ACITRETIN

MEDICATION(S)
ACITRETIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. For psoriasis: inadequate response, intolerance, or contraindication to methotrexate or cyclosporine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

ACTIMMUNE

MEDICATION(S)
ACTIMMUNE

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ACUTE SEIZURE AGENTS

MEDICATION(S)
NAYZILAM, VALTOCO 10 MG DOSE, VALTOCO 15 MG DOSE, VALTOCO 20 MG DOSE, VALTOCO 5 MG DOSE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Acute narrow-angle glaucoma.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ADALIMUMAB

MEDICATION(S)
HADLIMA, HADLIMA PUSHTOUCH, HUMIRA 10 MG/0.1ML PREF SY KT (ABBVIE PRODUCT ONLY), HUMIRA 20 MG/0.2ML PREF SY KT (ABBVIE PRODUCT ONLY), HUMIRA (2 PEN), HUMIRA (2 PEN) 40 MG/0.4ML AUT-IJ KIT (ABBVIE PRODUCT ONLY), HUMIRA (2 PEN) 80 MG/0.8ML AUT-IJ KIT (ABBVIE PRODUCT ONLY), HUMIRA (2 SYRINGE), HUMIRA 40 MG/0.4ML PREF SY KT (ABBVIE PRODUCT ONLY), HUMIRA-PSORIASIS/UVEIT STARTER

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Active non-radiographic axial spondyloarthritis (nr-axSpA).

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For rheumatoid arthritis (RA) and juvenile idiopathic arthritis (JIA): Documentation of inadequate response, intolerance, or contraindication to at least one conventional DMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine). For ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA): Documentation of inadequate response, intolerance, or contraindication to at least two NSAIDs. For moderate to severe plaque psoriasis (PsO): Documentation that the patient is a candidate for systemic therapy or phototherapy. Documentation of inadequate response, intolerance, or contraindication to at least one of the following: methotrexate, UVB therapy, or acitretin. For hidradenitis suppurativa (HS): Documentation of inadequate response, intolerance, or contraindication to at least one oral antibiotic (e.g., doxycycline, minocycline, amoxicillin-clavulanic acid, clindamycin, rifampin, dapsone). For Uveitis (UV): Documentation of inadequate response, intolerance, or contraindication to one or more oral or topical glucocorticoid (e.g., prednisone), immunosuppressant agent (e.g., methotrexate, azathioprine, mycophenolate), or periocular or intraocular injection (e.g., triamcinolone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with an appropriate specialist such as a rheumatologist, dermatologist, gastroenterologist, or ophthalmologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

ADEMPAS

MEDICATION(S)
ADEMPAS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Female patients who are pregnant or planning on becoming pregnant. Concurrent use with nitrates or nitric oxide donors in any form. Concurrent use with phosphodiesterase inhibitors. Pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of Pulmonary Arterial Hypertension WHO Group 1 with New York Heart Association (NYHA) Functional Class II-III by complete right heart catheterization (RHC) with results attached. Mean pulmonary artery pressure (mPAP) greater than 20 mmHg, pulmonary vascular resistance (PVR) greater than 2 wood units, and a mean pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. For WHO group IV: Confirmed diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) with documentation verifying that patient has recurrent or persisting pulmonary hypertension following pulmonary thromboendarterectomy or inoperable CTEPH.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist, pulmonologist, or practitioner at a Pulmonary Hypertension Association-Accredited center.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response or stabilization.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

ALOSETRON

MEDICATION(S)
ALOSETRON HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Exclude if male gender.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of severe diarrhea-predominant irritable bowel syndrome. Documentation of inadequate response, intolerance, or contraindication to an anti-diarrheal agent (e.g., loperamide).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

ALPHA1-PROTEINASE INHIBITORS

MEDICATION(S)
PROLASTIN-C

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Immunoglobulin A (IgA) deficient patients with antibodies against IgA.

