **BREXUCABTAGENE AUTOLEUCEL (Tecartus)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   a. Relapsed or refractory mantle cell lymphoma (MCL: type of white blood cell cancer that has returned or does not respond to treatment)
   b. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL: type of white blood cell cancer that has returned or does not respond to treatment)

B. You are 18 years of age or older

References:

1. Tecartus package insert. Santa Monica, CA. Kite Pharma, Inc. Revised October 2021. Accessed December 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
INFLIXIMAB Edition 1	REMICADE	01/28/2022	6/1/2021
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. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
   5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
   6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate
   4. You have previously tried at least 3 months of ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   5. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA:** You have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

C. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as, methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA:** You have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA:** You have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis

E. **If you have severe plaque psoriasis (PsO), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) **OR** psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried at least ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA:** You have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

F. **If you have moderate to severe Crohn's disease (CD), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      i. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA:** You are 6 to 17 years of age AND have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis
      ii. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLIXIMAB (JANSSEN), INFLECTRA AND AVSOLA:** You are 18 years of age or older AND have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis
      iii. **THIS CRITERIA ONLY APPLIES TO RENFLEXIS:** You are 6 years of age or older

G. **If you have moderate to severe ulcerative colitis (UC), approval also requires:**
   1. The medication is prescribed by or given in consultation with a gastroenterologist (doctor who specializes in conditions of the stomach, intestine and related organs)
   2. You have previously tried at least ONE standard therapy, unless there is a medical reason why you cannot (contraindication), such as corticosteroids (budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   3. You meet ONE of the following:
      i. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLECTRA, INFLIXIMAB (JANSSEN), AND AVSOLA:** You are 6 to 17 years of age AND have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis
      ii. **THIS CRITERIA ONLY APPLIES TO REMICADE, INFLECTRA, INFLIXIMAB (JANSSEN), AND AVSOLA:** You are 18 years of age or older AND have previously tried ONE of the following preferred agents unless there is a medical reason why you cannot (contraindication): Renflexis
      iii. **THIS CRITERIA ONLY APPLIES TO RENFLEXIS:** You are 6 years of age or older

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
    2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
    3. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
    4. Severe plaque psoriasis (PsO: dry, itchy scaly skin patches)
    5. Moderate to severe Crohn's disease (CD: type of inflammatory disease that affects lining of digestive tract)
    6. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)

B. **If you have moderate to severe rheumatoid arthritis (RA), renewal also requires:**
    1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
    2. You are currently using or have a contraindication to (a medical reason why you cannot use) methotrexate

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
    1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

D. **If you have ankylosing spondylitis (AS), renewal also requires:**
    1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy

E. **If you have severe plaque psoriasis (PsO), renewal also requires:**
    1. You have achieved or maintained clear or minimal disease OR you have experienced a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy

(Criteria continued on next page)

REQUIREMENTS: INFLIXIMAB (CONTINUED)

References:

1. Remicade package insert. Horsham, PA. Janssen Biotech, Inc. Revised October 2021. Accessed November 2021.
2. Avsola package insert. Thousand Oaks, CA. Amgen, Inc. Revised September 2021. Accessed November 2021.
3. Inflectra package insert. New York, NY. Pfizer Inc. Revised June 2021. Accessed November 2021.
4. Infliximab package insert. Horsham, PA. Janssen Biotech, Inc. Revised October 2021. Accessed December 2021.
5. Renflexis package insert. Jersey City, NJ. Organon & Co. Revised June 2021. Accessed November 2021.
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9. Terdiman JP, Gruss CB, Heidelbaugh JJ, Sultan S, Falck-Ytter YT; AGA Institute Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF-α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. Gastroenterology. 2013;145(6):1459-1463. doi:10.1053/j.gastro.2013.10.047.
10. 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.
11. 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.
12. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol. 2008;58(5):851-864. doi:10.1016/j.jaad.2008.02.040.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
PEMBROLIZUMAB Edition 5	KEYTRUDA	04/29/2022	04/29/2022

REQUIREMENTS:

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

A. You have ONE of the following:
   1. Unresectable or metastatic melanoma (type of skin cancer that has spread to other parts of the body or cannot be completely removed with surgery)
   2. Stage IIB, IIC, or III melanoma following complete resection (you have a type of skin cancer that involves the immune system after surgical removal)
   3. Non-small cell lung cancer (type of lung cancer that has spread to other parts of the body)
   4. Head and neck squamous cell carcinoma (type of neck cancer)
   5. Classical Hodgkin lymphoma (type of immune system cancer)
   6. Primary mediastinal large B-cell lymphoma (type of immune system cancer)
   7. Locally advanced or metastatic (disease has spread to other parts of the body) urothelial carcinoma (type of urinary system cancer)
   8. Unresectable or metastatic solid tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (type of cancer with genetic abnormalities that cannot be removed by surgery or has spread to other parts of the body)
   9. Unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC: type of colon or rectal cancer with genetic abnormalities that cannot be removed by surgery or has spread to other parts of the body)
   10. Locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma
   11. Locally advanced or metastatic carcinoma of the esophagus (type of throat/esophagus cancer) or gastroesophageal junction (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) that is not amenable to surgical resection or definitive chemoradiation
   12. Persistent, recurrent or metastatic cervical cancer
   13. Hepatocellular carcinoma (liver cancer)
   14. Recurrent locally advanced or metastatic Merkel cell carcinoma (type of skin cancer)
   15. Advanced renal cell carcinoma (kidney cancer)
   16. Advanced endometrial carcinoma (type of cancer that starts in the uterus)

(Criteria continued on next page)

REQUIREMENTS: PEMBROLIZUMAB (CONTINUED)

17. Bladder cancer
18. Unresectable or metastatic tumor mutational burden-high (TMB-H) solid tumors (type of cancer that cannot be removed with surgery or has spread to other parts of the body)
19. Recurrent or metastatic or locally advanced cutaneous squamous cell carcinoma (cSCC: a type of skin cancer that has returned or has spread to other parts of the body)
20. High-risk early stage or locally recurrent unresectable or metastatic Triple-Negative Breast Cancer (TNBC) (type of breast cancer that does not have three receptors and cannot be removed with surgery or has spread to other parts of the body)

B. **If you have Stage IIB, IIC, or III melanoma (skin cancer) after complete surgical removal, approval also requires:**
    1. The requested drug will be used as add-on (adjuvant) treatment
C. **If you have metastatic non-squamous non-small cell lung cancer (NSCLC), approval also requires:**
    1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for metastatic NSCLC (it is being used as first-line treatment)
    2. The medication is used in combination with pemetrexed and platinum chemotherapy
    3. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
D. **If you have metastatic squamous non-small cell lung cancer (NSCLC), approval also requires:**
    1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for metastatic NSCLC (it is being used as first-line treatment)
    2. The medication is used in combination with carboplatin and either paclitaxel or nab-paclitaxel

(Criteria continued on next page)

