

### Quartz Medicare Advantage (HMO)

# Part D medication prior authorization criteria

#### QuartzBenefits.com/MedicareAdvantage

These prior authorization criteria apply to Quartz Medicare Advantage and Dual Eligible members for medications covered under Medicare Part D benefits.

 Important plan information.

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### ABATACEPT (ORENCIA)

#### **Products Affected**

• Orencia Clickject

• Orencia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA): Diagnosis of moderately to severely active RA and trial and failure, contraindication or intolerance (TF/C/I) to any two of the following: adalimumab, etanercept, tofacitinib, upadacitinib, infliximab (Part B). Polyarticular juvenile idiopathic arthritis (PJIA): Diagnosis of moderately to severely active PJIA and TF/C/I to any two of the following: adalimumab (Humira), etanercept (j), tofacitinib (Xeljanz). Psoriatic arthritis (PsA): Diagnosis of moderate to severe PsA and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, tofacitinib, upadacitinib, infliximab (Part B).
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	Indefinite
Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.

### Adalimumab

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen

- Humira Pen-CD/UC/HS Starter
- Humira Pen-pediatric UC Starter Pack
- Humira Pen-PS/UV Starter

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A

Required Medical Information	Rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA): Diagnosis of moderately to severely active RA or PJIA and trial and failure to a 3 month trial of methotrexate. If methotrexate is contraindicated or not tolerated, than a 3 month trial with another disease modifying anti-rheumatic drug (DMARD) (eg, hydroxychloroquine, sulfasalazine, leflunomide, minocycline). Psoriatic arthritis (PsA): Diagnosis of active PsA and trial and failure, contraindication, or intolerance (TF/C/I) to a 3 month trial of methotrexate. Plaque psoriasis (PsO): Diagnosis of moderate to severe PsO and TF/C/I to two or more of the following: 1) Phototherapy (eg, PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B)), 2) Topical therapy (eg, corticosteroids, calcipotriene, retinoids, etc), 3) Oral therapy (eg, methotrexate, cyclosporine). Ankylosing spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA): Diagnosis of active AS or nr-axSpA and TF/C/I to a 2 month trial of prescription doses of two different NSAIDS (eg, naproxen, nabumetone, diclofenac). Crohn's disease (CD): Diagnosis of moderately to severely active CD and one of the following: 1) Patient is high risk (age less than 30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc)), 2) Patient is low risk and TF/C/I to a 2 month trial of 2 conventional therapies (6-mercaptopurine, azathioprine, methotrexate, corticosteroid), conventional therapy is clinically inappropriate based on location of disease, or demonstrated steroid dependence.
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA, AS, nr-axSpA: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. PsO, HS: Prescribed by or in consultation with a dermatologist. CD, UC: Prescribed by or in consultation with a gastroenterologist. Uveitis: Prescribed by or in consultation with an ophthalmologist or rheumatologist
Coverage Duration	Indefinite

Other Criteria	Ulcerative colitis (UC): Diagnosis of moderately to severely active UC and patient is a high-risk individual (extensive colitis, deep ulcers, age less than 40 years, High CRP and ESR, steroid- requiring disease, history of hospitalization, C difficile infection, CMV infection, etc) and has had a short course (2-4 weeks) of oral corticosteroids (unless contraindicated). Hidradenitis suppurativa (HS): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis: Diagnosis of non-infectious uveitis with ongoing symptoms despite TF/C/I to topical glucocorticoids and a systemic immunomodulator (eg, oral corticosteroids, methotrexate, cyclosporine). All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL- 12/23 inhibitor, etc) or janus kinase inhibitor.
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## AGALSIDASE BETA (FABRAZYME)

### **Products Affected**

• Fabrazyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Fabry Disease: Diagnosis of Fabry disease. Will not be used in combination with migalastat.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation of an expert in the treatment of Fabry Disease
Coverage Duration	Indefinite
Other Criteria	N/A

# ALOSETRON (LOTRONEX)

#### **Products Affected**

• Alosetron Hydrochloride

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Severe diarrhea-predominant irritable bowel syndrome (IBS): All of the following: 1) Diagnosis of severe diarrhea-predominant IBS, 2) Trial and failure, contraindication, or intolerance to a one month trial of conventional therapy (such as loperamide or diphenoxylate/atropine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by physician certified in the alosetron REMS program.
Coverage Duration	Indefinite
Other Criteria	N/A

### AMIFAMPRIDINE (FIRDAPSE, RUZURGI)

### **Products Affected**

• Firdapse

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS) (Initial): Diagnosis of LEMS confirmed by neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescriber is an expert in the treatment of neuromuscular disorders
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation from the previous 12 months of therapy indicating improvement or stabilization in muscle weakness compared to baseline

## AMIKACIN INHALED (ARIKAYCE)

### **Products Affected**

• Arikayce

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): Diagnosis of mycobacterium avium complex (MAC) lung disease. Documentation of positive sputum cultures despite at least 6 months of multidrug background guideline-based therapy. Being used as part of a combination antibacterial drug regimen.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with an infectious disease expert
Coverage Duration	(Initial): 6 months, (Reauth): 12 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. (Reauth): Achieves and/or maintains negative sputum culture by month 6.

# ANAKINRA (KINERET)

#### **Products Affected**

• Kineret

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): Rheumatoid arthritis (RA): Diagnosis of moderately to severely active RA and trial and failure, contraindication, or intolerance to any two of the following: adalimumab (Humira), etanercept (Enbrel), upadacitinib (Rinvoq), tofacitinib (Xeljanz), infliximab (Part B). Neonatal-onset multisystem inflammatory disease (NOMID): Diagnosis of NOMID. Deficiency of interleukin-1 antagonist: Diagnosis of interleukin-1 antagonist deficiency.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a rheumatologist
Coverage Duration	12 months
Other Criteria	All indications (Initial, Reauth): Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor. (Reauth): Clinical documentation from the previous 12 months that describes response as stable disease or improvement seen on therapy.

### **ANESTHETICS (TOPICAL)**

- Lidocaine OINT 5%
- Lidocaine PTCH 5%

- Lidocaine/prilocaine CREA
- Lidocan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For lidocaine 5% patch: Medication is being used to treat pain associated with post-herpetic neuralgia(PHN). For lidocaine 5% ointment: Medication is being used for one of the following: 1) The production of anesthesia of accessible mucous membranes of the oropharynx, or 2) Anesthetic lubricant for intubation, or 3) For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites. For lidocaine- prilocaine cream: Medication is being used as a topical anesthetic for use on one of the following: 1) Normal intact skin for local analgesia, or 2) Genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	(PHN): Indefinite. All other indications: 12 months
Other Criteria	This drug requires payment determination

### ANTIFUNGAL (BROAD SPECTRUM)

- Cresemba CAPS
- Noxafil PACK
- Posaconazole

- Posaconazole DR
- Voriconazole SUSR
- Voriconazole TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) Suspected or confirmed serious fungal infection and two of the following medications cannot be used (due to probable resistance, intolerance, or significant drug-drug interactions): fluconazole, ketoconazole, or itraconazole, 2) Prescribed by infectious disease, 3) Continuation of hospital therapy, or 4) Prophylaxis of serious fungal infections in patients with hematologic malignancies with severely compromised immunity (posaconazole only)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### **ANTINEOPLASTICS**

- Akeega
- Alecensa
- Alunbrig
- Augtyro
- Ayvakit
- Balversa
- Besremi
- Bexarotene
- Bosulif
- Braftovi CAPS 75MG
- Brukinsa
- Cabometyx
- Calquence
- Caprelsa
- Cometriq
- Copiktra
- Cotellic
- Daurismo
- Erivedge
- Erleada
- Erlotinib Hydrochloride TABS
- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG
- Everolimus TBSO
- Exkivity
- Firmagon INJ 120MG/VIAL, 80MG
- Fotivda
- Fruzaqla
- Gavreto
- Gefitinib
- Gilotrif
- Gleostine CAPS 100MG, 10MG, 40MG
- Iclusig
- Idhifa
- Imbruvica CAPS
- Imbruvica SUSP
- Imbruvica TABS 420MG, 560MG
- Inlyta
- Inqovi

- Inrebic
- Iwilfin
- Jakafi
- Jaypirca
- Koselugo
- Krazati
- Lapatinib Ditosylate
- Lenalidomide
- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose
- Lonsurf
- Loqtorzi
- Lorbrena
- Lumakras
- Lynparza TABS
- Lytgobi
- Mekinist
- Mektovi
- Nerlynx
- Ninlaro
- Nubeqa
- Odomzo
- Ogsiveo
- Ojjaara
- Onureg
- Orgovyx
- Orserdu
- Pazopanib Hydrochloride
- Pemazyre
- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose
- Pomalyst
- Qinlock
- Retevmo

- Revlimid
- Rezlidhia
- Rozlytrek
- Rubraca
- Rydapt
- Scemblix
- Sorafenib Tosylate TABS
- Sprycel
- Stivarga
- Sunitinib Malate
- Synribo
- Tabrecta
- Tafinlar
- Tagrisso
- Talzenna
- Tasigna
- Tazverik
- Tepmetko
- Thalomid
- Tibsovo
- Truqap
- Tukysa

- Turalio
- Valchlor
- Vanflyta
- Venclexta
- Venclexta Starting Pack
- Vitrakvi
- Vizimpro
- Vonjo
- Welireg
- Xalkori
- Xospata
- Xpovio
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Twice Weekly
- Xtandi
- Yonsa
- Zejula
- Zelboraf
- Zepzelca
- Zolinza
- Zydelig
- Zykadia TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, hematologist, neurologist, urologist, allergist, immunologist, or transplant specialist.
Coverage Duration	12 months

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### **ANTINEOPLASTICS (IV)**

- Alymsys
- Bortezomib INJ 1MG, 2.5MG, 3.5MG
- Elrexfio
- Epkinly
- Erbitux
- Herzuma
- Kanjinti
- Lunsumio
- Mvasi

- Ogivri INJ 1.1%; 420MG, 150MG
- Ontruzant
- Paclitaxel Protein-bound Particles
- Riabni
- Ruxience
- Talvey
- Trazimera
- Truxima
- Vegzelma
- Zirabev

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	This also requires payment determination and may be covered under Medicare Part B or D. Approve for continuation of therapy.

### **ANTISEIZURE NASAL SPRAY**

- Nayzilam
- Valtoco 10 Mg Dose

- Valtoco 15 Mg Dose
- Valtoco 20 Mg DoseValtoco 5 Mg Dose

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Seizure disorder: Documentation supports history of frequent episodes of acute seizure activity and acute seizure episodes are distinct from the patient's usual pattern
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or other specialist in the management of epilepsy
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of therapy

# APREMILAST (OTEZLA)

### **Products Affected**

• Otezla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (PsO) (mild): Diagnosis of mild PsO and TF/C/I to one conventional systemic agent (eg, methotrexate) AND one conventional topical agent (eg, topical corticosteroids, calcipotriene). Plaque psoriasis (PsO) (moderate to severe): Diagnosis of moderate to severe PsO and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, infliximab (Part B). Psoriatic arthritis (PsA): Diagnosis of moderate to severely active PsA and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, tofacitinib, upadacitinib, infliximab (Part B). Behcet's disease: Diagnosis of Behcet's disease with oral ulcers and TF/C/I to colchicine.
Age Restrictions	N/A
Prescriber Restrictions	PsO: Prescribed by or in consultation with a dermatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. Behcet's disease: Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Indefinite
Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.

# ARMODAFINIL (NUVIGIL)

#### **Products Affected**

• Armodafinil

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of obstructive sleep apnea (OSA), shift-work sleep disorder (SWSD), or narcolepsy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination.

# ASFOTASE ALFA (STRENSIQ)

### **Products Affected**

• Strensiq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Perinatal, infantile, or juvenile-onset hypophosphatasia (HPP) (Initial): Documented hypophosphatasia-related skeletal disease
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation from the previous 12 months demonstrating improvements in skeletal quality from baseline

# ATOGEPANT (QULIPTA)

### **Products Affected**

Qulipta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Migraine prevention: Patient has at least 4 migraine days per month. Trial and failure, contraindication, or intolerance to a generic preventive migraine medication (e.g., antidepressant [e.g., amitriptyline, venlafaxine], antiepileptic [e.g., divalproex sodium, topiramate], or antihypertensive [e.g., propranolol, verapamil]). Trial and failure, contraindication, or intolerance to galcanezumab (Emgality).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Not being used in addition to another CGRP inhibitor preventative.

