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: 9/14/2022

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ABALOPARATIDE Edition 2	TYMLOS	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of postmenopausal osteoporosis
B. The patient has not received a total of 24 months or more of parathyroid hormone therapy with Tymlos or Forteo
C. The patient meets **ONE** of the following criteria:
    1. The patient is at high risk for fractures as defined by **ONE** of the following:
        i. History of fragility or osteoporotic fracture(s)
        ii. Bone mineral density (BMD) T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip and/or 33% (one third) radius (wrist)
        iii. T-score between -1.0 and -2.5 AND FRAX score greater than or equal to 20% for any major fracture or greater than or equal to 3% for hip fracture
    2. The patient is unable to use oral therapy (e.g., upper gastrointestinal [GI]problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications in their daily routine)
    3. The patient has had a previous trial and failure of ONE oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication

References:

1. Tymlos package insert. Boston, MA. Radius Health Inc. Revised December 2021. Accessed June 2022.
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.

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:

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 - 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.

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.

(Criteria continued on next page)

REQUIREMENTS: ABATACEPT-SQ (CONTINUED)

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.

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

(Criteria continued on next page)

REQUIREMENTS: ABATACEPT-SQ (CONTINUED)

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.

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

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
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)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ACA ZERO COST SHARE OVERRIDE (CONTINUED)

E. Your doctor has provided documentation supporting ONE of the following:
   1. Two preferred medications are medically inappropriate for you (or one if only one agent is available)
   2. You have tried or have a documented medical contraindication (medical reason why you cannot take a medication) to two preferred medications (or one if only one agent is available)
   3. The requested medication is considered medically necessary for you (considerations may include severity of side effects and ability to adhere to appropriate use)

Appendix A: ACA Preventative Medications Zero Cost Share

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

Generic	Brand	Reviewed	Effective Date
ACALABRUTINIB Edition 1	CALQUENCE	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of ONE of the following:
    1. Mantle cell lymphoma (MCL
    2. Chronic lymphocytic leukemia (CLL)
    3. Small lymphocytic lymphoma (SLL)
C. **If the patient has mantle cell lymphoma (MCL), approval also requires:**
    1. Patient has received at least one prior therapy for mantle cell lymphoma

References:

1. Calquence package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised March 2022. Accessed June 2022.

ACETAMINOPHEN DAILY LIMIT OVERRIDE			
Generic	Brand	Reviewed	Effective Date
Acetaminophen Edition 1	N/A	7/29/2022	6/1/2021

REQUIREMENTS:

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

Approval requires the following rule be met:

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

References:

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

ACNE AGE RESTRICTION OVERRIDE Edition 2			
Generic	Brand	Reviewed	Effective Date
ADAPALENE	DIFFERIN	7/29/2022	7/29/2022
ADAPALENE/BENZOYL PEROXIDE	EPIDUO, EPIDUO FORTE		
TRETINOIN	ATRALIN, AVITA, RETIN-A, TRETIN-X, ALTRENO		
TRETINOIN MICROSPHERES	RETIN-A MICRO, RETIN-A MICRO PUMP		
TRIFAROTENE	AKLIEF		
TAZAROTENE	FABIOR, ARAZLO		

REQUIREMENTS:

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

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

(Criteria continued on next page)

REQUIREMENTS: ACNE AGE RESTRICTION OVERRIDE (CONTINUED)

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

References:

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

Generic	Brand	Reviewed	Effective Date
ADALIMUMAB Edition 3	HUMIRA	9/14/2022	9/14/2022

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 meets at least ONE of the following:
    1. 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
    2. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
    3. The patient has a history of ileocolonic resection
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.

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.

Generic	Brand	Reviewed	Effective Date
AFATINIB DIMALEATE Edition 2	GILOTRIF	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Metastatic, squamous non-small cell lung cancer (NSCLC)
    2. Metastatic non-small cell lung cancer (NSCLC)

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

C. **If patient has metastatic non-small cell lung cancer, approval also requires:**
    1. The patient's tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as shown by an FDA (Food and Drug Administration)-approved test
    2. The requested medication will be used as first-line treatment

References:

1. Gilotrif package insert. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. Revised April 2022. Accessed June 2022.

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.

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

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
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.

Generic	Brand	Reviewed	Effective Date
ALECTINIB Edition 1	ALECENSA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. The patient is positive for anaplastic lymphoma kinase (ALK) fusion oncogene as detected by an FDA (Food and Drug Administration)-approved test

References:

1. Alecensa package insert. South San Francisco, CA. Genentech USA, Inc. Revised September 2021. Accessed June 2022.

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.

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.

Generic	Brand	Reviewed	Effective Date
ALIROCUMAB Edition 3	PRALUENT	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has ONE of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
    3. Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
C. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
D. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70mg/dL
E. **If the patient is statin tolerant, approval also requires:**
    1. Patient will continue statin treatment in combination with Praluent
    2. Patient meets ONE of the following:
        i. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
        ii. Patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: ALIROCUMAB (CONTINUED)

F. **If patient is statin intolerant, approval also requires ONE of the following:**
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group
G. The patient previously had a trial of Repatha (evolocumab)

RENEWAL CRITERIA

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

A. The patient has ONE of the following diagnoses:
    1. Established cardiovascular disease
    2. Heterozygous familial hypercholesterolemia (HeFH)
    3. Homozygous familial hypercholesterolemia (HoFH)
B. The patient meets ONE of the following:
    1. Patient has continued to take a high intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) along with the requested medication
    2. Patient has continued therapy with a maximally tolerated dose of any statin along with the requested medication
    3. Patient has an absolute contraindication to statin therapy
    4. Patient has complete statin intolerance

References:

1. Praulent package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised April 2021. Accessed May 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 online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

Generic	Brand	Reviewed	Effective Date
ALPELISIB Edition 1	PIQRAY	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of advanced or metastatic breast cancer
B. The patient's breast cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative
C. The patient is either a postmenopausal female or a male
D. The requested medication will be used in combination with Faslodex (fulvestrant)
E. Patient has the presence of PIK3CA-mutation as detected by a Food and Drug Administration approved test
F. The patient has experienced disease progression on or after an endocrine-based regimen

References:

1. Piqray package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised May 2022. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
ALPELISIB Edition 1	VIJOICE	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient is 2 years of age or older
B. Patient has a diagnosis of PIK3CA-related overgrowth spectrum (PROS)
C. Patient has documented evidence of mutation in the PIK3CA gene
D. Prescribed by or in consultation with a PROS specialist (i.e., plastic surgeon, dermatologist, medical geneticist, oncologist, otolaryngologist, etc.)

RENEWAL CRITERIA

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

A. Patient has a diagnosis of PIK3CA-related overgrowth spectrum (PROS)
B. Patient has experienced ONE of the following:
    a. Reduction in size or volume of lesion(s) compared to baseline
    b. No appearance of new lesion(s) compared to baseline

References:

1. Vijoice package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised April 2022. Accessed May 2022.
2. Keppler-Noreuil KM, Rios JJ, Parker VE, et al. PIK3CA-related overgrowth spectrum (PROS): diagnostic and testing eligibility criteria, differential diagnosis, and evaluation. Am J Med Genet A. 2015;167A(2):287-295. doi:10.1002/ajmg.a.36836.

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.

Generic	Brand	Reviewed	Effective Date
AMIKACIN LIPOSOMAL/NEB. ACCESSR Edition 1	ARIKAYCE	07/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA, SEE BELOW)
Our guideline named **AMIKACIN LIPOSOMAL INHALATION (Arikayce)** requires the following rule(s) be met for approval:

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

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

A. The patient has *Mycobacterium avium complex* (MAC) lung disease
B. The patient has not had a positive *Mycobacterium avium complex* sputum culture after repeated negative cultures
C. The patient has experienced an improvement in symptoms
D. The patient meets ONE of the following:
    1. For first renewal requests, approval also requires documentation of at least ONE negative sputum culture for *Mycobacterium avium complex* by 6 months of Arikayce treatment
    2. For second or later renewal requests, approval also requires documentation of at least THREE negative sputum cultures for *Mycobacterium avium complex* by 12 months of Arikayce treatment

References:

1. Arikayce package insert. Bridgewater, NJ. Insmed Incorporated. Revised March 2020. Accessed May 2022.
2. Daley CL, Iaccarino JM, Lange C, et al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. Clin Infect Dis. 2020;71(4):905-913. doi:10.1093/cid/ciaa1125.

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.

ANABOLIC STEROIDS Edition 1			
Generic	Brand	Reviewed	Effective Date
OXYMETHOLONE	ANADROL-50	07/29/2022	6/1/2021
OXANDROLONE	OXANDRIN		

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

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

ANADROL-50

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

A. The patient has anemia or cachexia associated with AIDS
B. The patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes
C. The patient does not have ANY of the following reasons why they cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia
    3. Known or suspected nephrosis
    4. Known or suspected hypercalcemia
    5. Severe hepatic dysfunction
D. **If the patient has anemia, approval also requires:**
    1. The anemia is caused by one of the following conditions: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias, or Fanconi anemia

(Criteria continued on next page)

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)

E. **If the patient has cachexia associated with AIDS, approval also requires:**
    1. Patient is on anti-retroviral therapy
    2. Patient has a documented viral load of less than 200 copies per mL dated within the past 3 months
    3. Therapy is prescribed by or given in recommendation with a gastroenterologist, nutritional support specialist (SBS), or infectious disease specialist
    4. Patient meets ONE of the following:
        a. Patient has 10% unintentional weight loss over 12 months
        b. Patient has 7.5% unintentional weight loss over 6 months
        c. Patient has 5% body cell mass (BCM) loss within 6 months
        d. Patient has a BCM of less than 35% (men) and a body mass index (BMI) of less than 27kg per meter squared
        e. Patient has a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
        f. Patient has a BMI of less than 18.5 kg per meter squared

OXANDRIN

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

A. Patient has ONE of the following diagnoses:
    1. Weight loss
    2. Protein catabolism caused by long-term use of corticosteroids
    3. Bone pain accompanying osteoporosis
    4. Cachexia associated with AIDS
    5. Turner's Syndrome
B. Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes
C. Patient does not have ANY of the following reasons why they cannot use anabolic steroid therapy:
    1. Known or suspected prostate or breast cancer in male patients
    2. Known or suspected breast cancer in females with hypercalcemia
    3. Known or suspected nephrosis
    4. Known or suspected hypercalcemia
    5. Severe hepatic dysfunction

(Criteria continued on next page)

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)

D. **If patient has weight loss, approval also requires:**
    1. Patient's weight loss is caused by extensive surgery, chronic infections, or severe trauma
    2. Medication is being used as add-on therapy to help weight gain
E. **If patient has cachexia associated with AIDS, approval also requires:**
    1. Patient is on anti-retroviral therapy
    2. Patient has a documented viral load of less than 200 copies per mL dated within the past 3 months
    3. Therapy is prescribed by or given in consultation with a gastroenterologist, nutritional support specialist (SBS) or infectious disease specialist
    4. Patient meets ONE of the following:
        a. Patient has 10% unintentional weight loss over 12 months
        b. Patient has 7.5% unintentional weight loss over 6 months
        c. Patient has 5% body cell mass (BCM) loss within 6 months
        d. Patient has a BCM of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared
        e. Patient has a BCM of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squared
        f. Patient has a BMI of less than 18.5 kg per meter squared

RENEWAL CRITERIA

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

OXANDRIN and ANADROL-50

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

A. Patient has cachexia associated with AIDS
B. Patient is on anti-retroviral therapy
C. Patient's viral load is less than 200 copies per mL within the past 3 months
D. Patient has a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
E. Patient has not received more than 24 weeks of therapy in a calendar year

(Criteria continued on next page)

REQUIREMENTS: ANABOLIC STEROIDS (CONTINUED)

References:

1. Anadrol package insert. Marietta, GA. Unimed Pharmaceuticals, Inc. Revised August 2004. Accessed May 2022.
2. Oxandrin Package insert. New York, NY. Pfizer co. Revised June 2005. Accessed May 2022.
3. Wanke C, Kotler D; HIV Wasting Collaborative Consensus Committee. Collaborative recommendations: the approach to diagnosis and treatment of HIV wasting. J Acquir Immune Defic Syndr. 2004;37 Suppl 5:S284-S288. doi:10.1097/01.qai.0000144384.55091.0f.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
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.

ANTI-OBESITY AGENTS Edition 3			
Generic	Brand	Reviewed	Effective Date
NALTREXONE HCL/ BUPROPION HCL	CONTRAVE	7/29/2022	07/29/2022
PHENTERMINE/ TOPIRAMATE	QSYMIA		
ORLISTAT	XENICAL		
LIRAGLUTIDE	SAXENDA		
SEMAGLUTIDE	WEGOVY		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The request is for weight loss OR weight loss management
B. Documentation the patient has active enrollment in an exercise and caloric reduction program or a weight loss/behavioral modification program
C. **For Contrave requests, approval also requires:**
    1. The patient is 18 years of age or older
    2. The patient meets **ONE** of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)
D. **For Qsymia requests, approval also requires:**
    1. If the patient is aged 12 years to 17 years, approval also requires:
        a. The patient currently has a BMI of 95th percentile or greater for age and sex
    2. If the patient is 18 years of age or older, approval also requires the patient meets **ONE** of the following:
        a. Body mass index (BMI) of 30 kg/m^2 or greater
        b. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ANTI-OBESITY AGENTS (CONTINUED)

E. **For Xenical requests, approval also requires:**
   1. If the patient is aged 12 years to 17 years, approval also requires:
      a. The patient currently has a BMI of 95th percentile or greater for age and sex
   2. If the patient is 18 years of age or older, approval also requires the patient meets **ONE** of the following:
      a. Body mass index (BMI) of 30 kg/m^2 or greater
      b. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

F. **For Saxenda requests, approval also requires:**
   1. The patient is NOT currently taking a GLP-1 receptor agonist (e.g., Wegovy, Victoza, Byetta, Bydureon, Trulicity, Ozempic, etc.)
   2. If the patient is aged 12 years to 17 years, approval also requires:
      a. The patient has a body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs (International Obesity Task Force [IOTF] BMI Cut-Offs)
   3. If the patient is 18 years of age or older, approval also requires the patient meets **ONE** of the following:
      a. Body mass index (BMI) of 30 kg/m^2 or greater
      b. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

G. **For Wegovy requests, approval also requires:**
   1. The patient is NOT currently taking a GLP-1 receptor agonist (e.g., Saxenda, Victoza, Byetta, Bydureon, Trulicity, Ozempic, etc.)
   2. The patient is 18 years of age or older
   3. The patient meets **ONE** of the following:
      i. Body mass index (BMI) of 30 kg/m^2 or greater
      ii. BMI of 27 kg/m^2 or greater **AND** at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, hyperlipidemia, coronary heart disease, sleep apnea, etc.)

(Criteria continued on next page)

REQUIREMENTS: ANTI-OBESITY AGENTS (CONTINUED)

RENEWAL CRITERIA

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

A. The request is for weight loss OR weight loss management
B. **If the patient is requesting Xenical, renewal also requires:**
    1. The patient has lost at least 5% of baseline body weight after 3 months of treatment
C. **If the patient is requesting Contrave, renewal also requires:**
    1. The patient has lost at least 5% of baseline body weight after 3 months of treatment at the maintenance dose (two 8/90mg tablets twice daily)
D. **If the patient is requesting Qsymia 7.5/46mg, renewal also requires:**
    1. The patient has 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 the patient is requesting Qsymia 15/92mg, renewal also requires:**
    1. The patient has lost at least 5% of baseline body weight after 3 months of treatment at the requested maintenance dose
F. **If the patient is requesting Saxenda, renewal also requires:**
    1. The patient has lost at least 4% of baseline body weight after 4 months of treatment
G. **If the patient is requesting Wegovy, renewal also requires:**
    1. The patient has lost at least 5% of baseline body weight after 4 months of treatment

References:

1. Contrave package insert. Brentwood, TN. Currax Pharmaceuticals LLC. Revised November 2021. Accessed June 2022.
2. Qysmia package insert. Campbell, CA. Vivus, Inc. Reviewed June 2022. Accessed June 2022.
3. Xenical package insert. Montgomery, AL. H2-Pharma, LLC. Reviewed August 2017. Reviewed June 2022.
4. Saxenda package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised June 2022. Accessed June 2022.
5. Wegovy package insert. Plainsboro, NJ. Novo Nordisk Inc. Revised June 2021. Accessed June 2022
6. Styne DM, Arslanian SA, Connor EL, et al. Pediatric Obesity-Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(3):709-757. doi:10.1210/jc.2016-2573.
7. 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.
8. Cole TJ, Lobstein T. Extended international (IOTF) body mass index cut-offs for thinness, overweight and obesity. Pediatr Obes. 2012;7(4):284-294. doi:10.1111/j.2047-6310.2012.00064.x.

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.

(Criteria continued on next page)

REQUIREMENTS: ANTIMIGRAINE AGENTS (CONTINUED)

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.

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.

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

REQUIREMENTS:

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

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

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

A. The patient has a diagnosis of advanced Parkinson's disease
B. The patient has had improvement with motor fluctuations during 'OFF' episodes (such as improvement in speech, facial expression, tremor at rest, action or postural tremor of hands, rigidity, finger taps, hand movements, rapid alternating movements of hands, posture, leg agility, arising from chair)

References:

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

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.)

(Criteria continued on next page)

REQUIREMENTS: APREMILAST (CONTINUED)

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

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.

(Criteria continued on next page)

REQUIREMENTS: APREMILAST (CONTINUED)

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.

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.

Generic	Brand	Reviewed	Effective Date
ASFOTASE ALFA Edition 1	STRENSIQ	7/29/2022	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a documented diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) or juvenile-onset hypophosphatasia (HPP).
B. The patient was 18 years of age or younger at hypophosphatasia onset
C. Requested medication is prescribed by or given in consultation with an endocrinologist, geneticist, metabolic disorder specialist or physician who specializes in treatment of hypophosphatasia.
D. Presence of ONE of the following laboratory markers:
    1. The patient is positive for a tissue non-specific alkaline phosphatase (TNSALP) mutation in the *ALPL* gene as confirmed by genetic testing
    2. Patient meets at least **TWO** of the following criteria:
        a. Serum alkaline phosphatase level below that of normal range for patient's age
        b. Serum pyridoxal-5'-phosphate (PLP) levels elevated AND patient has not received vitamin B6 supplementation in the previous week
        c. Urine phosphoethanolamine (PEA) level above that of normal range for patient's age
E. Presence of **one or more** of the following clinical manifestations of HPP:
    1. Rachitic chest deformity
    2. Craniosynostosis
    3. Delay in skeletal growth resulting in delay of motor development
    4. Dental abnormalities such as premature loss of primary teeth
    5. Failure to thrive or growth failure/short stature
    6. Respiratory insufficiency
    7. Compromised exercise capacity
    8. History of vitamin B6 dependent seizures
    9. Nephrocalcinosis or history of elevated serum calcium
    10. History or presence of fracture after birth not due to injury or delayed fracture healing

(Criteria continued on next page)

REQUIREMENTS: ASFOTASE ALFA (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has experienced response to therapy as evidenced by improvement and/or stabilization in the any of the following:
    1. Skeletal manifestations according to radiographic findings
    2. Motor function
    3. Respiratory status
    4. Height velocity

References:

1. Strensiq package insert. Boston,MA. Alexion Pharmaceuticals, Inc. Revised June 2020. Accessed June 2022.
2. Millán JL, Plotkin H. Hypophosphatasia - pathophysiology and treatment. Actual osteol. 2012;8(3):164-182.

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.

Generic	Brand	Reviewed	Effective Date
AVAPRITINIB Edition 3	AYVAKIT	7/29/2022	7/29/2022

REQUIREMENTS:

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

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

References:

1. Ayvakit package insert. Cambridge, MA. Blueprint Medicines Corporation. Revised June 2021. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
AVATROMBOPAG Edition 1	DOPTELET	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has ONE of the following diagnoses:
    1. Thrombocytopenia due to chronic liver disease (CLD)
    2. Chronic immune thrombocytopenia (ITP)
C. The patient is not receiving other thrombocytopenia treatments such as Nplate (romiplostim), Mulpleta (lusutrombopag), Promacta (eltrombopag) or Tavalisse (fostamatinib)
D. **If patient has thrombocytopenia due to chronic liver disease, approval also requires:**
    1. The patient is scheduled to undergo a procedure 10 to 13 days after starting Doptelet (avatrombopag) therapy
    2. The patient has a platelet count of less than 50 x 10^9/L (50,000/µL) measured within the last 30 days
    3. The requested medication is prescribed by or given in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
E. **If patient has chronic immune thrombocytopenia (ITP), approval also requires:**
    1. The patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days **OR** patient has an active bleed
    2. The patient has previously tried or has a contraindication to corticosteroids or immunoglobulins **OR** patient had an insufficient response to splenectomy
    3. The requested medication is prescribed by or given in consultation with a hematologist or immunologist

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

A. The patient has a diagnosis of chronic immune thrombocytopenia (ITP)
B. The patient had a clinical response to therapy, as defined by an increase in platelet count or a reduction in bleeding events, compared to baseline

NOTE: For the diagnosis of thrombocytopenia due to chronic liver disease (CLD), please refer to the Initial Criteria section. Re-authorization is not permitted. Patients must meet the initial approval criteria for this diagnosis.

(Criteria continued on next page)

REQUIREMENTS: AVATROMBOPAG (CONTINUED)

References:

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

Generic	Brand	Reviewed	Effective Date
AXITINIB Edition 1	INLYTA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of advanced renal cell carcinoma (RCC)
B. The patient also meets ONE of the following:
    1. The patient has tried at least ONE systemic therapy for the treatment of advanced renal cell carcinoma such as Nexavar (sorafenib), Torisel (temsirolimus), Sutent (sunitinib), Votrient (pazopanib), Avastin (bevacizumab) in combination with interferon, etc.
    2. The requested medication will be used in combination with avelumab (Bavencio) as a first-line treatment
    3. The requested medication will be used in combination with pembrolizumab (Keytruda) as a first-line treatment

References:

1. Inlyta package insert. New York, NY. Pfizer inc. Reviewed June 2020. Accessed June 2022.

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.

AZTREONAM INHALED			
Generic	Brand	Reviewed	Effective Date
AZTREONAM Edition 2	CAYSTON	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of cystic fibrosis

B. The patient has a lung infection per culture of the airway demonstrating a gram-negative species, *Pseudomonas aeruginosa*

References:

1. Cayston package insert. Foster City, Ca. Gilead Sciences, Inc. Revised November 2019. Accessed June 2022.
2. Borowitz D, Robinson KA, Rosenfeld M, et al. Cystic Fibrosis Foundation evidence-based guidelines for management of infants with cystic fibrosis. J Pediatr. 2009 Dec; 155(6 Suppl):S73-S93.
3. Mogayzel PJ, Naureckas ET, Robinson KA, Brady C, Guill M, Lahiri T, Lubsch L, Matsui J, Oermann CM, Ratjen F, Rosenfeld M, Simon RH, Hazle L, Sabadosa K, Marshall BC, and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. Ann Am Thorac Soc. 2014 11 (10): 1640-50.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
BARICITINIB Edition 2	OLUMIANT	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Severe alopecia areata
B. The patient is 18 years of age or older
C. **For patients with moderate to severe rheumatoid arthritis, approval also requires:**
    1. The requested medication is prescribed by or given in consultation with a rheumatologist
    2. The patient has had a previous trial of **TWO** of the formulary preferred immunomodulators: Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz
D. **For patients with severe alopecia areata, approval also requires:**
    1. The requested medication is prescribed by or given in consultation with a dermatologist
    2. The patient has had least 50% scalp hair loss as measured by the Severity of Alopecia Tool (SALT) for more than 6 months
    3. The patient has had a previous trial of or contraindication to treatment with at least ONE conventional first-line therapy (e.g., intralesional corticosteroids, topical corticosteroids, systemic corticosteroids, topical immunotherapy, etc.)

NOTE: Olumiant is FDA-approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. This indication does not include outpatient use and will not be approvable under this policy.

(Criteria continued next page)

REQUIREMENTS: BARICITINIB (CONTINUED)

RENEWAL CRITERIA

The guideline named **BARICITINIB (Olumiant)** requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe rheumatoid arthritis (RA)
    2. Severe alopecia areata
B. **If the patient has moderate to severe rheumatoid arthritis, 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 the patient has a diagnosis of severe alopecia areata, renewal also requires ONE of the following:**
    1. The patient has achieved at least 80% scalp hair coverage or Severity of Alopecia Tool (SALT) score of 20 or less
    2. The patient has achieved a Scalp Hair Assessment PRO™ score of 0 or 1

References:

1. Olumiant package insert. Indianapolis, IN. Lilly USA, LLC. Revised June 2022. Accessed June 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. Messenger AG, McKillop J, Farrant P, McDonagh AJ, Sladden M. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Br J Dermatol. 2012;166(5):916-926. doi:10.1111/j.1365-2133.2012.10955.x.
4. Fukuyama M, Ito T, Ohyama M. Alopecia areata: Current understanding of the pathophysiology and update on therapeutic approaches, featuring the Japanese Dermatological Association guidelines. J Dermatol. 2022;49(1):19-36. doi:10.1111/1346-8138.16207.

Generic	Brand	Reviewed	Effective Date
BEDAQUILINE FUMARATE Edition 2	SIRTURO	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. The patient is 5 years of age or older
B. Patient has ONE of the following diagnoses:
    1. Pulmonary multi-drug resistant tuberculosis (MDR-TB)
    2. Pulmonary extensively drug resistant tuberculosis (XDR-TB)
C. The patient weighs at least 15kg
D. The requested medication is prescribed by or in consultation with an infectious disease specialist or a pulmonologist.
E. The requested medication will be used in combination with other anti-tuberculosis agents (e.g., levofloxacin, moxifloxacin, clofazimine, cycloserine, terizidone, pretomanid, linezolid, etc.).

References:

1. Sirturo package insert.Titusville, NJ. Janssen Products, LP. Revised September 2021. Accessed June 2022.
2. World Health Organization – Global Tuberculosis Report. 2021. Available at: https://apps.who.int/iris/rest/bitstreams/1379788/retrieve. Accessed on June 2, 2022.
3. World Health Organization – Consolidated guidelines on drug-resistant tuberculosis treatment. 2019. Available at: https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf Accessed on June 2, 2022.

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.

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.

Generic	Brand	Reviewed	Effective Date
BEMPEDOIC ACID Edition 2	NEXLETOL	7/29/2022	7/29/2022
BEMPEDOIC ACID AND EZETIMIBE	NEXLIZET		

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **BEMPEDOIC ACID (Nexletol, Nexlizet)** requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. Patient has **ONE** of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
C. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
D. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL
E. **If the patient is statin tolerant, approval also requires:**
    1. Patient will continue statin treatment in combination with Nexletol or Nexlizet
    2. Patient meets **ONE** of the following:
        i. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
        ii. Patient has been taking a maximally tolerated dose of any statin given that the patient cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: BEMPEDOIC ACID (CONTINUED)

F. **If the patient is statin intolerant, approval also requires ONE of the following:**
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **BEMPEDOIC ACID (Nexletol, Nexlizet)** requires the following rule(s) be met for renewal:

A. The patient has **ONE** of the following diagnoses:
    1. Established cardiovascular disease
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
B. Patient is responding positively to therapy as evidenced by lab results within the past 3 months showing an LDL-C reduction since initiation of therapy
C. The patient meets **ONE** of the following:
    1. The patient has continued therapy with a maximally tolerated dose of any statin
    2. The patient has an absolute contraindication to statin therapy
    3. The patient has complete statin intolerance

References:

1. Nexletol package insert. Ann Arbor, MI. Esperion Therapeutics, Inc. Revised February 2020. Accessed May 2022.
2. Nexlizet package insert. Ann Arbor, MI. Esperion Therapeutics, Inc. Revised February 2020. Accessed May 2022.
3. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in J Am Coll Cardiol. 2019 Sep 10;74(10):1429-1430] [published correction appears in J Am Coll Cardiol. 2020 Feb 25;75(7):840]. J Am Coll Cardiol. 2019;74(10):e177-e232. doi:10.1016/j.jacc.2019.03.010.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. doi:10.1161/CIR.0000000000000625.
5. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association [published correction appears in Stroke. 2021 Jul;52(7):e483-e484]. Stroke. 2021;52(7):e364-e467. doi:10.1161/STR.0000000000000375.