REQUIREMENTS: PEMBROLIZUMAB (CONTINUED)

E. **If you have non-small cell lung cancer (NSCLC), approval also requires:**
   1. You have not received prior systemic chemotherapy treatment (therapy that is given into the bloodstream) for NSCLC (it is being used as first-line treatment)
   2. The medication will be given as a single agent (not given in combination with chemotherapy)
   3. Non-small cell lung cancer tumors have programmed death-ligand 1 Tumor Proportion Score greater than or equal to 1% (you have a certain amount of a type of protein that is present in lung cancer) as determined by a Food and Drug Administration (FDA)-approved test
   4. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (types of gene mutations)
   5. You meet **ONE** of the following:
      i. You have stage III non-small cell lung cancer AND are not a candidate for surgical resection (removal) or definitive chemoradiation
      ii. You have metastatic non-small cell lung cancer (cancer that has spread to other parts of the body)

F. **If you have metastatic non-small cell lung cancer (NSCLC), approval also requires:**
   1. The medication will be given as a single agent (it is not given in combination with chemotherapy)
   2. Non-small cell lung cancer tumors have programmed death-ligand 1 Tumor Proportion Score greater than or equal to 1% (you have a certain amount of a type of protein that is present in lung cancer) as determined by a Food and Drug Administration (FDA)-approved test
   3. You experienced disease progression (disease has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
   4. You meet **ONE** of the following:
      i. You do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations (gene mutations)
      ii. You have an anaplastic lymphoma kinase (ALK) genomic tumor aberration (gene mutation) AND experienced disease progression (has gotten worse) on or after ALK-directed therapy such as Xalkori (crizotinib) or Zykadia (ceritinib)
      iii. You have an epidermal growth factor receptor (EGFR) genomic tumor aberration (gene mutation) AND experienced disease progression (has gotten worse) on or after EGFR-directed therapy such as Tarceva (erlotinib), Iressa (gefitinib) or Gilotrif (afatinib)

Criteria continued on next page)

REQUIREMENTS: PEMBROLIZUMAB (CONTINUED)

G. **If you have metastatic or unresectable, recurrent head and neck squamous cell carcinoma (HNSCC), approval also requires:**
    1. The medication is used as a first line treatment
    2. You meet **ONE** of the following:
        i. The medication will be given in combination with platinum and fluorouracil (FU)
        ii. The medication will be given as a single agent AND the tumors have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test
H. **If you have recurrent or metastatic head and neck squamous cell carcinoma (HNSCC), approval also requires:**
    1. You experienced disease progression (has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
    2. The medication will be given as a single agent
I. **If you have classical Hodgkin lymphoma (cHL), approval also requires ONE of the following:**
    1. You have refractory classical Hodgkin lymphoma (disease is resistant to treatment)
    2. You have relapsed (disease has returned) after 2 or more prior lines of therapy
J. **If you have primary mediastinal large B-cell lymphoma (PMBCL), approval also requires ONE of the following:**
    1. You have refractory primary mediastinal large B-cell lymphoma (type of immune system cancer that is resistant to treatment)
    2. You have relapsed (disease has returned) after 2 or more prior lines of therapy
K. **If you have locally advanced or metastatic urothelial carcinoma, approval also requires ONE of the following:**
    1. You are not eligible for any platinum-containing chemotherapy regardless of PDL1 (type of protein) status
    2. You experienced disease progression (has gotten worse) on or after treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
    3. You experienced disease progression (has gotten worse) within 12 months of neoadjuvant or adjuvant (add-on) treatment with platinum-containing chemotherapy such as cisplatin, carboplatin, oxaliplatin
L. **If you have bladder cancer, approval also requires:**
    1. You have Bacillus Calmette-Guerin (BCG; a type of anti-cancer treatment)-unresponsive, high-risk, non-muscle invasive bladder cancer with carcinoma in situ (a group of abnormal cells that have not spread) with or without papillary tumors
    2. You are ineligible for or have chosen not to undergo cystectomy (surgery to remove part of or all of the urinary bladder)

(Criteria continued on next page)

REQUIREMENTS: PEMBROLIZUMAB (CONTINUED)

M. **If you have unresectable or metastatic solid tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), approval also requires the following:**
    1. You have a solid tumor that has progressed (gotten worse) after using prior treatment and have no satisfactory alternative treatment options
N. **If you have recurrent locally advanced or metastatic carcinoma of the esophagus or gastroesophageal junction (GEJ), approval also requires ONE of the following:**
    1. The medication is used in combination with platinum- and fluoropyrimidine-based chemotherapy
    2. Your tumors have squamous cell histology and ALL of the following:
        i. The medication is used as a single agent
        ii. You have tumors that have PD-L1 (programmed death-ligand 1; a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test
        iii. You experienced disease progression (has gotten worse) after one or more prior lines of systemic therapy (treatment that spreads throughout the bloodstream)
O. **If you have persistent, recurrent or metastatic cervical cancer, approval also requires:**
    1. You meet **ONE** of the following:
        i. The requested medication will be used as a single agent and you have recurrent or metastatic disease, and you experienced disease progression (has gotten worse) on or after chemotherapy
        ii. The requested medication will be used in combination with chemotherapy, with or without bevacizumab, and your disease is persistent, recurrent, or metastatic
    2. You have tumors that have PD-L1 (a type of protein with a Combined Positive Score greater than or equal to 1) as determined by a Food and Drug Administration (FDA)-approved test
P. **If you have hepatocellular carcinoma, approval also requires:**
    1. You have previously been treated with sorafenib

(Criteria continued on next page)

REQUIREMENTS: PEMBROLIZUMAB (CONTINUED)

Q. **If you have advanced renal cell carcinoma (RCC), approval also requires ONE of the following:**
   1. You have not received prior systemic chemotherapy treatment (therapy that travels throughout the bloodstream) for renal cell carcinoma (it is used as first line treatment) and the requested medication will be used in combination with axitinib or lenvatinib
   2. The requested medication will be used for adjuvant treatment and you have intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesion

R. **If you have advanced endometrial carcinoma, approval also requires:**
   1. The medication is used in combination with lenvatinib (Lenvima) or as a single agent
   2. You do not have microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) biomarkers (characteristics that help determine what type of cancer you have and what treatment options there are for it)
   3. You experienced disease progression following prior systemic therapy (disease has gotten worse after previous treatment) in any setting
   4. You are not a candidate for curative surgery or radiation

S. **If you have unresectable or metastatic solid tumors, approval also requires:**
   1. Your solid tumors are tumor mutational burden-high (TMB-H: high number of changes found in the genes of the cancer cells) [at least 10 mutations/megabase], as determined by a Food Drug Administration (FDA)-approved test
   2. Your disease has worsened following prior treatment and you have no alternative treatment options

T. **If you have recurrent or metastatic or locally advanced cutaneous squamous cell carcinoma, approval also requires:**
   1. Your disease is not curable by surgery or radiation