### AZELAIC ACID (AZELEX, FINACEA)

#### **Products Affected**

• Azelex

• Azelaic Acid GEL

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(For 20% cream): Diagnosis of acne and trial and failure, contraindication, or intolerance to tretinoin AND adapalene. (For 15% gel): Diagnosis of rosacea
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# AZTREONAM INHALATION (CAYSTON)

#### **Products Affected**

Cayston

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF): Diagnosis of CF. Patient has evidence of pseudomonas aeruginosa in the lungs and recurrence despite prior use of tobramycin inhalation solution or documented tobramycin resistance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

### BELIMUMAB (BENLYSTA)

#### **Products Affected**

• Benlysta INJ 200MG/ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lupus nephritis or systemic lupus erythematosus (SLE) (Initial): Diagnosis of active lupus nephritis or active SLE (but not severe active central nervous system lupus). Symptoms persist despite treatment with at least two of the following: hydroxychloroquine, a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen, etc.), an immunosuppressant (e.g., azathioprine, methotrexate, etc) or corticosteroids (e.g., prednisone).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a rheumatologist, nephrologist, or other expert in the treatment of SLE
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy

## BELUMOSUDIL (REZUROCK)

### **Products Affected**

• Rezurock

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Graft-versus-host disease, chronic: Diagnosis of chronic graft- versus-host disease and previous failure of at least two prior lines of systemic therapies.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a specialist with experience in the treatment of GVHD (eg, hematologist, oncologist, immunologist, etc.)
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## BENRALIZUMAB (FASENRA)

### **Products Affected**

• Fasenra Pen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Eosinophilic asthma (EA): Diagnosis of EA with a documented blood eosinophil count of at least 150 cells/mm3 (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out). Symptoms are not well controlled or poorly controlled despite use of medium to high- dose inhaled corticosteroids with a long-acting bronchodilator or leukotriene modifier (unless history of intolerance or contraindication).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by, or in consultation with, an asthma specialist, allergist, immunologist, or pulmonologist.
Coverage Duration	Indefinite
Other Criteria	Eosinophilic asthma: Initial fill will be approved to allow 1 ml per 28 days for the first 3 months.

## BEROTRALSTAT (ORLADEYO)

### **Products Affected**

• Orladeyo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Will not be used in combination with other approved treatments for HAE prophylaxis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist or other provider with experience in the treatment of HAE
Coverage Duration	6 months
Other Criteria	(Reauth): Physician attestation of improvement of HAE (ie, reductions in attack frequency or attack severity).

### BRONCHITOL

### **Products Affected**

• Bronchitol

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has passed the Bronchitol Tolerance Test (BTT).
Age Restrictions	CF (initial): Patient is 18 years of age or older.
Prescriber Restrictions	CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center.
Coverage Duration	CF (initial): 6 months. CF (reauth): 12 months.
Other Criteria	CF (reauth): Patient demonstrates positive clinical response to therapy (e.g., improvement in lung function [forced expiratory volume in one second {FEV1}]).

# C1 ESTERASE INHIBITOR (CINRYZE, BERINERT)

#### **Products Affected**

• Cinryze

• Berinert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For treatment of hereditary angioedema (HAE) attacks (Berinert only): Diagnosis of HAE. Will not be used in combination with other approved treatments for acute attacks. For prophylaxis against HAE attacks (Cinryze only): Diagnosis of moderate to severe HAE. Trial and failure, contraindication or intolerance with BOTH Haegarda and lanadelumab (Takhzyro). Will not be used in combination with other approved treatments for HAE prophylaxis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist or other provider with experience in the treatment of HAE
Coverage Duration	Indefinite
Other Criteria	N/A

# C1 ESTERASE INHIBITOR (HAEGARDA)

#### **Products Affected**

• Haegarda

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Will not be used in combination with other approved treatments for HAE prophylaxis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist or other provider with experience in the treatment of HAE
Coverage Duration	6 months
Other Criteria	(Reauth): Physician attestation of improvement of HAE (ie, reductions in attack frequency or attack severity).

# CANNABIDIOL (EPIDIOLEX)

### **Products Affected**

• Epidiolex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut syndrome: Trial of or contraindication to both of the following: 1) topiramate or lamotrigine and 2) clobazam. Dravet syndrome: Diagnosis of Dravet syndrome. Tuberous sclerosis complex: Diagnosis of tuberous sclerosis complex.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of prior therapy

# CAPLACIZUMAB (CABLIVI)

### **Products Affected**

Cablivi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Thrombotic thrombocytopenic purpura, acquired (aTTP): Diagnosis of aTTP with at least one ADAMST13 level below 20 percent. Documentation showing that plasma exchange therapy and caplacizumab were started under the medical benefit. Plasma exchange has been discontinued and caplacizumab therapy will continue in combination with immunosuppressive therapy (e.g. systemic corticosteroids or rituximab). Patient has not had more than 2 recurrences of aTTP while on caplacizumab therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 months after plasma exchange is discontinued
Other Criteria	N/A

# **CENEGERMIN (OXERVATE)**

#### **Products Affected**

• Oxervate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Confirmed diagnosis of neurotrophic keratitis. Documentation of decreased or loss of corneal sensitivity and corneal epithelium changes. Documentation of treatment of underlying conditions if appropriate (i.e. herpetic eye disease, diabetes, dry eye, multiple sclerosis, etc). Discontinuation of ophthalmic steroids or avoidance of ophthalmic preservatives.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist.
Coverage Duration	2 months
Other Criteria	If being used in BOTH eyes, a quantity of 56 vials per 28 days will be approved.

## CERTOLIZUMAB (CIMZIA)

#### **Products Affected**

• Cimzia Starter Kit

• Cimzia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA): Diagnosis of moderately to severely active RA and trial and failure, contraindication or intolerance (TF/C/I) to any two of the following: adalimumab, etanercept, tofacitinib, upadacitinib, infliximab (Part B). Ankylosing spondylitis (AS): Diagnosis of active AS and TF/C/I to any two of the following: adalimumab, etanercept, secukinumab, tofacitinib, upadacitinib, infliximab (Part B). Active nonradiographic axial spondyloarthritis (nr-axSpA): Diagnosis of active nr-axSpA and TF/C/I to any two of the following: adalimumab, secukinumab, upadacitinib. Crohn's disease (CD): Diagnosis of moderately to severely active CD and TF/C/I to any two of the following: adalimumab, risankizumab, upadacitinib, infliximab (Part B). Plaque psoriasis (PsO) (moderate to severe): Diagnosis of moderate to severe PsO and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, infliximab (Part B). Psoriatic arthritis (PsA): Diagnosis of moderate to severe PsA and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, infliximab (Part B). Psoriatic arthritis (PsA): Diagnosis of moderate to severe PsA and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, infliximab (Part B). Psoriatic arthritis (PsA):
Age Restrictions	N/A
Prescriber Restrictions	RA, AS, nr-axSpA: Prescribed by or in consultation with a rheumatologist. PsO: Prescribed by or in consultation with a dermatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. CD: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite

Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus
	kinase inhibitor.

### CLOBAZAM FILM (SYMPAZAN)

### **Products Affected**

• Sympazan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut syndrome: Diagnosis of Lennox-Gastaut syndrome with continued seizure activity despite trial and failure, contraindication or intolerance to at least two antiepileptic drugs (e.g., levetiracetam, lamotrigine) and inability to swallow clobazam tablets or solution.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of prior therapy

## **C**ORTICOSTEROIDS (TOPICAL)- NONPREFERRED

#### **Products Affected**

- Bryhali
- Desoximetasone LIQD

- Halobetasol Propionate FOAM
- Lexette
- Verdeso

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Inadequate response to, or intolerance of, a preferred topical steroid of comparable potency and/or formulation.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## CYCLIN-DEPENDENT KINASE 4 AND 6 (CDK4/6) INHIBITORS

#### **Products Affected**

- Ibrance
- Kisqali
- Kisqali Femara 200 Dose

- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose
- Verzenio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	For abemaciclib only: Trial and failure, contraindication, or intolerance to palbociclib or ribociclib where indications align. Approve for continuation of therapy.

## CYCLOSPORINE (VERKAZIA)

#### **Products Affected**

• Verkazia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Vernal keratoconjunctivitis: Diagnosis of moderate to severe vernal keratoconjunctivitis (eg, visual deficit and/or continuous symptoms). Treatment failure with a three-week trial of ophthalmic cromolyn.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation from the previous 12 months that describes response as improvement seen on therapy

## DALFAMPRIDINE (AMPYRA)

### **Products Affected**

• Dalfampridine ER

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple sclerosis (MS): Diagnosis of MS. Patient is ambulatory (with or without assistance). Use of dalfampridine relating to ambulation with either baseline assessment (ex: timed 25-foot walk) or supporting documentation indicating difficulty ambulating (ex: gait contributing to falls, etc.)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	12 months.
Other Criteria	(Reauth): Clinical documentation from the previous 12 months that the patient has a diagnosis of multiple sclerosis and remains ambulatory (with or without assistance)

# DELAFLOXACIN (BAXDELA)

#### **Products Affected**

• Baxdela TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) Patient has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient, or 2) Outpatient treatment of bacterial resistant strains as ordered by, or in consultation with, an infectious disease specialist.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	2 weeks
Other Criteria	N/A

## DENOSUMAB (XGEVA)

#### **Products Affected**

• Xgeva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Giant cell tumor of bone: Treatment of giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Bone metastases from solid tumors, hypercalcemia of malignancy, or multiple myeloma: One of the following: 1) Prevention of skeletal-related events in patients with bone metastases from solid tumors or multiple myeloma, or 2) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy. History of trial and failure, contraindication or intolerance to zoledronic acid.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of prior therapy

### **DEUTETRABENAZINE (AUSTEDO)**

#### **Products Affected**

• Austedo

- Austedo XR
- Austedo XR Patient Titration Kit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chorea associated with Huntington's disease: Diagnosis of chorea associated with Huntington's disease. Trial and failure, contraindication, or intolerance to tetrabenazine. Tardive dyskinesia: Diagnosis of moderate to severe tardive dyskinesia and patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication (or patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or other expert in the treatment of Huntington's disease or tardive dyskinesia/movement disorders.
Coverage Duration	Indefinite
Other Criteria	N/A

## DEXTROMETHORPHAN / QUINIDINE (NUEDEXTA)

#### **Products Affected**

• Nuedexta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of pseudobulbar affect
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination.

### DICHLORPHENAMIDE (KEVEYIS)

#### **Products Affected**

• Dichlorphenamide

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, or related variants
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## DICLOFENAC (TOPICAL)

#### **Products Affected**

• Diclofenac Epolamine

- Diclofenac Sodium EXTERNAL SOLN 1.5%
- Diclofenac Sodium GEL 3%

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of acute pain due to one of the following: minor strain, sprain, contusion (for diclofenac 1.3% patches only). Diagnosis of actinic keratoses (for diclofenac 3% gel only). Diagnosis of osteoarthritis of the knee(s) and history of trial and failure, intolerance or contraindication to topical diclofenac 1% gel (for diclofenac 1.5% solution only)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	AK: 3 months. All other indications: Indefinite
Other Criteria	This drug also requires payment determination

## DRONABINOL (MARINOL)

#### **Products Affected**

• Dronabinol

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	Subject to Part B vs. Part D review. Part D coverage consideration for a diagnosis of nausea and vomiting associated with cancer chemotherapy requires a trial and failure, intolerance or contraindication to one conventional antiemetic therapy such as ondansetron, steroids indicated for emesis or aprepitant. No additional requirements for a diagnosis of anorexia associated with weight loss in patients with AIDS.

## DROXIDOPA (NORTHERA)

### **Products Affected**

• Droxidopa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neurogenic orthostatic hypotension (NOH) (Initial): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta- hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to fludrocortisone acetate and midodrine.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a neurologist or cardiologist.
Coverage Duration	(Initial): 2 months. (Reauth): 12 months
Other Criteria	(Reauth): Documentation of positive clinical response to therapy

## DUPILUMAB (DUPIXENT)

#### **Products Affected**

• Dupixent

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis: Diagnosis of moderate to severe atopic dermatitis. Trial and failure, contraindication, or intolerance to at least TWO of the following: topical corticosteroid, topical calcineurin inhibitor, topical phosphodiesterase 4 (PDE-4) inhibitor, topical janus kinase (JAK) inhibitor, or phototherapy. Eosinophilic asthma: Diagnosis of eosinophilic asthma with a blood eosinophil count of at least 150 cells/mm3 (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out). One of the following: 1) Symptoms are not well controlled despite a trial of at least 3 months on medium to high-dose inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier, or 2) Intolerance or contraindication to inhaled corticosteroids in combination with a long-acting bronchodilator or leukotriene modifier. Corticosteroid- dependent asthma: Diagnosis of corticosteroid-dependent asthma. Chronic rhinosinusitis with nasal polyposis: Documentation of evidence of nasal polyps by direct exam, endoscopy, or sinus CT scan. Persistent or worsening nasal polyps despite being on a daily nasal steroid. Inadequately controlled disease despite prior use of systemic steroids and/or endoscopic sinus surgery. Will be used in conjunction with maintenance intranasal steroids. Eosinophilic esophagitis (EoE): Diagnosis of EoE (confirmed by biopsy) with two or more episodes of dysphagia per week. Trial and failure, contraindication, or intolerance to a proton pump inhibitor (eg, omeprazole, rabeprazole, lansoprazole). Prurigo nodularis (PN): Diagnosis of PN with at least 3 months of symptoms. Severe pruritus (WI-NRS of at least 7) and at least 20 PN lesions in total. All indications: Will not be used in combination with other biologic therapies/systemic immunosuppressant therapies to treat inflammatory disease or autoimmune disease (e.g., rheumatoid arthritis, inflammatory bowel disease, asthma).

Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist, pulmonologist, gastroenterologist, or otolaryngologist.
Coverage Duration	Indefinite
Other Criteria	Atopic dermatitis, eosinophilic asthma, corticosteroid-dependent asthma, prurigo nodularis: Initial fill will be approved to allow a one- time loading dose. Eosinophilic esophagitis: Will be approved to allow 300mg once weekly.

### EDARAVONE (RADICAVA)

#### **Products Affected**

• Radicava ORS Starter Kit

• Radicava ORS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Amyotrophic lateral sclerosis (ALS): Diagnosis of definite or probable ALS based on El Escorial revised Airlie House diagnostic criteria. Independent living status (i.e., Japan ALS Severity Classification Grade 1 or 2). Score of 2 or more on all 12 items of the ALS Functional Rating Scale (ALSFRS-R) (assessed and documented within the last 3 months). Forced vital capacity (FVC) 80% or more (assessed and documented within the last 3 months). Duration of disease from the first symptom of 2 years or less. Patient is currently using riluzole or has a documented contraindication, intolerance, or lack of therapeutic effect of therapy.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a neurologist or other specialist in treating amyotrophic lateral sclerosis (ALS)
Coverage Duration	12 months
Other Criteria	(Initial): Initial fill will be approved to allow a one-time loading dose of oral suspension (70 ml per 28 days). (Reauth): Documentation that use of the drug has slowed the progression of ALS and function is improved relative to the expected natural course of the disease.

# ELAGOLIX (ORILISSA)

### **Products Affected**

• Orilissa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Severe hepatic impairment, known osteoporosis, current pregnancy
Required Medical Information	Moderate to severe pain associated with endometriosis: Previous trial and failure, contraindication or intolerance to NSAID (e.g., naproxen, ibuprofen) and oral contraceptive
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## ELAPEGADEMASE (REVCOVI)

#### **Products Affected**

• Revcovi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID)
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by an expert in the treatment of immune deficiencies
Coverage Duration	12 months
Other Criteria	(Reauth): Patient has experienced an objective improvement on therapy.

## ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (TRIKAFTA)

#### **Products Affected**

• Trikafta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF) (Initial): Patient is homozygous or heterozygous for the F508del CFTR mutation in the CF Transmembrane Conductase Regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a cystic fibrosis specialist or pulmonologist.
Coverage Duration	12 months
Other Criteria	(Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations, improvement in BMI from baseline, patient-specific description of benefit).

## ELTROMBOPAG (PROMACTA)

#### **Products Affected**

• Promacta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (Initial): Diagnosis of chronic ITP with platelet count less than 50,000/mcL and trial and failure, contraindication, or intolerance to two prior ITP therapies (e.g., corticosteroids, rituximab, azathioprine, danazol, or splenectomy. Chronic hepatitis C (Initial): Diagnosis of chronic hepatitis C and is initiating/undergoing treatment with pegylated interferon/ribavirin and patient has thrombocytopenia defined as platelets less than 75,000/mcL. Severe aplastic anemia (Initial): First-line treatment (in combination with standard immunosuppressive therapy) or treatment of severe (refractory) aplastic anemia in patient who has had an insufficient response to immunosuppressive therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, gastroenterologist, or infectious disease specialist
Coverage Duration	ITP: 12mo. Hepatitis C (Initial): 9 weeks, (Reauth): 24 weeks. Aplastic anemia: 16 weeks.
Other Criteria	(Reauth): Patient has experienced an increase in platelet count.

## ELUXADOLINE (VIBERZI)

#### **Products Affected**

• Viberzi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diarrhea predominant irritable bowel syndrome (IBS): Diagnosis of diarrhea predominant irritable bowel syndrome (IBS) and history of trial and failure, contraindication, or intolerance to conventional therapy (such as loperamide or diphenoxylate/atropine).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

### **ENZYME INHIBITORS FOR GAUCHER DISEASE**

#### **Products Affected**

• Miglustat

• Cerdelga

• Yargesa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of Gaucher disease type 1. Patient is unable to receive enzyme replacement therapy (due to allergy, hypersensitivity, etc). For eliglustat: Have been determined to be CYP2D6 extensive, intermediate, or poor metabolizers by an FDA approved test
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## ERENUMAB (AIMOVIG)

### **Products Affected**

• Aimovig

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Migraine prevention: Patient has at least 4 migraine days per month. Trial and failure, contraindication, or intolerance to a generic preventive migraine medication (e.g., antidepressant [e.g., amitriptyline, venlafaxine], antiepileptic [e.g., divalproex sodium, topiramate], or antihypertensive [e.g., propranolol, verapamil]). Trial and failure, contraindication, or intolerance to galcanezumab (Emgality)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Not being used in addition to another CGRP inhibitor preventative.

### **ERYTHROPOIESIS STIMULATING AGENTS**

#### **Products Affected**

- Aranesp Albumin Free INJ 100MCG/0.5ML, 100MCG/ML, 10MCG/0.4ML, 150MCG/0.3ML, 200MCG/0.4ML, 200MCG/ML, 25MCG/0.42ML, 25MCG/ML, 300MCG/0.6ML, 40MCG/0.4ML, 40MCG/ML, 500MCG/ML, 60MCG/0.3ML, 60MCG/ML
- Retacrit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): Chronic kidney disease (CKD) or cancer chemotherapy: Hemoglobin level of less than 10 g/dL. Anemia related to zidovudine therapy (epoetin alfa only): Hemoglobin level of less than 10 g/dL. Elective non-cardiac or non-vascular surgery (epoetin alfa only): Hemoglobin level of less than 13 g/dL.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Surgery: 2 months. All other indications: 12 months

Other Criteria	This drug also requires payment determination. This drug may be either bundled with and covered under end stage renal disease dialysis related services or covered under Medicare Part D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. CKD (Reauth): Patient is not receiving dialysis treatment. One of the following applies: 1) Hemoglobin level of less than 10g/dL, or 2) Hemoglobin level has reached 10g/dL and dose reduction/interruption is required to avoid RBC transfusion. Cancer chemotherapy (Reauth): One of the following: 1) Hemoglobin level of less than 10g/dL, or 2) Hemoglobin level does not exceed a level to avoid RBC transfusion. Anemia related to zidovudine therapy (Reauth): Hemoglobin level between 10g/dL and 12g/dL.
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### **ETANERCEPT**

#### **Products Affected**

• Enbrel INJ 25MG/0.5ML, 50MG/ML

- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA): Diagnosis of moderately to severely active RA or PJIA and trial and failure to a 3 month trial of methotrexate. If methotrexate is contraindicated or not tolerated, than a 3 month trial with another disease modifying anti-rheumatic drug (DMARD) (eg, hydroxychloroquine, sulfasalazine, leflunomide, minocycline). Psoriatic arthritis (PsA): Diagnosis of active PsA and trial and failure, contraindication, or intolerance (TF/C/I) to a 3 month trial of methotrexate. Plaque psoriasis (PsO): Diagnosis of moderate to severe PsO and TF/C/I to two or more of the following: 1) Phototherapy (eg, PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B)), 2) Topical therapy (eg, corticosteroids, calcipotriene, retinoids, etc), 3) Oral therapy (eg, methotrexate, cyclosporine). Ankylosing spondylitis (AS): Diagnosis of active AS and TF/C/I to a 2 month trial of prescription doses of two different NSAIDS (eg, naproxen, nabumetone, diclofenac).
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. PsO: Prescribed by or in consultation with a dermatologist.
Coverage Duration	Indefinite

Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.
	kinase inhibitor.

### EVOLOCUMAB (REPATHA)

#### **Products Affected**

• Repatha

- Repatha Pushtronex System
- Repatha Sureclick

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)), homozygous familial hypercholesterolemia (HoFH), or established cardiovascular disease. LDL-C greater than or equal to 70 mg/dL. One of the following: (1) Taking a high-intensity statin (i.e., atorvastatin 40-80mg daily, rosuvastatin 20-40mg daily) for a duration of at least 8 weeks and will continue statin therapy, (2) Cannot tolerate a high-intensity statin for a duration of at least 8 weeks and will continue statin therapy, (3) Patient is considered to be statin intolerant, or (4) Has a contraindication to statin use (e.g., active liver disease or persistently elevated serum transaminases).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist
Coverage Duration	(Initial): 12 months, (Reauth): Indefinite
Other Criteria	(Reauth): Clinical documentation from the previous 12 months demonstrating a reduction in LDL-C from baseline. Continued treatment with baseline lipid-lowering therapies.

## FECAL MICROBIOTA CAPSULE (VOWST)

#### **Products Affected**

• Vowst

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Clostridioides difficile (C diff) infection, prophylaxis: Patient has had at least 2 recurrent episodes of C diff infection (i.e., at least 3 C diff infection episodes) (recurrent episode defined as recurrence of diarrhea and positive C diff test within 8 weeks after treatment of prior episode). Has a positive stool test for toxigenic C diff from a recent stool sample. C diff infection is refractory to standard antibiotic therapy (vancomycin or fidaxomicin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an Infectious Disease specialist or Gastroenterologist
Coverage Duration	1 month
Other Criteria	N/A

## **FENFLURAMINE (FINTEPLA)**

#### **Products Affected**

• Fintepla

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lennox-Gastaut or Dravet syndrome-associated seizures: Trial and failure, contraindication or intolerance to cannabidiol and one of the following: valproic acid or clobazam
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of therapy

# FENTANYL (ACTIQ)

#### **Products Affected**

• Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	For the management of breakthrough cancer pain. Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: morphine sulfate at doses of greater than or equal to 60 mg/day, fentanyl transdermal patch at doses greater than or equal to 25 mcg/hr, oxycodone at a dose of greater than or equal to 30 mg/day, oral hydromorphone at a dose of greater than or equal to 8 mg/day, oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). Patient has a trial and failure, contraindication or intolerance to a generic short-acting opioid (eg, oxycodone, hydromorphone, morphine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pain specialist or hematologist/oncologist.
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination.

# FIDAXOMICIN (DIFICID)

#### **Products Affected**

• Dificid

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapse or recurrence after a treatment course with vancomycin and documentation (i.e., PCR positive, toxin assay, or colonoscopy) of recurrent C. difficile infection or documented low levels of neutralizing antibodies to C. difficile.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	10 days
Other Criteria	Approval will be granted if member has been receiving fidaxomicin as an inpatient during hospitalization and needs to complete the course of therapy as an outpatient.

# FILGRASTIM (NEUPOGEN)

#### **Products Affected**

• Neupogen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	A trial and failure, contraindication or intolerance to Nivestym is required except when used to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (acute hematopoietic radiation injury syndrome).

## FINERENONE (KERENDIA)

#### **Products Affected**

• Kerendia

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic kidney disease (CKD) associated with type 2 diabetes: Patient has urine albumin creatinine ratio (UACR) greater than or equal to 30 mg/g and estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2. Serum potassium level is less than or equal to 5 mEq/L prior to initiating treatment. Using the highest labeled dose that is tolerated of an angiotensin- converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB), unless not tolerated or contraindicated. Using the highest labeled dose that is tolerated of a sodium-glucose cotransporter-2 (SGLT2) drug that has an indication for CKD benefit (dapagliflozin, empagliflozin), unless not tolerated or contraindicated. UACR remains above 30 mg/g despite use of ACE-I/ARB and SGLT2
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## FOSTAMATINIB (TAVALISSE)

#### **Products Affected**

• Tavalisse

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic immune thrombocytopenia (ITP) with a platelet count less than or equal to 50,000/mcL and trial and failure, intolerance or contraindication to two prior ITP therapies (e.g., corticosteroids, azathioprine, danazol, splenectomy, rituximab, eltrombopag, romiplostim).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Indefinite
Other Criteria	N/A

## FREMANEZUMAB (AJOVY)

#### **Products Affected**

• Ajovy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Migraine prevention: Patient has at least 4 migraine days per month. Trial and failure, contraindication, or intolerance to a generic preventive migraine medication (e.g., antidepressant [e.g., amitriptyline, venlafaxine], antiepileptic [e.g., divalproex sodium, topiramate], or antihypertensive [e.g., propranolol, verapamil]). Trial and failure, contraindication, or intolerance to galcanezumab (Emgality)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Not being used in addition to another CGRP inhibitor preventative.

## GALCANEZUMAB (EMGALITY)

#### **Products Affected**

• Emgality

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Migraine prevention: Patient has at least 4 migraine days per month. Trial and failure, contraindication, or intolerance to 2 generic preventive migraine medications (e.g., antidepressant [e.g., amitriptyline, venlafaxine], antiepileptic [e.g., divalproex sodium, topiramate], or antihypertensive [e.g., propranolol, verapamil]). Initial fill will be approved to allow a one-time loading dose (2 ml per 30 days). Cluster headaches: Diagnosis of cluster headaches that are not rebound headaches due to medication overuse.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Not being used in addition to another CGRP inhibitor preventative.

## GALSULFASE (NAGLAZYME)

### **Products Affected**

• Naglazyme

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome): Diagnosis of mucopolysaccharidosis VI (MPS VI) (Maroteaux-Lamy syndrome) to improve walking and stair-climbing capacity
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation from the previous 12 months that the patient has had improvement (or stable) in ambulation.