Generic	Brand	Reviewed	Effective Date
BENRALIZUMAB Edition 2	FASENRA	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of severe asthma with an eosinophilic phenotype
B. The patient is 12 years of age or older
C. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
D. The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
E. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
F. The patient has asthma that is uncontrolled while maintained on ICS plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE or more of the following:
    1. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
    2. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
G. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler
H. The patient is not being treated on the requested medication concurrently with Xolair, Dupixent, Tezspire or another anti-IL5 asthma biologic (e.g., Nucala, Cinqair, etc.)

(Criteria continued on next page)

REQUIREMENTS: BENRALIZUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of severe asthma with an eosinophilic phenotype
B. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) or an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
C. The patient has shown a clinical response as evidenced by at least ONE of the following:
    1. Reduction in asthma exacerbation(s) compared to baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted FEV1from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

References:

1. Fasenra package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP, Revised February 2021. Accessed June 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.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.

Generic	Brand	Reviewed	Effective Date
BEROTRALSTAT HYDROCHLORIDE Edition 1	ORLADEYO	07/29/2022	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. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 12 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, danazol, etc.)

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

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

References:

1. Orladeyo package insert. Durham, N.C. BioCryst Pharmaceuticals, Inc. Revised March 2022. Accessed July 2022.
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.

BEXAROTENE Edition 1			
Generic	Brand	Reviewed	Effective Date
BEXAROTENE SOFTGEL	TARGRETIN	7/29/2022	6/1/2021
BEXAROTENE 1% TOPICAL GEL	TARGRETIN		

REQUIREMENTS:

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

A. The patient has a diagnosis of cutaneous T-cell lymphoma (CTCL)
B. **If the request is for oral bexarotene, approval also requires:**
    1. The patient's condition is refractory to at least ONE previous systemic therapy such as gemcitabine, methotrexate, liposomal doxorubicin, bortezomib, etc.
C. **If the request is for topical bexarotene treatment, approval also requires:**
    1. The patient has cutaneous T-cell lymphoma (CTCL) Stage IA or IB
    2. The patient meets ONE of the following:
        a. The patient's condition is refractory or persistent after previous therapy
        b. The patient has not tolerated previous therapy

References:

1. Targretin topical package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised October 2016. Accessed June 2022.
2. Targretin oral package insert. Bridgewater, NJ. Valeant Pharmaceuticals North America LLC. Revised April 2020. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
BINIMETINIB Edition 1	MEKTOVI	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of unresectable or metastatic melanoma
B. The patient has a BRAF V600E or V600K mutation 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 June 2022.

Generic	Brand	Reviewed	Effective Date
BOSUTINIB Edition 2	BOSULIF	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)
    2. Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML)
B. The patient is 18 years of age or older

References:

1. Bosulif package insert. New York, NY. Pfizer inc. Revised May 2021. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
BREMELANOTIDE Edition 2	VYLEESI	7/29/2022	7/29/2022

REQUIREMENTS:

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

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)
C. The patient meets **ALL** of the following:
    1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
    2. HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
    3. HSDD symptom causes marked distress or interpersonal difficulty
D. The patient is a premenopausal female
E. The patient has had a previous trial of bupropion, unless there is a contraindication
F. Patient is **NOT** currently using Addyi (flibanserin)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)
B. Patient is a premenopausal female
C. Patient is **NOT** currently using Addyi (flibanserin)
D. The patient has demonstrated continued improvement in symptoms of HSDD (e.g., increased sexual desire, lessened sexual distress, etc.)

References:

1. Vyleesi package insert. Cranbury, NJ. Palatin Technologies Inc. Revised October 2020. Accessed June 2022.
2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Female Sexual Dysfunction: ACOG Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists, Number 213. Obstet Gynecol. 2019;134(1):e1-e18. doi:10.1097/AOG.0000000000003324.

Generic	Brand	Reviewed	Effective Date
BRIGATINIB Edition 1	ALUNBRIG	7/29/2022	6/1/2021

REQUIREMENTS:

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

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

References:

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

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.

Generic	Brand	Reviewed	Effective Date
BROLUCIZUMAB-DBLL Edition 2	BEOVU	07/29/2022	07/29/2022

REQUIREMENTS:

Our guideline named **BROLUCIZUMAB-DBLL (Beovu)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Neovascular (wet) age-related macular degeneration (AMD)
    2. Diabetic macular edema (DME)
B. The requested medication is prescribed by or given in consultation with an ophthalmologist or retina specialist

References:

1. Beovu package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised May 2022. Accessed June 2022.
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.

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.

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.

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.

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.

C1 ESTERASE INHIBITOR Edition 1			
Generic	Brand	Reviewed	Effective Date
C1 ESTERASE INHIBITOR	BERINERT, CINRYZE HAEGARDA	07/29/2022	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. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 6 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE (e.g., Takhzyro, Haegarda, danazol, berotralstat, etc.)

HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 6 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE e.g., Takhzyro, Cinryze, danazol, berotralstat, etc.)

(Criteria continued on next page)

REQUIREMENTS: C1 ESTERASE INHIBITOR (CONTINUED)

BERINERT

Our guideline named **C1 ESTERASE INHIBITOR (Berinert)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by complement testing
C. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
D. The requested medication is being used for acute attacks of hereditary angioedema

RUCONEST

Our guideline named **C1 ESTERASE INHIBITOR (Ruconest)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by complement testing
C. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
D. The requested medication is being used for acute attacks of hereditary angioedema

RENEWAL CRITERIA

NOTE: For requests of Berinert or Ruconest, please refer to the initial criteria section.

CINRYZE

Our guideline named **C1 ESTERASE INHIBITOR (Cinryze)** requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

HAEGARDA

Our guideline named **C1 ESTERASE INHIBITOR (Haegarda)** requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

(Criteria continued on next page)

REQUIREMENTS: C1 ESTERASE INHIBITOR (CONTINUED)

References:

1. Berinert package insert. Kankakee, IL. CSL Behring LLC. Revised September 2021. Accessed July 2022.
2. Cinryze package insert. Lexington, MA. ViroPharma Biologics LLC. Revised January 2021. Accessed July 2022.
3. Haegarda package insert. Kankakee, IL. CSL Behring LLC. Revised January 2022. Accessed July 2022.
4. Ruconest package insert. Warren, NJ. Pharming Healthcare Inc. Revised April 2020. Accessed July 2022.
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.

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.

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)

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.

(Criteria continued on next page)

REQUIREMENTS: CANAKINUMAB (CONTINUED)

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.

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.

Generic	Brand	Reviewed	Effective Date
CAPLACIZUMAB-YHDP Edition 2	CABLIVI	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP)
C. The requested medication is prescribed by or given in consultation with a hematologist
D. Requested medication is used in combination withplasma exchange and immunosuppressive therapy (e.g., rituximab, corticosteroids, cyclosporine, mycophenolate mofetil, etc.)

RENEWAL CRITERIA

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

A. Patient has a diagnosis of acquired thrombotic thrombocytopenia purpura (aTTP)
B. Patient is responding positively to therapy as evidenced by, but not limited to, ANY of the following:
    1. platelet count increase
    2. neurological symptom reduction
    3. organ-damage marker improvement
C. Patient has received no more than 58 days of Cablivi therapy after completion of plasma exchange therapy
D. Patient has experienced less than 3 recurrences of aTTP while on the requested medication.

References:

1. Cablivi package insert. Cambridge, MA. Genzyme Corporation Revised February 2022. Accessed June 2022.
2. Joly BS, Coppo P, Veyradier A. Thrombotic thrombocytopenic purpura. Blood. 2017;129(21):2836-2846. doi:10.1182/blood-2016-10-709857.

Generic	Brand	Reviewed	Effective Date
CAPMATINIB Edition 1	TABRECTA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Patient is 18 years of age or older
C. Patient has tumors with a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test

References:

1. Tabrecta package insert. East Hanover, NJ, Novartis Pharmaceuticals Corporation. Revised January 2022. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
CENEGERMIN-BKBJ Edition 2	OXERVATE	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient is 2 years of age or older
B. Patient has a diagnosis of neurotrophic keratitis
C. Therapy is prescribed by or given in consultation with an ophthalmologist
D. Patient has loss of corneal sensitivity, corneal epithelium changes, and/or loss of tear production
E. Patient is refractory to at least ONE conservative treatment that includes artificial tears, ocular lubricants, topical antibiotics, therapeutic contact lenses

References:

1. Oxervate package insert. Boston, MA. Dompé U.S. Inc. Revised October 2019. Accessed July 2022.
2. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. Clin Ophthalmol. 2014;8:571-579. Published 2014 Mar 19. doi:10.2147/OPTH.S45921.

Generic	Brand	Reviewed	Effective Date
CERITINIB Edition 1	ZYKADIA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Patient has a tumor that is anaplastic lymphoma kinase (ALK) positive as confirmed by a Food and Drug Administration-approved test

References:

1. Zykadia package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised October 2021. Accessed June 2022.

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
CERTOLIZUMAB PEGOL Edition 3	CIMZIA	9/14/2022	9/14/2022

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 meets at least ONE of the following:
    a. The patient has had a previous trial of one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
    b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
    c. The patient has a history of ileocolonic resection
C. The patient is 18 years of age or older
D. 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.

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.

(Criteria continued on next page)

REQUIREMENTS: CERTOLIZUMAB PEGOL (CONTINUED)

6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.
7. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
8. Ward MM, Deodhar A, Gensler LS, Dubreuil M, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.

Generic	Brand	Reviewed	Effective Date
CHENODIOL Edition 2	CHENODAL	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. Patient is 18 years of age or older
B. Patient has one of the following diagnoses:
    1. radiolucent gallstones in a well-opacifying gallbladder
    2. cerebrotendinous xanthomatosis
C. **For patients with radiolucent gallstones, approval also requires:**
    1. Patient is not a candidate for surgery
    2. Patient has tried ursodiol, unless there is a contraindication
    3. Patient has not received previous chenodiol therapy for more than a total of 24 months

RENEWAL CRITERIA

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

A. Patient has a diagnosis of radiolucent gallstones (OR cerebrotendinous xanthomatosis)
B. **For the patients with radiolucent gallstones, renewal also requires:**
    1. Patient has **NOT** had chenodiol therapy for more than a total of 24 months
    2. Patient does **NOT** have complete dissolution or no gallstone seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
    3. Patient has partial gallstone dissolution seen on imaging (such as oral cholecystograms or ultrasonograms) after 12 months of therapy
C. **For the patients with cerebrotendinous xanthomatosis, renewal also requires the patient has experienced an improvement** in **ONE** of the following:
    1. Normalization of elevated serum or urine bile alcohols
    2. Normalization of elevated serum cholestanol levels
    3. Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

References:

1. Chenodal package insert. Fort Collins, CO. Manchester Pharmaceuticals, Inc. Revised September 2009. Accessed July 2022.
2. Salen G, Steiner RD. Epidemiology, diagnosis, and treatment of cerebrotendinous xanthomatosis (CTX). J Inherit Metab Dis. 2017;40(6):771-781. doi:10.1007/s10545-017-0093-8.
3. European Association for the Study of the Liver (EASL). Electronic address: easloffice@easloffice.eu. EASL Clinical Practice Guidelines on the prevention, diagnosis and treatment of gallstones. J Hepatol. 2016;65(1):146-181. doi:10.1016/j.jhep.2016.03.005.

Generic	Brand	Reviewed	Effective Date
CHOLIC ACID Edition 2	CHOLBAM	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. Patient has a diagnosis of a bile acid synthesis disorder due to one of the following:
    1. Peroxisomal disorders including Zellweger spectrum disorder
    2. Single enzyme defects
B. Diagnosis is confirmed by ONE of the following:
    1. Fast Atom Bombardment ionization – Mass Spectrometry (FAB-MS) analysis
    2. Molecular genetic testing
C. The requested medication is prescribed by or in consultation with a hepatologist, gastroenterologist, or metabolic disease specialist

RENEWAL CRITERIA

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

A. Patient has experienced an improvement in liver function as defined by at least ONE of the following criteria:
    1. ALT (alanine aminotransferase) or AST (aspartate transaminase) 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 on liver biopsy

References:

1. Cholbam package insert. San Diego, CA, Manchester Pharmaceuticals Inc. Revised October 2020. Accessed July 2022
2. Braverman NE, Raymond GV, Rizzo WB, et al. Peroxisome biogenesis disorders in the Zellweger spectrum: An overview of current diagnosis, clinical manifestations, and treatment guidelines. Mol Genet Metab. 2016;117(3):313-321. doi:10.1016/j.ymgme.2015.12.009.
3. Heubi JE, Setchell KDR, Bove KE. Inborn Errors of Bile Acid Metabolism. Clin Liver Dis. 2018;22(4):671-687. doi:10.1016/j.cld.2018.06.006.

Generic	Brand	Reviewed	Effective Date
CINACALCET Edition 2	SENISPAR	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has one of the following diagnoses:
    1. Parathyroid carcinoma
    2. Primary hyperparathyroidism and is unable to undergo parathyroidectomy
    3. Secondary hyperparathyroidism
C. The requested medication is prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist
D. **For patients with secondary hyperparathyroidism, approval also requires ALL of the following:**
        a. The patient has a diagnosis of chronic kidney disease (CKD)
        b. The patient is on hemodialysis.
        c. The patient has an intact parathyroid hormone (iPTH) level above normal range as defined by the laboratory reference values
        d. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to **ONE** phosphate binder (e.g. calcium acetatate, PhosLo, lanthanum carbonate, Fosrenol, sevelamer, Renvela, Renagel, etc.)
        e. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to **ONE** vitamin analog (e.g., calcitriol, doxercalciferol, paricalcitol, etc.)

The medication will not be approved if the patient has hypocalcemia (serum calcium less than the lower limit of the normal laboratory reference range).

RENEWAL CRITERIA

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

A. The patient has experienced a reduction in serum calcium level compared to baseline.

References:

1. Sensipar package insert. Thousand Oaks, CA. Amgen Inc. Revised December 2019. Accessed July 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

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.

Generic	Brand	Reviewed	Effective Date
CLOBAZAM Edition 1	SYMPAZAN	07/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of Lennox-Gastaut Syndrome
B. The requested medication will be used for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (e.g., in combination with lamotrigine or topiramate, etc.)
C. The patient is 2 years of age or older
D. The patient is unable to take tablets or suspension
E. The patient has had a trial of or contraindication to generic/branded clobazam products (Onfi)

References:

1. Sympazan package insert. Warren,NJ. Aquestive Therapeutics. Revised March 2021. Accessed June 2022.
2. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2018;91(24):1117. doi:10.1212/WNL.0000000000006636.

Generic	Brand	Reviewed	Effective Date
COBIMETINIB FUMARATE Edition 1	COTELLIC	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of unresectable or metastatic melanoma
B. Patient is positive for BRAF V600E OR V600K mutation
C. The requested medication will be used in combination with vemurafenib (Zelboraf)

References:

1. Cotellic package insert. South San Francisco, CA. Genentech USA, Inc. Revised January 2018. Accessed June 2022.

WELLFLEET RX STUDENT FORMULARY

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

Edition 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.

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.

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.

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.

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)

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)

(Criteria continued on next page)

REQUIREMENTS: CRIZANLIZUMAB-TMCA (CONTINUED)

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.

Generic	Brand	Reviewed	Effective Date
CRIZOTINIB Edition 2	XALKORI	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Metastatic non-small cell lung cancer (NSCLC)
    2. Relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL)

B. **If patient has metastatic non-small cell lung cancer, approval also requires ONE of the following:**
    1. Patient is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test
    2. Patient is ROS1-positive as detected by an FDA-approved test.

C. If patient has relapsed or refractory, systemic anaplastic large cell lymphoma, approval also requires BOTH of the following:
    1. Patient is 1 year of age and less than 22 years of age
    2. Patient is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

References:

1. Xalkori package insert. New York, NY. Pfizer Labs. Revised September 2021. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
CYSTEAMINE BITARTRATE Edition 2	PROCYSBI, CYSTAGON	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of nephropathic cystinosis
B. The patient is at least 1 year of age or older
C. The patient has previously tried an immediate-release formulation of cysteamine bitartrate such as Cystagon

References:

1. Procysbi package insert. Lake Forest, IL, Horizon Pharma USA Inc. Revised February 2022 Accessed June 2022
2. Cystagon package insert. Morgantown, WV. Mylan Pharmaceuticals Inc. Revised June 2007. Accessed June 2022.
3. Vaisbich MH, Satiro CAF, Roz D, et al. Multidisciplinary approach for patients with nephropathic cystinosis: model for care in a rare and chronic renal disease. J Bras Nefrol. 2019;41(1):131-141. doi:10.1590/2175-8239-JBN-2018-0139.

Generic	Brand	Reviewed	Effective Date
CYSTEAMINE HCL Edition 2	CYSTARAN, CYSTADROPS	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient has a diagnosis of cystinosis
B. The requested medication is prescribed by or in consultation with an ophthalmologist
C. The patient requires treatment for corneal cystine crystal accumulation or deposits

References:

1. Cystaran package insert**.** Gaithersburg, MD**.** Leadiant Biosciences, Inc.. Revised February 2022. Accessed June 2022.
2. Cystadrops package insert. Lebanon, NJ. Recordati Rare Diseases Inc. Revised August 2020. Accessed June 2022.
3. Wilmer MJ, Schoeber JP, van den Heuvel LP, Levtchenko EN. Cystinosis: practical tools for diagnosis and treatment. Pediatr Nephrol. 2011;26(2):205-215. doi:10.1007/s00467-010-1627-6.
4. Biswas S, Gaviria M, Malheiro L, Marques JP, Giordano V, Liang H. Latest Clinical Approaches in the Ocular Management of Cystinosis: A Review of Current Practice and Opinion from the Ophthalmology Cystinosis Forum. Ophthalmol Ther. 2018;7(2):307-322. doi:10.1007/s40123-018-0146-6.

Generic	Brand	Reviewed	Effective Date
DABRAFENIB MESYLATE Edition 2	TAFINLAR	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma
   2. Metastatic non-small cell lung cancer (NSCLC)
   3. Resectable melanoma
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC)
   5. Unresectable or metastatic solid tumors

B. **For patients with unresectable or metastatic melanoma, approval also requires ONE of the following:**
   1. Patient has BRAF V600E mutation as detected by an FDA (Food and Drug Administration)-approved test AND the requested medication will be used as a single agent
   2. Patient has BRAF V600E or V600K mutations as detected by an FDA-approved test AND the requested medication will be used in combination with Mekinist (trametinib)

C. **For patients with resectable melanoma, approval also requires ALL of the following:**
   1. Patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib) for adjuvant treatment
   3. The patient had involvement of lymph node(s) following complete resection of the melanoma and complete lymphadenectomy

D. **For patients with metastatic non-small cell lung cancer, approval also requires ALL of the following:**
   1. Patient has BRAF V600E mutation as detected by an FDA-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)

E. **For patients with locally advanced or metastatic anaplastic thyroid cancer, approval also requires ALL of the following:**
   1. Patient has BRAF V600E mutation as detected by an FDA-approved test
   2. The requested medication will be used in combination with Mekinist (trametinib)
   3. Patient has no satisfactory locoregional treatment options available

(Criteria continued on next page)

REQUIREMENTS: DABRAFENIB (CONTINUED)

F. **For patients with unresectable or metastatic solid tumors, approval also requires:**
   1. The patient is 6 years of age or older
   2. The patient has BRAF V600E mutation as detected by an FDA-approved test
   3. The requested medication will be used in combination with Mekinist (trametinib)
   4. The patient has progressed following prior treatment and does not have any satisfactory alternative treatment options

References:

1. Tafinlar package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Reviewed June 2022. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
DACOMITINIB Edition 1	VIZIMPRO	7/29/2022	6/1/2021

REQUIREMENTS:

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

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

References:

1. Vizimpro package insert. New York, NY. Pfizer Labs. Reviewed. December 2020. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
DALFAMPRIDIN Edition 1	AMPYRA	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

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

References:

1. Ampyra package insert. Ardsley, NY. Accorda Therapeutics, Inc. Revised November 2021. Accessed June 2022.
2. Brown TR, Simnad VI. A Randomized Crossover Trial of Dalfampridine Extended Release for Effect on Ambulatory Activity in People with Multiple Sclerosis. Int J MS Care. 2016 Jul-Aug;18(4):170-6.

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
DASATINIB Edition 2	SPRYCEL	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic, accelerated, or myeloid or lymphoid blast phase
    2. Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL)

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

C. **If patient has Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval also requires:**
    1. Patient is 18 years of age or older
    2. Patient has resistance or intolerance to prior therapy including imatinib (Gleevec)

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

References:

1. Sprycel package insert. Princeton, NJ. Bristol-Myers Squibb Company. Reviewed June 2021. Accessed June 2022.

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.

DEFERASIROX			
Generic	Brand	Reviewed	Effective Date
DEFERASIROX Edition 1	EXJADE, JADENU, JADENU SPRINKLE	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE)** requires the following rule(s) be met for approval:

A. The patient has one of the following diagnoses:
    1. Chronic iron overload due to blood transfusions
    2. Non-transfusion dependent thalassemia syndromes (NTDT)
B. The medication is prescribed by or given in consultation with a hematologist, hepatologist, or oncologist
C. **If the patient has chronic iron overload due to blood transfusions, approval also requires:**
    1. The patient is 2 years of age or older
    2. The patient has serum ferritin levels greater than 1000mcg/L (at least 2 lab values taken within the previous 3 months)
D. **If the patient has chronic iron overload resulting from non-transfusion dependent thalassemia syndromes (NTDT), approval also requires:**
    1. The patient is 10 years of age or older
    2. The patient has serum ferritin levels greater than 300mcg/L (at least 2 lab values taken within the previous 3 months)
    3. The patient has liver iron concentration (LIC) of at least 5mg Fe/g dry weight or greater
E. Requests for brand name Jadenu sprinkle packets, brand name Jadenu, and brand name Exjade require a trial and failure of the equivalent preferred product: generic deferasirox tablets, generic deferasirox tablets for suspension, or generic deferasirox granules

(Criteria continued on next page)

REQUIREMENTS: DEFERASIROX (CONTINUED)

RENEWAL CRITERIA

Our guideline named **DEFERASIROX (EXJADE, JADENU, JADENU SPRINKLE, DEFERASIROX)** requires the following rule(s) be met for renewal:

A. The patient has one of the following diagnoses:
    1. Chronic iron overload due to blood transfusions
    2. Non-transfusion dependent thalassemia syndromes (NTDT)
B. **If the patient has chronic Iron overload due to blood transfusions, renewal also requires:**
    1. The patient has serum ferritin levels of at least 500 mcg/L (at least 2 lab values taken within the previous 3 months)
C. **If the patient has chronic iron overload resulting from non-transfusion dependent thalassemia syndromes (NTDT), renewal also requires ONE of the following:**
    1. The patient has ferritin levels of at least 300mcg/L (at least 2 lab values taken within the previous 3 months)
    2. The patient has liver iron concentration (LIC) of at least 3mg Fe/g dry weight or greater

References:

1. Exjade package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2020. Accessed June 2022.
2. Jadenu package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised July 2020. Accessed June 2022.
3. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013;88(5):409-415. doi:10.1002/ajh.23405.
4. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013;130(2):64-73. doi:10.1159/000345734.

Generic	Brand	Date Revised	Effective Date
DEFERIPRONE Edition 2	FERRIPROX	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of transfusional iron overload due to a thalassemia syndrome, sickle cell disease or other anemias
B. The patient is 3 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist, hepatologist, or oncologist
D. The patient has a previous trial with generic deferasirox, Exjade, Jadenu, generic deferoxamine, or Desferal
E. The patient meets ONE of the following:
    1. The patient is experiencing intolerable toxicities, clinically significant adverse effects, or a contraindication to current chelation therapy with generic deferasirox, Exjade, Jadenu, generic deferoxamine, or Desferal
    2. The patient has failed chelation therapy with generic deferasirox, Exjade, Jadenu, generic deferoxamine, or Desferal as evidenced by serum ferritin levels remaining above 2500mcg/L (at least 2 lab values in the previous 3 months) despite treatment
F. Requests for brand name Ferriprox require a trial and failure of the equivalent preferred product: generic deferiprone

RENEWAL CRITERIA

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

A. Patient has a diagnosis of transfusional iron overload due to a thalassemia syndromes, sickle cell disease or other anemias
B. The patient has serum ferritin levels of at least 500mcg/L (at least 2 lab values in the previous 3 months)

References:

1. Ferriprox package insert. Cary, NC. Chiesi USA, Inc., Revised November 2021. Accessed June 2022.
2. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013;88(5):409-415. doi:10.1002/ajh.23405.
3. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013;130(2):64-73. doi:10.1159/000345734.

Generic	Brand	Reviewed	Effective Date
DEFEROXAMINE MESYLATE Edition 2	DESFERAL	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of chronic iron overload due to transfusion-dependent anemias
B. The requested medication is prescribed by or given in consultation with a hematologist, hepatologist, or oncologist
C. The patient is 3 years of age or older
D. The patient has serum ferritin levels greater than 1000mcg/L (at least 2 lab values in the previous 3 months)
E. Requests for brand name Desferal require a trial and failure of the equivalent preferred product: generic deferoxamine

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

A. The patient has a diagnosis of chronic iron overload due to transfusion-dependent anemias
B. The patient has serum ferritin levels of at least 500mcg/L (at least 2 lab values in the previous 3 months)

References:

1. Desferal package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised December 2011. Accessed June 2022.
2. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013;88(5):409-415. doi:10.1002/ajh.23405.
3. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Cross-talk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013;130(2):64-73. doi:10.1159/000345734.