U. **If you have Triple-negative breast cancer (TNBC), approval also requires:**
   1. The medication is used in combination with chemotherapy
   2. If you have locally recurrent unresectable or metastatic TNBC, the tumors express PD-L1 (programmed death-ligand 1; a type of protein with a Combined Positive Score greater than or equal to 10) as determined by a Food and Drug Administration (FDA)-approved test
   3. If you have high-risk early-stage TNBC, you use in combination with chemotherapy as neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery

(Criteria continued on next page)

REQUIREMENTS: PEMBROLIZUMAB (CONTINUED)

V. **If you have locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction adenocarcinoma, approval also requires**:
    1. The medication is used in combination with chemotherapy (trastuzumab and fluoropyrimidine- and platinum-containing agents)
    2. The medication is used as first-line therapy

References:

1. Keytruda package insert. Whitehouse Station, NJ, Merck & Co., Inc. Revised March 2022. Accessed March 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DUPILUMAB Edition 2	DUPIXENT	01/28/2022	01/28/2022

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

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

A. You have ONE of the following diagnoses:
    1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
    2. Moderate to severe asthma
    3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
    1. You meet at least ONE of the following for disease severity:
        a. Atopic dermatitis involving at least 10% of body surface area (BSA)
        b. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc)
    2. You have at least TWO of the following:
        a. Intractable pruritus (severe itching)
        b. Cracking and oozing/bleeding of affected skin
        c. Impaired activities of daily living
    3. The medication is prescribed by or given in consultation with a dermatologist (skin doctor) or allergist/immunologist (allergy doctor)
    4. You are 6 years of age or older
    5. You had an inadequate response or contraindication to (a medical reason why you cannot use) ONE of the following: topical corticosteroids, topical calcineurin inhibitors [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [Eucrisa (crisaborole)], or phototherapy (light therapy)

(Criteria continued on next page)

INITIAL CRITERIA CONTINUED- DUPILUMAB

C. **If you have moderate to severe asthma, approval also requires:**
   1. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) with a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months **OR** oral corticosteroid-dependent asthma
   2. You are 6 years of age or older
   3. You had prior therapy with medium, high-dose, or maximally tolerated inhaled corticosteroid [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline.
   4. You have experienced at least ONE asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
   5. Dupixent will be used as an add-on maintenance treatment
   6. You are not being concurrently treated with Xolair or an anti-IL5 asthma biologic such as Nucala, Cinqair, Fasenra
   7. The medication is prescribed by or given in consultation with a doctor specializing in pulmonary (lung/breathing) or allergy medicine

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
   1. You are 18 years of age or older
   2. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
   3. You have inadequately controlled disease as determined by **ONE** of the following:
      a. Use of systemic steroids in the past 2 years
      b. Endoscopic sinus surgery (using a small camera to help in surgery)
   4. Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
   5. The medication is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB
RENEWAL CRITERIA
REQUIREMENTS:

A. Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:
B. You have ONE of the following diagnoses:
    1. Moderate to severe atopic dermatitis (condition of red, itchy skin)
    2. Moderate to severe asthma
    3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
C. **If you have moderate to severe atopic dermatitis, renewal also requires:**
    1. You have experienced or maintained improvement in at least two of the following:
        a. Intractable pruritus (severe itching)
        b. Cracking and oozing/bleeding of affected skin
        c. Impaired activities of daily living
    2. You are 6 years of age or older
D. **If you have moderate to severe asthma, renewal also requires:**
    1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
    2. You have shown a clinical response as evidenced by ONE of the following:
        a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
        b. Decreased use of rescue medications
        c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
        d. Reduction in severity or frequency of asthma-related symptoms such as less wheezing, shortness of breath, coughing, etc.
E. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
    1. You had a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

References:

1. Dupixent package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised October 2021. Accessed December 2021.
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. 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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ABEMACICLIB Edition 2	VERZENIO	01/28/2022	01/28/2022

REQUIREMENTS:

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

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

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

(Criteria continued on next page)

CRITERIA CONTINUED- ABEMACICLIB

C. **If you have early breast cancer, approval also requires:**
   1. You are 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. Your disease is lymph node positive and at high risk of recurrence
   4. You have a Ki-67 score of 20% or greater as determined by a Food and Drug Administration (FDA)-approved test
   5. Your disease has NOT gotten worse following prior CDK (cyclin-dependent kinase) inhibitor therapy (class of drugs used for breast cancer)

References:

1. Verzenio package insert. Indianapolis, IL. Eli Lilly and Company. Revised October 2021. Accessed December 2021.
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
CORTICOTROPIN Edition 1	ACTHAR	01/28/2022	01/28/2022
CORTICOTROPIN	PURIFIED CORTROPHIN		

REQUIREMENTS:

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

A. You have infantile spasms (type of seizure disorder in young children)
B. You are less than 2 years of age

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

Other approved indications include:

1. Acute exacerbation (sudden worsening of symptoms) of multiple sclerosis
2. Rheumatic disorders (disease affecting joints in the body)
    a. Psoriatic arthritis (joint pain and swelling with red scaly skin patches)
    b. Rheumatoid arthritis (including juvenile rheumatoid arthritis)
    c. Ankylosing spondylitis (inflammation and stiffness affecting spine and large joints)
3. Collagen disease (diseases associated with defects in collagen)
    a. Systemic lupus erythematosus (condition where immune system attacks healthy tissue)
    b. Systemic dermatomyositis (polymyositis; inflammatory disease with muscle weakness and skin rash)
4. Dermatologic disease (diseases relating to the skin)
    a. Severe erythema multiforme (disorder affecting skin, mucous membranes, genitals and eyes)
    b. Stevens-Johnson syndrome (rare, serious skin disorder)
5. Allergic disease
    a. Serum sickness (immune system reaction to non-human proteins)
6. Ophthalmic disease (diseases involving the eye)
    a. Severe acute and chronic allergic and inflammatory processes involving the eye and its parts (such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, or anterior segment inflammation)
7. Respiratory disease (disease involving the lungs)
    a. Symptomatic sarcoidosis (abnormal collections of inflammatory cells in the lungs, skin or lymph nodes)

(Criteria continued on next page)

REQUIREMENTS: CORTICOTROPIN (CONTINUED)

8. Edematous state (accumulation of excessive amount of fluid)
    a. To induce a diuresis (increase urine production) or a remission (reduction) of proteinuria (protein in urine) in the nephrotic syndrome (kidney disorder that causes the body to pass too much protein in the urine) without uremia of the idiopathic type (high levels of waste products in the blood with no known cause), or that due to lupus erythematosus

References:

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

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
APREMILAST Edition 2	OTEZLA	01/28/2021	01/28/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for approval:

A. You have **ONE** of the following diagnoses:
   1. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   2. Mild to moderate plaque psoriasis (PsO: dry, itchy skin patches with scales)
   3. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   4. Behcet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

C. **If you have mild to moderate plaque psoriasis, approval requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving 2% to 15% of your body surface area (BSA)
   4. You have previously tried at least ONE or more forms of standard topical therapies, unless there is a medical reason why you cannot (contraindication), such as topical corticosteroids, topical calcipotriene, or topical tazarotene.
   5. You have not received prior therapy with a biologic (e.g., Humira, Skyrizi, Taltz, etc.)