## GANAXOLONE (ZTALMY)

### **Products Affected**

• Ztalmy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD): Diagnosis of seizures associated with CDD.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or other specialist in the management of epilepsy.
Coverage Duration	Indefinite
Other Criteria	N/A

### GLUCAGON-LIKE PEPTIDE 1 (GLP-1) AGONISTS

#### **Products Affected**

• Bydureon Bcise

- Byetta
- Trulicity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of type 2 diabetes mellitus.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## GLYCOPYRRONIUM TOPICAL (QBREXZA)

#### **Products Affected**

• Qbrexza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Primary axillary hyperhidrosis: Clinical documentation of a persistent or chronic cutaneous condition due to excessive sweating (eg, skin maceration, dermatitis, fungal infection).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

### **GROWTH HORMONE (NONPREFERRED)**

#### **Products Affected**

- Humatrope INJ 12MG, 24MG, 6MG
- Nutropin AQ Nuspin 10

- Nutropin AQ Nuspin 20
- Nutropin AQ Nuspin 5
- Serostim INJ 4MG, 5MG, 6MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Athletic enhancement. Anti-aging purposes. Growth failure with closed epiphyses for pediatric growth hormone deficiency (GHD).
Required Medical Information	(Initial): Growth failure associated with SHOX deficiency, chronic kidney disease (CKD), pediatric GHD, ISS, SGA, TS: Height at least 2 standard deviations (SD) below the mean height for normal children of the same age and gender. Adult GHD: 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. HIV-associated wasting, cachexia: Diagnosis of HIV with wasting or cachexia in patient currently on HIV antiretroviral therapy and has had an inadequate response to previous therapy. Short-bowel syndrome: Diagnosis of short-bowl syndrome. For all diagnoses other than HIV-associated wasting/cachexia, or growth failure associated with SHOX deficiency or CKD: Previous trial and failure, contraindication or intolerance with Norditropin is required.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, nephrologist, nutritional support specialist, or infectious disease specialist.
Coverage Duration	12 months

Other Criteria	(Reauth): Growth failure associated with SHOX deficiency, CKD, pediatric GHD, ISS, SGA, TS, and Noonan syndrome: Physician attestation of improvement (i.e., increased height or increased growth velocity) and documention of open epiphyses within past 12 months. Prader Willi Syndrome: Physician attestation of improvement in body composition. Adult GHD: documentation from the past 12 months showing benefits from therapy. HIV/wasting: Patient has shown clinical benefit in muscle mass/weight and is currently on antiretroviral therapy. This drug also requires payment determination.
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## **GROWTH HORMONE (PREFERRED)**

### **Products Affected**

• Norditropin Flexpro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Athletic enhancement. Anti-aging purposes. Growth failure with closed epiphyses for pediatric growth hormone deficiency (GHD)
Required Medical Information	(Initial): Pediatric GHD, ISS, SGA, TS, and Noonan syndrome: Height at least 2 standard deviations (SD) below the mean height for normal children of the same age and gender. Prader Willi syndrome (PWS): Physician attestation of confirmed genetic diagnosis. Adult GHD: 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.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	(Reauth): Pediatric GHD, ISS, SGA, TS, and Noonan syndrome: Physician attestation of improvement (i.e., increased height or increased growth velocity). PWS: physician attestation of improvement in body composition. This drug also requires payment determination.

## GUSELKUMAB (TREMFYA)

### **Products Affected**

• Tremfya

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (PsO) (moderate to severe): Diagnosis of moderate to severe PsO and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, infliximab (Part B). Psoriatic arthritis (PsA): Diagnosis of moderate to severely active PsA and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, tofacitinib, upadacitinib, infliximab (Part B).
Age Restrictions	N/A
Prescriber Restrictions	PsO: Prescribed by or in consultation with a dermatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	Indefinite
Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.

### HEPATITIS C AGENTS

### **Products Affected**

Mavyret

- Sofosbuvir/velpatasvir
- Vosevi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Hepatitis C: Diagnosis of chronic hepatitis C virus. Criteria will be applied consistent with current AASLD/IDSA guideline. Patient is not receiving medication in combination with another HCV direct acting antiviral agent. For sofosbuvir/ velpatasvir/ voxilaprevir (Vosevi) only, one of the following also applies: 1) Genotype 1a patients who failed a sofosbuvir-based regimen without an NS5A inhibitor must have a trial and failure, contraindication, or intolerance to glecaprevir/ pibrentasvir (Mavyret) or 2) For continuation of prior sofosbuvir/ velpatasvir/ voxilaprevir (Vosevi) therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	8 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

### ICATIBANT (FIRAZYR)

#### **Products Affected**

• Sajazir

• Icatibant Acetate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist or other provider with experience in the treatment of HAE
Coverage Duration	Indefinite
Other Criteria	N/A

## **ICOSAPENT ETHYL (VASCEPA)**

### **Products Affected**

• Icosapent Ethyl

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cardiovascular risk reduction with mild hypertriglyceridemia: Diagnosis of established cardiovascular disease OR diabetes mellitus with at least 2 additional risk factors for cardiovascular disease. Triglyceride levels at least 150 mg/dL. Using as an adjunct to maximally tolerated statin therapy (unless documented statin contraindication or intolerance). Hypertriglyceridemia (severe): Triglyceride levels at least 500 mg/dL. Trial and failure, contraindication, or intolerance to omega-3 acid ethyl esters capsules AND fenofibrate.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or other lipid specialist
Coverage Duration	Indefinite
Other Criteria	N/A

## ILOPROST (VENTAVIS)

### **Products Affected**

• Ventavis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH and trial and failure, intolerance or contraindication to inhaled treprostinil.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	Indefinite
Other Criteria	This medication may be covered under Medicare Part D or Part B depending on the location of administration.

# INOTERSEN (TEGSEDI)

### **Products Affected**

• Tegsedi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR): confirmed diagnosis of neuropathy due to hATTR with documentation of TTR gene mutation and biopsy proven amyloid deposits. Drug is not being used in combination another TTR-lowering agent (inotersen, patisiran, vutrisiran). Drug is not being used in combination with a TTR-stabilizing agent (diflunisal, tafamidis, tafamidis meglumine).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, cardiologist, or other expert in hATTR
Coverage Duration	(Initial): 12 months. (Reauth): Indefinite
Other Criteria	(Reauth): Clinical documentation from the previous 12 months of response to therapy or documentation of clinical stability

### INSULIN DEGLUDEC (TRESIBA)

#### **Products Affected**

- Insulin Degludec
- Insulin Degludec Flextouch

- Tresiba
- Tresiba Flextouch

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diabetes Mellitus: Trial and failure, contraindication or intolerance to a formulary insulin glargine product or the patient's daily basal insulin dose is greater than 100 units per day.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or diabetes specialist
Coverage Duration	Indefinite
Other Criteria	N/A

### **INSULIN POD**

#### **Products Affected**

- Omnipod 5 G6 Intro Kit (gen 5)
- Omnipod 5 G6 Pods (gen 5)
- Omnipod 5 G7 Intro Kit (gen 5)
- Omnipod 5 G7 Pods (gen 5)

- Omnipod Dash Pdm Kit (gen 4)
- Omnipod Dash Pods (gen 4)
- V-go 20
- V-go 30
- V-go 40

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diabetes Mellitus (DM): Diagnosis of Type 1 or Type 2 diabetes mellitus. Must meet 1 of the following: 1) Person must be an appropriate candidate for continuous subcutaneous insulin infusion pump, as indicated by ALL of the following: A) Person has completed comprehensive diabetes education program, B) Person has been using at least 3 daily injections of insulin with frequent self-adjustments of insulin dose for at least 6 months, C) Person has documented frequency of glucose self-testing average of at least 4 times per day for past 2 months, and D) Person meets 1 or more of the following: HbA1C greater than 7%, history of recurring hypoglycemia, wide fluctuations in blood glucose before mealtime, dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, or history of severe glycemic excursions, or 2) Person is established on an external insulin infusion pump and has documented frequency of glucose self-testing average of at least 4 times per day during previous month.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or other provider with expertise in the management of diabetes (e.g. CDE)
Coverage Duration	12 months

Other Criteria	(Reauth): Person has been evaluated within the past 12 months by an endocrinologist or other diabetes specialist and documentation
	supporting continuing use of the pump.

## INTERFERON GAMMA 1B (ACTIMMUNE)

#### **Products Affected**

• Actimmune

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# ISTURISA (S)

#### **Products Affected**

• Isturisa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient.
Age Restrictions	N/A
Prescriber Restrictions	Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Cushing's disease (initial, reauth): 12 months
Other Criteria	Cushing's disease (reauth): Patient demonstrates positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease).

### ITRACONAZOLE (SPORANOX)

#### **Products Affected**

• Itraconazole SOLN

• Itraconazole CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) Patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or 2) All of the following: A) Patient has a diagnosis of onychomycosis confirmed by culture or positive KOH test (capsule only), and B) Patient has had a trial and failure, intolerance or contraindication to oral terbinafine, or 3) Patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (oral solution only).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Systemic fungal infection: 12 months. Candidiasis, onychomycosis: 4 months
Other Criteria	N/A

# IVABRADINE (CORLANOR)

#### **Products Affected**

• Corlanor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Adult) Diagnosis of stable, symptomatic heart failure in sinus rhythm with a left ventricular ejection fraction less than or equal to 35% and a resting heart rate at least 70 beats per minute. Trial and failure, intolerance, or contraindication to maximally tolerated doses of at least one beta-blocker. (Pediatric) Diagnosis of stable, symptomatic heart failure due to dilated cardiomyopathy (with a left ventricular ejection fraction less than or equal to 45%) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	Indefinite
Other Criteria	N/A

## IVACAFTOR (KALYDECO)

#### **Products Affected**

• Kalydeco

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF) (Initial): Patient is heterozygous for a mutation in the CF Transmembrane Conductase Regulator (CFTR) gene that is responsive to ivacaftor as noted in the product labeling
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a cystic fibrosis specialist or pulmonologist.
Coverage Duration	12 months
Other Criteria	(Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations, improvement in BMI from baseline, patient-specific description of benefit).

### LANADELUMAB (TAKHZYRO)

### **Products Affected**

• Takhzyro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Will not be used in combination with other approved treatments for HAE prophylaxis.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an allergist or other provider with experience in the treatment of HAE
Coverage Duration	6 months
Other Criteria	(Reauth): Physician attestation of improvement of HAE (ie, reductions in attack frequency or attack severity).

## LASMIDITAN (REYVOW)

#### **Products Affected**

• Reyvow

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute migraine treatment: One of the following: 1) Trial and failure or intolerance to at least 2 triptan drugs (e.g. eletriptan, rizatriptan, sumatriptan, etc), or 2) Contraindication to triptan use and trial and failure, contraindication or intolerance to at least 2 non-triptan, prescription strength analgesics that are effective for migraine treatment (e.g., ibuprofen, naproxen, tramadol/acetaminophen, ergotamine, etc).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## LEFAMULIN (XENLETA)

#### **Products Affected**

• Xenleta TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) Patient has been receiving drug during hospitalization and needs to complete the course of therapy as an outpatient, or 2) Outpatient treatment of bacterial resistant strains as ordered by, or in consultation with, an infectious disease specialist and report of susceptibilities documenting resistance to preferred alternatives.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 month
Other Criteria	N/A

# LETERMOVIR (PREVYMIS)

#### **Products Affected**

• Prevymis TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cytomegalovirus (CMV)(prophylaxis): Prophylaxis of CMV infection and disease in CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) or high risk recipient (donor CMV seropositive/recipient CMV seronegative) of kidney transplant. Medication is initiated within the first 7 days post kidney transplant or 28 days post HSCT. Patient does not have active CMV infection (CMV PCR level over 250 IU/mL) and is not receiving preemptive treatment (ex. foscavir).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, infectious disease specialist, or transplant specialist
Coverage Duration	200 days post-transplant
Other Criteria	N/A

### LEUPROLIDE

#### **Products Affected**

- Eligard
- Leuprolide Acetate INJ 1MG/0.2ML, 22.5MG
- Lupron Depot (1-month)
- Lupron Depot (3-month)

- Lupron Depot (4-month)
- Lupron Depot (6-month)
- Lupron Depot-ped (1-month)
- Lupron Depot-ped (3-month)
- Lupron Depot-ped (6-month)

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of therapy.

# LEVODOPA (INBRIJA)

#### **Products Affected**

• Inbrija

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease (PD): Diagnosis of PD. Current treatment with combination of long-acting and short-acting carbidopa/levodopa. Patient experiencing intermittent "off" episodes.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or other expert in the treatment of Parkinson's disease
Coverage Duration	Indefinite
Other Criteria	N/A

### LOMITAPIDE (JUXTAPID)

#### **Products Affected**

• Juxtapid CAPS 10MG, 20MG, 30MG, 5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of homozygous familial hypercholesterolemia (HoFH) with either: 1) Clinical diagnosis (LDL-C greater than 500 mg/dL with xanthomas or family history of both parents with LDL-C levels greater than 250 mg/dL), OR 2) Genetic verification of HoFH. LDL-C level greater than 70 mg/dL. Trial and failure, contraindication, or intolerance to a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor unless there is genetic verification of receptor negative (null-null mutation) HoFH.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by, or in consultation with, a cardiologist or other specialist in the treatment of congenital lipid disorders
Coverage Duration	Initial: 12 months. Renewal: Indefinite
Other Criteria	(Renewal): Documentation of a clinically meaningful (at least a 10%) reduction in LDL-C from baseline

## LONAFARNIB (ZOKINVY)

#### **Products Affected**

• Zokinvy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Hutchinson-Gilford progeria syndrome or processing- deficient progeroid laminopathies.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the treatment of progeria or related syndromes
Coverage Duration	12 months
Other Criteria	(Renewal): Clinical documentation from the preceding 12 months indicating that use of the drug has slowed the disease progression and function is improved relative to the expected natural course of the disease.