Generic	Brand	Reviewed	Effective Date
DEFLAZACORT Edition 1	EMFLAZA	7/29/2022	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. The patient has a diagnosis of Duchenne muscular dystrophy
B. The patient is 2 years of age or older
C. The diagnosis is confirmed with genetic testing
D. The requested medication is prescribed by or recommended by a neurologist specializing in treatment of Duchenne muscular dystrophy (DMD) at a DMD treatment center
E. The patient has previously tried prednisone or prednisolone for at least 6 months and meets ONE of the following:
    1. Prednisone or prednisolone was ineffective, and the patient meets ALL of the following criteria:
        a. The patient is not in Stage 1: pre-symptomatic phase
        b. There is no steroid myopathy
        c. The patient has documentation that their disease is advanced as evidenced by inability to walk, inability to function, and/or inability to breathe using standard measures over time, consistent with advancing disease (stage 2 or higher). [NOTE: 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, 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. The patient had adverse side effects while on prednisone or prednisolone and there is documentation of literature-based evidence provided supporting the requested medication’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 the requested medication 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. The patient has Duchenne muscular dystrophy
B. The patient meets ONE of the following criteria:
    1. **For patients who are currently ambulatory (can walk), renewal also requires:**
        a. The patient has shown function stabilization or improvement in a standard set of ambulatory or functional status measures since being on the requested medication. These measures must be monitored, tracked, and documented consistently. [Note: 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]
    1. **For patients who are currently non-ambulatory (cannot walk), renewal also requires:**
        a. The patient has maintained or has a less than expected decrease in pulmonary function and/or upper limb strength assessed by standard measures since being on the requested medication. These measures must be monitored, tracked, and documented consistently. [Note: 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 June 2021. Accessed July 2022.
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	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient meets **ONE** of the following:
   1. The requested medication is prescribed by or given in consultation with an infectious disease (ID) specialist
   2. The patient has an acute bacterial skin or skin structure infection (ABSSSI) **OR** community-acquired bacterial pneumonia (CABP)

B. **For patients with an acute bacterial skin or skin structure infection, approval also requires:**
   1. The patient is at least 18 years of age
   2. The infection is caused by any of the following bacteria: Staphylococcus aureus (including methicillin-resistant [MRSA] *and methicillin susceptible [MSSA] isolates), Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), Streptococcus pyogenes, and Enterococcus faecalis, Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa*
   3. The patient does not have a diagnosis of animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitis ulcer formation, myonecrosis or ecthyma gangrenosum
   4. The patient meets **ONE** of the following criteria:
      a. If antimicrobial susceptibility test is available, the results of the test from the infection site are required to show the bacteria is both 1) resistant to **ONE** standard of care agent for acute bacterial skin or skin structure infection (e.g., sulfamethoxazole/trimethoprim, levofloxacin, clindamycin, cephalexin, or vancomycin, etc.), **AND** 2) delafloxacin will work against the bacteria
      b. If antimicrobial susceptibility test is not available, a trial of or contraindication to **ONE** of the following agents: a penicillin (e.g., amoxicillin), a fluoroquinolone (e.g., levofloxacin, ciprofloxacin, moxifloxacin, etc.), a cephalosporin (e.g., ceftriaxone, cephalexin, cefazolin, etc.), or a gram-positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, sulfamethoxazole/trimethoprim, vancomycin, etc.) is required

(Criteria continued on next page)

REQUIREMENTS: DELAFLOXACIN (CONTINUED)

C. **For patients with community-acquired bacterial pneumonia (CABP), approval also requires:**
   1. The patient is 18 years of age or older
   2. The infection is caused by any of the following bacteria: *Streptococcus pneumonia, Staphylococcus aureus (methicillin-susceptible [MSSA] isolates only), Klebsiella pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae, Chlamydia pneumoniae, Legionella pneumophila or Mycoplasma pneumoniae*
   3. The patient meets **ONE** of the following criteria:
      a. If antimicrobial susceptibility test is available, the results of the test from the infection site are required to show the bacteria is both 1) resistant to TWO standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid, etc.) **AND** 2) delafloxacin will work against the bacteria
      b. If antimicrobial susceptibility test is not available, a trial or contraindication to **TWO** standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid etc.) is required

References

1. Baxdela package insert. Lincolnshire, IL. Melinta Therapeutics, Inc. Revised June 2021. Accessed June 2022.
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.

Generic	Brand	Reviewed	Effective Date
DENOSUMAB Edition 2	PROLIA	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
   1. Postmenopausal osteoporosis
   2. Osteoporosis in a male patient
   3. Glucocorticoid-induced osteoporosis
   4. Bone loss in non-metastatic prostate cancer
   5. Bone loss in breast cancer.

B. **If the patient is a male with osteoporosis or a female with postmenopausal osteoporosis, approval also requires ALL of the following:**
   1. The patient is at very high risk for fracture defined as **ONE** of the following:
      a. History of fragility or osteoporotic fracture(s)
      b. Bone mineral density (BMD) T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip and/or 33% (one third) radius (wrist)
      c. Bone mineral density (BMD) T-score between -1.0 and -2.5 AND FRAX score greater than or equal to 20% for any major fracture or greater than or equal to 3% for hip fracture
   2. The patient has had a previous trial and failure of ONE oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication

C. **If the patient has glucocorticoid-induced osteoporosis, approval also requires:**
   1. The patient is currently receiving or will be initiating glucocorticoid therapy at an equivalent does of greater than or equal to 2.5mg/day for 3 months or more
   2. The patient is at high risk for fractures defined as **ONE** of the following:
      a. History of fragility or osteoporotic fracture(s)
      b. Bone mineral density (BMD) T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip and/or 33% (one third) radius (wrist)
      c. Bone mineral density (BMD) T-score between -1.0 and -2.5 AND FRAX score greater than or equal to 20% for any major fracture or greater than or equal to 3% for hip fracture
   3. The patient has had a previous trial and failure of **ONE** oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication

(Criteria continued on next page)

REQUIREMENTS: DENOSUMAB-PROLIA (CONTINUED)

D. **If the patient is a male with bone loss in non-metastatic prostate cancer, approval also requires:**
    1. The patient is currently receiving androgen deprivation therapy for non-metastatic prostate cancer [e.g., leuprolide (Lupron), bicalutamide (Casodex) or nilutamide (Nilandron)]
    2. The patient has had a previous trial and failure of **ONE** oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication
E. **If the patient is a female with bone loss in breast cancer, approval also requires:**
    1. The patient is currently receiving adjuvant aromatase inhibitor therapy for breast cancer [e.g., anastrozole (Arimidex), exemestane (Aromasin) or letrozole (Femara)]
    2. The patient has had a previous trial and failure of **ONE** oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication

References:

1. Prolia package insert. Thousand Oaks, CA. Amgen Inc. Revised May 2022. Accessed June 2022.
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.

Generic	Brand	Reviewed	Effective Date
DEUTETRABENAZINE Edition 1	AUSTEDO	7/29/2022	6/1/2021

REQUIREMENTS:

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

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

References:

1. Austedo package insert. Parsippany, NJ. Teva Pharmaceuticals USA, Inc. Revised May 2022.Accessed June 2022.
2. Armstrong MJ, Miyasaki JM. Evidence-based guideline: pharmacologic treatment of chorea in Huntington disease: report of the guideline development subcommittee of the American Academy of Neurology. Neurology. 2012;79:597-603.
3. Bhidayasiri R, Fahn S, Weiner WJ, et al. Evidence-based guideline: treatment of tardive syndromes: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2013;81(5):463-469.

Generic	Brand	Reviewed	Effective Date
DEXMEDETOMIDINE HCL Edition 1	IGALMI	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient is 18 years of age or older
B. Patient has a diagnosis of schizophrenia or bipolar I or II disorder
C. Prescribed by or in consultation with a mental health specialist or psychiatrist
D. Medication is prescribed concurrently with at least one standard maintenance treatment for schizophrenia or bipolar I or II disorder (e.g., aripiprazole, olanzapine, quetiapine, etc.)
E. Medication is being used for ACUTE treatment of agitation associated with schizophrenia or bipolar I or II disorder
F. Prescriber attests the requested medication will be administered under the supervision of a healthcare provider

RENEWAL CRITERIA

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

A. Patient has a diagnosis of schizophrenia or bipolar I or II disorder
B. Medication is being used for ACUTE treatment of agitation associated with schizophrenia or bipolar I or II disorder
C. Patient has experienced symptom improvement (i.e., impulse control, tension, hostility, uncooperativeness, or excitement) compared to baseline

References:

1. Igalmi package insert. New Haven, CT. BioXcel Therapeutics, Inc. Revised April 2022. Accessed May 2022.
2. Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia. Focus (Am Psychiatr Publ). 2020;18(4):493-497. doi:10.1176/appi.focus.18402.
3. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). Am J Psychiatry. 2002;159(4 Suppl):1-50.

Generic	Brand	Reviewed	Effective Date
DEXTROMETHORPHAN/ QUINIDINE Edition 1	NUEDEXTA	7/29/2022	6/1/2021

REQUIREMENTS:

Our guideline named **DEXTROMETHORPHAN with QUINIDINE (Nuedexta)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of pseudobulbar affect

References:

1. Nuedexta package insert. Aliso Viejo, CA. Avanir Pharmaceuticals, Inc. Revised June 2019. Accessed June 2022.
2. Pioro EP, Brooks BR, Cummings J, et al. Dextromethorphan plus ultra low-dose quinidine reduces pseudobulbar affect. Ann Neurol. 2010;68:693-702.

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	7/29/2022	6/1/2021

REQUIREMENTS:

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

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

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

References:

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

Generic	Brand	Reviewed	Effective Date
DICHLORPHENAMIDE Edition 2	KEVEYIS	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Primary hypokalemic periodic paralysis (HypoPP)
    2. Primary hyperkalemic periodic paralysis (HyperPP)
    3. Paramyotonia Congenita
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist or a physician who specializes in primary periodic paralysis
D. The patient has had a previous trial of or contraindication to treatment with acetazolamide

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

A. The patient has ONE of the following diagnoses:
    1. Primary hypokalemic periodic paralysis (HypoPP)
    2. Primary hyperkalemic periodic paralysis (HyperPP)
    3. Paramyotonia Congenita
B. The patient has experienced at least two fewer attacks per week compared to baseline

References:

1. Keveyis package insert. Trevose, PA. Strongbridge US Inc. Revised December 2019. Accessed June 2022
2. Sansone V, Meola G, Links TP, Panzeri M, Rose MR. Treatment for periodic paralysis. Cochrane Database Syst Rev. 2008;(1):CD005045. Published 2008 Jan 23. doi:10.1002/14651858.CD005045.pub2.

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.

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.

Generic	Brand	Reviewed	Effective Date
DORNASE ALFA Edition 2	PULMOZYME	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. Patient has a diagnosis of cystic fibrosis
B. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
C. If the request is for twice daily dosing, we require that the patient has tried and failed once daily dosing

References:

1. Pulmozyme package insert. South San Francisco, CA. Genentech, Inc. Revised July 2021. Accessed June 2022.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. April 1, 2013; 187(7): 680-689.

WELLFLEET RX STUDENT FORMULARY

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

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
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)

Generic	Brand	Reviewed	Effective Date
DUPILUMAB Edition 3	DUPIXENT	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe atopic dermatitis
    2. Moderate to severe asthma
    3. Chronic rhinosinusitis with nasal polyposis (CRSwNP)
    4. Eosinophilic esophagitis (EoE)

B. **If the patient has moderate to severe atopic dermatitis, approval also requires:**
    1. The patient is 6 months of age or older
    2. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
    3. The patient meets at least ONE of the following for disease severity:
        a. Atopic dermatitis involving at least 10% of body surface area (BSA)
        b. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
    4. The patient has had at least a 4-week trial with an inadequate response to at least ONE of the following, unless contraindication to all listed:
        a. moderate-or higher-potency topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate, etc.]
        b. topical calcineurin inhibitors [i.e., Elidel (pimecrolimus), Protopic (tacrolimus)]
        c. topical PDE-4 inhibitors [i.e., Eucrisa (crisaborole)]

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

C. **If the patient has moderate to severe asthma, approval also requires:**
   1. The patient is 6 years of age or older
   2. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
   3. The patient has moderate-to-severe asthma that is characterized as ONE of the following:
      a. Eosinophilic phenotype asthma with a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
      b. Oral corticosteroid-dependent asthma
   4. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
   5. The patient has asthma that is uncontrolled while maintained on an ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE or more of the following:
      a. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or increase in dose if already on oral corticosteroid) within the past 12 months
      b. At least ONE asthma exacerbation requiring hospitalization, urgent care, or emergency room visit within the past 12 months
   6. The requested medication will be used as an add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler
   7. The patient is not being treated on the requested medication concurrently with Xolair, Tezspire, or an anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra, etc.)

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

D. **If the patient has chronic rhinosinusitis with nasal polyposis, approval also requires:**
   1. The patient is 18 years of age or older
   2. The medication is prescribed by or given in consultation with an otolaryngologist allergist, or immunologist
   3. Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
   4. The patient is currently adherent to maintenance therapy with an intranasal corticosteroid (e.g., fluticasone, mometasone, etc.)
   5. The patient has inadequately controlled disease as determined by **ONE** of the following:
      a. Use of systemic corticosteroids in the past 2 years
      b. Endoscopic sinus surgery
   6. The requested medication will be used as add-on maintenance treatment in conjunction with maintenance intranasal steroids
   7. The patient is not being treated on the requested medication concurrently with Xolair or an anti-IL-5 biologic (e.g., Nucala, etc.)

E. **If the patient has eosinophilic esophagitis, approval also requires:**
   1. The patient is 12 years of age or older
   2. The requested medication is prescribed by or given in consultation with a gastroenterologist, allergist, or immunologist
   3. The patient weighs at least 40 kg (88 lbs)
   4. The patient exhibits symptoms of dysphagia
   5. The patient has failed to achieve less than 15 eosinophils/high power field (eos/hpf) despite a trial with at least ONE of the following pharmacological treatments:
      a. High dose proton pump inhibitor (e.g., omeprazole, esomeprazole, lansoprazole, etc.)
      b. Topical corticosteroid (i.e., budesonide, fluticasone propionate)

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

RENEWAL CRITERIA

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

A. The patient has ONE of the following diagnoses:
    1. Moderate to severe atopic dermatitis
    2. Moderate to severe asthma
    3. Chronic rhinosinusitis with nasal polyposis (CRSwNP)
    4. Eosinophilic esophagitis (EoE)
B. **If the patient has moderate to severe atopic dermatitis, renewal also requires:**
    1. The patient has shown a clinical response as evidenced by an improvement in symptoms (e.g., reduced body surface area affected, reduced pruritus, improvements in cracking, oozing, or bleeding of affected skin, reduced erythema, etc.)
C. **If the patient has moderate to severe asthma, renewal also requires:**
    1. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    2. The patient has shown a clinical response as evidenced by at least ONE of the following:
        a. Reduction in asthma exacerbation(s) as compared to baseline
        b. Decreased use of rescue medications
        c. Increase in percent predicted FEV1 from pretreatment baseline
        d. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
D. **If the patient has chronic rhinosinusitis with nasal polyposis, renewal also requires:**
    1. The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, improved sense of smell, reduced size of polyps, etc.)
E. **If the patient has eosinophilic esophagitis, renewal also requires:**
    1. The patient has had a clinical benefit compared to baseline as evidenced by BOTH of the following:
        a. Esophageal intraepithelial eosinophil count of 6 eosinophils/high power field (eos/hpf) or less
        b. Improvement in symptoms of dysphagia

(Criteria continued on next page)

CRITERIA CONTINUED- DUPILUMAB

References:

1. Dupixent package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised June 2022. Accessed June 2022.
2. Beck LA, Thaçi D, Hamilton JD, et al. Dupilumab treatment in adults with moderate-to-severe atopic dermatitis. *N Engl J Med*. 2014;371(2):130-139. doi:10.1056/NEJMoa1314768.
3. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. J Allergy Clin Immunol. 2020;146(6):1217-1270. doi:10.1016/j.jaci.2020.10.003.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
5. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71(1):116-132. doi:10.1016/j.jaad.2014.03.023.
6. Hirano I, Chan ES, Rank MA, et al. AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. Gastroenterology. 2020;158(6):1776-1786. doi:10.1053/j.gastro.2020.02.038.

Generic	Brand	Reviewed	Effective Date
DUVELISIB Edition 2	COPIKTRA	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. Patient has a ONE of the following diagnoses:
    1. Relapsed or refractory chronic lymphocytic leukemia (CLL)
    2. Small lymphocytic lymphoma (SLL)
B. You are 18 years of age or older
C. **If patient has relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), approval also requires:**
    1. Patient received at least two prior therapies for CLL or SLL

References:

1. Copiktra package insert. Needham, MA. Verastem, Inc. Revised December 2021. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
ECALLANTIDE Edition 1	KALBITOR	07/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient is 12 years of age or older
C. The diagnosis is confirmed by complement testing
D. The requested medication is being used for treatment of acute attacks of hereditary angioedema
E. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
F. The requested medication will be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and/or angioedema

References:

1. Kalbitor package insert. Lexington, MA. Dyax Corp. Revised December 2020. Accessed July 2022.
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.

Generic	Brand	Reviewed	Effective Date
EDARAVONE Edition 2	RADICAVA (inj) RADICAVA ORS	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **EDARAVONE (Radicava, Radicava ORS)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) according to the El Escorial - Revised (Airlie House) diagnostic criteria
B. The medication is prescribed by or given in consultation with a neurologist, neuromuscular disease specialist, or ALS specialist at an ALS Specialty Center or Care Clinic
C. The patient has a disease duration of 2 years or less
D. The patient has a percent Forced Vital Capacity (% FVC) of at least 80%
E. The patient has mild to moderate ALS disease defined by scores of 2 or higher in all 12 items of the ALSFRS-R (ALS Functional Rating Scale-Revised)

RENEWAL CRITERIA

Our guideline named **EDARAVONE (Radicava, Radicava ORS)** requires the following rule(s) be met for renewal:

A. The patient has a diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) according to the El Escorial - Revised (Airlie House) diagnostic criteria
B. The patient has improved or maintained baseline functional ability or demonstrated a less-than expected decline in functional ability from baseline as measured by functional assessments
C. The patient does not require invasive ventilation

References:

1. Radicava package insert. Jersey City, NJ. Mitsubishi Tanabe Pharma America, Inc. Revised May 2022. Accessed June 2022.
2. Brooks BR, Miller RG, Swash M, Munsat TL; World Federation of Neurology Research Group on Motor Neuron Diseases. El Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000;1(5):293-299. doi:10.1080/146608200300079536.
3. Cedarbaum JM, Stambler N, Malta E, Fuller C, Hilt D, Thurmond B, et al. The ALSFRS-R: a revised ALS functional rating
4. scale that incorporates assessments of respiratory function. J Neurol Sci. 1999; 169(1): 13–21.

Generic	Brand	Reviewed	Effective Date
ELAGOLIX Edition 1	ORILISSA	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of moderate to severe pain associated with endometriosis
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with an obstetrician/gynecologist
D. The patient has had a previous trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, meloxicam, naproxen, etc.) **AND** a progestin-containing preparation (e.g., combination hormonal contraceptive preparation, progestin-only therapy, etc.)
E. Requests for Orilissa 200mg twice daily will only be approved if the patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of moderate to severe pain associated with endometriosis
B. The patient has had improvement of pain related to endometriosis while on therapy
C. The patient has normal liver function or mild hepatic impairment (Child-Pugh Class A)

Requests will NOT be approved if the patient meets ONE of the following conditions:

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

References:

1. Orilissa package insert. North Chicago, IL. AbbVie Inc. Revised February 2021. Accessed June 2022.
2. Management of Endometriosis. ACOG Practice Bulletin. Clinical Management Guidelines for ObstetricanGynecologists. Number 114, July 2010. (Reaffirmed 2018) Obstetrics & Gynecology. 2010; 116(1): 223-236.

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.

Generic	Brand	Reviewed	Effective Date
ELAPEGADEMASE-LVLR Edition 1	REVCOVI	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **ELAPEGADEMASE-LVLR (Revcovi)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) as shown by **ONE** of the following:
    1. Confirmatory genetic test (detection of bi-allelic mutations in the ADA 1 gene)
    2. Suggestive laboratory findings such as elevated deoxyadenosine nucleotide (dAXP) levels or very low adenosine deaminase (ADA) catalytic activity **AND** the patient has hallmark signs/symptoms (e.g., recurrent infections, failure to thrive, persistent diarrhea, etc.)
B. The requested medication is prescribed by or given in consultation with an immunologist, hematologist/oncologist, or physician specializing in inherited metabolic disorders
C. The patient has failed or is not a candidate for hematopoietic cell transplant **OR** the requested medication will be used as a bridging therapy prior to planned hematopoietic cell transplant or gene therapy

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

A. The patient has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)
B. The patient has a clinical response to therapy as evidenced by improvement in trough plasma adenosine deaminase (ADA) activity, improvement in trough erythrocyte deoxyadenosine nucleotide (dAXP) levels and/or improvement in/maintenance of immune function compared to baseline (i.e., decrease in number and severity of infections)
C. The patient has not received successful hematopoietic cell transplantation (HCT) or gene therapy

References:

1. Revcovi package insert. Gaithersburg, MD. Leadiant Biosciences Inc. Revised December 2020. Accessed July 2022.
2. Kohn DB, Hershfield MS, Puck JM, et al. Consensus approach for the management of severe combined immune deficiency caused by adenosine deaminase deficiency. J Allergy Clin Immunol. 2019;143(3):852-863.

Generic	Brand	Reviewed	Effective Date
ELBASVIR/GRAZOPREVIR Edition 3	ZEPATIER	07/29/2022	07/29/2022

REQUIREMENTS:

Our guideline for **ELBASVIR/GRAZOPREVIR (Zepatier)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
B. The patient has HCV genotype 1 or genotype 4
C. The patient is 12 years of age or older OR weighs at least 30 kg
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection that shows at least **ONE** detectable HCV RNA level within the last 6 months
F. The patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis
G. The patient has previously tried **preferred** agents, sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) [genotype 1, 4, 5, 6 only], unless they have a contraindication to both. [NOTE: Patients with previous failure (i.e., did not achieve SVR) of a completed full course of treatment with sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) will NOT be approved.]
H. Patients with genotype 1a infection require testing for baseline NS5A (nonstructural protein 5A) polymorphisms
I. Concurrent ribavirin use with the requested medication is required if the patient meets ANY of the following:
    1. The patient has genotype 1a or 1b infection and was previously treated with HCV protease inhibitor triple therapy [HCV NS3/4A protease inhibitor (i.e., Victrelis, Incivek, Olysio) plus peginterferon/ribavirin]
    2. The patient has genotype 1a infection, is treatment-naïve, and has baseline resistance-associated NS5A polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)
    3. The patient has genotype 1a infection, was previously treated with peginterferon plus ribavirin, and has baseline resistance-associated NS5A polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)
    4. The patient has genotype 4 infection and was previously treated with peginterferon plus ribavirin

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REQUIREMENTS: ELBASVIR/GRAZOPREVIR (CONTINUED)

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient is taking Sovaldi (sofosbuvir) with the requested medication
B. The patient has moderate or severe hepatic impairment (Child-Pugh B or C)
C. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References

1. Zepatier package insert. Whitehouse Station, NJ. Merck & Co. Revised May 2022. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

Generic	Brand	Reviewed	Effective Date
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR Edition 2	TRIKAFTA	7/29/2022	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. Patient is 6 years of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Patient meets ONE of the following:
    1. Documentation that the patient has at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
    2. Documentation that the patient has at least ONE of the following mutations in the CFTR gene:

Table 5: List of *CFTR* Gene Mutations that are Responsive to TRIKAFTA

3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*
A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C;S1251N*†	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del**	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y;G576A;R668C†	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*
E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W;D1270N*†	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W;V201M*†	*S364P*	*Y161S*
E116K	*G576A;R668C*†	*L165S*	*R74W;V201M;D1270N*†	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data *[see Clinical Studies (14)]*.
† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

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REQUIREMENTS: ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (CONTINUED)

RENEWAL CRITERIA

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    1. Patient has improved, maintained, or demonstrated less than expected decline in FEV_1
    2. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    3. Patient has experienced a reduction in rate of pulmonary exacerbations

References:

1. Trikafta package insert. Boston, Ma. Vertex Pharmaceuticals Incorporated. Revised October 2021. Accessed June 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.

Generic	Brand	Reviewed	Effective Date
ELIGLUSTAT TARTRATE Edition 1	CERDELGA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of type 1 (non-neuronopathic) Gaucher disease
B. The patient is 18 years of age or older
C. Twice daily dosing will be approved if the patient is an extensive or immediate metabolizer of CYP2D6 (cytochrome P450 2D6) inhibitors
D. Once daily dosing will be approved if the patient is a poor metabolizer of CYP2D6 (cytochrome P450 2D6)

References:

1. Cerdelga package insert. Cambridge, MA. Genzyme Corporation. Revised July 2021. Accessed June 2022.
2. Biegstraaten M, Cox TM, Belmatoug N, et al. Management goals for type 1 Gaucher disease: An expert consensus document from the European working group on Gaucher disease. Blood Cells Mol Dis. 2018;68:203-208. doi:10.1016/j.bcmd.2016.10.008.

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.

Generic	Brand	Reviewed	Effective Date
ELTROMBOPAG Edition 1	PROMACTA	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Chronic immune thrombocytopenia (ITP)
    2. Thrombocytopenia due to chronic hepatitis C
    3. Severe aplastic anemia
B. **If patient is greater than 12 years of age and the request is for Promacta packets, approval also requires:**
    1. Patient has previously had a trial of Promacta tablets
    2. Patient has a medical need for powder packets
C. **If patient has chronic immune thrombocytopenia, approval also requires:**
    1. Patient is 1 year of age or older
    2. Patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days **OR** patient has an active bleed
    3. Patient has previously tried or has a contraindication to corticosteroids or immunoglobulins, **or** patient had an insufficient response to a splenectomy
    4. The requested medication is prescribed by or given in consultation with a hematologist or immunologist
    5. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)
D. **If patient has thrombocytopenia due to chronic hepatitis C, approval also requires:**
    1. The patient's thrombocytopenia does not allow them to start interferon-based therapy or limits the patient's ability to maintain interferon-based therapy
    2. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)
E. **If patient has severe aplastic anemia, approval also requires ONE of the following:**
    1. Patient is 2 years of age or older and the requested medication will be used in combination with standard immunosuppressive therapy as first-line treatment
    2. Patient did not have a good enough response to immunosuppressive therapy

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

REQUIREMENTS: ELTROMBOPAG CONTINUED)

RENEWAL CRITERIA

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

A. Patient has a diagnosis of chronic immune thrombocytopenia (ITP)
B. Patient had a clinical response to therapy, as defined by an increase in platelet count or reduction in bleeding events, compared to baseline

NOTE: For the diagnoses of thrombocytopenia due to chronic hepatitis C or severe aplastic anemia, please refer to the Initial Criteria section. Re-authorization is not permitted. Patients must meet the initial approval criteria for these diagnoses.

References:

1. Promacta package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised February 2021. Accessed June 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. Killick SB, Bown N, Cavenagh J, et al. Guidelines for the diagnosis and management of adult aplastic anaemia [published correction appears in Br J Haematol. 2016 Nov;175(3):546]. Br J Haematol. 2016;172(2):187-207. doi:10.1111/bjh.13853.

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.

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.

Generic	Brand	Reviewed	Effective Date
EMICIZUMAB-KXWH Edition 1	HEMLIBRA	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

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

RENEWAL CRITERIA

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

A. The patient has a diagnosis of hemophilia A congenital factor VIII deficiency
B. The patient has shown clinical benefit after using the medication compared to baseline

References:

1. Hemlibra package insert. South San Francisco, CA. Genentech, Inc. Revised June 2022. Accessed June 2022.
2. National Hemophilia Foundation. MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders (Revised April 2022). MASAC Document 272. Available at: https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-272-masac-recommendations-concerning-products-licensed-for-the-treatment-of-hemophilia-and-other-bleeding-disorders. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
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.