D. **If you have moderate to severe plaque psoriasis, approval requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of your body surface area (BSA) or psoriatic lesions (rashes) affecting your face, hands, feet, or genital area
   4. You have previously tried at least **ONE** or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication), such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine

(Criteria continued on next page)

REQUIREMENTS: APREMILAST (CONTINUED)

E. **For the diagnosis of oral ulcers associated with Behcet's disease, approval requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (joint pain and inflammation doctor)
   3. You have previously tried **ONE** or more conservative treatments such as colchicine, topical corticosteroid, oral corticosteroid, unless there is a medical reason why you cannot (contraindication)

RENEWAL CRITERIA

The guideline named **APREMILAST (Otezla)** requires the following rule(s) be met for renewal:

A. You have psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches), mild to moderate plaque psoriasis (PsO: dry, itchy skin patches with scales), or moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales), or Behcet's disease (disorder causing blood vessel inflammation throughout your body) with oral ulcers or history of recurrent oral ulcers based on clinical symptoms

B. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have mild to moderate plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

D. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   2. You have achieved clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

E. **If you have Behcet's Disease with oral ulcers or history of recurrent oral ulcers based on clinical symptoms, renewal also requires:**
   1. You have achieved or maintained clinical benefit compared to baseline such as an improvement in pain scores, number of ulcers, etc.

References:

1. Otezla package insert. Thousand Oaks, CA. Amgen Inc. Revised December 2021. Accessed December 2021.
2. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on biologics. *Journal of American Academy of Dermatology*. 2008;58(5):851-864. doi: 10.1016/j.jaad.2008.02.040.
3. Menter A, Gottlieb A, Feldman S, Van Voorhees AS, Leonardi CL, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *Journal of American Academy of Dermatology*. 2008;58(5):826-850. doi:10.1016/j.jaad.2008.02.039.
4. Criteria for diagnosis of Behçet's disease. International Study Group for Behçet's Disease. Lancet. 1990;335(8697):1078-80.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
SECUKINUMAB Edition 3	COSENTYX	01/28/2022	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **SECUKINUMAB (Cosentyx)** requires a diagnosis of moderate to severe plaque psoriasis, **OR** Psoriatic arthritis, **OR** Juvenile psoriatic arthritis, **OR** Ankylosing spondylitis, **OR** Non-radiographic axial spondyloarthritis, **OR** Enthesitis-related arthritis. In addition, the following criteria must also be met:

A. **If you have moderate to severe plaque psoriasis (PsO), approval also requires:**
   1. You are 6 years of age and older
   2. The requested medication is prescribed by or given in consultation with a dermatologist (skin doctor)
   3. You have psoriatic lesions (rashes) involving greater than or equal to 10% of body surface area (BSA) OR psoriatic lesions (rashes) affecting the hands, feet, genital area, or face
   4. You have previously tried ONE or more forms of standard therapies, unless there is a medical reason why you cannot (contraindication): PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   5. **MUST** try and fail **FOUR** preferred agents from at least **three** of the following subgroupings prior to the use of any non-preferred agent as clinically appropriate:
      i. Tumor Necrosis Factor Inhibitor (TNFi): Enbrel, Humira, Cimzia, or an infliximab product (e.g., Remicade, biosimilars)
      ii. Interleukin (IL)-23 blocker: Skyrizi, Tremfya
      iii. IL-12/23 blocker: Stelara SC
      iv. IL-17 blocker: Taltz
      v. Phosphodiesterase type 4 (PDE4) blocker: Otezla

(Criteria continued next page)

REQUIREMENTS: SECUKINUMAB (CONTINUED)

B. **If you have psoriatic arthritis (PsA), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. **MUST** try and fail **THREE** preferred agents from at least **two** of the following subgroups prior to the use of any non-preferred agent as clinically appropriate:
      i. TNFi: Enbrel, Humira, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Simponi SC, or Simponi Aria
      ii. IL-23 blocker: Tremfya
      iii. IL-12/23 blocker: Stelara SC
      iv. IL-17 blocker: Taltz
      v. Janus Kinase (JAK) inhibitor: Xeljanz/Xeljanz XR
         1. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product
      vi. PDE4 blocker: Otezla

C. **If you have psoriatic arthritis (JPsA), approval also requires:**
   1. You are 2 years of age to 17 years of age
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints) or dermatologist (skin doctor)
   3. You have previously tried ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

D. **If you have ankylosing spondylitis (AS), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (a doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. **MUST** try and fail **TWO** preferred agents prior to the use of any non-preferred agent as clinically appropriate: Enbrel, Humira, Taltz

(Criteria continued next page)

REQUIREMENTS: SECUKINUMAB (CONTINUED)

E. **If you have non-radiographic axial spondyloarthritis (nr-axSpA), approval also requires:**
   1. You are 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
   4. You have ONE of the following signs of inflammation:
      i. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      ii. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
   5. **MUST** try and fail **TWO** preferred agents prior to the use of any non-preferred agent as clinically appropriate: Taltz and Cimzia

F. **If you have enthesitis-related arthritis (ERA)**, **approval also requires:**
   1. You are 4 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   3. You have previously tried ONE DMARD (disease-modifying anti-rheumatic drugs), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

RENEWAL CRITERIA

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

A. You have ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO: dry, itchy skin patches with scales)
   2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
   3. Juvenile psoriatic arthritis (JPsA: joint pain and swelling with red scaly skin patches)
   4. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
   5. Non-radiographic axial spondyloarthritis (nr-axSpA: type of inflammation in the spine that does not show any visible damage on X-rays)
   6. Enthesitis-related arthritis (ERA: inflammation and stiffness affecting areas where tendons, ligaments, or joints attach to bone)

(Criteria continued next page)

REQUIREMENTS: SECUKINUMAB (CONTINUED)

B. **If you have moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. You have achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index: used to measure the severity and extent of psoriasis) of at least 50% or more while on therapy.

C. **If you have psoriatic arthritis (PsA), renewal also requires:**
   1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

D. **If you have juvenile psoriatic arthritis (JPsA), renewal also requires:**
   1. You have experienced or maintained improvement in flare events, tender joint count, or swollen joint count while on therapy

E. **If you have ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nraxSpA), renewal also requires:**
   1. You have experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI: diagnostic test which allows a physician to determine the effectiveness of a current medication) while on therapy.