### LUMACAFTOR/IVACAFTOR (ORKAMBI)

#### **Products Affected**

• Orkambi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF) (Initial): Patient is homozygous for the F508del CFTR mutation in the CF Transmembrane Conductase Regulator (CFTR) gene. If 6 years of age or older, must have history of trial and failure, contraindication or intolerance to elexacaftor/tezacaftor/ivacaftor.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a cystic fibrosis specialist or pulmonologist.
Coverage Duration	12 months
Other Criteria	(Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations, improvement in BMI from baseline, patient-specific description of benefit).

## MARALIXIBAT (LIVMARLI)

### **Products Affected**

• Livmarli

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cholestatic pruritus due to Alagille syndrome (ALGS) (Initial): Diagnosis of cholestatic pruritus due to ALGS with supporting labs (ie. total serum bile acid greater than 3 times the upper limit of normal, unexplained fat-soluble vitamin deficiency, etc). Patient has nothad a liver transplant or decompensated liver disease. Patient has presence ofmoderate to severe pruritus. Trial and failure, contraindication or intolerance toat least two medications for pruritus (ie, cholestyramine, rifampin, naltrexone).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with an expert in the treatment of cholestasis (ie, hepatologist, gastroenterologist)
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation from the previous 12 months of therapy indicating improvement or stabilization in pruritus compared to baseline (ie, change in patient reported itch, change in sleeping habits due to itch, etc.) and the individual is tolerating therapy (ie, does not have chronic diarrhea requiring ongoing intravenous fluids, bile acid reduction, etc.)

## MARIBAVIR (LIVTENCITY)

### **Products Affected**

• Livtencity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cytomegalovirus (CMV) infection: Diagnosis is based on clinical history and laboratory testing. Positive history of stem cell or solid organ transplant. Documentation of baseline viral load prior to initiating. Prior treatment failure with at least one of the following ganciclovir, valganciclovir, cidofovir or foscarnet.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist, infectious Disease, or transplant specialist.
Coverage Duration	16 weeks
Other Criteria	N/A

## MAVACAMTEN (CAMZYOS)

### **Products Affected**

• Camzyos

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypertrophic cardiomyopathy with left ventricular outflow tract obstruction: Diagnosis of obstructive hypertrophic cardiomyopathy with New York Heart Association (NYHA) class II-III symptoms and left ventricular ejection fraction (LVEF) of at least 55%. Previous trial and failure, contraindication, or intolerance to a class 1a antiarrhythmics (ie, disopyramide) in combination with a beta- blocker (ie, metoprolol, carvedilol) OR calcium channel blocker (ie, diltiazem, verapamil).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or other expert in the treatment of hypertrophic cardiomyopathy
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation from the previous 12 months that described response as stable disease or improvement seen on therapy.

## MECASERMIN (INCRELEX)

### **Products Affected**

• Increlex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Insulin-like growth factor deficiency (IGFD) (Initial): Diagnosis of IGFD. Documentation of open epiphyses on last bone radiograph. Growth Hormone (GH) gene deletion (Initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH. Documentation of open epiphyses on last bone radiograph.
Age Restrictions	Less than 18 years old
Prescriber Restrictions	(Initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	12 months
Other Criteria	(Reauth): Evidence of positive response to therapy and documentation of open epiphyses.

### MEPOLIZUMAB (NUCALA)

### **Products Affected**

• Nucala INJ 100MG/ML, 40MG/0.4ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Eosinophilic asthma (EA): Diagnosis of EA with a documented blood eosinophil count of at least 150 cells/mm3 (other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out). Symptoms are not well controlled or poorly controlled despite use of medium to high- dose inhaled corticosteroids with a long-acting bronchodilator or leukotriene modifier (unless history of intolerance or contraindication). Eosinophilic granulomatosis with polyangiitis (EGPA): Confirmed diagnosis of relapsed or refractory EGPA defined as both of the following: 1) Blood eosinophil level of at least 10% or absolute eosinophil count greater than 1000 cells/ul with other causes ruled out, and 2) At least two of the following organ systems/features of EGPA disease: A) histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatosis inflammation, B) neuropathy, C) pulmonary infiltrates, D) sino-nasal abnormality, E) cardiomyopathy, F) glomerulonephritis, G) alveolar hemorrhage , H) palpable purpura, and I) positive antineutrophil cytoplasmic antibody [ANCA]. Patient has had a trial and failure, intolerance or contraindication to prednisone and an immunosuppressant (e.g., cyclophosphamide, azathioprine). Hypereosinophilic syndrome (HES): Diagnosis of HES for at least 6 months without an identifiable non-hematologic secondary cause (i.e. cancer, imatinib-sensitive conditions, etc). Blood eosinophil count of 1,000 cells/mcL on at least two occasions. Worsening of HES symptoms despite use of steroid-sparing preventive treatments for at least 4 weeks (eg, hydroxyurea, interferon-alfa, cyclosporine).
Age Restrictions	N/A

Prescriber Restrictions	Prescribed by or in consultation with an asthma specialist, allergist, otolaryngologist, immunologist, pulmonologist, hematologist, or rheumatologist.
Coverage Duration	Indefinite
Other Criteria	Chronic rhinosinusitis with nasal polyposis (CRSwNP): Documentation of evidence of nasal polyps by direct exam, endoscopy, or sinus CT scan. Persistent or worsening nasal polyps despite being on a daily nasal steroid. Inadequately controlled disease despite prior use of systemic steroids and/or endoscopic sinus surgery. Will be used in conjunction with maintenance intranasal steroids.

# METRELEPTIN (MYALEPT)

### **Products Affected**

• Myalept

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lipodystrophy (Initial): Diagnosis of congenital or acquired generalized lipodystrophy. Trial and failure, contraindication, or intolerance to metformin and at least one statin medication (i.e., atorvastatin, rosuvastatin, simvastatin, etc).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# MIFEPRISTONE (KORLYM)

### **Products Affected**

• Mifepristone TABS 300MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hyperglycemia in Cushing syndrome: Hyperglycemia occurring secondary to hypercortisolism in patient with endogenous Cushing syndrome who has type 2 diabetes mellitus or glucose intolerance and has failed surgery (or is not a surgical candidate).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# MIGALASTAT (GALAFOLD)

### **Products Affected**

• Galafold

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Severe renal impairment (EGFR less than 30mL/min/1.73m2) or ESRD requiring dialysis.
Required Medical Information	Patient has a confirmed diagnosis of Fabry disease with documentation of an amenable galactosidase alpha gene (GLA) variant. Patient will not be using migalastat in combination with enzyme replacement therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# MITAPIVAT (PYRUKYND)

#### **Products Affected**

• Pyrukynd Taper Pack

• Pyrukynd

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hemolytic anemia (Initial): Diagnosis of hemolytic anemia in adult with pyruvate kinase deficiency.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or other expert in treating hemolytic anemia
Coverage Duration	(Initial): 6 months. (Reauth): 12 months
Other Criteria	Hemolytic anemia (Reauth): Diagnosis of hemolytic anemia in adult with pyruvate kinase deficiency. Clinical documentation from the previous 6 (initial) or 12 months that demonstrates a response to therapy such as improvement of hemoglobin, reduction in markers of hemolysis (eg, indirect bilirubin, lactate dehydrogenase (LDH), or haptoglobin), reduction in required RBC transfusions.

# MODAFINIL (PROVIGIL)

#### **Products Affected**

• Modafinil TABS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of excessive sleepiness due to narcolepsy, obstructive sleep apnea, or shift work disorder
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination.

# MULTIPLE SCLEROSIS (1) - PREFERRED AGENTS

#### **Products Affected**

- Avonex INJ 30MCG/0.5ML
- Avonex Pen
- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack
   CDPK 0
- Extavia
- Fingolimod Hydrochloride
- Gilenya CAPS 0.25MG
- Glatiramer Acetate

- Glatopa
- Plegridy
- Plegridy Starter Pack
- Rebif
- Rebif Rebidose
- Rebif Rebidose Titration Pack
- Rebif Titration Pack
- Teriflunomide

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Multiple sclerosis (MS): Diagnosis of a relapsing form of MS (including clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	N/A

# MULTIPLE SCLEROSIS (2)- NONPREFERRED

### **Products Affected**

• Mavenclad

• Kesimpta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of a relapsing form of MS (including relapsing-remitting disease and active secondary progressive disease) (cladribine and ofatumumab) or clinically-isolated syndrome (ofatumumab). Trial/failure to fingolimod or dimethyl fumarate OR contraindication, intolerance, or inability to take to fingolimod and dimethyl fumarate.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	N/A

# NATALIZUMAB (TYSABRI)

### **Products Affected**

• Tysabri

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsing forms of multiple sclerosis (MS) (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease): One of the following: 1) Trial and failure with fingolimod or dimethyl fumarate, or 2) Contraindication or intolerance to both fingolimod and dimethyl fumarate. Crohn Disease (CD): Diagnosis of moderate to severe CD. Trial and failure, contraindication or intolerance to adalimumab (Humira) and infliximab (Part B).
Age Restrictions	N/A
Prescriber Restrictions	MS: Prescribed by or in consultation with a neurologist. CD: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	This also requires payment determination and may be covered under Medicare Part B or D.

# NINTEDANIB (OFEV)

#### **Products Affected**

• Ofev

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosed with idiopathic pulmonary fibrosis (IPF) (confirmed by high-resolution computed tomography), systemic sclerosis associated interstitial lung disease (SSC-ILD), or chronic fibrosing interstitial lung diseases with a progressive phenotype.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	Indefinite
Other Criteria	N/A

# NITISINONE (ORFADIN, NITYR)

#### **Products Affected**

• Nityr

• Nitisinone

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hereditary tyrosinemia: Diagnosis of hereditary tyrosinemia type 1 with detectable succinylacetone blood or urine levels
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# NON-SOLID DOSAGE FORMS

#### **Products Affected**

- Aspruzyo Sprinkle
- Atorvaliq
- Famotidine SUSR
- Katerzia
- Lansoprazole TBDD

- Naproxen SUSP
- Norliqva
- Sevelamer Carbonate PACK
- Thyquidity
- Valsartan SOLN
- Zonisade

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Intolerance to or inability to take solid dosage form.

# **OBETICHOLIC ACID (OCALIVA)**

### **Products Affected**

Ocaliva

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Primary biliary cholangitis: Diagnosis of primary biliary cholangitis with an alkaline phosphatase level greater than 1.6 times the upper limit of normal (ULN) and/or a total bilirubin between 1-2 times the ULN. Patient does not have compensated cirrhosis with portal hypertension or a history of decompensated cirrhosis. Will be used in combination with ursodiol unless patient has had a trial and failure, contraindication, or intolerance to ursodiol.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# ODEVIXIBAT (BYLVAY)

#### **Products Affected**

• Bylvay (pellets)

• Bylvay

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pruritus associated with progressive familial intrahepatic cholestasis (PFIC) (Initial): Diagnosis of pruritus associated with progressive familial intrahepatic cholestasis (PFIC) confirmed by genetic testing. Genetic testing does not indicate PFIC type 2 with ABCB11 variant encoding for nonfunctioning or absence of bile salt export pump protein (BSEP-3). Patient has not had a liver transplant, biliary diversion surgery within the past 6 months, or decompensated liver disease. Patient has presence of moderate to severe pruritus. Trial and failure, contraindication or intolerance to at least two medications for pruritus (ie, cholestyramine, rifampin, naltrexone).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with an expert in the treatment of cholestasis (ie, hepatologist, gastroenterologist)
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation from the previous 12 months of therapy indicating improvement or stabilization in pruritus compared to baseline (ie, change in patient reported itch, change in sleeping habits due to itch, etc.) and the individual is tolerating therapy (ie, does not have chronic diarrhea requiring ongoing intravenous fluids, bile acid reduction, etc.)