Generic	Brand	Reviewed	Effective Date
ENASIDENIB Edition 1	IDHIFA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of relapsed or refractory acute myeloid leukemia
B. Patient is 18 years of age or older
C. Patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA (Food and Drug Administration)-approved diagnostic test

References:

1. Idhifa package insert. Cambridge, MA. Agios Pharmaceuticals. Revised November 2020. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
ENCORAFENIB Edition 1	BRAFTOVI	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Unresectable or metastatic melanoma
    2. Metastatic colorectal cancer
B. **If patient has unresectable or metastatic melanoma, approval also requires:**
    1. Patient has a BRAF V600E or V600K mutation as detected by an FDA (Food and Drug Administration)-approved test
    2. The medication will be used in combination with Mektovi (binimetinib)
C. **If patient has metastatic colorectal cancer, approval also requires:**
    1. Patient has a BRAF V600E mutation as detected by an FDA (Food and Drug Administration)-approved test
    2. The medication will be used in combination with Erbitux (cetuximab)
    3. Patient has previously received treatment

References:

1. Braftovi package insert. Boulder, Colorado. Array BioPharma Inc. Reviewed February 2022. Accessed June 2022.

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)

(Criteria continued on next page)

REQUIREMENTS: ENDOTHELIN RECEPTOR ANTAGONISTS (CONTINUED)

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

OPSUMIT

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

A. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
B. The patient is 18 years of age or older
C. Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters:
    1. Mean pulmonary artery pressure (PAP) of ≥ 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.

(Criteria continued on next page)

REQUIREMENTS: ENDOTHELIN RECEPTOR ANTAGONISTS (CONTINUED)

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.

Generic	Brand	Reviewed	Effective Date
ENTRECTINIB Edition 1	ROZLYTREK	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Metastatic non-small cell lung cancer
    2. Solid tumor (e.g., sarcoma, breast cancer, colorectal cancer, etc.)

B. **If patient has metastatic non-small cell lung cancer (NSCLC), approval also requires BOTH of the following:**
    1. Patient is 18 years of age or older
    2. Patient has *ROS1*-positive tumors

C. **If patient has a solid tumor, approval also requires ALL of the following:**
    1. Patient is 12 years of age or older
    2. The solid tumor has a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation
    3. The tumor is metastatic or surgical resection is likely to result in severe morbidity
    4. There are no satisfactory alternative treatments, or patient has progressed after treatment

References:

1. Rozlytrek package insert. South San Francisco, Ca. Genentech, Inc. Revised November 2021. Accessed June 2022.

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.

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.

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.

Generic	Brand	Reviewed	Effective Date
EPTINEZUMAB-JJMR Edition 3	VYEPTI	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches
B. **If patient has episodic migraines (0-14 headache days per month), approval also requires:**
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
    4. The patient has had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, Emgality, or Nurtec ODT
C. **If patient has chronic migraines (15 or more headache days per month), approval also requires:**
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox
    4. Patient has had a previous trial of TWO of the preferred CGRP inhibitors: Aimovig, Ajovy, or Emgality

(Criteria continued on next page)

REQUIREMENTS: EPTINEZUMAB-JJMR (CONTINUED)

RENEWAL CRITERIA

Our guideline named **EPTINEZUMAB-JJMR (Vyepti)** requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines
B. Patient has responded to therapy as evidenced by at least **ONE** of the following:
    a. The patient has experienced a reduction in migraine or headache frequency by at least 2 days per month compared to baseline
    b. The patient has experienced a reduction in migraine severity compared to baseline
    c. The patient has experienced a reduction in migraine duration compared to baseline

References:

1. Vyepti package insert. Bothell, WA. Lundbeck Seattle BioPharmaceuticals, Inc. Revised April 2022. Accessed June 2022.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

Generic	Brand	Reviewed	Effective Date
ERDAFITINIB Edition 1	BALVERSA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of locally advanced or metastatic urothelial carcinoma (mUC)
B. Patient is 18 years of age or older
C. Patient has susceptible fibroblast growth factor receptor (FGFR3 or FGFR2) genetic alterations as detected by a Food and Drug Administration (FDA)-approved companion diagnostic test
D. Patient meets ONE of the following:
    1. Patient has progressed during or following at least one line of prior platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)
    2. Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (such as cisplatin, carboplatin, oxaliplatin)

References:

1. Balversa package insert. Horsham, PA. Janssen Products. Revised April 2022. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
ERENUMAB-AOOE Edition 2	AIMOVIG	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches
B. **If patient has episodic migraines (0-14 headache days per month), approval also requires:**
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
C. **If the patient has chronic migraines (15 or more headache days per month), approval also requires:**
    1. Patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. Patient has had a previous trial of at least ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine or Botox

RENEWAL CRITERIA
Our guideline named **ERENUMAB-AOOE (Aimovig)** requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines.
B. Patient has responded to therapy as evidenced by at least **ONE** of the following:
    1. Patient has experienced less migraines or headache attacks by at least 2 days per month compared to baseline
    2. Patient has experienced a lessening in migraine severity compared to baseline
    3. Patient has experienced a lessening in migraine duration compared to baseline

(Criteria continued on next page)

REQUIREMENTS: ERENUMAB-AOOE (CONTINUED)

References:

1. Aimovig package insert. Thousand Oaks, CA. Amgen Inc. Revised May 2021. Accessed June 2022.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ERLOTINIB Edition 1	TARCEVA	7/22/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses
    1. Metastatic non-small cell lung cancer
    2. Locally advanced, unresectable, or metastatic pancreatic cancer

B. **If patient has metastatic non-small cell lung cancer (NSCLC), approval also requires:**
    1. Patient's tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA (Food and Drug Administration)-approved test

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

References:

1. Tarceva package insert. South San Francisco, CA. Genentech USA, Inc. Revised October 2016. Accessed June 2022.

ERYTHROPOIESIS STIMULATING AGENTS Edition 1			
Generic	Brand	Reviewed	Effective Date
DARBEPOETIN	ARANESP	7/29/2022	6/1/2021
EPOETIN ALFA	EPOGEN PROCRIT		
EPOETIN ALFA-EPBX	RETACRIT		
METHOXY PEGEPOETIN BETA	MIRCERA		

REQUIREMENTS:

INITIAL CRITERIA FOR PROCRIT (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Procrit)** requires the following rules be met for approval:

A. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
    5. Patients undergoing elective, noncardiac, or nonvascular surgery.

B. **For patients with anemia associated with chronic kidney disease, approval also requires:**
    1. The patient has a hemoglobin level of less than 10g/dL

C. **For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires ONE of the following:**
    1. The patient has a hemoglobin level of less than 11g/Dl
    2. The patient's hemoglobin level has decreased at least 2g/dL below their baseline level.

D. **For patients with anemia related to zidovudine therapy, approval also requires:**
    1. The patient has a hemoglobin level of less than 10g/dL

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

INITIAL CRITERIA FOR ARANESP (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **ERYTHROPOIESIS STIMULATING AGENTS (Aranesp)** requires the following rule(s) be met for approval:

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

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

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

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

A. The patient has ONE of the following diagnoses:
   1. Anemia due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered cancer chemotherapy
   3. Anemia related to zidovudine therapy
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. The patient is undergoing elective, noncardiac, or nonvascular surgery.

B. **For patients with anemia associated with chronic kidney disease, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 10g/dL

C. **For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 11g/dL **OR** their hemoglobin has decreased at least 2g/dL below their baseline level

D. **For patients with anemia related to zidovudine therapy, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 10g/dL

E. **For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has tried a lower ribavirin dose, unless there is a contraindication
   3. The patient's hemoglobin level is less than 10g/dL

F. **For patients undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 13g/dL

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

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

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

A. The patient has ONE of the following diagnoses:
   1. Anemia due to chronic kidney disease
   2. Anemia due to the effect of concomitantly administered cancer chemotherapy
   3. Anemia related to zidovudine therapy
   4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa
   5. The patient is undergoing elective, noncardiac, or nonvascular surgery

B. **For patients with anemia associated with chronic kidney disease, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 10g/dL

C. **For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 11g/dL OR their hemoglobin has decreased at least 2g/dL below their baseline level

D. **For patients with anemia related to zidovudine therapy, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 10g/dL

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

F. **For patients undergoing elective, noncardiac, or nonvascular surgery, approval also requires:**
   1. The patient has tried Procrit
   2. The patient has a hemoglobin level of less than 13g/dL

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

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

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

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

RENEWAL CRITERIA FOR PROCRIT

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

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

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

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

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

RENEWAL CRITERIA FOR ARANESP

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

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

(Criteria continued on next page)

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

RENEWAL CRITERIA FOR EPOGEN

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

A. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

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

C. **For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
    1. The patient has a hemoglobin level between 10g/dL and 12 g/dL

D. **For patients with anemia related to zidovudine therapy, renewal also requires:**
    1. The patient has a hemoglobin level between 10g/dL and 12 g/dL

E. **For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
    1. The patient has a hemoglobin level between 10g/dL and 12 g/dL

(Criteria continued on next page)

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

RENEWAL CRITERIA FOR RETACRIT

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

A. The patient has ONE of the following diagnoses:
    1. Anemia due to chronic kidney disease
    2. Anemia due to the effect of concomitantly administered cancer chemotherapy
    3. Anemia related to zidovudine therapy
    4. Anemia due to hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa

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

C. **For patients with anemia due to the effect of concomitantly administered cancer chemotherapy, renewal also requires:**
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL

D. **For patients with anemia related to zidovudine therapy, renewal also requires:**
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL

E. **For patients with anemia due to concurrent hepatitis C combination treatment with ribavirin plus an interferon alfa or peginterferon alfa, renewal also requires:**
    1. The patient has a hemoglobin level between 10g/dL and 12g/dL

(Criteria continued on next page)

REQUIREMENTS: ERYTHROPOIESIS STIMULATING AGENTS (CONTINUED)

RENEWAL CRITERIA FOR MIRCERA

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

A. The patient has anemia associated with chronic kidney disease
B. **For patients who are 18 years of age or older and are currently receiving dialysis treatment, renewal also requires ONE of the following:**
    1. The patient has a hemoglobin level of less than 11g/dL
    2. The patient has a hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
C. **For patients who are 18 years of age or older and are NOT receiving dialysis treatment, renewal also requires ONE of the following:**
    1. The patient has a hemoglobin level of less than 10g/dL
    2. The patient has a hemoglobin level that has reached 10g/dL and dose reduction/interruption is required to reduce the need for blood transfusions
D. **For patients who are between 5 and 17 years of age, renewal also requires:**
    1. The patient is currently receiving dialysis treatment
    2. The patient has ONE of the following:
        a. A hemoglobin level of less than 11g/dL
        b. A hemoglobin level that has reached 11g/dL and dose reduction/interruption is required to reduce the need for blood transfusions

References:

1. Aranesp package insert. Thousand Oaks, Ca. Amgen Inc. Revised January 2019. Accessed June 2022.
2. Epogen package insert. Thousand Oaks, Ca. Amgen Inc. Revised July 2018. Accessed June 2022.
3. Procrit package insert. Thousand Oaks, Ca. Amgen Inc. Revised. Reviewed July 2018. Accessed June 2022.
4. Retacrit package insert. Lake Forest, IL.Pfizer Company. Reviewed June 2020. Accessed June 2022.
5. Mircera package insert. South San Francisco, CA. Reviewed June 2018. Accessed June 2022.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;2(Suppl):279-335.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
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.

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.

Generic	Brand	Reviewed	Effective Date
ETELCALCETIDE Edition 2	PARSABIV	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of secondary hyperparathyroidism
C. The requested medication is prescribed by or in consultation with an endocrinologist or nephrologist
D. The patient has a diagnosis of chronic kidney disease
E. The patient is on hemodialysis
F. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to ONE phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.)
G. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to ONE vitamin analog (e.g., calcitriol, doxercalciferol, paricalcitol, etc.)
H. The patient has tried and had an inadequate response to, intolerance to, or has a contraindication to cinacalcet (Sensipar)
I. The patient is NOT taking another calcimimetic agent (i.e., cinacalcet [Sensipar])

RENEWAL CRITERIA

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

A. The patient has experienced a reduction in serum calcium level compared to baseline

References:

1. Parsabiv package insert. Thousand Oaks, CA. KAI Pharmaceuticals, Inc. Revised February 2021. Accessed July 2022.
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.

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.

EVEROLIMUS Edition2			
Generic	Brand	Reviewed	Effective Date
EVEROLIMUS	AFINITOR	7/29/2022	07/29/2022
EVEROLIMUS	AFINITOR DISPERZ		

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

REQUIREMENTS:

AFINITOR DISPERZ

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

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

AFINITOR

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

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

(Criteria continued on next page)

REQUIREMENTS: EVEROLIMUS (CONTINUED)

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

References:

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

Generic	Brand	Reviewed	Effective Date
EVINACUMAB-DGNB Edition 3	EVKEEZA	07/29/2022	07/29/2022

REQUIREMENTS:

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for approval:

A. Patient is 12 years of age or older
B. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
C. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
D. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL
E. **If patient is statin tolerant, approval also requires**:
    1. Patient will continue statin treatment in combination with the requested medication
    2. Patient meets ONE of the following:
        a. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for at least 8 weeks
        b. Patient has been taking a maximally tolerated dose of any statin for at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
F. **If patient is statin intolerant, approval also requires ONE of the following**:
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group
G. If patient is statin intolerant, approval also requires the requested medication will be used as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (i.e., PCSK9 inhibitors, lomitapide, mipomersen, or lipoprotein apheresis)

(Continued on next page)

REQUIREMENTS: EVINACUMAB-DGNB (CONTINUED)

RENEWAL CRITERIA

Our guideline named **EVINACUMAB-DGNB (Evkeeza)** requires the following rule(s) be met for renewal:

A. Patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH)
B. If statin tolerant, patient will continue with statin treatment in combination with the the requested medication
C. If patient is statin intolerant, patient will continue with other low-density lipoprotein-cholesterol (LDL-C) lowering therapies (i.e., PCSK9 inhibitors, lomitapide, mipomersen, or lipoprotein apheresis) in combination with the requested medication
D. Patient is responding positively to therapy as evidenced by lab results within the past 3 months showing an LDL-C reduction compared to baseline

References:

1. Evkeeza package insert. Tarrytown, NY. Regeneron Pharmaceuticals, Inc. Revised February 2021. Accessed May 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.

Generic	Brand	Reviewed	Effective Date
EVOLOCUMAB Edition 2	REPATHA	07/29/2022	7/29/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Established cardiovascular disease such as history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis
    2. Heterozygous familial hypercholesterolemia (HeFH) confirmed by genetic testing, Simon Broome criteria or Dutch Lipid Clinical Network criteria
    3. Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
B. **If patient has diagnosis of established cardiovascular disease, approval also requires:**
    1. Patient is 18 years of age or older
C. **If patient has a diagnosis of Heterozygous familial hypercholesterolemia (HeFH) or Homozygous familial hypercholesterolemia (HoFH), approval also requires:**
    1. Patient is 10 years of age or older
D. The medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
E. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70mg/dL
F. **If patient is statin tolerant, approval also requires:**
    1. Patient will continue statin treatment in combination with the requested medication
    2. Patient meets **ONE** of the following:
        a. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for at least 8 weeks
        b. Patient has been taking a maximally tolerated dose of any statin for at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

(Criteria continued on next page)

REQUIREMENTS: EVOLOCUMAB (CONTINUED)

G. **If patient is statin intolerant, approval also requires ONE of the following:**
   1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction
   2. Patient has complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when patient stopped each statin. Some adverse effects include: creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

RENEWAL CRITERIA

Our guideline named **EVOLOCUMAB (Repatha)** requires the following rules be met for renewal:

A. Patient has ONE of the following diagnoses:
   1. Established cardiovascular disease
   2. Heterozygous familial hypercholesterolemia (HeFH)
   3. Homozygous familial hypercholesterolemia (HoFH)

B. Patient meets **ONE** of the following:
   1. Patient has continued to take a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) with the requested medication
   2. Patient has continued therapy with a maximally tolerated dose of any statin with the requested medication
   3. Patient has an absolute contraindication to statin therapy
   4. Patient has complete statin intolerance

References:

1. Repatha package insert. Thousand Oaks, CA. Amgen Inc. Revised September 2021. Accessed May 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 online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

WELLFLEET RX STUDENT FORMULARY

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

Edition 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)

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.

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.

Generic	Brand	Reviewed	Effective Date
FENTANYL NASAL SPRAY Edition 2	LAZANDA	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient has at least ONE of the following diagnoses:
    a. Cancer-related pain
    b. The patient is receiving palliative care or end-of-life care
    c. The patient is enrolled in hospice
B. The patient is currently taking a maintenance dose of a controlled-release pain medication (e.g., MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. The patient has had a trial of an oral immediate-release pain medication (e.g., morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless they have difficulty swallowing tablets or capsules OR there is a contraindication
D. The patient has had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a contraindication
E. The patient has had a trial of Abstral or Fentora (which also requires a prior authorization), unless there is a contraindication

References:

1. Lazanda package insert. Northbrook, IL. West Therapeutic Development. Revised March 2021. Accessed June 2022.
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.

Generic	Brand	Reviewed	Effective Date
FENTANYL SUBLINGUAL SPRAY Edition 2	SUBSYS	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient has at least ONE of the following diagnoses:
    1. Cancer-related pain
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The patient is currently using the requested medication with a controlled-release pain medication (e.g., MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Kadian, Avinza or the generic forms of any of these drugs)
C. The patient has had a trial of an oral immediate-release pain medication (e.g., morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless they have difficulty swallowing tablets or capsules OR there is a contraindication
D. The patient has had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization), unless there is a contraindication
E. The patient has had a trial of Abstral or Fentora, all of which may also require a prior authorization, unless there is a contraindication

References:

1. Subsys package insert. Northbrook, IL. West Therapeutic Development, LLC. Revised March 2021. Accessed June 2022.
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.

Generic	Brand	Reviewed	Effective Date
FENTANYL TRANSDERMAL PATCH Edition 2	DURAGESIC	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient meets at least ONE of the following:
    1. The patient meets the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The requested medication is not prescribed on an 'as needed' basis
C. Requests for dosing every 48 hours requires a trial of transdermal fentanyl patch dosed every 72 hours

References:

1. Duragesic package insert. Titusville, NJ. Janssen Pharmaceuticals, Inc. Revised March 2021. Accessed June 2022.
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.

FENTANYL TRANSMUCOSAL AGENTS			
Generic	Brand	Reviewed	Effective Date
FENTANYL CITRATE Edition 2	ACTIQ, ABSTRAL, FENTORA	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient has at least ONE of the following diagnoses:
    1. Cancer-related pain
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The patient is currently using the requested medication with a controlled-release pain medication (e.g., MS Contin, Oxycontin, Oramorph SR, Duramorph, Roxanol SR, Duragesic, Avinza or the generic forms of any of these drugs)
C. The patient has had a trial of an oral immediate-release pain medication (e.g., morphine sulfate immediate-release [MSIR], Percodan, Percocet, Vicodin, Tylenol with Codeine, Dilaudid, Demerol or the generic forms of any of these), unless they have difficulty swallowing tablets or capsules OR there is a contraindication
D. The patient has had a trial of generic fentanyl citrate lozenge (which also requires a prior authorization) unless there is a contraindication

References:

1. Actiq package insert. Parsippany, NJ. Teva Pharmaceuticals. Revised March 2021. Accessed June 2022.
2. Abstral package insert. Solana Beach, CA. Sentynl Therapeutics, Inc. Reviewed October 2019. Accessed June 2022.
3. Fentora package insert. Parsippany, NJ. Teva Pharmaceuticals. Reviewed March 2021. Accessed June 2022.
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.

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.

Generic	Brand	Reviewed	Effective Date
FLIBANSERIN Edition 2	ADDYI	7/29/2022	07/29/2022

REQUIREMENTS:

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

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD).
C. The patient meets **ALL** of the following criteria:
    1. Persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity that has persisted for at least 6 months
    2. HSDD is **NOT** a result of a co-existing medical or psychiatric condition, a problem within the relationship or the effects of a medication or drug substance
    3. HSDD symptom causes marked distress or interpersonal difficulty
D. The patient is a premenopausal female
E. The patient has had a previously had a trial of bupropion, unless there is a contraindication
F. The patient is **NOT** currently using Vyleesi (bremelanotide)

RENEWAL CRITERIA

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

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

References:

1. Addyi package insert. Raleigh, NC. Sprout Pharmaceuticals, Inc. Revised September 2021. Accessed June 2022.
2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Female Sexual Dysfunction: ACOG Practice Bulletin Clinical Management Guidelines for Obstetrician-Gynecologists, Number 213. Obstet Gynecol. 2019;134(1):e1-e18. doi:10.1097/AOG.0000000000003324.

Generic	Brand	Reviewed	Effective Date
FLUOROURACIL 0.5% CREAM Edition 1	CARAC	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of actinic or solar keratosis
B. The patient has previously tried at least **ONE** of the following:
    1. Generic topical agents (e.g., imiquimod 5%, diclofenac 3%, fluorouracil 5%, etc.)
    2. Preferred topical agents (e.g., Picato)

References:

1. Carac package insert**.** Bridgewater, NJ. Bausch Health US, LLC. Revised May 2022. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
FOSTAMATINIB Edition 2	TAVALISSE	7/29/2022	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. Patient has a diagnosis of chronic immune thrombocytopenia (ITP)
B. Patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist or immunologist
D. Patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days **OR** patient has an active bleed
E. Patient has had a previous trial of or contraindication to corticosteroids or immunoglobulins **OR** an insufficient response to a splenectomy
F. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Promacta (eltrombopag)
G. Patient has a previous trial of or contraindication to Doptelet (avatrombopag), Nplate (romiplostim), or Promacta (eltrombopag)

RENEWAL CRITERIA

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

A. Patient has chronic immune thrombocytopenia (ITP)
B. Patient has had a clinical response to therapy, as defined by an increase in platelet count or a reduction in bleeding events, compared to baseline

References:

1. Tavalisse package insert. South San Francisco, CA. Rigel Pharmaceuticals, Inc. Revised April 2018. Accessed June 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.

Generic	Brand	Reviewed	Effective Date
FOSTEMSAVIR Edition 1	RUKOBIA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection
B. The patient is 18 years of age or older
C. The requested medication will be used in combination with other antiretroviral(s)
D. The patient is treatment experienced
E. The patient has multidrug-resistant HIV-1 infection
F. The patient is failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

References:

1. Rukobia package insert. Research Triangle Park, NC. ViiV Healthcare. Revised January 2022. Accessed June 2022.
2. Saag MS, Gandhi RT, Hoy JF, et al. Antiviral drugs for treatment and prevention of HIV infection in adults. 2020 recommendations of the International Antiviral Society-USA Panel. JAMA. 2020;324(16):1651-1669.

Generic	Brand	Reviewed	Effective Date
FREMANEZUMAB-VFRM Edition 3	AJOVY	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

Our guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches

B. **If patient has episodic migraines (0-14 headache days per month), approval also requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed for the preventive treatment of migraines
   3. The patient has had a previous trial of at least ONE of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

C. If patient has chronic migraines (15 or more headache days per month), approval also requires:
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed for the preventive treatment of migraines
   3. The patient has had a previous trial of at least **ONE** of the following preventative migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox

RENEWAL CRITERIA

The guideline named **FREMANEZUMAB-VFRM (Ajovy)** requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines

B. Patient has responded to therapy as evidenced by at least **ONE** of the following:
   1. The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month compared to baseline
   2. The patient has experienced a reduction in migraine severity compared to baseline
   3. The patient has experienced a reduction in migraine duration compared to baseline

(Criteria continued on next page)

REQUIREMENTS: FREMANEZUMAB-VFRM (CONTINUED)

References:

1. Ajovy package insert. North Wales, PA. Teva Pharmaceuticals USA, Inc. Revised September 2021. Accessed June 2022.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

Generic	Brand	Reviewed	Effective Date
GALCANEZUMAB-GNLM Edition 2	EMGALITY	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for approval:

A. Patient has a diagnosis of migraine headaches or episodic cluster headaches
B. **If patient has episodic migraines (0-14 headache days per month), approval also requires:**
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine
C. **If patient has chronic migraines (15 or more headache days per month), approval also requires:**
    1. The patient is 18 years of age or older
    2. The requested medication is prescribed for the preventive treatment of migraines
    3. The patient has had a previous trial t ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, cyproheptadine, or Botox
D. **If patient has episodic cluster headaches, approval also requires:**
    1. The patient is 18 years of age or older

(Criteria continued on next page)

REQUIREMENTS: GALCANEZUMAB-GNLM (CONTINUED)

RENEWAL CRITERIA

Our guideline named **GALCANEZUMAB-GNLM (Emgality)** requires the following rule(s) be met for renewal:

A. The requested medication is being prescribed for preventive treatment of migraines OR for the treatment of episodic cluster headaches
B. **If patient has migraines, renewal also requires the patient has responded to therapy as evidenced by at least ONE of the following:**
    1. The patient has experienced a reduction in migraine or headache frequency of at least 2 days per month compared to baseline
    2. The patient has experienced a reduction in migraine severity compared to baseline
    3. The patient has experienced a reduction in migraine duration compared to baseline
C. **If patient has episodic cluster headaches, renewal also requires:**
    1. The patient has had improvement in episodic cluster headache frequency compared to baseline

References:

1. Emgality package insert. Indianapolis, IN. Eli Lilly and Company. Revised May 2022. Accessed June 2022.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.1345.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

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:

A. You are 2 years of age or older
B. Prescribed by or in consultation with a neurologist or epileptologist
C. 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)
D. Your seizures are inadequately controlled by at least 2 previous treatment regimens (i.e., clobazam, felbamate, lamotrigine, levetiracetam, topiramate, valproic acid, vigabatrin, zonisamide, etc.)
E. 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:

A. You have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD), as confirmed by genetic test
A. 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.

Generic	Brand	Reviewed	Effective Date
GEFITINIB Edition 1	IRESSA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of metastatic non-small cell lung cancer (NSCLC)
B. Patient has tumors with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA (Food and Drug Administration)-approved test

References:

1. Iressa package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised May 2021. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
GILTERITINIB FUMARATE Edition 1	XOSPATA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of relapsed or refractory acute myeloid leukemia (AML)
B. Patient is 18 years of age or older
C. You have FMS-like tyrosine kinase 3 (FLT3) mutation as detected by a Food and Drug Administration-approved test

References:

1. Xospata package insert. Northbrook, Illinois. Astellas Pharma US, Inc. Revised January 2022. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
GLASDEGIB MALEATE Edition 1	DAURISMO	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has newly-diagnosed acute myeloid leukemia (AML)
B. The requested medication will be used in combination with low-dose cytarabine
C. Patient is 75 years of age or older, **OR** patient has comorbidities that prevents the use of intensive induction chemotherapy

References:

1. Daurismo package insert. New York, NY. Pfizer Labs, Inc. Revised March 2020. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
GLECAPREVIR/ PIBRENTASVIR Edition 3	MAVYRET	7/29/2022	07/29/2022

REQUIREMENTS

The guideline named **GLECAPREVIR/PIBRENTASVIR (Mavyret)** requires the following rule(s) be met for approval:

A. The patient is 3 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. The patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis
G. The patient has previously tried **preferred** agents, sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) [genotype 1, 4, 5, 6 only], unless they have a contraindication to both. [NOTE: Patients with previous failure (i.e., did not achieve SVR) of a completed full course of treatment with sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) will NOT be approved.]

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has moderate or severe hepatic impairment (Child-Pugh B or C)
B. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References:

1. Mavyret package insert. North Chicago, IL. AbbVie Inc. Revised June 2021. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

Generic	Brand	Reviewed	Effective Date
GLYCEROL PHENYLBUTYRATE Edition 1	RAVICTI	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a urea cycle disorder
B. Documentation of confirmation of urea cycle disorder via enzymatic, biochemical, or genetic testing
C. The patient is 2 months of age or older
D. The requested medication will be used as adjunctive therapy along with dietary protein restriction
E. The patient's disorder cannot be managed by dietary protein restriction and/or amino acid supplementation alone
F. The patient does **NOT** have a deficiency of N-acetylglutamate synthetase or acute hyperammonemia
G. The patient has previously tried Buphenyl (sodium phenylbutyrate), unless there is a contraindication

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

A. The patient has a urea cycle disorder
B. The patient has had clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, mental status clarity, etc.).