F. **If you have enthesitis-related arthritis (ERA), renewal also requires:**
   1. You have experienced or maintained improvement in flare events, tender joint count, or swollen joint count while on therapy

References:

1. Cosentyx package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2021. Accessed December 2021.
2. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on biologics. *Journal of American Academy of Dermatology*. 2008;58(5):851-864. doi: 10.1016/j.jaad.2008.02.040
3. Menter A, Gottlieb A, Feldman S, Van Voorhees AS, Leonardi CL, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *Journal of American Academy of Dermatology*. 2008;58(5):826-850. doi:10.1016/j.jaad.2008.02.039.
4. 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.
5. Hahn YS. Enthesitis-related Arthritis. J Rheum Dis 2018;25:221-230. doi: 10.4078/jrd.2018.25.4.221.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ABATACEPT – SQ Edition 3	ORENCIA - SQ, ORENCIA CLICKJECT – SQ	01/28/2022	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **ABATACEPT - SQ (Orencia - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis (PJIA), psoriatic arthritis (PsA), or used for prophylaxis of acute graft versus host disease (aGVHD). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, Rinvoq, or Xeljanz/XR.

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older
D. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, Xeljanz/XR, or Actemra SC.

For patients with psoriatic arthritis (PsA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Stelara SC, Otezla, Tremfya, Taltz, or Xeljanz/XR.

(Criteria continued on next page)

REQUIREMENTS: ABATACEPT-SQ (CONTINUED)

For patients using for prophylaxis of acute graft versus host disease (aGVHD), approval requires:

A. The patient is 2 years of age or older
B. Therapy is prescribed by or given in consultation with a hematologist or oncologist
C. The requested medication will be used in combination with a calcineurin inhibitor (i.e., cyclosporine, tacrolimus, or pimecrolimus) and methotrexate
D. The patient will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **ABATACEPT - SQ (Orencia - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criteria must be met:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

References:

1. Orencia package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised December 2021. Accessed December 2021.
2. 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 C. *Arthritis Care & Research*. 2013;65(10):1551-1563. doi:10.1002/acr.22087.
3. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care & Research*. 2011;63(4):465-482. doi:10.1002/acr.20460.
4. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis & Rheumatology*. 2015;68(1):1-26. doi:10.1002/acr.22783.
5. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on biologics. *Journal of American Academy of Dermatology*. 2008;58(5):851-864. doi: 10.1016/j.jaad.2008.02.040.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ABATACEPT/MALTOSE Edition 3	ORENCIA – IV	01/28/2022	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **ABATACEPT - IV (Orencia - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, psoriatic arthritis, or used for prophylaxis of acute graft versus host disease (aGVHD). In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
A. The patient is 18 years of age or older
B. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, Renflexis, Rinvoq, or Xeljanz/XR

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older
D. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Enbrel, Humira, Xeljanz/XR, or Actemra SC

For patients with psoriatic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. The patient has had a previous trial of any **TWO** of the following formulary preferred immunomodulators: Enbrel, Humira, Stelara, Otezla, Tremfya, Taltz, or Xeljanz/XR

(Criteria continued on next page)

REQUIREMENTS: ABATACEPT-IV (CONTINUED)

For patients using for prophylaxis of acute graft versus host disease (aGVHD), approval requires:

E. The patient is 2 years of age or older
F. Therapy is prescribed by or given in consultation with a hematologist or oncologist
G. The requested medication will be used in combination with a calcineurin inhibitor (i.e., cyclosporine, tacrolimus, or pimecrolimus) and methotrexate
H. The patient will be undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **ABATACEPT - IV (ORENCIA - IV)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, or moderate to severe polyarticular juvenile idiopathic arthritis for renewal. In addition, the following criterion must be met:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

References:

1. Orencia package insert. Princeton, NJ. Bristol-Myers Squibb Company. Revised December 2021. Accessed December 2021.
2. 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 C. *Arthritis Care & Research*. 2013;65(10):1551-1563. doi:10.1002/acr.22087.
3. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care & Research*. 2011;63(4):465-482. doi:10.1002/acr.20460.
4. Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis & Rheumatology*. 2015;68(1):1-26. doi:10.1002/acr.22783.
5. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on biologics. *Journal of American Academy of Dermatology*. 2008;58(5):851-864. doi: 10.1016/j.jaad.2008.02.040

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
RITUXIMAB Edition 2	RITUXAN	01/28/2022	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. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints) (excludes Rituxan Hycela and Riabni)
   2. Non-Hodgkin's Lymphoma (NHL: type of blood cancer)
   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: type of blood and bone marrow cancer)
   8. Wegener's Granulomatosis (WG: a condition that causes inflammation of the blood vessels)
   9. Microscopic Polyangiitis (MPA: blood vessel inflammation, which can damage organ systems) (excludes Rituxan Hycela)
   10. Moderate to severe Pemphigus Vulgaris (PV: immune disease with blisters that break out on the skin and on the lining of the mouth) (excludes Rituxan Hycela and Riabni)

(Criteria continued on next page)

REQUIREMENTS: RITUXIMAB (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. Your request is for Rituxan, Riabni, Truxima, or Ruxience
   3. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
   4. You are currently using methotrexate, unless there is a medical reason why you cannot (contraindication)
   5. You have previously tried at least ONE DMARD (disease modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   6. You have previously tried any **TWO** of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (Immediate Release/Extended Release)

C. **If you have Non-Hodgkin's Lymphoma (NHL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)

D. **If you have Chronic Lymphocytic Leukemia (CLL), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
   3. You are currently using chemotherapy at the same time with the requested medication

E. **If you have Wegener's Granulomatosis (WG) or Microscopic Polyangiitis (MPA), approval also requires:**
   1. You are 2 years of age or older
   2. Your request is for Rituxan, Riabni, Truxima, or Ruxience
   3. You are currently on glucocorticoids (steroids such as methylprednisolone or prednisone) along with the requested medication

F. **If you have moderate to severe Pemphigus Vulgaris (PV), approval also requires:**
   1. You are 18 years of age or older
   2. Your request is for Rituxan, Riabni, Truxima, or Ruxience

(Criteria continued on next page)

REQUIREMENTS: RITUXIMAB (CONTINUED)

G. **If you have 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. You are 6 months of age or older
    2. Your request is for Rituxan
    3. The medication is prescribed by or given in consultation with an oncologist (cancer/tumor doctor)
    4. Your disease is previously untreated and advanced stage
    5. You are currently using chemotherapy at the same time with the requested medication

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

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

A. You have moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count from baseline while on therapy for renewal

References:

1. Rituxan package insert. South San Francisco, CA. Genentech, Inc. Revised December 2021. Accessed December 2021.
2. Riabni package insert. Thousand Oaks, CA. Amgen, Inc. Revised December 2020. Accessed November 2021.
3. Truxima package insert. North Wales, PA. Teva Pharmaceuticals USA, Inc. Revised May 2020. Accessed November 2021.
4. Ruxience package insert. New York, NY. Pfizer Inc. Revised November 2021. Accessed November 2021.
5. Rituxan Hycela package insert. South San Francisco, CA. Genentech, Inc. Revised June 2021. Accessed November 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TOFACITINIB CITRATE Edition 4	XELJANZ, XELJANZ XR	04/29/2022	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe ulcerative colitis or ankylosing spondylitis. In addition, the following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist
C. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
D. You have previously tried any ONE of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira

For patients with psoriatic arthritis (PsA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. You have previously tried any ONE of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira

For patients with moderate to severe ulcerative colitis (UC), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a gastroenterologist
C. 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
D. The patient meets at least ONE of the following:
    i. Patient had at least a 3-month trial with inadequate response to Humira
    ii. Patient has tried Humira but were unable to tolerate a 3-month trial

    Note: If the patient already has a previous trial with an infliximab product (i.e., Remicade, biosimilars) or Simponi subcutaneous, then this can be accepted in place of Humira)

(Criteria continued next page)

REQUIREMENTS- TOFACITINIB (CONTINUED)

For patients with polyarticular course juvenile idiopathic arthritis (pcJIA), approval requires:

A. You are 2 years of age or older
B. Therapy is prescribed by or given in consultation with rheumatologist (doctor who specializes in conditions that affect the muscles and skeletal system, especially the joints)
C. You have previously tried at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, unless there is a medical reason why you cannot (contraindication)
D. You have previously tried any ONE of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira

If you have ankylosing spondylitis (AS), approval also requires:

A. You are 18 years of age or older
B. The medication is prescribed by or given in consultation with a rheumatologist (doctor who specializes in conditions that affects the muscles and skeletal system, especially the joints)
C. You have previously tried an NSAID (non-steroidal anti-inflammatory drug), unless there is a medical reason why you cannot (contraindication)
D. You have previously tried any ONE of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira

RENEWAL CRITERIA

The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) to be met for renewal:

A. You have ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA: inflammation and stiffness in joints)
    2. Psoriatic arthritis (PsA: joint pain and swelling with red scaly skin patches)
    3. Moderate to severe ulcerative colitis (UC: type of inflammatory disease that affects lining of digestive tract)
    4. Polyarticular juvenile idiopathic arthritis (pcJIA: inflammation of more than 5 joints)
    5. Ankylosing spondylitis (AS: inflammation and stiffness affecting spine and large joints)
B. **If you have moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), renewal also requires:**
    1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

(Criteria continued next page)

REQUIREMENTS- TOFACITINIB (CONTINUED)

References

1. Xeljanz package insert. New York, New York. Pfizer. Revised December 2021. Accessed April 2022.
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. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on biologics. *Journal of American Academy of Dermatology*. 2008;58(5):851-864. doi: 10.1016/j.jaad.2008.02.040.
4. Sandborn WJ, Su C, Sands BE, et al. Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2017;376(18):1723-1736.
5. Ulcerative Colitis Clinical Pathway. American Gastroenterological Association. Available at: http://campaigns.gastro.org/algorithms/UlcerativeColitis/ Accessed 6/2018.
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, 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 C. *Arthritis Care & Research*. 2013;65(10):1551-1563. doi:10.1002/acr.22087.
8. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care & Research*. 2011;63(4):465-482. doi:10.1002/acr.20460.
9. Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2016;68(2):282-98.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
UPADACITINIB Edition 4	RINVOQ	04/29/2022	04/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **UPADACITINIB** (Rinvoq) requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe atopic dermatitis, or ulcerative colitis. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis (RA), approval requires:

A. The patient is 18 years of age or older
B. Therapy is prescribed by or given in consultation with a rheumatologist
C. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
D. You have previously tried any ONE of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira
    1. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

For patients with psoriatic arthritis (PsA), approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist or dermatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 18 years of age or older
D. You have previously tried any ONE of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira
    1. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

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REQUIREMENTS: UPADACITINIB (CONTINUED)

For patients with moderate to severe atopic dermatitis (AD), approval also requires:

A. You meet at least ONE of the following for disease severity:
1. Atopic dermatitis involving at least 10% of body surface area (BSA)
2. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc)

B. You have at least TWO of the following:
1. Intractable pruritus (severe itching)
2. Cracking and oozing/bleeding of affected skin
3. Impaired activities of daily living

C. The medication is prescribed by or given in consultation with a dermatologist or allergist/immunologist

D. You are 12 years of age or older

E. You had an inadequate response or contraindication to (a medical reason why you cannot use) ONE of the following: topical corticosteroids, topical calcineurin inhibitors [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [Eucrisa (crisaborole)], or phototherapy (light therapy)

F. You meet at least ONE of the following:
1. You 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)
2. You have tried at least ONE traditional systemic therapy but were 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)

For patients with moderately to severely active ulcerative colitis, approval requires ALL of the following:

A. You are 18 years of age or older

B. Therapy is prescribed by or given in consultation with a gastroenterologist

C. You 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

D. You meet at least ONE of the following:
   i. You had at least a 3-month trial with inadequate response to Humira
   ii. You have tried Humira but were unable to tolerate a 3-month trial

Note: If the patient already has a previous trial with an infliximab product (i.e., Remicade, biosimilars) or Simponi subcutaneous, then this can be accepted in place of Humira)

(Criteria continued next page)

REQUIREMENTS: UPADACITINIB (CONTINUED)

RENEWAL CRITERIA

The guideline named **UPADACITINIB (Rinvoq)** requires for renewal:

A. You have 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

B. **If you have moderate to severe rheumatoid arthritis (RA) or psoriatic arthritis (PsA), renewal also requires:**
   1. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **If you have moderate to severe atopic dermatitis, renewal also requires:**
   1. You have experienced or maintained improvement in at least two of the following:
      a. Intractable pruritus (severe itching)
      b. Cracking and oozing/bleeding of affected skin
      c. Impaired activities of daily living

References

1. Rinvoq package insert. North Chicago, IL. AbbVie Inc. Revised March 2022. Accessed March 2022.
2. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 2. Psoriatic Arthritis: Overview and guidelines of care for treatment with an emphasis on biologics. *Journal of American Academy of Dermatology*. 2008;58(5):851-864. doi: 10.1016/j.jaad.2008.02.040.
3. 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.
4. 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.
5. 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.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
TOCILIZUMAB - SQ Edition 2	ACTEMRA – SQ	01/28/2022	01/28/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), giant cell arteritis (GCA), polyarticular juvenile idiopathic arthritis (PJIA), or systemic juvenile idiopathic arthritis (SJIA) for approval. In addition, the following criteria must also be met:

For patients with moderate to severe rheumatoid arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient is 18 years of age or older
C. The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
D. The patient had a previous trial of the following preferred immunomodulator: Humira

For patients with giant cell arteritis, approval requires:

A. The patient is 18 years of age or older

For patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD), approval requires:

A. The patient is 18 years of age or older

For patients with polyarticular juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older
D. The patient had a previous trial of the following preferred immunomodulator: Humira

(Criteria continued next page)

REQUIREMENTS: TOCILIZUMAB-SQ (CONTINUED)

For patients with systemic juvenile idiopathic arthritis, approval requires:

A. Therapy is prescribed by or given in consultation with a rheumatologist
B. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
C. The patient is 2 years of age or older

The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

RENEWAL CRITERIA

The guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires a diagnosis of moderate to severe rheumatoid arthritis (RA), giant cell arteritis (GCA), systemic sclerosis-associated interstitial lung disease (SSc-ILD), systemic juvenile idiopathic arthritis (SJIA), or polyarticular juvenile idiopathic arthritis (PJIA) for renewal. In addition, the following criteria must be met:

For patients with moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis, approval requires:

A. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

References:

1. Actemra package insert. South San Francisco, CA. Genentech, Inc. Revised March 2021. Accessed December 2021.
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, 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 C. *Arthritis Care & Research*. 2013;65(10):1551-1563. doi:10.1002/acr.22087.
4. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: Initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. *Arthritis Care & Research*. 2011;63(4):465-482. doi:10.1002/acr.20460.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
DARATUMUMAB HYALURONIDASE-FIHJ Edition 3	DARZALEX FASPRO	01/28/2022	01/28/2022

REQUIREMENTS:

Our guideline named **DARATUMUMAB-HYALURONIDASE-FIHJ (Darzalex Faspro)** requires the following rule(s) be met for approval:

B. You have multiple myeloma (plasma cell cancer) OR Light Chain (AL) Amyloidosis (abnormal accumulation of amyloid protein in your body)
C. You are 18 years of age or older
D. You meet ONE of the following criteria:
    1. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive daratumumab in combination with bortezomib, melphalan and prednisone
    2. You have newly diagnosed multiple myeloma, are not eligible for autologous stem cell transplant (cells from your own body), AND will receive daratumumab in combination with lenalidomide and dexamethasone
    3. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment), received at least one prior therapy AND will receive daratumumab in combination with lenalidomide and dexamethasone
    4. You have newly diagnosed multiple myeloma, are eligible for autologous stem cell transplant AND will receive daratumumab in combination with bortezomib, thalidomide, and dexamethasone.
    5. You have received at least one prior therapy AND will receive daratumumab in combination with bortezomib and dexamethasone
    6. You have received at least three prior lines of therapy, including a proteasome inhibitor (class of drug for multiple myeloma) AND an immunomodulatory agent (drug that changes the immune response or the functioning of the immune system) AND you will receive daratumumab as monotherapy (will not be used in combination with another drug)
    7. You are refractory (resistant) to both a proteasome inhibitor and an immunomodulatory agent AND will receive daratumumab as monotherapy (will not be used in combination with another drug)

(Criteria continued on next page)

REQUIREMENTS: DARATUMUMAB-HYALURONIDASE-FIHJ (CONTINUED)

8. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment) AND you received at least one prior therapy including lenalidomide and a proteasome inhibitor AND you will receive daratumumab in combination with pomalidomide and dexamethasone
9. You have relapsed or refractory multiple myeloma and have received one to three lines of prior therapy AND will receive daratumumab in combination with carfilzomib and dexamethasone
10. You have newly diagnosed light chain (AL) amyloidosis AND will receive daratumumab in combination with bortezomib, cyclophosphamide, and dexamethasone AND you do not have NYHA Class IIIB or Class IV cardiac disease AND your diagnosis does not include Mayo Stage IIIB disease.

Note: Proteasome inhibitors include: bortezomib, carfilzomib, or ixazomib; immunomodulatory agents include: lenalidomide, pomalidomide, or thalidomide.

References:

1. Darzalex Faspro package insert. Horsham, PA. Janssen Biotech, Inc. Revised November2021. Accessed December 2021.

WELLFLEET RX STUDENT FORMULARY

CARFILZOMIB			
Generic	Brand	Reviewed	Effective Date
CARFILZOMIB Edition 2	KYPROLIS	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You have relapsed or refractory multiple myeloma (plasma cell cancer that has returned or is not completely responsive to treatment)
B. You are 18 years of age or older
C. You meet **ONE** of the following criteria:
    1. You have previously received one to three lines of therapy AND will use Kyprolis in combination with ONE of the following regimens:
        i. lenalidomide and dexamethasone; OR
        ii. dexamethasone; OR
        iii. daratumumab and dexamethasone
        iv. daratumumab and hyaluronidase-fihj and dexamethasone
    2. You have previously received one or more lines of multiple myeloma therapy and will be using Kyprolis alone

References:

1. Kyprolis package insert. Thousand Oaks, CA. Onyx Pharmaceuticals, Inc. Revised November 2021. Accessed December 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BELZUTIFAN Edition 1	WELIREG	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You are 18 years of age or older
B. The medication is prescribed by or in consultation with an oncologist or hematologist
C. You have a diagnosis of von Hippel-Lindau (VHL) disease
D. You require therapy for at least ONE of the following associated diagnoses not requiring immediate surgery:
    1. Renal cell carcinoma (RCC)
    2. Central nervous system (CNS) hemangioblastomas
    3. Pancreatic neuroendocrine tumors (pNET)

References:

1. Welireg package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised August 2021. Accessed December 2021.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
AVACOPAN Edition 1	TAVNEOS	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You are 18 years of age or older
B. Prescribed by or in consultation with a rheumatologist
C. You have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (i.e., granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA])
D. You have tested positive for either anti-PR3 or anti-MPO antibodies
E. Your 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. You are 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. You have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (i.e., granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA])
B. Submitted documentation shows you have experienced or maintained improvement in disease activity from baseline 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.]
C. You are 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 October 2021. Accessed December 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ROPEGINTERFERON ALFA-2B-NJFT Edition 1	BESREMI	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You are 18 years of age or older
B. Prescribed by or in consultation with an oncologist/hematologist
C. You have a diagnosis of polycythemia vera
D. You have tried or have a documented medical contraindication (a medical reason why you cannot) to hydroxyurea.

References:

1. Besremi package insert. Burlington, MA. PharmaEssentia Corporation. Revised November 2021. Accessed December 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MARALIXIBAT Edition 1	LIVMARLI	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You are 1 year of age or older
B. Prescribed by or in consultation with a hepatologist
C. You have a diagnosis of Alagille syndrome (ALGS)
E. You have a deletion or mutation of the JAG1 gene or NOTCH2 gene as detected by an FDA (Food and Drug Administration)-approved test
D. You have severe cholestatic pruritus (itching due to reduction or stoppage of bile flow) symptoms.
E. Your 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:

D. You have a diagnosis of Alagille syndrome (ALGS) and severe cholestatic pruritus symptoms.
E. Submitted documentation shows you have 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. Livmarli package insert. Foster City, CA. Mirum Pharmaceuticals, Inc. Revised September 2021. Accessed December 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ASCIMINIB Edition 1	SCEMBLIX	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You are 18 years of age or older
B. Prescribed by or in consultation with an oncologist or hematologist
C. You have a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML)
D. Your disease is in chronic phase (CP)
E. You meet ONE of the following criteria:
    1. You have been previously treated with two or more tyrosine kinase inhibitors (TKIs)
    2. You 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 October 2021. Accessed December 2021.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
VOSORITIDE Edition 1	VOXZOGO	01/28/2022	01/28/2022