# OLANZAPINE/SAMIDORPHAN MALATE (LYBALVI)

#### **Products Affected**

• Lybalvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Schizophrenia / Bipolar I: Diagnosis of schizophrenia and/or bipolar I disorder. Patient is at high risk of weight gain. Trial and failure, contraindication or intolerance intolerance to two of the following: risperidone, clozapine, olanzapine, quetiapine, ziprasidone, aripiprazole, lurasidone, cariprazine.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist
Coverage Duration	12 months
Other Criteria	N/A

# OMADACYCLINE (NUZYRA)

### **Products Affected**

• Nuzyra

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Medication is being used to treat an infection that is proven or strongly suspected to be caused by susceptible bacteria.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	1 month
Other Criteria	N/A

# OMALIZUMAB (XOLAIR)

### **Products Affected**

• Xolair

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Asthma: All of the following: Moderate to severe asthma, serum IgE level greater than or equal to 30 IU/mL, positive test or in vitro reactivity to common aeroallergens (eg, dust mites, pet dander, etc), and inadequately controlled asthma despite at least 3 months of use of medium to high-dose inhaled corticosteroids and long- acting beta agonist (LABA) or leukotriene modifiers. Chronic idiopathic urticaria (CIU): Chronic (at least 3 months), refractory urticaria despite use of BOTH of the following: scheduled high- dose nonsedating antihistamines and at least one short course of corticosteroids. Chronic rhinosinusitis with nasal polyposis (CRSwNP): Documentation of evidence of nasal polyps by direct exam, endoscopy, or sinus CT scan. Persistent or worsening nasal polyps despite being on a daily nasal steroid. Inadequately controlled disease despite prior use of systemic steroids and/or endoscopic sinus surgery greater than 6 months ago. Will be used in conjunction with maintenance intranasal steroids.
Age Restrictions	N/A
Prescriber Restrictions	CRSwNP: Prescribed by or in consultation with a specialist experienced in the treatment of nasal polyps (eg, allergist, otolaryngologist)
Coverage Duration	Indefinite
Other Criteria	N/A

# **OTESECONAZOLE (VIVJOA)**

### **Products Affected**

• Vivjoa

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Vulvovaginal candidiasis (recurrent): Current diagnosis of vulvovaginal candidiasis with positive KOH test. History of recurrent vulvovaginal candidiasis with 3 or more episodes of vulvovaginal candidiasis in the past 12 months. Person is not of reproductive potential (ie postmenopausal, permanent infertility, tubal ligation, etc). Trial and failure, contraindication, or intolerance of maintenance fluconazole therapy (at least 6 months).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

# OZANIMOD (ZEPOSIA)

#### **Products Affected**

• Zeposia

- Zeposia 7-day Starter Pack
- Zeposia Starter Kit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Relapsing forms of multiple sclerosis (MS) (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease): Trial and failure, contraindication or intolerance to both fingolimod and dimethyl fumarate. Ulcerative colitis (UC): Trial and failure, contraindication or intolerance to any two of the following: adalimumab (Humira), tofacitinib (Xeljanz), upadacitinib (Rinvoq), infliximab (Part B).
Age Restrictions	N/A
Prescriber Restrictions	MS: Prescribed by or in consultation with a neurologist. UC: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	N/A

# PARATHYROID HORMONE

#### **Products Affected**

• Tymlos

• Teriparatide

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	(Initial): One of the following diagnoses and associated criteria: 1) Diagnosis of postmenopausal osteoporosis defined as bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND at very high risk of fracture defined by AT LEAST ONE of the following: recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very low T-score (less than -3.0), high risk for falls, or history of injurious falls, or 2) Diagnosis of postmenopausal osteopenia defined as BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND at very high risk of fracture defined by AT LEAST ONE of the following: recent fracture (e.g. within past 12 months), fracture while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoid use), very high FRAX (major osteoporotic fracture at least 30%, hip fracture at least 4.5%), high risk for falls, or history of injurious falls, or 3) Diagnosis of osteoporosis related to prolonged steroid use and has (i.e. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week), or 4) Male with a diagnosis of primary osteoporosis, hypogonadal osteoporosis, or high risk for fracture (defined as history of osteoporotic fracture or multiple risk factors for fracture) AND meets one of the following: A) Failed therapy with at least one bisphosphonate (i.e. low-trauma fractures or decrease in BMD while on alendronate 70 mg per week), OR B) T-score of less than -2.5 and at least one fragility fracture.
Age Restrictions	N/A

Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation of a positive clinical response to therapy. Treatment duration with abaloparatide (Tymlos) and/or teriparatide has not exceeded a total of 24 months during the patient's lifetime (unless patient remains at or returns to having a high risk for fracture).

# PARATHYROID HORMONE (NATPARA)

### **Products Affected**

• Natpara

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypocalcemia: Diagnosis of hypocalcemia due to chronic hypoparathyroidism. Patient has symptomatic hypocalcemia or a corrected serum calcium less than 8.0 mg/dL.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Indefinite
Other Criteria	N/A

# PASIREOTIDE (SIGNIFOR)

### **Products Affected**

• Signifor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cushing disease: Diagnosis of Cushing disease and pituitary surgery is not an option or is not curative. Trial and failure, contraindication, or intolerance to octreotide.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# **PEGCETACOPLAN (EMPAVELI)**

### **Products Affected**

• Empaveli

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Paroxysmal nocturnal hemoglobinuria (PNH): Confirmed diagnosis of PNH by flow cytometry. Low hemoglobin (less than or equal to 9 mg/dL with symptoms of anemia), elevated lactate dehydrogenase level (LDH at least 1.5 X ULN) and/or number of transfusions in last year. Documentation of the clinical manifestations of disease (eg, major vascular event, transfusion dependence, renal insufficiency, disabling fatigue and/or other end organ manifestations). Documentation of receipt of Advisory Committee on Immunization Practices (ACIP) recommended vaccinations at least two weeks prior to therapy initiation as outlined in drug REMS program. Drug is not being used in combination with another complement inhibitor. Combination of pegcetacoplan may be considered for circumstances where all three individual complement inhibitors failed to adequately control anemia (eculizumab or ravulizumab) or there are signs of ongoing hemolysis (pegcetacoplan
Age Restrictions	At least 18 years old
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation of improvement or clinical stability in hemoglobin, lactate dehydrogenase, haptoglobin level and/or number of transfusions in the past year. This drug also requires payment determination and may be covered under Medicare Part B or D.

# **PEGVALIASE (PALYNZIQ)**

## **Products Affected**

• Palynziq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of phenylketonuria (PKU). Patient has uncontrolled blood phenylalanine (Phe) concentrations greater than 600 micromol/L (10mg/dL) despite at least a two month trial of sapropterin. Sapropterin must be discontinued prior to start of pegvaliase.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	(Reauth): Patient has experienced an objective improvement on therapy. Not on concurrent sapropterin.

# **PEGVISOMANT (SOMAVERT)**

### **Products Affected**

• Somavert

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acromegaly: Diagnosis of acromegaly and both of the following: 1) Inadequate response to surgery, and 2) Trial and failure or intolerance to somatostatin therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	Indefinite
Other Criteria	N/A

# **PEGYLATED INTERFERONS (PEGASYS, PEGINTRON)**

#### **Products Affected**

• Pegasys

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic Hepatitis B: Used for treatment of adults with HBeAg positive or HBeAg negative chronic Hepatitis B who have compensated liver disease and evidence of viral replication and liver inflammation. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepB: 48 wks. HepC: As indicated in package labeling or hcvguidelines.org
Other Criteria	N/A

# **PIMAVANSERIN (NUPLAZID)**

#### **Products Affected**

• Nuplazid TABS 10MG

• Nuplazid CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease psychosis with documented hallucinations or delusions and dose reductions and alterations in scheduling of dopaminergic agents led to increased Parkinson's symptoms.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of prior therapy

# **PIRFENIDONE (ESBRIET)**

#### **Products Affected**

• Pirfenidone TABS 267MG, 801MG

• Pirfenidone CAPS

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosed with idiopathic pulmonary fibrosis (IPF) confirmed by high-resolution computed tomography
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	Indefinite
Other Criteria	N/A

# **PRUCALOPRIDE (MOTEGRITY)**

### **Products Affected**

• Motegrity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic idiopathic constipation (CIC): Diagnosis of CIC and trial and failure, contraindication, or intolerance to lubiprostone and linaclotide.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# **PULMONARY ARTERIAL HYPERTENSION**

#### **Products Affected**

- Adempas
- Ambrisentan
- Opsumit
- Orenitram
- Orenitram Titration Kit Month 1

- Orenitram Titration Kit Month 2
- Orenitram Titration Kit Month 3
- Tracleer
- Uptravi TABS
- Uptravi Titration Pack

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	Indefinite
Other Criteria	N/A

# QUININE SULFATE (QUALAQUIN)

#### **Products Affected**

• Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Malaria: Diagnosis of uncomplicated chloroquine-resistant malaria. Will be used in combination with other antimalarial agents.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A

# RELUGOLIX-ESTRADIOL-NORETHINDRONE (MYFEMBREE)

#### **Products Affected**

• Myfembree

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Has received a total of 24 months cumulative treatment with relugolix-estradiol-norethindrone (Myfembree). Patient is postmenopausal.
Required Medical Information	Heavy menstrual bleeding: Diagnosis of heavy menstrual bleeding due to uterine fibroids. Trial and failure, intolerance, or contraindication to TWO of the following: Combined estrogen- progestin oral contraceptives, levonorgestrel-releasing intrauterine device (IUD), tranexamic acid. Moderate to severe pain associated with endometriosis: Previous trial and failure, contraindication or intolerance to an NSAID (e.g., naproxen, ibuprofen) and oral contraceptive.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an expert in the treatment of obstetrics and/or gynecology
Coverage Duration	24 months
Other Criteria	N/A

# **RETINOIDS-TOPICAL**

#### **Products Affected**

- Aklief
- Altreno
- Avita
- Duobrii

- Tazarotene CREA
- Tazarotene GEL
- Tazorac CREA 0.05%
- Tretinoin CREA
- Tretinoin GEL

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	Wrinkles, photoaging, melasma
Required Medical Information	(For tretinoin): Acne: Diagnosis of acne. (For trifarotene): Diagnosis of acne and trial and failure, contraindication, or intolerance to tretinoin AND adapalene. (For tazarotene): One of the following: 1) Diagnosis of psoriasis, or 2) Diagnosis of acne and trial and failure, contraindication, or intolerance to tretinoin AND adapalene. (For halobetasol/tazarotene): Diagnosis of psoriasis and trial and failure, contraindication, or intolerance to one preferred high or super-high potency topical corticosteroid (eg, clobetasol propionate, desoximetasone, fluocinonide, halobetasol, triamcinolone 0.5%, etc).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# RILUZOLE (TIGLUTIK)

#### **Products Affected**

• Tiglutik

Teglutik

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of amyotrophic lateral sclerosis (ALS) and a trial of riluzole tablets was not tolerated due to an inability to swallow solid dosage forms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# RIMEGEPANT (NURTEC)

### **Products Affected**

• Nurtec

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute migraine treatment: One of the following: 1) Trial and failure or intolerance to at least 2 triptan drugs (e.g. eletriptan, rizatriptan, sumatriptan, etc), or 2) Contraindication to triptan use and trial and failure, contraindication or intolerance to at least 2 non-triptan, prescription strength analgesics that are effective for migraine treatment (e.g., ibuprofen, naproxen, tramadol/acetaminophen, ergotamine, etc). Migraine prevention: Patient has at least 4 migraine days per month. Trial and failure, contraindication, or intolerance to a generic preventive migraine medication (e.g., antidepressant [e.g., amitriptyline, venlafaxine], antiepileptic [e.g., divalproex sodium, topiramate], or antihypertensive [e.g., propranolol, verapamil]). Trial and failure, contraindication, or intolerance to galcanezumab (Emgality). Not being used in addition to another CGRP inhibitor preventative.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# RISANKIZUMAB (SKYRIZI)

#### **Products Affected**

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 600MG/10ML
- Skyrizi Pen

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Psoriatic arthritis (PsA): Diagnosis of active PsA and trial and failure, contraindication, or intolerance (TF/C/I) to a 3 month trial of methotrexate. Plaque psoriasis (PsO): Diagnosis of moderate to severe PsO and TF/C/I to two or more of the following: 1) Phototherapy (eg, PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B)), 2) Topical therapy (eg, corticosteroids, calcipotriene, retinoids, etc), 3) Oral therapy (eg, methotrexate, cyclosporine). Crohn's disease (CD): Diagnosis of moderately to severely active CD and one of the following: 1) Patient is high risk (age less than 30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc)), 2) Patient is low risk and TF/C/I to a 2 month trial of 2 conventional therapies (6-mercaptopurine, azathioprine, methotrexate, corticosteroid), conventional therapy is clinically inappropriate based on location of disease, or demonstrated steroid dependence.
Age Restrictions	N/A
Prescriber Restrictions	PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. PsO: Prescribed by or in consultation with a dermatologist. CD: Prescribed by or in consultation with a gastroenterologist.

Coverage Duration	Indefinite
Other Criteria	PsO, PsA: Will be approved to allow 150 mg per 28 days for the first dose. All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.

# RISDIPLAM (EVRYSDI)

#### **Products Affected**

• Evrysdi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Spinal muscular atrophy (SMA) (Initial): Diagnosis of SMA based on documentation of gene mutation analysis with bi-allelic SMN1 mutations (5q-autosomal recessive point mutation/deletion) phenotype 1, 2 or 3. Does not have advanced SMA (e.g. permanent ventilatory dependence, tracheostomy, complete limb paralysis, etc).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or other clinician with expertise in management and treatment of neuromuscular disorders
Coverage Duration	12 months
Other Criteria	(Renewal): Documentation indicating that patient has improved, maintained, or demonstrated less than expected decline in motor function assessments compared to baseline, OR in other muscle function.