References:

1. Ravicti package insert. Lake Forest, IL. Horizon Therapeutics USA, Inc. Revised September 2021. Accessed June 2022.
2. Diaz GA, Krivitzky LS, Mokhtarani M, et al. Ammonia control and neurocognitive outcome among urea cycle disorder patients treated with glycerol phenylbutyrate. Hepatology. 2013;57(6):2171-2179.

GLYCOPYRRONIUM TOPICAL			
Generic	Brand	Reviewed	Effective Date
GLYCOPYRRONIUM 2.4% CLOTH Edition 1	QBREXZA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of primary axillary hyperhidrosis
B. The patient is 9 years of age or older
C. The patient has had a trial of a prescription strength aluminum chloride product (e.g., Drysol)

References:

1. Qbrexza package insert. Menlo Park, California. Dermira, Inc. Revised April 2021. Accessed June 2022.
2. International Hyperhidrosis Society. Primary axillary hyperhidrosis treatment algorithm. Updated September 23, 2018. Available at: https://sweathelp.org/treatments-hcp/clinical-guidelines/primary-focalhyperhidrosis/primary-focal-axillary.html. Accessed June 2022.

WELLFLEET RX 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

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-IV (CONTINUED)

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

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

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.

(Criteria continued on next page)

REQUIREMENTS: GOLIMUMAB-IV (CONTINUED)

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.

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.

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.

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.

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
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.

ALLERGEN EXTRACT-HOUSE DUST MITE			
Generic	Brand	Reviewed	Effective Date
HOUSE DUST MITE Edition 1	ODACTRA	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of allergic rhinitis caused by house dust mites, with or without conjunctivitis
B. The patient's diagnosis is confirmed by in vitro testing for IgE antibodies *to Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts
C. The patient is between 18 and 65 years old
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent symptoms of allergic rhinitis presenting at least 4 days a week or for at least 4 weeks
F. The patient has moderate to severe symptoms of allergic rhinitis (i.e., troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work)
G. The patient has a current claim or prescription for auto-injectable epinephrine within the past 365 days

RENEWAL CRITERIA

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

A. The patient has experienced an improvement in signs and symptoms of allergic rhinitis from baseline

References:

1. Odactra package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised August 2019. Accessed June 2022.
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.

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 Orthovisc:

A. The patient is at least 21 years of age
B. The patient has failed a minimum of a 6-week trial of non-pharmacologic therapy such as education, exercise, use of insoles or braces, weight reduction and physical therapy
C. The patient had a previous trial of intra-articular steroids

For patients who have been previously treated on the same knee with Synvisc, Synvisc-One, Hyalgan, Euflexxa, Supartz, Gel-One, Monovisc, Orthovisc, Hymovis, or Gelsyn-3 approval requires:

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

References:

1. Euflexxa package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised July 2016. Accessed 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.

Generic	Brand	Reviewed	Effective Date
HYDROMORPHONE HCL ER Edition 2	EXALGO	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient meets at least ONE of the following:
    1. The patient meets the definition of opioid tolerance. This is defined as those who are taking, for one week or longer, at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone/day, 25mg oral oxymorphone/day, 8mg oral hydromorphone/day, or an equianalgesic dose of another opioid
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The requested medication is **NOT** prescribed on an as-needed basis
C. Dosages above 16mg require recommendation from a pain specialist

References:

1. Exalgo package insert. Webster Groves, MO. SpecGx LLC. Revised October 2019. Accessed June 2022.
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.

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.

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
IBRUTINIB Edition 1	IMBRUVICA	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Mantle cell lymphoma (MCL)
    2. Chronic lymphocytic leukemia (CLL)
    3. Small lymphocytic lymphoma (SLL)
    4. Waldenström's macroglobulinemia (WM)
    5. Marginal zone lymphoma (MZL)
    6. Chronic graft versus host disease
B. Patient is 18 years of age or older
C. Requests for Ibrutinib 140mg or 280mg tablets requires patient has had a trial of Ibrutinib 140mg capsules, unless there is a contraindication
D. **If patient has mantle cell lymphoma, approval also requires:**
    1. Patient has received at least one prior therapy for mantle cell lymphoma
E. **If patient has marginal zone lymphoma, approval also requires BOTH of the following:**
    1. Patient needs systemic therapy
    2. Patient has received at least one prior anti-CD20-based therapy (such as Rituxan)
F. **If patient has chronic graft versus host disease, approval also requires:**
    1. Patient has failed one or more lines of systemic therapy

References:

1. Imbruvica package insert. Horsham, PA. Reviewed Janssen Biotech, Inc. Revised May 2022. Accessed June 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
ICATIBANT Edition 1	FIRAZYR	07/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient is 18 years of age or older
C. The diagnosis is confirmed via complement testing
D. The requested medication is being used for treatment of acute attacks of hereditary angioedema
E. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist

References:

1. Firazyr package insert. Lexington, MA. Takeda Pharmaceutical Company. Revised October 2021. Accessed July 2022.
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.

Generic	Brand	Reviewed	Effective Date
IDELALISIB Edition 2	ZYDELIG	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. Patient has a diagnosis of relapsed chronic lymphocytic leukemia (CLL)
B. The requested medication will be used in combination with rituximab in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities

References:

1. Zydelig package insert. Foster City, CA. Gilead Sciences, Inc. Revised February 2022. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
ILOPROST Edition 1	VENTAVIS	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization Group 1
B. The requested medication is prescribed by or given in consultation with a cardiologist or pulmonologist
C. The patient has documentation confirming a diagnosis of pulmonary arterial hypertension based on right heart catheterization with the following values:
    1. Mean pulmonary artery pressure (PAP) greater than or equal to 25 mmHg
    2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    3. Pulmonary vascular resistance (PVR) greater than 3 Wood units
D. The patient has New York Heart Association-World Health Organization (NYHA-WHO) Functional Class III-IV symptoms

RENEWAL CRITERIA

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

A. The patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization Group 1
B. The patient meets at least ONE of the following:
    1. The patient has shown improvement from baseline in the 6-minute walk distance test
    2. The patient has remained stable in the 6-minute walk distance test AND their New York Heart Association-World Health Organization (NYHA-WHO) functional class has remained stable or improved

References:

1. Ventavis package insert. South San Francisco, CA. Actelion Pharmaceuticals US, Inc. Revised March 2022. Accessed July 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. 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.

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.

(Criteria continued on next page)

REQUIREMENTS: IMMUNE GLOBULIN (CONTINUED)

18. Stiebel-Kalish H, Robenshtok E, Hasanreisoglu M, Ezrachi D, Shimon I, Leibovici L. Treatment modalities for Graves' ophthalmopathy: systematic review and metaanalysis. J Clin Endocrinol Metab. 2009;94(8):2708-2716. doi:10.1210/jc.2009-0376.
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.
20. Yolken R, Kinney J, Wilde J, Willoughby R, Eiden J. Immunoglobulins and other modalities for the prevention and treatment of enteric viral infections. J Clin Immunol. 1990;10(6 Suppl):80S-87S. doi:10.1007/BF00918695.
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.
29. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society Guideline on management of paraproteinemic demyelinating neuropathies. Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society--first revision. J Peripher Nerv Syst. 2010;15(3):185-195. doi:10.1111/j.1529-8027.2010.00278.x.
30. Elovaara I, Apostolski S, van Doorn P, et al. EFNS guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases: EFNS task force on the use of intravenous immunoglobulin in treatment of neurological diseases [published correction appears in Eur J Neurol. 2009 Apr;16(4):547]. Eur J Neurol. 2008;15(9):893-908. doi:10.1111/j.1468-1331.2008.02246.x.
31. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol. 2015;136(5):1186-205.e2078. doi:10.1016/j.jaci.2015.04.049.
32. Marie I, Mouthon L. Therapy of polymyositis and dermatomyositis. Autoimmun Rev. 2011;11(1):6-13. doi:10.1016/j.autrev.2011.06.007.
33. Hallek M, Cheson BD, Catovsky D, et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. Blood. 2018;131(25):2745-2760. doi:10.1182/blood-2017-09-806398.
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.
35. Frankovich J, Swedo S, Murphy T, et al. Clinical Management of Pediatric Acute-Onset Neuropsychiatric Syndrome: Part II—Use of Immunomodulatory Therapies. J Child Adolesc Psychopharmacol. 2017;27(7):574.
36. Murrell DF, Peña S, Joly P, et al. Diagnosis and management of pemphigus: Recommendations of an international panel of experts. J Am Acad Dermatol. 2020;82(3):575-585.e1. doi:10.1016/j.jaad.2018.02.021.
37. Huang YC, Li YC, Chen TJ. The efficacy of intravenous immunoglobulin for the treatment of toxic epidermal necrolysis: a systematic review and meta-analysis. Br J Dermatol. 2012;167(2):424-432. doi:10.1111/j.1365-2133.2012.10965.x.

(Criteria continued on next page)

REQUIREMENTS: IMMUNE GLOBULIN (CONTINUED)

38. McKinney RE Jr, Katz SL, Wilfert CM. Chronic enteroviral meningoencephalitis in agammaglobulinemic patients. Rev Infect Dis. 1987;9(2):334-356. doi:10.1093/clinids/9.2.334.
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.

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.

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)

WELLFLEET RX STUDENT FORMULARY

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)

References:

1. Cetrotide package insert. Rockland, MA. EMD Serono, Inc. Revised May 2018. Accessed February 2022.
2. Pregnyl package insert. Roseland, NJ. Organon USA Inc. Revised April 2011. Accessed February 2022.
3. Novarel package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised September 2018. Accessed February 2022.
4. Ganirelix acetate package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised June 2021. Accessed February 2022.
5. Menopur package insert. Parsippany, NJ. Ferring Pharmaceuticals Inc. Revised May 2018. Accessed February 2022.
6. Ovidrel package insert. Rockland, MA. EMD Serono, Inc. Revised June 2018. Accessed February 2022.
7. Gonal-F package insert. Rockland, MA. EMD Serono, Inc. Revised December 2020. Accessed February 2022.
8. Gonal -F RFF package insert. Rockland, MA. EMD Serono, Inc. Revised December 2020 Accessed February 2022.
9. Follistim AQ package insert. Whitehouse Station, NJ. Merck & Co., Inc. Revised August 2011. Accessed February 2022.
10. Infertility Workup for the Women's Health Specialist: ACOG Committee Opinion, Number 781. Obstet Gynecol. 2019;133(6):e377-e384. doi:10.1097/AOG.0000000000003271.
11. ACOG Committee on Practice Bulletins-Gynecology. ACOG Practice Bulletin. Clinical management guidelines for obstetrician-gynecologists number 34, February 2002. Management of infertility caused by ovulatory dysfunction. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2002;99(2):347-358. doi:10.1016/s0029-7844(01)01768-9.
12. Practice Committee of American Society for Reproductive Medicine, Birmingham, Alabama. Gonadotropin preparations: past, present, and future perspectives. Fertil Steril. 2008;90(5 Suppl):S13-S20. doi:10.1016/j.fertnstert.2008.08.031.
13. Practice Committees of the American Society for Reproductive Medicine and Society for Reproductive Endocrinology and Infertility. Electronic address: asrm@asrm.org. Use of exogenous gonadotropins for ovulation induction in anovulatory women: a committee opinion. Fertil Steril. 2020;113(1):66-70. doi:10.1016/j.fertnstert.2019.09.020.
14. American Association of Clinical Endocrinologists (AACE) Hypogonadism Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients--2002 update. Endocr Pract. 2002;8(6):439-456.
15. Minhas S, Bettocchi C, Boeri L, et al. European Association of Urology Guidelines on Male Sexual and Reproductive Health: 2021 Update on Male Infertility [published online ahead of print, 2021 Sep 9]. Eur Urol. 2021;S0302-2838(21)01982-5. doi:10.1016/j.eururo.2021.08.014.
16. Centers for Disease Control and Prevention. 2018 Assisted Reproductive Technology Fertility Clinic Success Rates Report. Atlanta (GA): US Dept of Health and Human Services; 2020.
17. Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. Fertil Steril. 2013;99(1):37-43. doi:10.1016/j.fertnstert.2012.09.028
18. Oocyte cryopreservation. Committee Opinion No. 584. American College of Obstetricians and Gynecologists. Obstet Gynecol 2014;123:221–2.

Generic	Brand	Reviewed	Effective Date
INFIGRATINIB Edition 1	TRUSELTIQ	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma)
B. Prescribed by or in consultation with a hematologist/oncologist
C. Patient is 18 years of age or older
D. You have a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test

References:

1. Truseltiq package insert. Brisbane, CA. QED Therapeutics, Inc. Revised May 2021. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
INFLIXIMAB Edition 2	REMICADE	09/14/2022	9/14/2022
INFLIXIMAB	INFLIXIMAB (JANSSEN)		
INFLIXIMAB-ABDA	RENFLEXIS		
INFLIXIMAB-AXXQ	AVSOLA		
INFLIXIMAB-DYYB	INFLECTRA		

REQUIREMENTS:

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

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

A. 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 meet at least ONE of the following:
      a. 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
      b. You have fistulizing disease (perianal, enterocutaneous, or rectovaginal)
      c. You have a history of ileocolonic resection
   3. You meet ONE of the following:
      a. **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
      b. **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
      c. **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:
      a. **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
      b. **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
      c. **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.
6. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2021;73(7):1108-1123. doi:10.1002/art.41752.
7. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158(5):1450-1461. doi:10.1053/j.gastro.2020.01.006.
8. 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.
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
INSULIN REGULAR, HUMAN Edition 1	AFREZZA	7/29/2022	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. The patient has type 1 or type 2 diabetes
B. The patient is 18 years of age or older
C. The patient has a baseline spirometry to measure FEV_1
D. **For patient with type 1 diabetes, approval also requires:**
    1. The patient is using a long-acting insulin with the requested medication, and they have tried a formulary rapid acting insulin: Humalog
E. **For patients with type 2 diabetics, approval also requires:**
    1. The patient has tried a formulary rapid acting insulin: Humalog
    2. The patient's prescriber has indicated that they are physically unable or unwilling to use injectable insulin

RENEWAL CRITERIA

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

A. The patient has type 1 or type 2 diabetes
B. The patient has documentation of follow up spirometry to measure FEV_1 after 6 months of treatment and annually thereafter
C. The patient's FEV_1 has NOT declined 20% or more from baseline
D. **For patients with type 1 diabetes,** approval requires that they are using a long-acting insulin at the same time with the requested medication

References:

1. Afrezza package insert. Danbury, CT. MannKind Corporation. Revised February 2020. Accessed June 2022.
2. ADA Standards of Medical Care in Diabetes, Diabetes Care January 2020;43(Suppl. 1). Available at: http://care.diabetesjournals.org/content/43/Supplement_1. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
INOTERSEN SODIUM Edition 2	TEGSEDI	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
D. The patient has symptomatic polyneuropathy as determined by a baseline assessment (i.e., modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, etc.)
E. The patient has a documented diagnosis of hATTR as confirmed by **ONE** of the following:
    1. Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR (transthyretin) protein
    2. DNA genetic sequencing to confirm hATTR mutation

RENEWAL CRITERIA

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

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

References:

1. Tegsedi package insert. Waltham, MA. Sobi, Inc. Revised May 2021. Accessed June 2022.
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.

Generic	Brand	Reviewed	Effective Date
INTERFERON ALFA-2B Edition 2	INTRON A	7/29/2022	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **INTERFERON ALFA-2B (Intron A)** requires the following rule(s) be met for approval:

A. The requested medication is being used to treat one of the following:
   1. Chronic hepatitis C
   2. Hairy cell leukemia
   3. Condylomata acuminate
   4. AIDS-related Kaposi's sarcoma
   5. Chronic hepatitis B
   6. Malignant melanoma
   7. Chronic phase, Philadelphia chromosome positive chronic myelogenous leukemia
   8. Follicular lymphoma
   9. Multiple myeloma
   10. Polycythemia vera
   11. Renal cell carcinoma

B. **If the patient has chronic hepatitis C, approval also requires:**
   1. Patient is infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C
   2. Therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis
   3. Patient has compensated liver disease
   4. The requested medication will be used with ribavirin, unless there is a contraindication
   5. Patient has had a previous trial of or contraindication to a peginterferon product

(Criteria continued on next page)

REQUIREMENTS: INTERFERON ALFA-2B (CONTINUED)

RENEWAL CRITERIA

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

A. The request is for continuation of current therapy or renewal with Intron A therapy
B. **If patient is being treated for chronic hepatitis C, renewal also requires:**
    1. Therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis

References:

1. Intron A. package insert. Whitehouse Station, NJ. Merck & Co, Inc. Revised November 2021. Accessed June 2022.
2. Guilhot F, Chastang C, Michallet M, et al. Interferon alfa-2b combined with cytarabine versus interferon alone in chronic myelogenous leukemia. French Chronic Myeloid Leukemia Study Group. N Engl J Med. 1997;337(4):223-229. doi:10.1056/NEJM199707243370402.
3. Rini BI, Halabi S, Rosenberg JE, et al. Bevacizumab plus interferon alfa compared with interferon alfa monotherapy in patients with metastatic renal cell carcinoma: CALGB 90206. J Clin Oncol. 2008;26(33):5422-5428. doi:10.1200/JCO.2008.16.9847.
4. Barlogie B, Kyle RA, Anderson KC, et al. Standard chemotherapy compared with high-dose chemoradiotherapy for multiple myeloma: final results of phase III US Intergroup Trial S9321 [published correction appears in J Clin Oncol. 2006 Jun 10;24(17):2687. Moore, Dennis F Jr [added]]. J Clin Oncol. 2006;24(6):929-936. doi:10.1200/JCO.2005.04.5807.
5. McMullin MF, Harrison CN, Ali S, et al. A guideline for the diagnosis and management of polycythaemia vera. A British Society for Haematology Guideline [published correction appears in Br J Haematol. 2019 Apr;185(1):198]. Br J Haematol. 2019;184(2):176-191. doi:10.1111/bjh.15648.

Generic	Brand	Reviewed	Effective Date
INTERFERON GAMMA-1B, RECOMB. Edition 1	ACTIMMUNE	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD)
   2. Severe malignant osteopetrosis (SMO)

B. **For patients with chronic granulomatous disease, approval also requires:**
   1. The medication is prescribed by or given in consultation with a hematologist, infectious disease specialist, or immunologist

C. **For patients with severe malignant osteopetrosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist

RENEWAL CRITERIA

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

A. The patient has ONE of the following diagnoses:
   1. Chronic granulomatous disease (CGD)
   2. Severe malignant osteopetrosis (SMO)

B. The patient has shown clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections, etc.)

C. The patient has not received hematopoietic cell transplantation

References:

1. Actimmune package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised March 2021. Accessed June 2022.
2. Wu C, Econs M, DiMeglio L, et al. Diagnosis and management of osteopetrosis: consensus guidelines from the osteopetrosis working group. The Journal of Clinical Endocrinology & Metabolism. 2017;102:9:3111-3123.
3. Arnold D, Heimall J. A review of chronic granulomatous disease. Advanced Therapy. 2017;34:2543-2557.

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
ISTRADEFYLLINE Edition 1	NOURIANZ	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of Parkinson's disease
B. The patient is 18 years of age or older
C. The patient is experiencing 'OFF' episodes
D. The requested medication will be used along with levodopa/carbidopa
E. The patient has had a previous trial of or contraindication to **TWO** Parkinson's agents from **TWO** different drug classes:
    1. Dopamine agonists (e.g., ropinirole, pramipexole, rotigotine, etc.)
    2. Monoamine oxidase-inhibitors (e.g., selegiline, rasagiline, etc.)
    3. Catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone, etc.)

References:

1. Nourianz package insert. Bedminster, NJ. Kyowa Kirin Inc. Revised May 2020. Accessed June 2022.
2. Fox SH, Katzenschlager R, Lim SY, et al. International Parkinson and movement disorder society evidencebased medicine review: Update on treatments for the motor symptoms of Parkinson's disease. Mov Disord. 2018;33(8):1248-1266.

Generic	Brand	Reviewed	Effective Date
IVACAFTOR Edition 1	KALYDECO	7/29/2022	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. Patient is 4 months of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Documentation that patient is NOT homozygous for the F508del mutation in the CFTR gene
E. If patient is between 4 months and less than 6 years of age, **Ivacaftor packets** will be approved. Documentation of patient weight is required
F. Documentation that patient has ONE of the following mutations in the CFTR gene

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. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    1. Patient has maintained, or demonstrated less than expected decline in FEV_1
    2. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    3. Patient has experienced a reduction in rate of pulmonary exacerbations

References:

1. Kalydeco package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised December 2020. Accessed June 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.

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.

Generic	Brand	Reviewed	Effective Date
IXAZOMIB CITRATE Edition 1	NINLARO	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a diagnosis of multiple myeloma
B. The requested medication will be used in combination with lenalidomide and dexamethasone
C. Patient has received at least one prior therapy such as bortezomib, carfilzomib, thalidomide, lenalidomide, melphalan or stem cell transplantation

References:

1. Ninlaro package insert. Cambridge, MA. Takeda Pharmaceutical Company Limited. Revised April 2022. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
GLUTAMINE (L-GLUTAMINE) Edition 2	ENDARI	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of sickle cell disease
B. The patient is 5 years of age or older
C. The requested medication is prescribed by or given in consultation with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
D. The patient has had a previous trial of or contraindication to hydroxyurea
E. The patient will be using the requested medication concurrently with hydroxyurea, unless there is a contraindication
F. The patient has experienced acute complications of sickle-cell disease (e.g., sickle cell-related vaso-occlusive crises (VOC), hospitalizations, acute chest syndrome (ACS), etc.)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of sickle cell disease
B. The patient has maintained or experienced a reduction in acute complications of sickle-cell disease (e.g., number of sickle cell-related vaso-occlusive crises (VOC), hospitalizations, acute chest syndrome (ACS), etc.)

References:

1. Endari package insert. Torrance, CA. Emmaus Medical, Inc. Revised October 2020. Accessed July 2022.
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.

Generic	Brand	Reviewed	Effective Date
LANADELUMAB-FLYO Edition 1	TAKHZYRO	07/29/2022	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. The patient has a diagnosis of hereditary angioedema (HAE)
B. The diagnosis is confirmed by documented complement testing
C. The patient is 12 years of age or older
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or hematologist
E. The requested medication is being used for prevention of hereditary angioedema attacks
F. The patient will not be using the requested medication in combination with an alternative preventive agent for HAE (e.g., Cinryze, Haegarda, danazol, berotralstat, etc.)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of hereditary angioedema (HAE)
B. The patient has experienced clinical improvement in HAE attacks as evidenced by reductions in attack frequency or attack severity compared to baseline

References:

1. Takhzyro package insert. Lexington, MA. Dyax Corp. Revised February 2022. Accessed July 2022.
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.

Generic	Brand	Reviewed	Effective Date
LAPATINIB DITOSYLATE Edition 2	TYKERB	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient has a diagnosis of advanced or metastatic breast cancer
B. The patient has tumors which are human epidermal growth factor receptor 2 (HER2) positive
C. Prescribed by or in consultation with a hematologist or oncologist
D. **If the requested medication will be used in combination with Xeloda (capecitabine), approval also requires ALL of the following:**
    1. The patient has advanced or metastatic breast cancer
    2. Patient has previously received treatment with Herceptin (trastuzumab), an anthracycline (e.g., daunorubicin, doxorubicin, epirubicin, idarubicin), AND a taxane (e.g., paclitaxel, docetaxel)
E. **If the requested medication will be used in combination with Femara (letrozole), approval also requires ALL of the following:**
    1. The patient has tumors which are hormone receptor-positive
    2. The patient has metastatic breast cancer
    3. The patient is a postmenopausal woman

References:

1. Tykerb package insert. East Hanover, New Jersey. Novartis Pharmaceuticals Corporation. Revised March 2022. Accessed June 2022.

Generic	Brand	Reviewed	Effective Date
LAROTRECTINIB Edition 1	VITRAKVI	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. Patient has a solid tumor
B. The patient's tumor has a neurotrophic receptor tyrosine kinase (*NTRK)* gene fusion without a known acquired resistance mutation
C. The patient's tumor is metastatic or surgical resection is likely to result in severe morbidity
D. There are no satisfactory alternative treatments, or the patient's tumor has gotten worse after treatment
E. **Requests for Vitrakvi oral solution also require ONE of the following:**
    1. The patient is a pediatric patient (less than 18 years of age)
    2. Patient is unable to take Vitrakvi capsules due to difficulty swallowing (or dysphagia)
    3. The patient has other medical need for the oral solution

References:

1. Vitrakvi package insert. Whippany, NJ. Bayer HealthCare Pharmaceuticals Inc. Reviewed March 2021. Accessed June 2022.

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.

Generic	Brand	Reviewed	Effective Date
LEDIPASVIR/SOFOSBUVIR Edition 2	HARVONI	07/29/2022	07/29/2022

REQUIREMENTS:

The guideline named **LEDIPASVIR/SOFOSBUVIR (Harvoni)** requires the following rule(s) be met for approval:

A. The patient is 3 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 4, 5, or 6
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. **For patients with decompensated cirrhosis (Child-Pugh B or C), approval also requires:**
    1. The patient has decompensated cirrhosis (Child-Pugh B or C)
    2. The requested medication will be taken in combination with ribavirin, unless there is a contraindication

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References:

1. Harvoni package insert. Foster City, CA. Gilead Sciences, Inc. Revised March 2020. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

Generic	Brand	Reviewed	Effective Date
LEFAMULIN Edition 2	XENLETA	7/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient's infection is caused by any of the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae,* or *Chlamydophila pneumoniae*
C. The patient meets at least **ONE** of the following criteria:
    1. Request is for continuation of therapy initiated in a hospital from which member was discharged
    2. Request is for continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication
    3. The patient has a diagnosis of community-acquired bacterial pneumonia (CABP) and meets ONE of the following criteria (a or b):
        a. Antimicrobial susceptibility test is available **AND** the infection site culture results indicate pathogenic organism(s) exhibiting BOTH of the following:
            i. Resistance to at least **TWO** standard of care agents for community-acquired bacterial pneumonia (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone)
            ii. Susceptibility to lefamulin (Xenleta)
        b. Antimicrobial susceptibility test is unavailable **AND** the patient has had a trial of at least **TWO** standard of care agents (e.g., azithromycin, doxycycline, levofloxacin, moxifloxacin, amoxicillin, ceftriaxone, linezolid, etc.) for community-acquired bacterial pneumonia, unless there is a contraindication

References:

1. Xenleta package insert. Fort Washington, PA. Nabriva Therapeutics US, Inc. Revised June 2021. Accessed July 2022.
2. Metlay JP, Waterer GW, Long AC et al. Diagnosis and Treatment of Adults with Community-acquired Pneumonia: An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Disease Society of America, Am J Respir Crit Care Med. 2019 Oct; 200(7): e45-67.

Generic	Brand	Reviewed	Effective Date
LENALIDOMIDE Edition 1	REVLIMID	7/29/2022	6/1/2021

REQUIREMENTS:

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

A. The patient has **ONE** of the following diagnoses:
    1. Multiple myeloma (MM)
    2. Anemia due to a myelodysplastic syndrome (MDS)
    3. Mantle cell lymphoma (MCL)
    4. Follicular lymphoma (FL)
    5. Marginal zone lymphoma (MZL)

B. The patient is 18 years of age or older

C. **If the patient has anemia due to a myelodysplastic syndrome, approval also requires:**
    1. The patient has a deletion 5q abnormality

D. **If the patient has mantle cell lymphoma, approval also requires:**
    1. Patient has relapsed or progressed after two prior therapies and one of the therapies tried must be Velcade (bortezomib) (Note: Velcade may be covered under the medical benefit and/or require prior authorization).