REQUIRED MEDICAL INFORMATION
Diagnosis of emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Documentation of testing that confirms one of the following homozygous protein phenotypes: Pi*ZZ, Pi*Z(null) or Pi*(null)(null) AND labs that show baseline (pretreatment) serum alpha1-antitrypsin concentration of less than 11 micromol/L as documented by either of the following: less than 57 mg/dL as determined by nephelometry OR less than 80mg/dL as determined by radial immunodiffusion.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

ALVAIZ

MEDICATION(S)
ALVAIZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis: (1) chronic immune thrombocytopenia (ITP), (2) persistent immune thrombocytopenia, (3) thrombocytopenia in patients with chronic hepatitis C, or (4) severe aplastic anemia. For ITP and persistent immune thrombocytopenia: Documentation that baseline platelet count is less than 30,000/mcL. Documentation of inadequate response, intolerance, or contraindication to glucocorticoids (prednisone, dexamethasone or methylprednisolone), immunoglobulins, or splenectomy. For chronic hepatitis C: Documentation of patient's degree of thrombocytopenia (e.g. less than 75,000/mcL) that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For severe aplastic anemia: Documentation that baseline platelet count is less than 30,000/mcL. Documentation of inadequate response, intolerance, or contraindication to immunosuppressive therapy.

AGE RESTRICTION
For ITP and persistent immune thrombocytopenia: 6 years or older. For thrombocytopenia in patients with chronic hepatitis C and severe aplastic anemia: 18 years or older.

PRESCRIBER RESTRICTION
For ITP, persistent immune thrombocytopenia, and severe aplastic anemia: Prescribed by or in consultation with a hematologist. For thrombocytopenia in patients with chronic hepatitis C: Prescribed by or in consultation with a hematologist, hepatologist, gastroenterologist, or infectious disease specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: Confirmation that patient had a positive clinical response and remains at risk for bleeding complications.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of one of the following: Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), or Recurrent Pericarditis (RP). For DIRA: Patient weight of at least 10 kg. Documentation showing need for maintenance of remission. For RP: Documentation of an inadequate response, intolerance, or contraindication to at least one of the following: nonsteroidal anti-inflammatory drugs, colchicine, or corticosteroids.

AGE RESTRICTION
For CAPS, FCAS, MWS, RP: 12 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

ARIKAYCE

MEDICATION(S)
ARIKAYCE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of Mycobacterium avium complex (MAC) lung disease. Confirmation that the medication is being used as part of a combination antibacterial drug regimen. Confirmation that the patient did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or an infectious disease specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

AUSTEDO

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT TITRATION 12 & 18 & 24 & 30 MG TBER THPK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Congenital long QT syndrome. History of cardiac arrhythmias. Hepatic impairment. Concurrent use of MAO inhibitors. Concurrent use of reserpine, tetrabenazine, or valbenazine. For a diagnosis of Chorea associated with Huntington’s Disease: suicidal patients and patients with untreated or inadequately treated depression.

REQUIRED MEDICAL INFORMATION
Initial: For Tardive Dyskinesia: Documented diagnosis of Tardive Dyskinesia including copy of Abnormal Involuntary Movement Scale (AIMS) assessment. Documentation that other movement disorders (such as Parkinson’s disease, Chorea associated with Huntington’s Disease) have been excluded with documentation attached. Documentation of current or former chronic use of a dopamine antagonist (e.g., antipsychotic [first or second generation], metoclopramide, prochlorperazine, droperidol, promethazine, etc). For Chorea associated with Huntington’s Disease: Documentation showing that other movement disorders (such as Tardive Dyskinesia or Parkinson’s disease) have been excluded with documentation attached. Documentation showing confirmation of a diagnosis of Chorea associated with Huntington’s Disease with documentation attached.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or psychiatrist.

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: For Tardive Dyskinesia: Improvement in symptoms of Tardive Dyskinesia with an updated AIMS assessment. Documentation must be attached. For Chorea associated with Huntington’s Disease: Stabilization or improvement in symptoms of Chorea with medical records attached.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

BENLYSTA

MEDICATION(S)
BENLYSTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of either systemic lupus erythematosus (SLE) or active lupus nephritis (LN). For SLE: Documentation of inadequate response, intolerance, or contraindication to at least 1 standard therapy (e.g. hydroxychloroquine, mycophenolate, azathioprine). For LN: Documentation of inadequate response, intolerance, or contraindication to at least 1 standard therapy (e.g. mycophenolate, IV or oral cyclophosphamide, azathioprine, oral glucocorticoid).