REQUIREMENTS:

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

A. You are 5 years of age or older
B. Prescribed by or in consultation with a pediatric endocrinologist
C. You have a diagnosis of achondroplasia confirmed by genetic testing (detected mutation in the FGFR3 gene)
D. Your 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:

D. You have a diagnosis of achondroplasia confirmed by genetic testing (detected mutation in the FGFR3 gene)
E. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)
F. You have shown a response to therapy as indicated by improvement in annualized growth velocity

References:

1. Voxzogo package insert. Novato, CA. BioMarin Pharmaceutical Inc. Revised November 2021. Accessed December 2021.
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
ODEVIXIBAT Edition 1	BYLVAY	04/29/2022	04/29/2022

REQUIREMENTS:

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

A. You are 3 months of age or older
B. Prescribed by or in consultation with a hepatologist
C. You have a diagnosis of progressive familial intrahepatic cholestasis (PFIC) Type 1 or 2
D. You have severe cholestatic pruritus (itching due to reduction or stoppage of bile flow) symptoms.
E. Your 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 **ODEVIXIBAT (Bylvay)** requires the following rule(s) be met for renewal:

A. You have a diagnosis of progressive familial intrahepatic cholestasis (PFIC) and severe cholestatic pruritus symptoms.
B. Submitted documentation shows you have 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 July 2021. Accessed February 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
MITAPIVAT Edition 1	PYRUKYND	04/29/2022	04/29/2022

REQUIREMENTS:

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

A. You are 18 years of age or older
B. Prescribed by or in consultation with a hematologist
C. You have a diagnosis of pyruvate kinase (PK) deficiency
D. You have documented presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant, confirmed by biochemical testing
E. You do 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. You have symptoms of chronic hemolysis (i.e., anemia, iron overload, jaundice, etc.)
G. You have 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. You have a diagnosis of pyruvate kinase (PK) deficiency confirmed by biochemical testing
B. You have 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 2022.
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
PACRITINIB Edition 1	VONJO	04/29/2022	04/29/2022

REQUIREMENTS:

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

A. You are 18 years of age or older
B. Prescribed by or in consultation with an oncologist or hematologist
C. You have a diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
D. You have 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. You have a diagnosis of intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis
D. You have experienced or maintained symptom improvement as evidenced by **ONE** of the following:
    1. You have a spleen volume reduction of 35% or greater from baseline after 6 months of therapy
    2. You have a 50% or greater reduction in total symptom score on the modified Myelofibrosis Symptom Assessment Form (MFSAF) v2.0
    3. You have a 50% or greater reduction in palpable (can be felt by external examination) spleen length

References:

1. Vonjo package insert. Seattle, WA. CTI Biopharma Corp. Revised February 2022. Accessed March 2022.
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.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
GANAXOLONE Edition 1	ZTALMY	04/29/2022	04/29/2022

REQUIREMENTS:

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

E. You are 2 years of age or older
F. Prescribed by or in consultation with a neurologist or epileptologist
G. You have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD), as confirmed by genetic test (detection of pathogenic or likely pathogenic variant in the CDKL5 gene)
H. Your seizures are inadequately controlled by at least 2 previous treatment regimens (i.e., clobazam, felbamate, lamotrigine, levetiracetam, topiramate, valproic acid, vigabatrin, zonisamide, etc.)
I. You have experienced a minimum of 16 major motor seizures (i.e., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal to bilateral tonic-clonic) per 28 days over at least a 2-month period

RENEWAL CRITERIA

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

B. You have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD), as confirmed by genetic test
E. You have experienced or maintained symptom improvement as evidenced by a reduction in the 28-day frequency of major motor seizures compared to baseline

References:

1. Ztalmy package insert. Radnor, PA. Marinus Pharmaceuticals, Inc. Revised March 2022. Accessed March 2022.
2. Olson HE, Demarest ST, Pestana-Knight EM, et al. Cyclin-Dependent Kinase-Like 5 Deficiency Disorder: Clinical Review. Pediatr Neurol. 2019;97:18-25. doi:10.1016/j.pediatrneurol.2019.02.015.

WELLFLEET RX STUDENT FORMULARY

INFERTILITY Edition 1			
Generic	Brand	Reviewed	Effective Date
CETRORELIX ACETATE	CETROTIDE	04/29/2022	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. You are using the requested drug for ONE of the following:
    1. You are undergoing ovulation induction and you or your partner have a diagnosis of infertility
    2. You are undergoing assisted reproductive technology (ART) and you or your partner have a diagnosis of infertility
    3. You are undergoing treatment of hypogonadotropic hypogonadism and have a diagnosis of infertility
    4. You are undergoing fertility preservation

B. Submitted documentation indicates you have 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. **Your request is for human chorionic gonadotropin (hCG) (e.g., Novarel, Pregnyl, Ovidrel, etc) and ONE of the following:**
    1. You are undergoing ovulation induction
    2. You are undergoing assisted reproductive technology (ART)

(Criteria continued on next page)

REQUIREMENTS: INFERTILITY (CONTINUED)

D. **If your 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. You do not have primary testicular failure (testicles are unable to produce sperm)
   2. You have low pretreatment testosterone levels
   3. You have low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

E. **If your request is for Menopur for follicle stimulation while undergoing ovulation induction or ART, approval also requires ONE of the following:**
   1. You have completed three or more previous cycles of clomiphene or letrozole
   2. You have a risk factor for poor ovarian response to clomiphene or letrozole
   3. You have a contraindication or exclusion to clomiphene and letrozole
   4. You are 37 years of age or older

F. **If your request is for Menopur for stimulation of sperm production, approval also requires ALL of the following:**
   1. You do not have primary testicular failure (testicles are unable to produce sperm)
   2. You have low pretreatment testosterone levels
   3. You have low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels

G. **If your request is for Follistim AQ for follicle stimulation while undergoing ovulation induction or ART, approval also requires ONE of the following:**
   1. You have completed three or more previous cycles of clomiphene or letrozole
   2. You have a risk factor for poor ovarian response to clomiphene or letrozole
   3. You have a contraindication or exclusion to clomiphene and letrozole
   4. You are 37 years of age or older
   5. You have a previous trial and failure with Gonal-f or Gonal-f RFF

H. **If your request is for Follistim AQ for stimulation of sperm production, approval also requires ALL of the following:**
   1. You do not have primary testicular failure (testicles are unable to produce sperm)
   2. You have low pretreatment testosterone levels
   3. You have low or low-normal follicle stimulating hormone (FSH) or luteinizing hormone (LH) levels
   4. You have a previous trial and failure with Gonal-f or Gonal-f RFF

(Criteria continued on next page)

REQUIREMENTS: INFERTILITY (CONTINUED)

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

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