E. **If the patient has follicular lymphoma, approval also requires:**
    1. Patient has previously been treated for follicular lymphoma
    2. The requested medication is being taken in combination with a rituximab product

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

References:

1. Revlimid package insert. Summit, NJ. Celgene Corporation. Revised May 2022. Accessed June 2022.

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.

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.

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.

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.

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.

Generic	Brand	Reviewed	Effective Date
LOMITAPIDE Edition 2	JUXTAPID	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient is 18 years of age or older
B. Patient has a diagnosis of Homozygous familial hypercholesterolemia (HoFH) confirmed by either genetic testing or untreated LDL-C greater than 500 mg/dL together with either xanthoma before 10 years of age or evidence of HeFH in both parents
C. The requested medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
D. Documentation of recent (within the last 60 days) LDL (low density lipoprotein) cholesterol level greater than or equal to 70 mg/dL
E. **If patient is statin tolerant, approval also requires:**
    1. Patient will continue statin treatment in combination with Juxtapid
    2. Patient meets **ONE** of the following criteria:
        i. Patient has been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily) for a duration of at least 8 weeks
        ii. Patient has been taking a maximally tolerated dose of any statin for a duration of at least 8 weeks and cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
F. **If patient is statin intolerant, approval also requires ONE of the following:**
    1. Patient has an absolute contraindication to statin therapy such as active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, or hypersensitivity reaction
    2. Patient has complete statin intolerance as defined by severe and intolerable adverse effects such as creatine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group. These must have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin.
G. Patient previously had a trial of Repatha (evolocumab) unless the patient does not have functional LDL receptors

(Criteria continued on next page)

REQUIREMENTS: LOMITAPIDE (CONTINUED)

References:

1. Juxtapid package insert. Cambridge, MA. Aegerion Pharmaceuticals, Inc. Revised December 2019. Accessed May 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 online ahead of print, 2021 May 24]. *Stroke*. 2021;STR0000000000000375.

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.

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.

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.

Generic	Brand	Reviewed	Effective Date
LUMACAFTOR/IVACAFTOR Edition 2	ORKAMBI	7/29/2022	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. Patient is 2 years of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Documentation that patient is homozygous for the *F508del*-CFTR mutation
E. If the patient is between 2 years and less than 6 years of age, **Orkambi packets** will be approved. Documentation of patient weight is required

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

A. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    1. Patient has improved, maintained, or demonstrated less than expected decline in FEV_1
    2. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    3. Patient has experienced a reduction in rate of pulmonary exacerbations

References:

1. Orkambi package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised August 2018. Accessed June 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.

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.

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.

Generic	Brand	Reviewed	Effective Date
LUSUTROMBOPAG Edition 2	MULPLETA	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA

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

A. Patient is 18 years of age or older
B. Patient has a diagnosis of thrombocytopenia due to chronic liver disease (CLD)
C. The requested medication is prescribed by or given in consultation with a hematologist, gastroenterologist, hepatologist, immunologist, or endocrinologist
D. Patient is scheduled to undergo a procedure 8 to 14 days after starting Mulpleta (lusutrombopag) therapy
E. Patient has a platelet count of less than $50x10^9$/L (50,000/µL) measured within the last 30 days
F. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Promacta (eltrombopag) or Tavalisse (fostamatinib)
G. Patient has a previous trial of or contraindication to Doptelet (avatrombopag)

RENEWAL CRITERIA (SEE INITIAL CRITERIA)

NOTE: Re-authorization is not permitted. Patients must meet the initial approval criteria.

References:

1. Mulpleta package insert. Florham Park, NJ. Shionogi Inc. Revised July 2018. Accessed June 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.

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.

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)
A. 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:

A. You have a diagnosis of Alagille syndrome (ALGS) 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. 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.

Generic	Brand	Reviewed	Effective Date
MAVACAMTEN Edition 1	CAMZYOS	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient is 18 years of age or older
B. Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM)
C. Prescribed by or in consultation with a cardiologist
D. Patient has documented evidence of ALL the following:
    1. Symptomatic New York Heart Association (NYHA) class II or III obstructive HCM
    2. Left ventricular ejection fraction (LVEF) of at least 55%
    3. Valsalva left ventricular outflow tract (LVOT) peak gradient of at least 50 mmHg at rest or with provocation
E. Patient has previous trial with inadequate response or contraindication to ONE of the following:
    1. Non-vasodilating beta blockers (i.e., atenolol, bisoprolol, metoprolol, nadolol, pindolol, propranolol, sotalol, timolol)
    2. Non-dihydropyridine calcium channel blockers (i.e., diltiazem, verapamil)
F. Patient will NOT concurrently be taking any of the following regimens along with the requested medication:
    1. dual therapy with beta blocker and calcium channel blocker
    2. disopyramide
    3. ranolazine

RENEWAL CRITERIA

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

A. Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM)
B. Patient has responded positively to therapy as evidenced by ONE of the following when compared to baseline:
    1. Mixed venous oxygen tension (pVO2) improvement by at least 1.5ml/kg/min plus at least one NYHA class reduction
    2. Mixed venous oxygen tension (pVO2) improvement by at least 3.0ml/kg/min without any NYHA class worsening

(Criteria continued next page)

REQUIREMENTS: MAVACAMTEN (CONTINUED)

References:

1. Camzyos package insert. Brisbane, CA. MyoKardia, Inc. Revised April 2022. Accessed May 2022.
2. Writing Committee Members, Ommen SR, Mital S, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Thorac Cardiovasc Surg. 2021;162(1):e23-e106. doi:10.1016/j.jtcvs.2021.04.001.

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.

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.

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.

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.

Generic	Brand	Reviewed	Effective Date
MEPOLIZUMAB Edition 3	NUCALA	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. Severe asthma with an eosinophilic phenotype
    2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome
    3. Hypereosinophilic syndrome (HES)
    4. Chronic rhinosinusitis with nasal polyps (CRSwNP)

B. **If the patient has eosinophilic granulomatosis with polyangiitis, approval also requires:**
    1. The patient is 18 years of age or older
    2. The patient has been stable on oral corticosteroids (OCS) with inadequate response, unless there is a contraindication

C. **If the patient has hypereosinophilic syndrome (HES), approval also requires:**
    1. The patient is 12 years of age or older
    2. The patient has had HES for 6 months or more without an identifiable non-hematologic secondary cause
    3. The patient has been stable on oral corticosteroids, immunosuppressive, or cytotoxic therapy with inadequate response and will continue as maintenance therapy along with the requested medication, unless there is a contraindication

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

D. **If the patient has chronic rhinosinusitis with nasal polyps (CRSwNP), approval also requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with an otolaryngologist, allergist, or immunologist
   3. Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
   4. The patient is currently adherent to maintenance therapy with an intranasal corticosteroid (e.g., fluticasone, mometasone, etc.)
   5. The patient has inadequately controlled disease as determined by **ONE** or more of the following:
      a. Use of systemic corticosteroids in the past 2 years
      b. Endoscopic sinus surgery
   6. The requested medication will be used as add-on maintenance treatment in conjunction with maintenance intranasal steroids
   7. The patient is not being treated on the requested medication concurrently with Xolair or Dupixent

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

E. **If the patient has severe asthma with an eosinophilic phenotype, approval also requires:**
   1. The patient is 6 years of age or older
   2. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
   3. The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
   4. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA)(e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
   5. The patient has asthma that is uncontrolled while maintained on ICS plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE of the following:
      a. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
      b. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
   6. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication [i.e., LAMA, LABA, LTRA, theophylline]) OR an ICS-containing combination inhaler
   7. The patient is not being treated on the requested medication concurrently with Xolair, Dupixent, Tezspire or another anti-IL-5 asthma biologic (e.g., Cinqair, Fasenra, etc.)

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has ONE of the following diagnoses:
    1. Severe asthma with an eosinophilic phenotype
    2. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome
    3. Hypereosinophilic syndrome (HES)
    4. Chronic rhinosinusitis with nasal polyps (CRSwNP)

B. **If the patient has eosinophilic granulomatosis with polyangiitis (EGPA), renewal also requires the following:**
    1. The patient has had a clinical benefit compared to baseline (e.g., reduction in number of relapses, reduction in rate of relapse, etc.)

C. **If the patient has hypereosinophilic syndrome (HES), renewal also requires the following:**
    1. The patient has had a clinical benefit compared to baseline (e.g., reduction in number of disease flares, reduction in total steroid use, reduction in absolute eosinophil count, etc.)

D. **If the patient has severe asthma with an eosinophilic phenotype, renewal also requires ALL of the following:**
    1. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
    2. The patient has shown a clinical response as evidenced by ONE of the following:
        a. Reduction in asthma exacerbation(s)compared to baseline
        b. Decreased use of rescue medications
        c. Increase in percent predicted FEV_1 from pretreatment baseline
        d. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

E. If the patient has chronic rhinosinusitis with nasal polyps (CRSwNP), renewal also requires:
    1. The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, improved sense of smell, or reduced size of polyps, etc.)

(Criteria continued on next page)

REQUIREMENTS: MEPOLIZUMAB (CONTINUED)

References:

1. Nucala package insert. Research Triangle Park, NC. GlaxoSmithKline. Revised January 2022. Accessed June 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. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
4. Shomali W, Gotlib J. World Health Organization-defined eosinophilic disorders: 2019 update on diagnosis, risk stratification, and management. Am J Hematol. 2019;94(10):1149-1167. doi:10.1002/ajh.25617.
5. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss) (EGPA) Consensus Task Force recommendations for evaluation and management. Eur J Intern Med. 2015;26(7):545-553. doi:10.1016/j.ejim.2015.04.022.

Generic	Brand	Reviewed	Effective Date
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.

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.

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.

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.

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.

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.

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)

WELLFLEET RX STUDENT FORMULARY

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.

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.

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.

ALLERGEN EXTRACT-MIXED GRASS POLLEN			
Generic	Brand	Reviewed	Effective Date
GR POL-ORC/SW VER/RYE/KENT/TIM Edition 1	ORALAIR	7/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **ALLERGEN EXTRACT-MIXED GRASS POLLEN (Oralair)** requires the following rule(s) be met for approval:

A. The patient has a diagnosis of allergic rhinitis caused by grass pollen
B. The patient is between 5 and 65 years of age
C. The patient's diagnosis is confirmed by a positive skin prick test and/or a positive titer to specific IgE (Immunoglobulin E) antibodies for any of the five grass types included in Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens)
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent and moderate-to-severe symptoms of allergic rhinitis [Note: persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work]
F. The patient has a current claim or prescription for auto-injectable epinephrine

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

A. The patient has experienced an improvement in signs and symptoms of allergic rhinitis compared to baseline.

References:
1. Oralair package insert. Lenoir, N.C. GREER Laboratories, Inc. Revised November 2018. Accessed July 2022.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

Generic	Brand	Reviewed	Effective Date
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.

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.

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
NATALIZUMAB Edition 2	TYSABRI	9/14/2022	9/14/2022

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 meet at least ONE of the following:
      a. 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
      b. You have fistulizing disease (perianal, enterocutaneous, or rectovaginal)
      c. You have a history of ileocolonic resection
   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, Skyrizi, or Stelara

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.

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.

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.

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.

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
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.

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.

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.

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

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:
      a. You have previously tried any TWO agents indicated for the treatment of multiple sclerosis (MS) (**Please note:** The following agents are preferred and may also require prior authorization: Avonex, Copaxone/Glatiramer/Glatopa, Gilenya, Plegridy, Rebif, Betaseron, dimethyl fumarate, Mavenclad, Mayzent, Vumerity, Aubagio, Kesimpta)
      b. You show signs of severe disease requiring high-efficacy disease modifying therapy (DMT) such as high lesion (affected areas) volume and/or count, walking disability, or rapid decline

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.

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.

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:
        a. Surgical resection (removal by surgery)
        b. Pituitary irradiation (radiation therapy directed at the pituitary)
        c. 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.

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.

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

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.

Edition3	Reviewed	Effective Date
Off Label Policy	07/29/2022	07/29/2022
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: (*see VT specific criteria for exception)

1. **VT specific criteria**: The drug is approved by the FDA, except for drugs which are medically accepted for treatment of cancer
2. Off-Label use is supported by sufficient scientific evidence which includes ONE of the following:
    a. Supported by at least ONE nationally recognized drug database such as the following authoritative compendia (list is not all-inclusive):
        i. NCCN: The level of evidence for the indication is Category 1 or 2A
        ii. DrugDex: The level of evidence for the indication is Class III
        iii. AHFS-DI (The American Hospital Formulary Service Drug Information): The narrative text is supportive
        iv. Clinical Pharmacology: The narrative text is supportive
        v. Lexi-Drugs: The indication is listed as "Use: Off-Label" and rated as "Evidence Level A."
        vi. The American Medical Association Drug Evaluations
        vii. The United States Pharmacopoeia Dispensing Information, volume 1
        viii. Drug Information for Health Care Professionals
    b. Supported by TWO separate articles in major peer reviewed medical journals/clinical practice guidelines. (**Exception:** Cancer indications will only require evidence from ONE article or clinical practice guideline); AND

(Criteria continued on next page)

REQUIREMENTS: OFF-LABEL POLICY (CONTINUED)

3. The drug is prescribed for the treatment of a life-threatening condition including cancer, HIV or AIDS (This requirement DOES NOT apply to the following states: **IL**, **MA**, 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.

Generic	Brand	Reviewed	Effective Date
OLANZAPINE/SAMIDORPHAN Edition 1	LYBALVI	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has one of the following diagnoses:
    1. Schizophrenia
    2. Bipolar I disorder
C. The requested medication is prescribed by or given in consultation with a psychiatrist or mental health specialist
D. The patient does not have a known opioid use disorder
E. The patient is not dependent on opioids for a chronic medical condition
F. The patient has tried and failed at least **TWO** preferred oral generic second-generation antipsychotics (e.g., olanzapine, aripiprazole, quetiapine, risperidone, etc.)
G. **For patients with Bipolar I disorder, approval also requires at least ONE of the following:**
    1. The requested medication is being used as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
    2. The requested medication is being used as maintenance monotherapy treatment

(Criteria continued next page)

REQUIREMENTS: OLANZAPINE/SAMIDORPHAN (CONTINUED)

RENEWAL CRITERIA

The guideline named **OLANZAPINE/SAMIDORPHAN (Lybalvi)** requires the following rule(s) to be met for renewal:

A. The patient has one of the following diagnoses:
    1. Schizophrenia
    2. Bipolar I disorder
B. The patient has experienced or maintained an improvement in symptoms compared to baseline

References

1. Lybalvi package insert. Waltham, MA. Alkermes, Inc. Revised May 2021. Accessed July 2022.
2. American Psychiatric Association. Practice Guideline for the treatment of patients with bipolar disorder, Second Edition. April 2002. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/bipolar.pdf. Accessed July 2022.
3. American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia. Third Edition. 2021. Available at: https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890424841. Accessed July 2022.

WELLFLEET RX STUDENT FORMULARY

Generic	Brand	Reviewed	Effective Date
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:
      a. 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
      b. Your cancer is homologous recombination deficiency (HRD: type of gene mutation) positive
         i. HRD status is defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
         ii. Lynparza will be used in combination with bevacizumab

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by 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:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. The requested medication will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin, degarelix)

References:

1. Lynparza package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised March 2022. Accessed March 2022.

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.

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.

Generic	Brand	Reviewed	Effective Date
OMALIZUMAB Edition 3	XOLAIR	7/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has ONE of the following diagnoses:
   1. Nasal polyps
   2. Chronic spontaneous urticaria (CSU)
   3. Moderate to severe persistent asthma

B. **For patients with nasal polyps, approval also requires ALL of the following:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with an otolaryngologist, allergist, or immunologist
   3. Documentation of evidence of nasal polyps by direct examination, endoscopy or sinus CT scan
   4. The patient is currently adherent to maintenance therapy with an intranasal corticosteroid (e.g., fluticasone, mometasone, etc.)
   5. The patient has inadequately controlled disease as determined by ONE of the following:
      a. Use of systemic corticosteroids in the past 2 years
      b. Endoscopic sinus surgery
   6. The requested medication will be used as add-on maintenance treatment in conjunction with maintenance intranasal steroids
   7. The patient is not being treated on the requested medication concurrently with Dupixent or an anti-IL-5 biologic (e.g., Nucala, etc.)

(Criteria continued on next page)

REQUIREMENTS: OMALIZUMAB (CONTINUED)

C. For patients with chronic spontaneous urticaria (CSU), approval also requires ALL of the following:

1. The patient is 12 years of age or older
2. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
3. The patient still experiences hives on most days of the week for at least 6 weeks
4. The patient remains symptomatic despite a trial with second generation (non-sedating) H1 antihistamine therapy (i.e., cetirizine, desloratadine, fexofenadine, levocetirizine, or loratadine) at maximized dosing used continuously for at least 2 weeks
5. Patient remains symptomatic despite a two-week continuous trial of at least ONE of the following:
    a. Higher dose (up to four times the recommended dose) of the second generation (non-sedating) H1 antihistamine therapy
    b. Addition of another second generation (non-sedating) H1 antihistamine to existing therapy
    c. Addition of a leukotriene receptor antagonist (LTRA) to existing therapy
    d. Addition of a H2-antagonist to existing therapy
    e. Addition of a first generation H1 antihistamine taken at bedtime to existing therapy

(Criteria continued on next page)

REQUIREMENTS: OMALIZUMAB (CONTINUED)

D. **For patients with moderate to severe persistent asthma, approval requires ALL of the following:**
   1. The patient is 6 years of age or older
   2. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
   3. The patient has a baseline positive skin prick or RAST test to a perennial aeroallergen
   4. The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
   5. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
   6. The patient has asthma that is uncontrolled while maintained on an ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler AND experienced ONE or more of the following:
      a. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
      b. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
   7. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler
   8. The patient is not being treated on the requested medication concurrently with Dupixent, Tezspire, or an anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra, etc.)

(Criteria continued on next page)

REQUIREMENTS: OMALIZUMAB (CONTINUED)

RENEWAL CRITERIA

Our guideline named **OMALIZUMAB (Xolair)** the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
   1. Nasal polyps
   2. Chronic spontaneous urticaria (CSU)
   3. Moderate to severe persistent asthma

B. **For patients with nasal polyps, renewal also requires:**
   1. The patient has had a clinical benefit compared to baseline (e.g., improvements in nasal congestion, improved sense of smell, reduced size of polyps, etc.)

C. **For patients with chronic spontaneous urticaria, renewal also requires:**
   1. The patient has had a clinical benefit compared to baseline (e.g., decreased severity of itching, decreased number of hives, decreased size of hives, etc.)

D. **For patients with moderate to severe persistent asthma, renewal also requires:**
   1. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
   2. The patient has shown a clinical response as evidenced by at least ONE of the following:
      a. Reduction in asthma exacerbation(s) compared to baseline
      b. Decreased use of rescue medications
      c. Increase in percent predicted FEV_1 from pretreatment baseline
      d. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

References:

1. Xolair package insert. South San Francisco, CA. Genentech, Inc. Revised July 2021. Accessed June 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. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.
4. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. Allergy. 2019;74(12):2312-2319. doi:10.1111/all.13875.
5. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-1277. doi:10.1016/j.jaci.2014.02.036.

OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR Edition 2			
Generic	Brand	Reviewed	Effective Date
OMBITASVIR/ PARITAPREVIR/ RITONAVIR/DASABUVIR	VIEKIRA PAK	07/29/2022	07/29/2022
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. The patient is 18 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection shown with at least ONE detectable HCV RNA level within the past 6 months
F. The patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis
G. The patient is treatment naïve or treatment experienced with peginterferon and ribavirin
H. The patient has previously tried **preferred** agents, sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni), unless contraindication to both. [**NOTE:** Patients with previous failure (i.e., did not achieve SVR) of a completed full course of treatment with sofosbuvir/velpatasvir (Epclusa) or ledipasvir/sofosbuvir (Harvoni) will NOT be approved)
I. **For patients with chronic HCV genotype 1a, approval also requires:**
    1. The requested medication will be used concurrently with ribavirin

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has moderate or severe liver impairment (Child Pugh B or C)
B. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

(Criteria continued on next page)

REQUIREMENTS: OMBITASVIR/PARITAPREVIR/RITONAVIR/DASABUVIR (CONTINUED)

References

1. Viekira Pak/Viekira Pak XR package insert. North Chicago, IL. AbbVie Inc. Revised November 2019. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

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.

OPIOID-BENZODIAZEPINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/29/2022	7/23/2021

REQUIREMENTS:

Our guideline named **OPIOID-BENZODIAZEPINE CONCURRENT USE** allows for an approval of the use of an opioid in combination with a benzodiazepine when at least ONE of the following criteria is met:

A. The patient has active cancer
B. The patient is receiving palliative care or end-of-life care
C. The patient is enrolled in a hospice
D. The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
E. The patient has a diagnosis of sickle cell disease
F. The patient's doctor confirms to proceed with the concurrent use of an opioid and a benzodiazepine for a clinically appropriate indication

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from the CMS 2019 Call Letter:
"We expect that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit (which can be overridden by the pharmacist) to prompt additional safety review at the time of dispensing beginning in 2019."*CMS 2019 Call Letter, page 251*
The claim will deny when there is concurrent use of benzodiazepines and opioids with any overlap in day supply. This can be overridden at POS or by a Prior Authorization. If the pharmacy does not submit the specified PPS codes, the claim should reject unless a prior approval is in place.
This guideline allows an approval for patients with one of the following conditions:

- Diagnosis of active cancer
- Receiving palliative care or end-of-life care
- Enrolled in hospice
- Resident of a long-term care facility or intermediate care for intellectually disabled
- Diagnosis of sickle cell disease
- Physician attestation that the prescriber is aware that the patient is concurrently receiving a benzodiazepine with an opioid(s) and would like to proceed with an opioid and benzodiazepine

(Continued on next page)

REQUIREMENTS: OPIOID-BENZODIAZEPINE CONCURRENT USE (CONTINUED)

References:

1. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/MEDICARE/HEALTH-PLANS/MEDICAREADVTGSPECRATESTATS/DOWNLOADS/ANNOUNCEMENT2019.PDF [Accessed 7/6/22].
2. Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point of Sale (POS) Safety Edits. Available at: https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-2021.pdf [Accessed 7/06/22].
3. CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/122120-cms-2482-f-medicaid-dur-ofr-master-webposting-508.pdf [Accessed 7/06/22].
4. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource-Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
5. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

OPIOID-BUPRENORPHINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/29/2022	7/23/2021

REQUIREMENTS:

Our guideline named **OPIOID-BUPRENORPHINE CONCURRENT USE** allows approval for use of an opioid in combination with buprenorphine or a buprenorphine-containing agent when at least ONE of the following rule(s) is met:

A. The patient has active cancer
B. The patient is receiving palliative care or end-of-life care
C. The patient is enrolled in a hospice
D. The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
E. The patient's doctor confirms that the patient has discontinued or will be discontinuing opioid dependency treatment with buprenorphine or buprenorphine-containing agents and the patient needs to resume chronic opioid treatment. Consultation with an addiction medicine specialist is recommended.
F. The patient's doctor is aware that the patient is currently receiving buprenorphine, or a buprenorphine containing agent for treatment of opioid dependency and has confirmed to proceed with opioid treatment for an acute, clinically appropriate indication. Consultation with an addiction medicine specialist is recommended

RATIONALE

To ensure appropriate use of opioids and addressing prescription opioid overuse from a medication safety perspective while preserving patient access to medically necessary drug regimens. In addition, align with the opioid restrictions from CMS guidance. For further information, please refer to the Drug Monograph for Opioid-Buprenorphine Concurrent Use.

References:

1. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Available at: https://www.cms.gov/MEDICARE/HEALTH-PLANS/MEDICAREADVTGSPECRATESTATS/DOWNLOADS/ANNOUNCEMENT2019.PDF [Accessed 7/06/22].
2. CMS 2482 Final Rule - SUPPORT II: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. Available at: https://www.cms.gov/files/document/frequently-asked-questions-about-formulary-level-opioid-point-sale-safety-edits-2021.pdf [Accessed 7/06/22].
3. Osman H, Shrestha S, Temin S, et al. Palliative Care in the Global Setting: ASCO Resource Stratified Practice Guideline. *J Glob Oncol*. 2018;4:1-24.
4. Ferrell BR, Twaddle ML, Melnick A, Meier DE. National Consensus Project Clinical Practice Guidelines for Quality Palliative Care Guidelines, 4th Edition. *J Palliat Med*. 2018;21(12):1684-1689.

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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WELLFLEET RX STUDENT FORMULARY

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.

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.

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WELLFLEET RX STUDENT FORMULARY

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.

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.

OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE Edition 2			
Generic	Brand	Reviewed	Effective Date
N/A	N/A	7/29/2022	7/23/2021

REQUIREMENTS:

Our guideline named **OPIOID-SOMA-BENZODIAZEPINE CONCURRENT USE** allows an approval for use of an opioid in combination with Soma (carisoprodol) along with a benzodiazepine medication when one of the following criteria is met:

A. The patient has active cancer
B. The patient is receiving palliative care or end-of-life care
C. The patient is enrolled in a hospice
D. The patient is a resident of a long-term care facility or intermediate care for intellectually disabled
E. The patient's doctor confirms that the use of an opioid concurrently with Soma (carisoprodol) along with a benzodiazepine medication is intended and for a clinically appropriate indication

RATIONALE

To mitigate the risk of the overdose from dangerous combinations of CNS depressants while preserving patient access to drug regimens if deemed medically necessary.

The Opioid-Benzodiazepine-Soma Concurrent Use at POS edit will identify and deny concurrent use of opioids, benzodiazepines, and carisoprodol when there is an overlap in day supply (for at least one drug from each 'class'). This edit will reject the claim that creates the three-drug overlap. The edit will have internal reject codes REJ- 433- 1204, and the following parameters:

1. Triple drug overlap = 1 day
2. Prescriber threshold = 1 prescriber
3. Exceptions =
    a. Cancer diagnosis (edit will lookback for presence of claims related to these diseases in the past 180 days to automatically exclude from the edit)
    b. Hospice or palliative care (edit will look for hospice attribute on claims to automatically exclude from the edit)
    c. Long Term Care residence (edit will look for patient residence code to automatically exclude from the edit)

Please note that sickle cell disease will not be included in the exception criteria. Although opioids and benzodiazepines can be used in managing pain crises, treatment guidelines do not mention skeletal muscle relaxants such as carisoprodol as a typical treatment modality.

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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.

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.

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:
        a. You have progressed (your condition has worsened) while on or after EGFR tyrosine kinase-inhibitor therapy. Examples of EGFR tyrosine kinase-inhibitor therapy include Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
        b. You are not currently receiving therapy with an EGFR tyrosine kinase-inhibitor such as Tarceva (erlotinib), Iressa (gefitinib), or Gilotrif (afatinib dimaleate)
    2. You are positive for epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (types of genes) mutations as confirmed by an FDA-approved test AND you have not received prior systemic treatment (therapy that travels through the blood) for metastatic non-small cell lung cancer
D. **If you have non-small cell lung cancer, approval also requires ALL of the following:**
    1. The requested medication is being used as adjuvant therapy (add-on treatment) after tumor resection (surgical removal of a tumor)
    2. You are positive for an epidermal growth factor receptor (EGFR: type of protein) exon 19 deletions or exon 21 L858R (type of genes) mutations as confirmed by a FDA-approved test

References:

1. Tagrisso package insert. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised January 2022. Accessed March 2022.

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.