# ROFLUMILAST (ZORYVE)

### **Products Affected**

• Zoryve CREA

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (PsO): Diagnosis of PsO. One of the following: 1) Trial and failure, contraindication, or intolerance to one formulary high or super-high potency topical corticosteroid (eg, betamethasone dipropionate, clobetasol, fluocinonide, etc), or 2) Patient has involvement of face or other sensitive area and trial and failure, contraindication, or intolerance to one formulary non- steroid therapy (eg, calcipotriene, acitretin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist
Coverage Duration	Indefinite
Other Criteria	N/A

# RUXOLITINIB (OPZELURA)

### **Products Affected**

• Opzelura

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis (Initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to treatment with a topical corticosteroid and a topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus). Vitiligo (Initial): Diagnosis of nonsegmental vitiligo. Area being treated does not exceed 10% body surface area (BSA). Patient meets one of the following: 1) Vitiligo affects one of the following areas: face, skin folds, and/or genitalia, 2) Trial and failure or contraindication to a medium-to-high potency topical corticosteroid, 3) Patient has steroid-induced atrophy, or 4) Patient has a history of long-term topical corticosteroid use.
Age Restrictions	N/A
Prescriber Restrictions	Vitiligo (Initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation of a positive response to therapy.

### SAPROPTERIN (KUVAN)

#### **Products Affected**

• Sapropterin Dihydrochloride

• Javygtor

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Phenylketonuria (PKU) (Initial): Diagnosis of PKU. Patient is not on concurrent pegvaliase therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	(Initial): 2 months. (Reauth): 12 months
Other Criteria	(Reauth): Patient has experienced an objective improvement on therapy. Patient is not on concurrent pegvaliase therapy.

## SATRALIZUMAB (ENSPRYNG)

### **Products Affected**

• Enspryng

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Neuromyelitis optica spectrum disorder (NMOSD) (Initial): Diagnosis of NMOSD confirmed by positive serologic test for anti- aquaporin-4 (AQP4) receptor antibody. Trial and failure, contraindication, or intolerance with at least one of the following: rituximab, mycophenolate or azathioprine. Medication will not be used in combination with other biologic treatments for NMOSD (ie, rituximab, inebilizumab, eculizumab). Initial fill will be approved to allow a one-time loading dose (2 ml per 28 days).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist, neurologist, or other specialist in NMOSD treatment
Coverage Duration	12 months
Other Criteria	(Renewal): Clinical documentation from the previous 12 months that describes the person's response as stable disease or improvement seen on therapy

### SECUKINUMAB (COSENTYX)

#### **Products Affected**

• Cosentyx

- Cosentyx Sensoready Pen
- Cosentyx Unoready

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Psoriatic arthritis (PsA): Diagnosis of active PsA and trial and failure, contraindication, or intolerance (TF/C/I) to a 3 month trial of methotrexate. Plaque psoriasis (PsO): Diagnosis of moderate to severe PsO and TF/C/I to two or more of the following: 1) Phototherapy (eg, PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B)), 2) Topical therapy (eg, corticosteroids, calcipotriene, retinoids, etc), 3) Oral therapy (eg, methotrexate, cyclosporine). Ankylosing spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA): Diagnosis of active AS or nr-axSpA and TF/C/I to a 2 month trial of prescription doses of two different NSAIDS (eg, naproxen, nabumetone, diclofenac). Enthesitis-related arthritis (ERA): Diagnosis of ERA. TF/C/I to at least one NSAID (eg, naproxen, nabumetone, diclofenac) and one DMARD (eg, methotrexate, sulfasalazine). Hidradenitis suppurativa (HS): Diagnosis of moderate to severe hidradenitis suppurativa.
Age Restrictions	N/A
Prescriber Restrictions	AS, nr-axSpA, ERA: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. PsO, HS: Prescribed by or in consultation with a dermatologist.
Coverage Duration	Indefinite

Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor. HS: Will be approved to allow 300mg weekly for the first 5 weeks, then will allow a quantity of 300mg every 14 days thereafter.
	thereafter.

# SILDENAFIL (REVATIO)

#### **Products Affected**

• Sildenafil Citrate TABS 20MG

• Sildenafil Citrate SUSR

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH. (Sildenafil oral suspension only): One of the following: A) Intolerance to generic sildenafil tablets, or B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral-motor difficulties, or dysphagia.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination

## SODIUM OXYBATE (XYREM)

### **Products Affected**

• Sodium Oxybate

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of cataplexy or excessive daytime sleepiness associated with narcolepsy and trial and failure, contraindication or intolerance to modafinil or armodafinil.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	(Initial): 3 months. (Reauth): Indefinite
Other Criteria	(Reauth): Clinical documentation of objective symptom improvement.

# SODIUM PHENYLBUTYRATE-TAURURSODIOL (RELYVRIO)

#### **Products Affected**

• Relyvrio

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of amyotrophic lateral sclerosis (ALS). Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG). Patient has had ALS symptoms for less than or equal to 18 months. Patient has a percent (%) forced vital capacity (%FVC) or slow vital capacity (%SVC) greater than or equal to 60% at the start of treatment. Patient does not require permanent noninvasive ventilation or invasive ventilation.
Age Restrictions	N/A
Prescriber Restrictions	ALS (initial, reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS.
Coverage Duration	Initial, Reauth: 6 months
Other Criteria	Reauth: Patient demonstrates slowed disease progression from baseline.

# SOLRIAMFETOL (SUNOSI)

### **Products Affected**

• Sunosi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Excessive daytime sleepiness (EDS) in narcolepsy: Diagnosis of EDS in narcolepsy. Obstructive sleep apnea (OSA): The patient has had prior treatment, or is on ongoing treatment, to address the obstructive causes of OSA. All indications: Trial and failure, contraindication, or intolerance to modafinil or armodafinil.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine.
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination

## STIRIPENTOL (DIACOMIT)

### **Products Affected**

• Diacomit

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Dravet syndrome-associated seizures: Medication will be used in combination with clobazam AND valproic acid.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of prior therapy

### TACROLIMUS (PROGRAF GRANULES)

### **Products Affected**

• Prograf PACK

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	All indications: Patient has difficulty swallowing or other medical reasons which prevent use of the capsule formulation and trial and failure, contraindication, or intolerance to one alternative medication (e.g., cyclosporine, mycophenolate, sirolimus, etc).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	Approve for continuation of prior therapy

# TADALAFIL (ADCIRCA)

#### **Products Affected**

• Tadalafil TABS 20MG

• Alyq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH): Diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination.

# TADALAFIL (CIALIS)

#### **Products Affected**

• Tadalafil TABS 2.5MG, 5MG

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Benign prostatic hyperplasia (BPH): Diagnosis of BPH
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	This drug also requires payment determination.

### TAFAMIDIS (VYNDAQEL, VYNDAMAX)

#### **Products Affected**

• Vyndaqel

• Vyndamax

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Amyloid cardiomyopathy (Initial): Diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). New York Heart Association (NYHA) functional class I, II, or III heart failure.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation from the previous 12 months indicating a response to therapy. Patient has not progressed to NYHA class IV heart failure.

# TASIMELTEON (HETLIOZ)

#### **Products Affected**

• Tasimelteon

• Hetlioz LQ

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Non-24-hour sleep-wake disorder (Non-24): Diagnosis of non-24- hour sleep-wake disorder and patient is totally blind (has no light perception). Smith-Magenis syndrome: Diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist in sleep disorders or neurologist.
Coverage Duration	Indefinite
Other Criteria	N/A

# TEDIZOLID (SIVEXTRO)

### **Products Affected**

• Sivextro

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute bacterial skin infection: Report of susceptibilities documenting resistance to alternatives including linezolid or patient has contraindication or intolerance use of linezolid (e.g., taking serotonergic agents, etc)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	1 month
Other Criteria	N/A

# TEDUGLUTIDE (GATTEX)

### **Products Affected**

• Gattex

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Short bowel syndrome (SBS) (Initial): Diagnosis of SBS and patient is dependent on parenteral nutrition.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	(Initial): 6 months. (Reauth): Indefinite
Other Criteria	(Reauth): Patient has experienced an objective improvement on therapy.

# TELOTRISTAT (XERMELO)

### **Products Affected**

• Xermelo

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Carcinoid syndrome diarrhea: Diagnosis of diarrhea secondary to carcinoid tumor. Symptomatic (greater than 3 bowel movements per day) despite treatment with a somatostatin analog such as octreotide, lanreotide, pasireotide) for at least 3 months. Medication will be used in combination with a somatostatin analog.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Indefinite
Other Criteria	N/A

# **TENOFOVIR ALAFENAMIDE (VEMLIDY)**

#### **Products Affected**

• Vemlidy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B and previous trial and failure, contraindication or intolerance to both of the following: tenofovir disoproxil fumarate and entecavir (unless documented lamivudine resistance).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

### TESTOSTERONE

#### **Products Affected**

- Testosterone GEL
   20.25MG/1.25GM, 25MG/2.5GM,
   40.5MG/2.5GM, 50MG/5GM
- Testosterone Cypionate INJ 100MG/ML, 200MG/ML

- Testosterone Enanthate INJ
- Testosterone Pump

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG): Diagnosis of HG and two pre-treatment serum total testosterone (T) levels less than reference range for the lab.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

## **TEZACAFTOR/IVACAFTOR (SYMDEKO)**

#### **Products Affected**

• Symdeko

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF) (Initial): Patient meets ONE of the following: 1) Patient is homozygous for the F508del CFTR mutation in the CF Transmembrane Conductase Regulator (CFTR) gene. Trial and failure, contraindication or intolerance to both elexacaftor/tezacaftor/ivacaftor (Trikafta) and lumacaftor/ivacaftor (Orkambi), 2) Patient is heterozygous for the F508del CFTR mutation in the CFTR gene and trial and failure, contraindication or intolerance to elexacaftor/tezacaftor/ivacaftor (Trikafta), or 3) Patient is heterozygous for a CFTR mutation that is responsive to tezacaftor/ivacaftor as noted in the product labeling and trial and failure, contraindication or intolerance to elexacaftor/tezacaftor/ivacaftor (Trikafta).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a cystic fibrosis specialist or pulmonologist.
Coverage Duration	12 months
Other Criteria	(Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations, improvement in BMI from baseline, patient-specific description of benefit).

## TEZEPELUMAB (TEZSPIRE)

### **Products Affected**

• Tezspire

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	All Indications: One of the following: A) Symptoms not well controlled despite a 3-month trial of medium to high-dose inhaled corticosteroids (ICS) in combination with a long-acting bronchodilator (LABA), long-acting muscarinic antagonist (LAMA) or leukotriene modifier OR, B) Patient has intolerance to medium to high dose ICS with a LABA, LAMA, or leukotriene modifier. Exceptions based on adverse effects from ICS or comorbid conditions include: cataracts in patients over 40 years old, glaucoma, recurrent thrush, dysphonia, growth inhibition, diagnosis of osteoporosis (treatment resistant to FDA approved osteoporosis treatment). Eosinophilic asthma: documented blood eosinophil count of at least 150 cells/mm3 and other causes of eosinophilia such as hyper-eosinophilic syndromes, neoplastic disease, or parasitic disease have been ruled out. Trial and failure, contraindication, or intolerance (TF/C/I) to at least two self- administered biologic therapies for eosinophilic asthma. Allergic asthma: Diagnosis of moderate-to-severe persistent allergic asthma as defined by Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Guidelines (Step 5). Serum IgE level at least 30 international units (IU)/mL. Positive skin tests or in vitro reactivity to common aeroallergens (eg, pet dander, etc). TF/C/I to at least one self-administered biologic therapy for allergic asthma. Severe asthma: All the following: A) History of at least 2 asthma exacerbations requiring hospitalization, within the past 12 months, B) Asthma is non- eosinophilic (ie, eosinophils less than 150 cells/uL), C) Asthma is non-allergic (ie. serum IgE level less than 30 IU/mL, negative skin tests or in vitro reactivity to common aeroallergens), D) If oral corticosteroid dependent asthma.

Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an asthma specialist (allergist, immunologist, pulmonologist)
Coverage Duration	Indefinite
Other Criteria	N/A

### THROMBOPOIETIN RECEPTOR AGONISTS FOR LIVER FAILURE

#### **Products Affected**

• Mulpleta

• Doptelet

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Chronic liver disease-associated thrombocytopenia (scheduled to undergo procedure): Documentation of platelet count less than 50,000/mcL due to liver cirrhosis and scheduled procedure with moderate to high bleeding risk scheduled in the next 14 days. Chronic immune thrombocytopenia (cITP) (avatrombopag only): Diagnosis of cITP with platelet count less than 50,000/mcL and previous trial and failure, contraindication or intolerance to two prior ITP therapies (e.g., corticosteroids, rituximab, azathioprine, danazol, or splenectomy).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist, surgeon, hematologist, or gastroenterologist.
Coverage Duration	Surgery: 5 days (avatrombopag), 7 days (lusutrombopag). cITP: 12 months
Other Criteria	(avatrombopag only) Surgery: Quantity exception of 15 tablets (for a 5 day supply) will be approved. cITP (Reauth): Documentation of clinical response with increase in platelet count (ex: above 50,000/mcL)

### TOBRAMYCIN (TOBI) INHALED

#### **Products Affected**

• Tobramycin NEBU 300MG/5ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF): Diagnosis of cystic fibrosis and history of recurrent pseudomonas aeruginosa lung infections.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances.