AGE RESTRICTION
5 years or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a rheumatologist or nephrologist

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Documentation of a positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

BESREMI

MEDICATION(S)
BESREMI, BESREMI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Documentation of inadequate response, intolerance, or contraindication to hydroxyurea. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

BEXAROTENE GEL

MEDICATION(S)
BEXAROTENE 1 % GEL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist, hematologist, oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

BIMZELX

MEDICATION(S)
BIMZELX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For moderate to severe plaque psoriasis (PsO): Documentation that the patient is a candidate for systemic therapy or phototherapy. Documentation of inadequate response, intolerance, or contraindication to at least one of the following: methotrexate, UVB therapy, or acitretin. For active ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA): Documentation of inadequate response, intolerance, or contraindication to at least two NSAIDs. For hidradenitis suppurativa (HS): Documentation of inadequate response, intolerance, or contraindication to at least one oral antibiotic (e.g., doxycycline, minocycline, amoxicillin-clavulanic acid, clindamycin, rifampin, dapsone).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a rheumatologist or dermatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

BOTULINUM TOXINS

MEDICATION(S)
BOTOX, XEOMIN

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Sialorrhea associated with disorders of the nervous system or neurologic dysfunction. Hemifacial spasm. Laryngeal dystonia. Spasticity associated with cerebral palsy.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
FOR ALL REQUESTS: Documentation of diagnosis. Proposed injection site(s) and the dose that will be injected into each site. Documentation showing injections will be given no sooner than every 12 weeks. FOR INITIAL REQUESTS: 1) For OAB with symptoms of urge urinary incontinence, urgency, and frequency: Dose no more than 100 units/treatment. 2) For urinary incontinence due to detrusor overactivity associated with a neurologic condition: Dose no more than 200 units/treatment. 3) For prophylaxis of headaches in adult patients with chronic migraine: Documentation showing patient has at least 15 headache days per month with headache lasting 4 hours a day or longer. Documentation of inadequate response, intolerance, or contraindication to at least 2 different classes of prophylactic medications (e.g., beta blockers [such as propranolol, metoprolol], antidepressants [such as venlafaxine], antiepileptics [such as topiramate, valproic acid or its derivatives], verapamil)) OR documentation showing inadequate response, intolerance, or contraindication to at least one calcitonin gene-related peptide (CGRP) inhibitor. Dose no more than 195 units/treatment. 4) For severe primary axillary hyperhidrosis: documentation of dose no more than 100 units/treatment. 5) For upper or lower limb spasticity in muscle groups FDA-approved for treatment: documentation of dose no more than 400 units/treatment. 6) For blepharospasm associated with dystonia: documentation of dose no more than 200 units/treatment. 7) For strabismus associated with dystonia: documentation of dose no more than 25 units per muscle per injection. 8) For sialorrhea associated with disorders of the nervous system or neurologic dysfunction: dose no more than 100 units/treatment. 9) For cervical dystonia: dose no more than 300 units/treatment.

AGE RESTRICTION
18 years of age or greater for diagnoses of OAB, urinary incontinence, prophylaxis of headaches in

patients with chronic migraine, severe primary axillary hyperhidrosis. 16 years of age or greater for diagnosis of cervical dystonia. 12 years of age or greater for diagnoses of blepharospasm or strabismus associated with dystonia.

PRESCRIBER RESTRICTION

For OAB, urinary incontinence: Prescribed by or in consultation with a urologist, neurologist. For migraine headaches: Prescribed by or in consultation with a neurologist. For upper limb spasticity, cervical dystonia: Prescribed by or in consultation with a neurologist, physiatrist. For blepharospasm, strabismus: Prescribed by or in consultation with an ophthalmologist. For severe primary axillary hyperhidrosis: Prescribed by or in consultation with a dermatologist, neurologist, physiatrist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

For reauthorization for all indications: Dose consistent with total units for diagnosis (per initial request criteria). Documentation supporting the need for repeat treatment(s) occurring no sooner than every 12 weeks. For prophylaxis of headaches: Documentation showing a reduction in migraine frequency or severity from baseline.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