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
B. 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.

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:
        a. You are a postmenopausal female OR a male
        b. You have NOT received endocrine (hormone)-based therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        c. Your disease has NOT worsened after 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:
        a. Your disease has worsened after endocrine (hormone) therapy (such as letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
        b. 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
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:
    a. Severe combined immunodeficiency (SCID)
    b. Acquired immunodeficiency syndrome (AIDS)
    c. Chemotherapy recipient
    d. 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
    a. Chronic lung disease (respiratory distress and/or the need for positive pressure respiratory support or oxygen)
    b. 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:
      a. 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:
         i. You need medication to control chronic heart failure and will require heart surgical procedures
         ii. You have moderate to severe pulmonary hypertension (high blood pressure in the lungs)
      b. 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:
      a. Severe combined immunodeficiency (SCID)
      b. Acquired immunodeficiency syndrome (AIDS)
      c. Chemotherapy recipient
      d. 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:
      a. Supplemental oxygen
      b. Diuretic (drug that makes you urinate)
      c. Chronic systemic corticosteroid therapy
   3. You are receiving a heart transplant during RSV season
   4. You have cystic fibrosis and at least ONE of the following:
      a. Previous hospitalization for pulmonary exacerbation in the first year of life
      b. Abnormalities on chest radiography, or chest computed tomography that persist when stable
      c. Weight for length is less than the 10^{th} percentile.

(Criteria continued on next page)

REQUIREMENTS: PALIVIZUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. 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/ .

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.

Generic	Brand	Reviewed	Effective Date
PARATHYROID HORMONE Edition 1	NATPARA	10/29/2021	6/1/2021

REQUIREMENTS:

Our guideline for **PARATHYROID HORMONE (Natpara)** 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.

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.

Generic	Brand	Reviewed	Effective Date
PATISIRAN Edition 2	ONPATTRO	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
D. The patient has symptomatic polyneuropathy as determined by a baseline assessment (i.e., modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, etc.)The patient has a documented diagnosis of hATTR as confirmed by **ONE** of the following:
    1. Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm the presence of TTR (transthyretin) protein
    2. DNA genetic sequencing to confirm hATTR mutation

RENEWAL CRITERIA

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

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

References:

1. Onpattro package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised May 2021. Accessed June 2022.
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.

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.

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.

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:
    1. You have a persistent peanut allergy (your peanut allergy has not gone away)
    2. If you have undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 3 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 0.35 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months
    3. If you have NOT undergone a purposeful food challenge: you have documentation of a persistent peanut allergy based on a positive skin prick test (wheal diameter of 8 mm or greater) (skin test to check for peanut allergy) OR peanut-specific immunoglobulin E (IgE level at 14 kUA/L or greater) (blood test that indicates an allergy to peanuts) within the past 24 months

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.

PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON) Edition 2			
Generic	Brand	Reviewed	Effective Date
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	07/29/2022	07/29/2022
PEGINTERFERON ALFA-2B	PEGINTRON		

REQUIREMENTS:

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

A. The patient has one of the following diagnoses:
   1. Chronic hepatitis C virus (HCV) infection
   2. Chronic hepatitis B infection

B. The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, a doctor specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model

C. **For patients with chronic hepatitis B, approval also requires:**
   1. The patient is 3 years of age or older
   2. The patient does not have cirrhosis
   3. The patient has tested positive for HBeAg
   4. The patient has evidence of viral replication with high serum ALT

D. **For patients with chronic hepatitis C, approval also requires:**
   1. The patient is 3 years of age or older
   2. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
   3. The requested medication is being used in combination with ribavirin, unless there is a contraindication
   4. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months

References:

1. Pegasys package insert. South San Francisco, CA. Genentech USA, Inc. Revised March 2021. Accessed July 2022.
2. Pegintron package insert. Whitehouse Station, NJ. Marck Shapr & Dohme Corp. Revised January 2019. Accessed July 2022.
3. Ghany MG, Morgan TR; AASLD-IDSA Hepatitis C Guidance Panel. Hepatitis C Guidance 2019 Update: American Association for the Study of Liver Diseases-Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Hepatology*. 2020;71(2):686-721. doi:10.1002/hep.31060.
4. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

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.

Generic	Brand	Reviewed	Effective Date
PEGLOTICASE Edition 1	KRYSTEXXA	07/29/2022	6/1/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of chronic gout that is refractory to conventional therapy
B. The patient is 18 years of age or older
C. The patient has symptomatic gout as evidenced by at least **ONE** of the following:
    1. At least 3 or more gout flares in the previous 18 months
    2. History of at least 1 gout tophus
    3. Gouty arthritis
D. The patient has had baseline serum uric acid levels of at least 8 mg/dL while on conventional gout medications (e.g., allopurinol [Zyloprim], lesinurad [Zurampic], febuxostat [Uloric], etc.)
E. The patient does not have a glucose-6-phosphate dehydrogenase (G6PD) deficiency
F. The patient will NOT be taking urate-lowering therapy (e.g., xanthine oxidase inhibitors, febuxostat, probenecid, lesinurad, etc.) concurrently with the requested medication
G. The patient has experienced failure, contraindication, intolerance or inadequate response to previous trial with a maximum tolerated dose for **TWO** conventional gout medications for at least 3 months (e.g., allopurinol, probenecid, lesinurad, febuxostat etc.)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of chronic gout
B. The patient has experienced a clinical response to therapy as evidenced by a sustained serum uric level below 6 mg/dL

References:

1. Krystexxa package insert. Deerfield, IL. Horizon Therapeutics USA, Inc. Revised March 2021. Accessed July 2022.
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.

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.

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.

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:
        a. You have blood levels of the copper-protein ceruloplasmin less than 20mg/dL; or
        b. Your liver biopsy (sample cells taken from your liver) shows you have an abnormally high amount of copper (greater than 250mcg/g dry weight) **OR** the presence of Kayser-Fleischer rings (rings around the iris of your eye); or
        c. Your diagnosis has been confirmed by genetic testing for ATP7B (type of gene) mutations

(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:
      a. Kidney stone analysis shows that there is cystine (an amino acid);
      b. Urine analysis shows there are hexagonal cystine crystals in your urine that are pathognomonic (signs relating to the disease)
      c. You have a family history of cystinuria with positive tests results in the 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):
      a. Increased fluid intake
      b. Modest reductions in sodium and protein intake
      c. Urinary alkalinization (a process that makes urine basic)
   4. The medication is prescribed by or given in consultation with a nephrologist (kidney doctor)
   5. For Cuprimine requests, you must have a previous trial of Depen (penicillamine) **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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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

(Criteria continued on next page)

REQUIREMENTS: PYRIMETHAMINE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of congenital toxoplasmosis, please refer to Initial Criteria section. Our guideline for **PYRIMETHAMINE (Daraprim)** requires the following rule(s) be met for renewal:

A. The request is ONE of the following:
    1. Acute treatment of toxoplasmosis (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

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

Edition 2	Reviewed	Effective Date
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)

REQUIREMENTS: QUANTITY LIMIT EXCEPTION (CONTINUED)

Appendix A:

Requests for endocrine treatment of gender-dysphoric/gender-incongruent persons should utilize the following dosing chart taken from the Endocrine Society Clinical Practice Guidelines. Doses outside these parameters will require the provider to submit medical literature supporting the requested dose.

Transgender females		
Estrogen		
Oral		
	Estradiol	2.0–6.0 mg/d
Transdermal		
	Estradiol transdermal patch (New patch placed every 3–5 d)	0.025–0.2 mg/d
Parenteral		
	Estradiol valerate or cypionate	5–30 mg IM every 2 wk 2–10 mg IM every week
Anti-androgens		
	Spironolactone	100–300 mg/d
	GnRH agonist (Lupron Depot)	3.75 mg SQ (SC) monthly 11.25 mg SQ (SC) 3-monthly
Transgender males		
Testosterone		
Parenteral testosterone		
	Testosterone enanthate or cypionate	100–200 mg SQ (IM) every 2 wk or SQ (SC) 50% per week
	Testosterone undecanoate	1000 mg every 12 wk
Transdermal testosterone		
	Testosterone gel	50–100 mg/d
	Testosterone transdermal patch	2.5–7.5 mg/d

References:

1. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658.
2. World Professional Association for Transgender Health. (2012). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People [7th Version]. https://www.wpath.org/publications/soc .

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.

Generic	Brand	Reviewed	Effective Date
RAVULIZUMAB-CWVZ Edition 3	ULTOMIRIS	7/29/2022	7/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH)
   2. Atypical hemolytic uremic syndrome (aHUS)
   3. Generalized myasthenia gravis (gMG)

B. **For patients with paroxysmal nocturnal hemoglobinuria (PNH), approval also requires:**
   1. The patient is 1 month of age or older weighing 5kg or greater
   2. There is documentation of the patient's current weight
   3. The requested medication is prescribed by or given in consultation with a hematologist
   4. The patient has confirmed paroxysmal nocturnal hemoglobinuria as supported by **ALL** of the following via flow cytometry:
      a. At least 2 different GPI-protein deficiencies (i.e., CD55, CD59) on at least 2 cell lineages (i.e., erythrocytes, granulocytes)
      b. Paroxysmal nocturnal hemoglobinuria granulocyte clone size of 10% or greater
   5. The patient meets **ONE** of the following:
      a. The patient is transitioning from alternative complement inhibitor therapy (such as Soliris)
      b. There is evidence of intravascular hemolysis (e.g., lactate dehydrogenase level of at least 1.5 times the upper limit of normal, hemoglobinuria, etc.)
      c. The patient has history of major adverse vascular event from thromboembolism

C. **For patients with atypical hemolytic uremic syndrome (aHUS), approval also requires:**
   1. The patient is one month of age or older weighing 5kg or greater
   2. There is documentation of the patient's current weight

(Criteria continued on next page)

REQUIREMENTS: RAVULIZUMAB-CWVZ (CONTINUED)

D. **For patients with generalized myasthenia gravis (gMG), approval also requires:**
   1. The patient is 18 years of age or older weighing 40kg or greater
   2. Therapy is prescribed by or in consultation with a neurologist
   3. The patient diagnosis is confirmed by a positive anti-acetylcholine receptor (AChR) antibody test
   4. The patient has Myasthenia Gravis Foundation of America class II, III, or IV
   5. The patient has had a trial of corticosteroids, unless there is contraindication
   6. The patient meets ONE of the following:
      i. Failure of treatment with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate, etc.)
      ii. Failure of treatment with at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange

RENEWAL CRITERIA

Our guideline named **RAVULIZUMAB-CWVZ (Ultomiris)** requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
   1. Paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder in which red blood cells break apart prematurely)
   2. Atypical hemolytic uremic syndrome (aHUS)
   3. Generalized myasthenia gravis (gMG)

B. **For patients with paroxysmal nocturnal hemoglobinuria, renewal also requires:**
   1. The patient has shown a clinical benefit (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase and hemoglobin levels, etc.) compared to baseline
   2. There is documentation patient's current weight is 5kg or greater

C. **For patients with atypical hemolytic uremic syndrome, renewal also requires:**
   1. There is documentation patient's current weight is 5kg or greater

D. **For patients with generalized myasthenia gravis, renewal also requires:**
   1. The patient has shown clinical benefit according to validated gMG instruments (e.g., Myasthenia Gravis Activities of Daily Living tool, Quantitative Myasthenia Gravis tool, etc.) compared to baseline
   2. There is documentation patient's current weight is 40kg or greater

(Criteria continued on next page)

REQUIREMENTS: RAVULIZUMAB-CWVZ (CONTINUED)

References:

1. Ultomiris package insert. Boston, MA. Alexion Pharmaceuticals, Inc. Reviewed April 2022. Accessed June 2022.
2. Borowitz MJ, Craig FE, Digiuseppe JA, et al. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Cytometry B Clin Cytom. 2010;78(4):211-230. doi:10.1002/cyto.b.20525.
3. Loirat C, Fakhouri F, Ariceta G, et al. An international consensus approach to the management of atypical hemolytic uremic syndrome in children. Pediatr Nephrol. 2016;31(1):15-39. doi:10.1007/s00467-015-3076-8.
4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790.
5. Jaretzki A 3rd, Barohn RJ, Ernstoff RM, et al. Myasthenia gravis: recommendations for clinical research standards. Task Force of the Medical Scientific Advisory Board of the Myasthenia Gravis Foundation of America. Ann Thorac Surg. 2000;70(1):327-334. doi:10.1016/s0003-4975(00)01595-2.

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.

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.

Generic	Brand	Reviewed	Effective Date
RESLIZUMAB Edition 2	CINQAIR	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of severe asthma with an eosinophilic phenotype
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a pulmonologist, allergist, or immunologist
D. The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
E. The patient is currently adherent to treatment with an inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone, etc.) PLUS at least ONE other maintenance medication such as a long-acting inhaled beta2-agonist (LABA) (e.g., formoterol, salmeterol, etc.), a long-acting muscarinic antagonist (LAMA) (e.g., tiotropium, aclidinium, etc.), a leukotriene receptor antagonist (LTRA) (e.g., montelukast, zafirlukast, etc.), theophylline, OR an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
F. The patient has asthma that is uncontrolled while maintained on ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) or an ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.) AND experienced ONE or more of the following:
    1. At least TWO asthma exacerbations requiring treatment with a systemic corticosteroid (or an increase in dose if already on oral corticosteroid) within the past 12 months
    2. At least ONE asthma exacerbation requiring hospitalization, urgent care or emergency room visit within the past 12 months
G. The requested medication will be used as add-on maintenance treatment with continued use of ICS plus at least ONE other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) or ICS-containing combination inhalers (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
H. The patient is not being treated on the requested medication concurrently with Xolair, Dupixent, Tezspire or another anti-IL5 asthma biologic (e.g., Nucala, Fasenra)
I. The patient must have a previous trial and failure with at least ONE preferred agent: Dupixent, Fasenra, or Nucala

(Criteria continued on next page)

REQUIREMENTS: RESLIZUMAB (CONTINUED)

RENEWAL CRITERIA

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

A. The patient has a diagnosis of severe asthma with an eosinophilic phenotype
B. The patient is currently adherent to maintenance therapy with an inhaled corticosteroid (ICS) plus one other maintenance medication (i.e., LAMA, LABA, LTRA, theophylline) or ICS-containing combination inhaler (e.g., Advair, Breo Ellipta, Dulera, Symbicort, Trelegy, etc.)
C. The patient has shown a clinical response as evidenced by at least ONE of the following:
    1. Reduction in asthma exacerbation(s) compared to baseline
    2. Decreased use of rescue medications
    3. Increase in percent predicted $FEV_1$from pretreatment baseline
    4. Reduction in severity or frequency of asthma-related symptoms such as wheezing, shortness of breath, coughing, etc.

References:

1. Cinqair package insert. West Chester, PA. Teva Respiratory, LLC. Revised February 2020. Accessed June 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. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org.

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.

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.

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.

Generic	Brand	Reviewed	Effective Date
RIMEGEPANT Edition 5	NURTEC ODT	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient is being treated for ONE of the following:
    1. Acute migraine headache
    2. Episodic migraine headaches
B. **If patient has acute migraine headache, approval also requires:**
    1. The patient is 18 years of age or older
    2. The patient has had a previous trial of at least ONE triptan (e.g., sumatriptan, rizatriptan, etc.), unless there is a contraindication
C. **If patient has episodic migraines (0-14 headache days per month), approval also requires**
    1. The patient is 18 years of age or older
    2. The requested medication is being prescribed for preventive treatment of migraines
    3. The patient has had a previous trial of at least ONE of the following preventive migraine treatments: Valproic acid/divalproex sodium, topiramate, propranolol, timolol, amitriptyline, venlafaxine, atenolol, nadolol, lisinopril, candesartan, clonidine, guanfacine, carbamazepine, nebivolol, pindolol, or cyproheptadine

RENEWAL CRITERIA
Our guideline named **RIMEGEPANT (Nurtec ODT)** requires the following rule(s) be met for renewal:

A. Patient is being treated for ONE of the following:
    1. Acute migraine headache
    2. Episodic migraine headaches

(Criteria continued on next page)

REQUIREMENTS: RIMEGEPANT CONTINUED)

B. **If patient has acute migraines, renewal also requires ONE of the following:**
   1. Patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINEACT])
   2. Patient has experienced clinical improvement as defined by ONE of the following:
      a. Ability to function normally within 2 hours of dose
      b. Headache pain disappears within 2 hours of dose
      c. Treatment works consistently in majority of migraine attacks

C. **If patient has episodic migraines, renewal also requires:**
   1. The requested medication is being prescribed for preventive treatment of migraines
   2. Patient has responded to therapy as evidenced by at least ONE of the following:
      a. The patient has experienced less migraines or headache attacks by at least 2 days per month compared to baseline
      b. The patient has experienced a lessening in migraine severity compared to baseline
      c. The patient has experienced a lessening in migraine duration compared to baseline

References:

1. Nurtec ODT package insert. New Haven, CT. Biohaven Pharmaceuticals, Inc. Reviewed May 2021. Accessed June 2022.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

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.

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.

Generic	Brand	Reviewed	Effective Date
RISANKIZUMAB-RZAA Edition 4	SKYRIZI	9/14/2022	09/14/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO)
   2. Psoriatic arthritis (PsA)
   3. Moderately to severely active Crohn's disease (CD)

B. The patient is 18 years of age or older

C. **For patients with moderate to severe plaque psoriasis (PsO), approval requires:**
   1. The requested medication is prescribed by or given in consultation with a dermatologist
   2. The patient has 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
   3. 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

D. **For patients with psoriatic arthritis (PsA), approval requires:**
   1. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
   2. The patient has had a previous trial of at least one of the following DMARDs (disease-modifying antirheumatic drugs) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

E. **For patients with moderately to severely active Crohn's disease (CD), approval requires:**
   1. The requested medication is prescribed by or given in consultation with a gastroenterologist
   2. The patient meets at least ONE of the following:
      a. The patient has had a previous trial of at least ONE of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
      b. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
      c. The patient has a history of ileocolonic resection

(Criteria continued on next page)

REQUIREMENTS: RISANKIZUMAB-RZAA (CONTINUED)

RENEWAL CRITERIA

The guideline named **RISANKIZUMAB-RZAA (Skyrizi)** requires the following rule(s) be met for renewal:

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe plaque psoriasis (PsO)
   2. Psoriatic arthritis (PsA)
   3. Moderately to severely active Crohn's disease (CD)

B. **For patients with moderate to severe plaque psoriasis (PsO), renewal also requires:**
   1. 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

C. **For patients with 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

References

1. Skyrizi package insert. North Chicago, IL. AbbVie Inc. Revised June 2022. Accessed June 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. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022.

Generic	Brand	Reviewed	Effective Date
RISDIPLAM Edition 2	EVRYSDI	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of type 1, type 2, or type 3 spinal muscular atrophy (SMA)
B. The requested medication is prescribed by or given in consultation with a neurologist, neuromuscular specialist, or spinal muscular atrophy (SMA) specialist
C. The diagnosis of spinal muscular atrophy (SMA) is confirmed by documentation of a gene mutation analysis indicating mutations or deletions of both alleles of the survival motor neuron 1 (SMN1) gene reported (i.e., homozygous deletions, homozygous mutations, or compound heterozygous mutations)
D. The patient is not being treated on the requested medication concurrently with Spinraza (nusinersen) or Zolgensma (onasemnogene abeparvovec)
E. There is documentation showing up to four copies of survival motor neuron 2 (SMN2)
F. The patient does not have permanent ventilator dependence (e.g., invasive ventilation/tracheostomy, non-invasive ventilation beyond use for naps and nighttime sleep, etc.)
G. There is documentation showing the patient had a baseline motor function assessment (e.g., Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), etc.)
H. If the patient previously had gene therapy with Zolgensma, then there is documentation they had less than expected clinical benefit per motor function assessment

RENEWAL CRITERIA

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

A. The patient has a diagnosis of type 1, type 2, or type 3 spinal muscular atrophy (SMA)
B. The patient has shown a clinical response as evidenced by at least ONE of the following:
    1. The patient has improved, maintained, or demonstrated a less than expected decline in motor function assessments compared to baseline(e.g., Hammersmith Infant Neurological Examination (HINE), Hammersmith Functional Motor Scale - Expanded (HFMSE),Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND), etc.)
    2. The patient has improved, maintained, or demonstrated a less than expected decline in other muscle function such as pulmonary function (i.e., ventilator dependence)

(Criteria continued on next page)

REQUIREMENTS: RISDIPLAM (CONTINUED)

References:

1. Evrysdi package insert. South San Francisco, CA. Genentech, Inc. Revised May 2022. Accessed June 2022.
2. Committee Opinion No. 691: Carrier Screening for Genetic Conditions. *Obstet Gynecol*. 2017;129(3):e41-e55. doi:10.1097/AOG.0000000000001952
3. Arnold WA, Kassar D, Kissel JT. Spinal Muscular Atrophy: Diagnosis and Management in a New Therapeutic Era. Muscle Nerve 2015 Feb; 51(2): 157-167.
4. Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. *J Neuromuscul Dis*. 2018;5(2):145-158. doi:10.3233/JND-180304.

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.

Generic	Brand	Reviewed	Effective Date
ROMIPLOSTIM Edition 1	NPLATE	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. Patient has ONE of the following diagnoses:
    1. Immune thrombocytopenia (ITP)
    2. Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS)
B. **If patient has immune thrombocytopenia (ITP), approval also requires:**
    1. Patient is 1 year of age or older
    2. Patient has a platelet count of less than 30 x 10^9/L (30,000/µL) measured within the last 30 days **OR** patient has an active bleed
    3. Patient has previously tried or has a contraindication to corticosteroids or immunoglobulins, **OR** patient had an insufficient response to a splenectomy
    4. The requested medication is prescribed by or given in consultation with a hematologist or immunologist
    5. Patient is not receiving other thrombocytopenia treatments such as Doptelet (avatrombopag), Nplate (romiplostim), Mulpleta (lusutrombopag), or Tavalisse (fostamatinib)
    6. **If patient is between 1 and 17 years old, approval also requires:**
        a. Patient has had immune thrombocytopenia (ITP) for at least 6 months
C. **If patient has hematopoietic syndrome of acute radiation syndrome, approval also requires:**
    1. The requested medication is prescribed by or given in consultation with a hematologist
    2. Patient has been acutely exposed to myelosuppressive doses of radiation

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

A. Patient has a diagnosis of immune thrombocytopenia (ITP)
B. Patient had a clinical response to therapy, as defined by an increase in platelet count or a reduction in bleeding events, compared to baseline

NOTE: For the diagnoses of Hematopoietic Syndrome of Acute Radiation Syndrome (HSARS), please refer to the Initial Criteria section. Re-authorization is not permitted. Patients must meet the initial approval criteria for this diagnosis.

(Continued on next page)

REQUIREMENTS: ROMIPLOSTIM (CONTINUED)

References:

1. Nplate package insert. Thousand Oaks, CA. Amgen Inc. Revised February 2022. Accessed June 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. Christensen DM, Iddins CJ, Parrillo SJ, Glassman ES, and Goans RE. Management of ionizing radiation injuries and illnesses, part 4: acute radiation syndrome. J Am Osteopath Assoc. 2014;114: 702-711. doi: 10.7556/jaoa.2014.138.

Generic	Brand	Reviewed	Effective Date
ROMOSOZUMAB-AQQG Edition 2	EVENITY	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of postmenopausal osteoporosis
B. The patient has not received a total of 12 months or more of Evenity therapy.
C. The patient meets **ONE** of the following criteria:
    1. The patient is at high risk for fractures as defined by **ONE** of the following:
        a. History of fragility or osteoporotic fracture(s)
        b. Bone mineral density [BMD] T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip and/or 33% (one third) radius (wrist).
        c. T-score between -1.0 and -2.5 **AND** FRAX score greater than or equal to 20% for any major fracture or greater than or equal to 3% for hip fracture
    2. The patient is unable to use oral therapy (e.g., upper gastrointestinal [GI] problems - unable to tolerate oral medication, lower GI problems - unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)
    3. The patient has had a previous trial and failure of ONE oral or injectable bisphosphonate such as Fosamax (alendronate), Actonel (risedronate), Boniva (ibandronate), Reclast (zoledronic acid), unless there is a contraindication

References:

1. Evenity package insert. Thousand Oaks, CA. Amgen Inc. Revised April 2020. Accessed June 2022.
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.

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
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
RUXOLITINIB PHOSPHATE Edition 3	JAKAFI	4/29/2022	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.

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.

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.

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
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.

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.

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.

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:
        a. Tumor Necrosis Factor Inhibitor (TNFi): Enbrel, Humira, Cimzia, or an infliximab product (e.g., Remicade, biosimilars)
        b. Interleukin (IL)-23 blocker: Skyrizi, Tremfya
        c. IL-12/23 blocker: Stelara SC
        d. IL-17 blocker: Taltz
        e. 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:
      a. TNFi: Enbrel, Humira, Cimzia, an infliximab product (e.g., Remicade, biosimilars), Simponi SC, or Simponi Aria
      b. IL-23 blocker: Tremfya
      c. IL-12/23 blocker: Stelara SC
      d. IL-17 blocker: Taltz
      e. Janus Kinase (JAK) inhibitor: Xeljanz/Xeljanz XR
         i. A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product
      f. 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:
      a. C-reactive protein (CRP: a measure of how much inflammation you have) levels above the upper limit of normal
      b. Sacroiliitis (type of inflammation where lower spine and pelvis connect) on magnetic resonance imaging (MRI)
   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.

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.

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:
        a. Two proteasome inhibitors (such as bortezomib, carfilzomib)
        b. Two immunomodulatory agents (such as lenalidomide, pomalidomide)
        c. One anti-CD38 monoclonal antibody (such as daratumumab)
E. **If 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.

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.

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.

Generic	Brand	Reviewed	Effective Date
SETMELANOTIDE ACETATE Edition 3	IMCIVREE	7/29/2022	7/29/2022

REQUIREMENTS:

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

A. The request is for chronic weight loss management
B. The patient is at least 6 years of age or older
C. The requested medication is prescribed by or in consultation with an endocrinologist, a geneticist, or a physician who specializes in metabolic disorders
D. The patient has obesity which is due to ONE of the following:
    1. Proopiomelanocortin (POMC) deficiency
    2. Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency
    3. Leptin receptor (LEPR) deficiency
    4. Bardet-Biedl syndrome (BBS)
E. For patients with POMC, PSCK1 or LEPR deficiency, approval requires the patient meets the following criteria:
    1. If the patient is at least 18 years of age, then they currently have body mass index (BMI) of 30 kg/m2 or greater
    2. If the patient is 6 to 17 years of age, then they currently have a BMI in the 95th percentile or greater for age and sex
    3. Confirmed genetic testing shows variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
F. For patients with Bardet-Biedl Syndrome, approval requires the patient meets ONE of the following criteria:
    1. If the patient is at least 18 years of age, then they currently have body mass index (BMI) of 30 kg/m2 or greater
    2. If the patient is 6 to 17 years of age, then they currently have a BMI in the 97th percentile or greater for age and sex

(Criteria continued on next page)

REQUIREMENTS: SETMELANOTIDE (CONTINUED)

RENEWAL CRITERIA

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

A. The request is for chronic weight loss management
B. The patient has obesity which is due to ONE of the following:
    1. Proopiomelanocortin (POMC) deficiency
    2. Proprotein convertase subtilisin/kexin type 1 (PCSK1) deficiency
    3. Leptin receptor (LEPR) deficiency
    4. Bardet-Biedl syndrome (BBS)
C. The patient has shown a clinical response as evidenced by ONE or more of the following:
    1. At least a 5% loss of baseline body weight
    2. At least a 5% loss of baseline body mass index (BMI)

References:

1. Imcivree package insert. Boston, MA. Rhythm Pharmaceuticals Inc. Revised June 2022. Accessed June 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.
3. Guo DF, Rahmouni K. Molecular basis of the obesity associated with Bardet-Biedl syndrome. Trends Endocrinol Metab. 2011;22(7):286-293. doi:10.1016/j.tem.2011.02.009.