# TOCILIZUMAB (ACTEMRA)

#### **Products Affected**

• Actemra Actpen

• Actemra INJ 162MG/0.9ML

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA): Diagnosis of moderately to severely active RA and trial and failure, contraindication or intolerance (TF/C/I) to any two of the following: adalimumab, etanercept, upadacitinib, tofacitinib, infliximab (Part B). Polyarticular juvenile idiopathic arthritis (PJIA): Diagnosis of moderately to severely active PJIA and TF/C/I to any two of the following: adalimumab, etanercept, tofacitinib. Systemic juvenile idiopathic arthritis (SJIA): TF/C/I to a 3 month trial of corticosteroids and methotrexate. Systemic sclerosis-associated interstitial lung disease (SSc-ILD): TF/C/I to at least one standard treatment (eg, mycophenolate mofetil, cyclophosphamide). Giant cell arteritis (GCA): One of the following: 1) Symptoms relapsed despite use of corticosteroids or methotrexate, 2) Contraindication or intolerance to methotrexate or corticosteroids, or 3) Inability to taper corticosteroids.
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA, SJIA: Prescribed by or in consultation with a rheumatologist. SSC-ILD: Prescribed by or in consultation with a rheumatologist or pulmonologist.
Coverage Duration	Indefinite
Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.

## TOFACITINIB (XELJANZ)

#### **Products Affected**

• Xeljanz XR

• Xeljanz

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA): Diagnosis of moderately to severely active RA or PJIA and trial and failure to a 3 month trial of methotrexate. If methotrexate is contraindicated or not tolerated, than a 3 month trial with another disease modifying anti-rheumatic drug (DMARD) (eg, hydroxychloroquine, sulfasalazine, leflunomide, minocycline). Psoriatic arthritis (PsA): Diagnosis of active PsA and trial and failure, contraindication, or intolerance (TF/C/I) to a 3 month trial of methotrexate. Ankylosing spondylitis (AS): Diagnosis of active AS and TF/C/I to a 2 month trial of prescription doses of two different NSAIDS (eg, naproxen, nabumetone, diclofenac). Ulcerative colitis (UC): Diagnosis of moderately to severely active UC and has had a short course (2-4 weeks) of oral corticosteroids (unless contraindicated).
Age Restrictions	N/A
Prescriber Restrictions	RA, PJIA, AS: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. UC: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor. TF/C/I to 1 or more preferred TNF blockers (for uses where TNF blockers are indicated)

# TOLVAPTAN (JYNARQUE)

### **Products Affected**

• Jynarque

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Autosomal dominant polycystic kidney disease (ADPKD): Diagnosis of ADPKD and estimated glomerular filtration rate of at least 25 mL/min.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a nephrologist or other expert in kidney disease
Coverage Duration	12 months
Other Criteria	(Reauth): Clinical documentation that current laboratory values for liver and kidney function remain within acceptable treatment ranges.

## TOLVAPTAN (SAMSCA)

### **Products Affected**

• Tolvaptan

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of hypervolemic and euvolemic hyponatremia that is severe (less than 125 mEq/L) or symptomatic less severe hyponatremia (NaCl 125 mEq/L - 134 mEq/L). Medication is being initiated in a hospital.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# TRIHEPTANOIN (DOJOLVI)

### **Products Affected**

• Dojolvi

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Long-chain fatty acid oxidation disorder (LC-FAOD): Diagnosis of long-chain fatty acid oxidation disorder, confirmed by disease- specific elevation of acylcarnitine, enzyme activity assay below lower limit of normal, and/or genetic testing showing mutation associated with long-chain fatty acid oxidation disorders.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a metabolic disease provider who specializes in the management of fatty acid oxidation disorders
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation from preceding 12 months to show object improvement from prior to initiating triheptanoin (eg improved cardiac symptoms/function, decreased hospitalizations or urgent care visits, decreased hypoglycemic episodes, etc.)

# UBROGEPANT (UBRELVY)

### **Products Affected**

• Ubrelvy

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Acute migraine treatment: One of the following: 1) Trial and failure or intolerance to at least 2 triptan drugs (e.g. eletriptan, rizatriptan, sumatriptan, etc), or 2) Contraindication to triptan use and trial and failure, contraindication or intolerance to at least 2 non-triptan, prescription strength analgesics that are effective for migraine treatment (e.g., ibuprofen, naproxen, tramadol/acetaminophen, ergotamine, etc).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

# UPADACITINIB (RINVOQ)

### **Products Affected**

• Rinvoq

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA): Diagnosis of moderately to severely active RA and trial and failure to a 3 month trial of methotrexate. If methotrexate is contraindicated or not tolerated, than a 3 month trial with another disease modifying anti-rheumatic drug (DMARD) (eg, hydroxychloroquine, sulfasalazine, leflunomide, minocycline). Psoriatic arthritis (PsA): Diagnosis of active PsA and trial and failure, contraindication, or intolerance (TF/C/I) to a 3 month trial of methotrexate. Ankylosing spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA): Diagnosis of active AS or nr-axSpA and TF/C/I to a 2 month trial of prescription doses of two different NSAIDS (eg, naproxen, nabumetone, diclofenac). Ulcerative colitis (UC): Diagnosis of moderately to severely active UC and patient is a high-risk individual (extensive colitis, deep ulcers, age less than 40 years, High CRP and ESR, steroid-requiring disease, history of hospitalization, C difficile infection, CMV infection, etc) and has had a short course (2-4 weeks) of oral corticosteroids (unless contraindicated). Crohn's disease (CD): Diagnosis of moderately to severely active CD and one of the following: 1) Patient is high risk (age less than 30 at diagnosis, extensive anatomic involvement, perianal and/or severe rectal disease, deep ulcers, prior surgical resection, stricturing and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation (i.e. uveitis, erythema nodosum, pyoderma gangrenosum, spondyloarthropathy, etc)), 2) Patient is low risk and TF/C/I to a 2 month trial of 2 conventional therapies (6-mercaptopurine, azathioprine, methotrexate, corticosteroid), conventional therapy is clinically inappropriate based on location of disease, or demonstrated steroid dependence.
Age Restrictions	N/A

Prescriber Restrictions	RA, AS, nr-axSpA: Prescribed by or in consultation with a rheumatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. AD: Prescribed by or in consultation with a dermatologist. CD, UC: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Indefinite
Other Criteria	Atopic Dermatitis (AD): Diagnosis of moderate to severe AD. TF/C/I to at least TWO of the following: topical corticosteroid, topical calcineurin inhibitor, topical phosphodiesterase 4 (PDE-4) inhibitor, topical janus kinase (JAK) inhibitor, or phototherapy. All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor. TF/C/I to 1 or more preferred TNF blockers (for uses where TNF blockers are indicated)

## URIDINE TRIACETATE (XURIDEN)

## **Products Affected**

• Xuriden

PA Criteria	Criteria Details	
Indications	All Medically-accepted Indications.	
Off-Label Uses	N/A	
Exclusion Criteria	N/A	
Required Medical Information	Hereditary orotic aciduria: Diagnosis of hereditary orotic aciduria.	
Age Restrictions	N/A	
Prescriber Restrictions	N/A	
Coverage Duration	(Initial): 3 months. (Reauth): Indefinite	
Other Criteria	(Reauth): Prescriber provides clinical documentation of improvement from baseline in both hematologic parameters (white blood cell count, red blood cell counts, etc) and urine orotic acid levels.	

## USTEKINUMAB (STELARA)

#### **Products Affected**

• Stelara INJ 45MG/0.5ML, 90MG/ML

PA Criteria	Criteria Details	
Indications	All Medically-accepted Indications.	
Off-Label Uses	N/A	
Exclusion Criteria	N/A	
Required Medical Information	Plaque psoriasis (PsO) (moderate to severe): Diagnosis of moderate to severe PsO and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, infliximab (Part B). Psoriatic arthritis (PsA): Diagnosis of active PsA and TF/C/I to any two of the following: adalimumab, etanercept, risankizumab, secukinumab, tofacitinib, upadacitinib, infliximab (Part B), Simponi Aria (Part B). Crohn's disease (CD): Diagnosis of moderately to severely active CD and TF/C/I to any two of the following: adalimumab, upadacitinib, infliximab (Part B). Ulcerative colitis (UC): Diagnosis of moderately to severely active UC and TF/C/I to any two of the following: adalimumab, upadacitinib, infliximab (Part B). Ulcerative colitis (UC): Diagnosis of moderately to severely active UC and TF/C/I to any two of the following: adalimumab, tofacitinib, upadacitinib, infliximab (Part B).	
Age Restrictions	N/A	
Prescriber Restrictions	PsO: Prescribed by or in consultation with a dermatologist. PsA: Prescribed by or in consultation with a rheumatologist or dermatologist. CD, UC: Prescribed by or in consultation with a gastroenterologist.	
Coverage Duration	Indefinite	
Other Criteria	PsO, PsA: Will be approved to allow a quantity of 1 dose per 28 days for the first fill for loading dose. CD, UC: Will be approved to allow a quantity of 1 dose every 56 days. All indications: Patient is not receiving requested medication in combination with another biologic disease modifying anti-rheumatic drug (DMARD) (eg, TNF antagonist, IL-12/23 inhibitor, etc) or janus kinase inhibitor.	

# VALBENAZINE (INGREZZA)

## **Products Affected**

• Ingrezza

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Tardive dyskinesia (Initial): Diagnosis of moderate to severe tardive dyskinesia. Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication (or patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a neurologist, psychiatrist, or other expert in the treatment of tardive dyskinesia.
Coverage Duration	Indefinite
Other Criteria	N/A

# VERICIGUAT (VERQUOVO)

## **Products Affected**

• Verquvo

PA Criteria	Criteria Details	
Indications	All Medically-accepted Indications.	
Off-Label Uses	N/A	
Exclusion Criteria	N/A	
Required Medical Information	Heart failure (HF): Diagnosis of symptomatic chronic HF and ejection fraction less than 45%. Heart-failure hospitalization within the past 6 months. Current use of the following HF treatments: a beta blocker and an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB). If use of an ACE inhibitor or ARB is not tolerated or contraindicated, an aldosterone antagonist (e.g. spironolactone, eplerenone) may be used instead.	
Age Restrictions	N/A	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or other specialist in the treatment of heart failure	
Coverage Duration	Indefinite	
Other Criteria	N/A	

# VOCLOSPORIN (LUPKYNIS)

### **Products Affected**

• Lupkynis

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Lupus nephritis: Diagnosis of biopsy-confirmed lupus nephritis. Documentation of active nephritis despite use of mycophenolate with corticosteroids (unless intolerance or contraindication). Medication will be used in combination with mycophenolate and corticosteroids (unless intolerance or contraindication). Not used in combination with cyclophosphamide.
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a nephrologist, rheumatologist, or other specialist in the treatment of lupus nephritis
Coverage Duration	(Initial): 6 months, (Reauth): 12 months
Other Criteria	(Reauth): Clinical documentation from the previous 6 to 12 months demonstrating benefits from therapy.

# VORAPAXAR (ZONTIVITY)

### **Products Affected**

• Zontivity

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	History of myocardial infarction (MI) or established peripheral arterial disease (PAD): Diagnosis of PAD or a history of MI. Cardiologist statement that the patient is at increased risk of thrombotic cardiovascular events despite being on combination therapy with both aspirin and P2Y12 therapy (clopidogrel, ticagrelor, or prasugrel).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist
Coverage Duration	Indefinite
Other Criteria	N/A

# VOXELOTOR (OXBRYTA)

### **Products Affected**

Oxbryta

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Sickle Cell Disease (SCD) (Initial): Diagnosis of sickle cell disease with persistent anemia. Patient is currently taking hydroxyurea, or has a history of trial and failure, contraindication, or intolerance to hydroxyurea. Baseline hemoglobin (Hb) is between 5.5 - 10.5 g/dL (prior to use of voxelotor). Not used in combination with crizanlizumab (Adakveo).
Age Restrictions	N/A
Prescriber Restrictions	(Initial): Prescribed by or in consultation with a hematologist or other provider experienced in the treatment of SCD.
Coverage Duration	12 months
Other Criteria	(Renewal): Clinical documentation from the previous 12 months demonstrating a response to therapy (i.e. decreased frequency of sickle cell hospitalizations or urgent care visits, decreased frequency of vasoocclusive crisis, reduction is use of pain medications, improved quality of life (e.g. decreased pain, fewer missed day of work/school, increase in activities, etc)

# ZURANOLONE (ZURZUVAE)

## **Products Affected**

• Zurzuvae

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A
Exclusion Criteria	N/A
Required Medical Information	Postpartum Depression (PPD): One of the following: A) Diagnosis of severe PPD or B) Both of the following: a) Diagnosis of mild to moderate PPD, and b) Trial and failure, contraindication, or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine). Onset of symptoms in the third trimester or within 4 weeks of delivery. Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae.
Age Restrictions	PPD: Patient is 18 years of age or older.
Prescriber Restrictions	N/A
Coverage Duration	14 days
Other Criteria	Approve for continuation of prior therapy.

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