ALLERGEN EXTRACT- SHORT RAGWEED POLLEN			
Generic	Brand	Reviewed	Effective Date
WEED POLLEN- SHORT RAGWEED Edition 2	RAGWITEK	7/29/2022	7/23/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of allergic rhinitis caused by short ragweed pollen
B. The patient is between 5 and 65 years of age
C. The patient's diagnosis is confirmed by a positive skin prick test and/or a positive titer to specific IgE (Immunoglobulin E) antibodies for short ragweed pollen
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent and moderate-to-severe symptoms of allergic rhinitis [Note: persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work]
F. The patient has a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

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

A. The patient has experienced an improvement in signs and symptoms of allergic rhinitis compared to baseline

References:

1. Ragwitek package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised April 2021. Accessed July 2022.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

Generic	Brand	Reviewed	Effective Date
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.

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.**
    1. MSLT mean sleep latency 8 minutes or less, including REM sleep episodes during 2* or more test periods (aka SOREMPs)
        a. *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
    2. 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.**
    1. 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.
    2. The presence of at least one of the following:
        a. MSLT shows mean sleep latency 8 minutes or less
        b. 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).

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WELLFLEET RX STUDENT FORMULARY

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	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.**
    1. MSLT mean sleep latency 8 minutes or less, including REM sleep episodes during 2* or more test periods (aka SOREMPs)
        a. *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
    2. 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

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.

Generic	Brand	Reviewed	Effective Date
SODIUM ZIRCONIUM CYCLOSILICATE Edition 1	LOKELMA	7/29/2022	6/1/2021

REQUIREMENTS:

The guideline named **SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma)** requires the following rule(s) be met for approval:

A. The patient is 18 years of age or older
B. The patient has a diagnosis of non-life threatening hyperkalemia
C. The requested drug is **NOT** being used as an emergency treatment for life-threatening hyperkalemia
D. The requested drug will **NOT** be used in a patient currently receiving dialysis
E. The requested drug is being prescribed by or in consultation with a nephrologist or cardiologist
F. The patient has attempted any **ONE** of the following approaches in an effort to reduce the modifiable risks for hyperkalemia:
    a. Limit to taking no more than one of the following drugs at any given time:
        1. Angiotensin converting enzyme inhibitor (ACE-I)
        2. Angiotensin receptor blocker (ARB)
    b. Consideration of dose reduction of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE-I's, ARB's, aldosterone antagonists)
    c. The patient has tried to treat hyperkalemia with loop diuretics (e.g., bumetanide, ethacrynic acid, furosemide, torsemide) if estimated glomerular filtration rate (eGFR) is below 30mL/min/1.73 m^2, or with loop diuretics or thiazide diuretics (e.g., chlorthalidone, hydrochlorothiazide, metolazone) if eGFR is 30 mL/min/1.73 m^2 or above

References:

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

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR Edition 2	SOVALDI	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
B. The patient is 3 to 17 years old with chronic HCV genotype 2 or 3
C. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
D. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
E. The patient has compensated cirrhosis (Child-Pugh A) or does not have cirrhosis
F. The patient has previously tried the **preferred** agent, sofosbuvir/velpatasvir (Epclusa), unless they have a contraindication. [NOTE: Patients with previous failure (i.e. did not achieve SVR) of a completed full course of treatment with sofosbuvir/velpatasvir (Epclusa) will NOT be approved.]
G. The requested medication will be used in combination with ribavirin

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions
B. The patient has moderate or severe hepatic impairment (Child-Pugh B or C)

References:

1. Sovaldi package insert. Foster City, CA. Gilead Sciences, Inc. Revised March 2020. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022.

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR/ VELPATASVIR Edition 3	EPCLUSA	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 3 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
D. The requested medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least ONE detectable HCV RNA level within the last 6 months
F. **For patients with decompensated cirrhosis (Child Pugh B or C), approval also requires:**
    1. The requested medication will be used concurrently with ribavirin, unless there is a contraindication

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

References:

1. Epclusa package insert. Foster City, CA. Gilead Sciences, Inc. Revised April 2022. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022.

Generic	Brand	Reviewed	Effective Date
SOFOSBUVIR/ VELPATASVIR/ VOXILAPREVIR Edition 2	VOSEVI	07/29/2022	07/29/2022

REQUIREMENTS:

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

A. The patient is 18 years of age or older
B. The patient has a diagnosis of chronic hepatitis C virus (HCV) infection
C. The patient has chronic HCV genotype 1, 2, 3, 4, 5, or 6
D. The medication is prescribed by or given in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis, or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
E. The patient has documentation of chronic HCV infection with at least **ONE** detectable HCV RNA level within the last 6 months
F. The patient has compensated cirrhosis (Child-Pugh A) OR does not have cirrhosis
G. **For patients with chronic HCV genotype 1b, 2, 4, 5, or 6, approval also requires:**
    1. The patient has previously failed a full course of therapy with a direct-acting antiviral (DAA) regimen that **contains** an NS5A inhibitor (e.g., ledipasvir/sofosbuvir (Harvoni), sofosbuvir/velpatasvir (Epclusa), Mavyret, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination, etc.)
H. **For patients with chronic HCV genotype 1a or genotype 3, approval also requires ONE of the following:**
    1. The patient has previously failed a full course of therapy with a DAA regimen that **contains** an NS5A inhibitor (e.g., ledipasvir/sofosbuvir (Harvoni), sofosbuvir/velpatasvir (Epclusa), Mavyret, Technivie, Viekira Pak or Viekira XR, Zepatier, or Daklinza/Sovaldi combination, etc.)
    2. The patient has previously failed a full course of therapy with a DAA regimen that contains sofosbuvir (Sovaldi) **without** an NS5A inhibitor (e.g., Sovaldi/ribavirin, Sovaldi/peginterferon/ribavirin, Olysio/Sovaldi, etc.)

The requested medication will NOT be approved for patients exhibiting ANY of the following:

A. The patient has moderate or severe hepatic impairment (Child-Pugh B or C)
B. The patient has a limited life expectancy of less than 12 months due to non-liver related comorbid conditions

(Criteria continued on next page)

WELLFLEET RX STUDENT FORMULARY

REQUIREMENTS: SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (CONTINUED)

References:

1. Vosevi package insert. Foster City, CA. Gilead Sciences, Inc. Revised November 2019. Accessed July 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.
3. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. [Accessed 07/07/2022].

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:
        a. 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)
        b. 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)
        c. 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.

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.

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 female 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.

Generic	Brand	Reviewed	Effective Date
SOTORASIB Edition 1	LUMAKRAS	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. Patient is 18 years or older
B. Prescribed by or in consultation with a hematologist/oncologist
C. The patient has locally advanced or metastatic non-small cell lung cancer (NSCLC)
D. The patient has a tumor with an abnormal KRAS G12C gene mutation as determined by an FDA-approved test
E. Patient has received at least ONE prior systemic therapy

References:

1. Lumakras package insert. Thousand Oaks, CA. Amgen Inc. Revised May 2021. Accessed June 2022.

WELLFLEET RX STUDENT FORMULARY

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

Edition 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

(Criteria continued on next page)

REQUIREMENTS: STEP THERAPY EXCEPTION (CONTINUED)

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

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.

SUFENTANIL			
Generic	Brand	Reviewed	Effective Date
SUFENTANIL CITRATE Edition 2	DSUVIA	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient has ONE of the following diagnoses:
    1. The patient has acute pain
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The patient is 18 years of age or older
C. The patient's pain is severe enough to require an opioid analgesic for which alternative treatments are inadequate. [Note: Alternative treatments that may be inadequate include non-opioid analgesic products or opioid combination products]
D. The patient's treatment center is a Dsuvia Risk Evaluation and Mitigation Strategy (REMS) certified medically supervised healthcare setting, such as a hospital, surgical center, or emergency department

References:

1. Dsuvia package insert. Redwood City, CA. AcelRx Pharmaceuticals, Inc. Revised May 2021. Accessed July 2022.
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
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.

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.

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)

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)

(Criteria continued on next page)

REQUIREMENTS: TAFAMIDIS (Vyndaqel, Vyndamax)

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.

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.

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.

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.

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.

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.

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.

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.

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.

Generic	Brand	Reviewed	Effective Date
TERIFLUNOMIDE Edition 1	AUBAGIO	01/28/2022	6/1/2021

REQUIREMENTS:

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.

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).

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.
10. 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 .
11. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658.
12. Unger CA. Hormone therapy for transgender patients. Transl Androl Urol. 2016;5(6):877-884. doi:10.21037/tau.2016.09.04.
13. Boni C, Pagano M, Panebianco M, et al. Therapeutic activity of testosterone in metastatic breast cancer. Anticancer Res. 2014;34(3):1287-1290.
14. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and Management of Testosterone Deficiency: AUA Guideline. J Urol. 2018;200(2):423-432. doi:10.1016/j.juro.2018.03.115.
15. Wanke C, Kotler D; HIV Wasting Collaborative Consensus Committee. Collaborative recommendations: the approach to diagnosis and treatment of HIV wasting. J Acquir Immune Defic Syndr. 2004;37 Suppl 5:S284-S288. doi:10.1097/01.qai.0000144384.55091.0f.
16. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men With Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744. doi:10.1210/jc.2018-00229.

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.

Generic	Brand	Reviewed	Effective Date
TEZACAFTOR/IVACAFTOR Edition 1	SYMDEKO	7/29/2022	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. Patient is 6 years of age or older
B. Patient has a diagnosis of cystic fibrosis
C. The requested medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert
D. Documentation that patient is either homozygous for the *F508del*-CFTR gene mutation; **OR** documentation that patient has at least one of the following mutations in the CFTR gene:

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. Patient has a diagnosis of cystic fibrosis
B. Patient has shown improvement in clinical status compared to baseline as shown by ONE of the following:
    1. Patient has improved, maintained, or demonstrated less than expected decline in FEV_1
    2. Patient has improved, maintained, or demonstrated less than expected decline in BMI
    3. Patient has experienced a reduction in rate of pulmonary exacerbations

References:

1. Symdeco package insert. Boston, MA. Vertex Pharmaceuticals Inc. Revised December 2020. Accessed June 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.

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.

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.

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.

ALLERGEN EXTRACT- TIMOTHY GRASS POLLEN			
Generic	Brand	Reviewed	Effective Date
GRASS POLLEN TIMOTHY, STD Edition 2	GRASTEK	7/29/2022	7/23/2021

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

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

A. The patient has a diagnosis of allergic rhinitis caused by grass pollen
B. The patient is between 5 and 65 years of age
C. The patient's diagnosis is confirmed by a positive skin prick test and/or a positive titer to specific IgE (Immunoglobulin E) antibodies for Timothy grass or cross-reactive grass pollens
D. The requested medication is prescribed by or given in consultation with an allergist, immunologist, or other physician experienced in the diagnosis and treatment of allergic diseases
E. The patient has persistent and moderate-to-severe symptoms of allergic rhinitis [Note: persistent symptoms are defined as symptoms presenting at least 4 days a week or for at least 4 weeks, and moderate-to-severe symptoms include: troublesome symptoms, sleep disturbance, impairment of daily activities, or impairment of school or work]
F. The patient has a current claim or prescription for auto-injectable epinephrine

RENEWAL CRITERIA

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

A. The patient has experienced an improvement in signs and symptoms of allergic rhinitis compared to baseline

References:

1. Grastek package insert. Swindon, Wiltshire UK. Catalent Pharma Solutions Limited. Revised December 2019. Accessed July 2022.
2. Greenhawt M, Oppenheimer J, Nelson M, et al. Sublingual immunotherapy: A focused allergen immunotherapy practice parameter update. Ann Allergy Asthma Immunol. 2017;118(3):276-282.e2. doi:10.1016/j.anai.2016.12.009.

Generic	Brand	Reviewed	Effective Date
TIVOZANIB HCL Edition 1	FOTIVDA	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient has a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC)
B. Patient is 18 years of age or older
C. The medication is being prescribed by or given in consultation with a hematologist or oncologist
D. The patient previously had two or more prior systemic therapies

References

1. Fotivda package insert. Boston, MA. AVEO Pharmaceuticals, Inc. Revised March 2021. Accessed June 2022.

TOBRAMYCIN INHALED			
Generic	Brand	Reviewed	Effective Date
TOBRAMYCIN Edition 2	BETHKIS, TOBRAMYCIN	07/29/2022	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. Patient has a diagnosis of cystic fibrosis
B. Patient has a lung infection per culture of the airway demonstrating a gram-negative species, *Pseudomonas aeruginosa.*

References:

1. TOBI Inhalation Solution package insert. East Hanover, NJ. Novartis Pharmaceuticals. Revised October 2018. Accessed June 2022.
2. TOBI Podhaler [package insert]. East Hanover, NJ. Novartis Pharmaceuticals; Revised July 2020. Accessed June 2022.
3. Bethkis package insert. Woodstock, IL. Catalent Pharma Solutions, LLC. Revised December 2019. Accessed June 2022.
4. Kitabis Pak package insert. Woodstock, IL. Catalent Pharma Solutions, LLC. Revised December 2019. Accessed June 2022.
5. Tobramycin Inhalation Solution package insert. Parsippany, NJ. Teva Pharmaceuticals USA. Revised February 2020. Accessed June 2022.
6. 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.
7. 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.

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

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

(Criteria continued next page)

REQUIREMENTS: TOCILIZUMAB - IV (CONTINUED)

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.

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.

Generic	Brand	Reviewed	Effective Date
TOFACITINIB CITRATE Edition 6	XELJANZ, XELJANZ XR	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA)
   2. Psoriatic arthritis (PsA)
   3. Moderate to severe ulcerative colitis (UC)
   4. Polyarticular juvenile idiopathic arthritis (pcJIA)
   5. Ankylosing spondylitis (AS)

B. **For patients with moderate to severe rheumatoid arthritis (RA), approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist
   3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira
      a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

C. **For patients with psoriatic arthritis (PsA), approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
   3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira
      a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

D. **For patients with moderate to severe ulcerative colitis (UC), approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a gastroenterologist
   3. The patient has previously tried the following formulary preferred TNF blocker: Humira
      a. A trial with an infliximab product (i.e., Remicade, biosimilars) or Simponi subcutaneous also counts.

(Criteria continued next page)

REQUIREMENTS- TOFACITINIB (CONTINUED)

E. **For patients with polyarticular course juvenile idiopathic arthritis (pcJIA), approval requires:**
   1. The patient is 2 years of age or older
   2. The requested medication is prescribed by or given in consultation with rheumatologist
   3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira
      a. A trial of Simponi (Aria or subcutaneous) also counts.

F. **For patients with ankylosing spondylitis (AS), approval also requires:**
   1. The patient is 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist
   3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira
      a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

RENEWAL CRITERIA

The guideline named **TOFACITINIB (Xeljanz, Xeljanz XR)** requires the following rule(s) to be met for renewal:

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA)
   2. Psoriatic arthritis (PsA)
   3. Moderate to severe ulcerative colitis (UC)
   4. Polyarticular juvenile idiopathic arthritis (pcJIA)
   5. Ankylosing spondylitis (AS)

B. **For patients with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), or polyarticular course juvenile idiopathic arthritis (pcJIA), renewal also requires:**
   1. The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

C. **For patients with ankylosing spondylitis, renewal also requires:**
   1. 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 next page)

REQUIREMENTS- TOFACITINIB (CONTINUED)

References

1. Xeljanz package insert. New York, New York. Pfizer. Revised December 2021. Accessed July 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
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.

TOPICAL ONYCHOMYCOSIS TREATMENTS			
Generic	Brand	Reviewed	Effective Date
TAVABOROLE Edition 2	KERYDIN	7/29/2022	7/29/2022
EFINACONAZOLE	JUBLIA		

REQUIREMENTS:

Our guideline named **TOPICAL ONYCHOMYCOSIS (Kerydin, Jublia)** requires the following rule(s) be met for approval:

A. Patient is 6 years of age or older
B. Patient has a diagnosis of onychomycosis of the toenails
C. Patient has complicating factors such as diabetes, peripheral vascular disease (narrowed blood vessels cause low blood flow), a suppressed immune system, or pain surrounding the nail or soft tissue
D. Patient has previously tried and failed BOTH of the following, unless there is a documented contraindication or clinically significant adverse reaction:
    1. Oral terbinafine OR oral itraconazole
    2. Ciclopirox topical solution

References:

1. Kerydin package insert. New York, NY. Pfizer Labs. Revised July 2018. Accessed May 2022.
2. Jublia package insert. Bridgewater, NJ. Bausch Health US, LLC. Revised March 2022. Accessed May 2022.
3. Lipner SR, Scher RK. Onychomycosis: Treatment and prevention of recurrence. J Am Acad Dermatol. 2019 Apr;80(4):853-867. doi: 10.1016/j.jaad.2018.05.1260. Epub 2018 Jun 28.

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.

Generic	Brand	Reviewed	Effective Date
TRAMADOL Edition 2	QDOLO	7/29/2022	7/23/2021

REQUIREMENTS:

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

A. The patient has **ONE** of the following:
    1. The request is for the management of pain severe enough to require an opioid analgesic for which alternative treatments are inadequate
    2. The patient is receiving palliative care or end-of-life care
    3. The patient is enrolled in hospice
B. The patient is 18 years of age or older
C. The patient has previously tried generic tramadol or a generic tramadol with acetaminophen product unless there is a contraindication
D. The patient is unable to take oral solid formulations of tramadol or tramadol with acetaminophen

References:

1. Qdolo package insert. Athens, GA. Athena Bioscience, LLC. Revised September 2020. Accessed June 2022.
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.

Generic	Brand	Reviewed	Effective Date
TRAMETINIB DIMETHYL SULFOXIDE Edition 2	MEKINIST	07/29/2022	07/29/2022

REQUIREMENTS:

Our guideline named **TRAMETINIB DIMETHYL SULFOXIDE (Mekinist)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
   1. Unresectable or metastatic melanoma
   2. Metastatic non-small cell lung cancer (NSCLC)
   3. Resectable melanoma
   4. Locally advanced or metastatic anaplastic thyroid cancer (ATC)
   5. Unresectable or metastatic solid tumors

B. **For patients with unresectable or metastatic melanoma, approval also requires ALL of the following:**
   1. The patient has BRAF V600E or V600K mutations as detected by an FDA (Food and Drug Administration)-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

C. **For patients with metastatic non-small cell lung cancer (NSCLC), approval also requires ALL of the following:**
   1. The patient has a BRAF V600E mutation as detected by an FDA-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)

D. **For patients with resectable melanoma, approval also requires ALL of the following:**
   1. The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib) for adjuvant treatment
   3. The patient had involvement of lymph node(s), following complete resection of the melanoma and complete lymphadenectomy

E. **For patients with locally advanced or metastatic anaplastic thyroid cancer (ATC), approval also requires ALL of the following:**
   1. The patient has BRAF V600E mutation as detected by an FDA-approved test
   2. The requested medication will be used in combination with Tafinlar (dabrafenib)
   3. The patient does not have any satisfactory locoregional treatment options available

(Criteria continued on next page)

REQUIREMENTS- TRAMETINIB DIMETHYL SULFOXIDE (CONTINUED)

F. **For patients with unresectable or metastatic solid tumors, approval also requires ALL of the following:**
   1. The patient is 6 years of age or older
   2. The patient has BRAF V600E mutation as detected by an FDA-approved test
   3. The requested medication will be used in combination with Tafinlar (dabrafenib)
   4. The patient has progressed following prior treatment and does not have any satisfactory alternative treatment options

References:

1. Mekinist package insert. East Hanover, NJ. Novartis Pharmaceuticals Corporation. Revised June 2022. Accessed June 2022.

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:
        a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg
        b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
        c. Pulmonary vascular resistance (PVR) greater than 3 Wood units
    3. You have NYHA-WHO Functional Class III or IV symptoms (a way to classify how limited you are during physical activity)
    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.

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

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.

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.

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
UBROGEPANT Edition 1	UBRELVY	07/29/2022	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. The patient is being treated for acute migraine headache
B. The patient 18 years of age or older
C. The patient has had previous trial of at least ONE triptan (e.g., sumatriptan, rizatriptan, etc.), unless there is a contraindication

RENEWAL CRITERIA

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

A. Patient is being treated for acute migraine headache
B. The patient meets ONE of the following:
    1. The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire (assessment tool used to help guide treatment such as migraine assessment of current therapy [MIGRAINEACT])
    2. The patient has experienced clinical improvement as defined by ONE of the following:
        a. Ability to function normally within 2 hours of dose
        b. Headache pain disappears within 2 hours of dose
        c. Treatment works consistently in majority of migraine attacks

References:

1. Ubrelvy package insert. Madison, NJ. Allergan, Inc. Revised December 2019. Accessed June 2022.
2. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in Headache. 2019 Apr;59(4):650-651]. Headache. 2019;59(1):1-18. doi:10.1111/head.13456.
3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202.

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.

Generic	Brand	Reviewed	Effective Date
UPADACITINIB Edition 6	RINVOQ	07/29/2022	07/29/2022

REQUIREMENTS:

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)
The guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) be met for approval:

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA)
   2. Psoriatic arthritis (PsA)
   3. Moderate to severe atopic dermatitis (AD)
   4. Moderately to severely active ulcerative colitis (UC)
   5. Ankylosing spondylitis (AS)

B. **For patients with moderate to severe rheumatoid arthritis (RA), approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist
   3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira
      a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

C. **For patients with psoriatic arthritis (PsA), approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist or dermatologist
   3. The patient has previously tried any ONE of the following formulary preferred TNF blockers: Enbrel or Humira
      a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

(Criteria continued next page)

REQUIREMENTS: UPADACITINIB (CONTINUED)

D. **For patients with moderate to severe atopic dermatitis (AD), approval also requires:**
   1. The patient is 12 years of age or older
   2. The patient meets at least ONE of the following for disease severity:
      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.
   3. The requested medication is prescribed by or given in consultation with a dermatologist, allergist, or immunologist
   4. The patient has had at least a 4-week trial with an inadequate response to at least ONE of the following, unless contraindication to all listed:
      a. moderate-or higher-potency topical corticosteroids [e.g., betamethasone dipropionate, clobetasol propionate, etc.]
      b. topical calcineurin inhibitors [i.e., Elidel (pimecrolimus), Protopic (tacrolimus)]
      c. topical PDE-4 inhibitors [i.e., Eucrisa (crisaborole)]
   5. The patient meets at least ONE of the following:
      a. Patient has had at least a 4-month trial with inadequate response to at least ONE traditional systemic therapy (e.g., methotrexate, azathioprine, cyclosporine, or mycophenolate mofetil)
      b. Patient has tried at least ONE traditional systemic therapy but was unable to tolerate a 4-month trial

      Note: If the patient already has a previous trial with a biologic (i.e., Dupixent, Adbry, etc.), then this can be accepted in place of traditional systemic therapy)

E. **For patients with moderately to severely active ulcerative colitis, approval requires ALL of the following:**
   1. Patient is 18 years of age or older
   2. Therapy is prescribed by or given in consultation with a gastroenterologist
   3. Patient meets at least ONE of the following:
      a. Patient has had at least a 3-month trial with inadequate response to Humira
      b. Patient has 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)

F. **For patients with ankylosing spondylitis (AS), approval requires:**
   1. The patient is 18 years of age or older
   2. The requested medication is prescribed by or given in consultation with a rheumatologist
   3. The patient has previously tried any **ONE** of the following formulary preferred TNF blockers (class of drugs): Enbrel or Humira
      a. A trial of Cimzia, an infliximab product (e.g., Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

RENEWAL CRITERIA

The guideline named **UPADACITINIB (Rinvoq)** requires the following rule(s) to be met for renewal:

A. The patient has ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA)
   2. Psoriatic arthritis (PsA)
   3. Moderate to severe atopic dermatitis (AD)
   4. Moderately to severely active ulcerative colitis (UC)
   5. Ankylosing Spondylitis (AS)
B. **For patients with 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. **For patients with moderate to severe atopic dermatitis, renewal also requires:**
   1. Patient has shown a clinical response as evidenced by an improvement in symptoms (e.g., reduced body surface area affected, reduced pruritus, improvements in cracking, oozing, or bleeding of affected skin, reduced erythema, etc.)
D. **For patients with ankylosing spondylitis, renewal also requires:**
   1. 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 next page)

REQUIREMENTS: UPADACITINIB (CONTINUED)

References

1. Rinvoq package insert. North Chicago, IL. AbbVie Inc. Revised April 2022. Accessed July 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.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613. doi:10.1002/art.41042.

Generic	Brand	Reviewed	Effective Date
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
USTEKINUMAB Edition 2	STELARA	9/14/2022	9/14/2022

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:

A. Therapy is prescribed by or given in consultation with a gastroenterologist
B. The patient meets at least ONE of the following:
    1. 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
    2. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
    3. The patient has a history of ileocolonic resection
C. The patient is 18 years of age or older
D. 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 July 2022. Accessed August 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.

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.

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.

Generic	Brand	Reviewed	Effective Date
VEDOLIZUMAB Edition 2	ENTYVIO	9/14/2022	9/14/2022

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 meets at least ONE of the following:
    1. 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
    2. The patient has fistulizing disease (perianal, enterocutaneous, or rectovaginal)
    3. The patient has a history of ileocolonic resection
C. The patient is 18 years of age or older
D. The patient has had a previous trial of or contraindication to **ONE** of the following formulary preferred immunomodulators: Humira, Skyrizi, or Stelara

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.

(Criteria continued on next page)

REQUIREMENTS: VEDOLIZUMAB (CONTINUED)

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.
3. Lichtenstein GR, Loftus EV, Isaacs KL, Regueiro MD, Gerson LB, Sands BE. ACG Clinical Guideline: Management of Crohn's Disease in Adults [published correction appears in Am J Gastroenterol. 2018 Jul;113(7):1101]. Am J Gastroenterol. 2018;113(4):481-517. doi:10.1038/ajg.2018.27.
4. Feuerstein JD, Isaacs KL, Schneider Y, et al.; AGA Institute Clinical Guidelines Committee. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020 Apr;158(5):1450-1461.

Generic	Brand	Reviewed	Effective Date
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.

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.

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.

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.

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.

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.

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.

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
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:

A. You have a diagnosis of achondroplasia confirmed by genetic testing (detected mutation in the FGFR3 gene)
B. Your bone growth plates (epiphyses) are open (as confirmed by radiograph of the wrist and hand)
C. 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
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.

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

REQUIREMENTS:

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

A. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy
B. The patient is 18 years of age or older
C. The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
D. The patient has symptomatic polyneuropathy as determined by a baseline assessment (i.e., modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, etc.)
E. The patient has a documented diagnosis of hATTR as confirmed by **ONE** of the following:
    1. Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR (transthyretin) protein
    2. DNA genetic sequencing to confirm hATTR mutation

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

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

References:

1. Amvuttra package insert. Cambridge, MA. Alnylam Pharmaceuticals, Inc. Revised June 2022. Accessed June 2022.
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.

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.