BRAND MAJOR DEPRESSIVE DISORDER AGENTS

MEDICATION(S)
AUVELITY 45-105 MG TAB ER, AUVELITY TITRATION PACK, EMSAM, EXXUA, EXXUA TITRATION PACK, FETZIMA, FETZIMA TITRATION, RALDESY, TRINTELLIX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Major Depressive Disorder. Documentation of an inadequate response, intolerance, or contraindication to two of the following: selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, atypical agents, serotonin modulators, tricyclics. For Raldesy: Documentation showing inability to or difficulty with swallowing solid dosage forms. For Auvelity for agitation associated with dementia due to Alzheimer’s disease: Chart notes documenting diagnosis. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

BRIVIACT

MEDICATION(S)
BRIVARACETAM 100 MG TAB, BRIVARACETAM 10 MG/ML SOLUTION, BRIVARACETAM 10 MG TAB, BRIVARACETAM 25 MG TAB, BRIVARACETAM 50 MG TAB, BRIVARACETAM 75 MG TAB, BRIVIACT 100 MG TAB, BRIVIACT 10 MG/ML SOLUTION, BRIVIACT 10 MG TAB, BRIVIACT 25 MG TAB, BRIVIACT 50 MG TAB, BRIVIACT 75 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of partial-onset seizures. Documentation of an inadequate response, intolerance, or contraindication to levetiracetam and at least one of the following: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, oxcarbazepine, topiramate. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

CARGLUMIC ACID

MEDICATION(S)
CARGLUMIC ACID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Documentation showing use as adjunctive therapy to standard of care for treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, propionic acidemia (PA), or methylmalonic acidemia (MMA). Documentation showing use as maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with prescriber experienced in metabolic disorders.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

CAYSTON

MEDICATION(S)
CAYSTON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of cystic fibrosis (CF) and lung infection with airway cultures positive for Pseudomonas aeruginosa.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist, a physician who specializes in the treatment of cystic fibrosis, or an infectious disease specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

CERDELGA

MEDICATION(S)
CERDELGA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of type 1 Gaucher Disease (GD1) and documentation that patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-approved genetic test.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

CFTR MODULATORS

MEDICATION(S)
KALYDECO, ORKAMBI, TRIKAFTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes that show that the diagnosis of cystic fibrosis is confirmed. Chart notes that show that appropriate genetic testing has been conducted. Chart notes showing that lab work (baseline liver function tests, including alanine aminotransferase, aspartate aminotransferase and bilirubin) has been assessed prior to initiation of treatment. For Kalydeco: Confirmation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. For Orkambi: Confirmation of homozygous for the F508del mutation in the CFTR gene. For Trikafta: Confirmation of at least one variant in the CFTR gene that is either responsive based on clinical and/or in vitro data or results in production of CFTR protein.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with pulmonologist, endocrinologist, or pediatrician.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

CGRP ANTAGONISTS

MEDICATION(S)
AIMOVIG, EMGALITY, EMGALITY (300 MG DOSE), NURTEC, QULIPTA, UBRELVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another CGRP antagonist for the same indication.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For preventive treatment of chronic migraines (Aimovig, Emgality, Qulipta): Notes showing the patient has at least 15 headache days per month. For preventive treatment of episodic migraine (Aimovig, Emgality, Nurtec, Qulipta): Notes showing the patient has at least 4 migraine headache days per month. For acute treatment of migraine (Nurtec, Ubrelvy): Documentation of inadequate response, intolerance, or contraindication to at least 1 triptan. For episodic cluster headaches (Emgality 100 mg/mL strength only): Notes showing the patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization for preventive treatment of chronic or episodic migraine: The patient has had a reduction in migraine frequency or severity from baseline. For reauthorization for episodic cluster headache: The patient has had a reduction in weekly cluster headache attacks from baseline. For reauthorization for acute treatment of migraine: confirmation of positive clinical response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

CLOBAZAM

MEDICATION(S)
CLOBAZAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS), refractory seizures/epilepsy, or seizures associated with Dravet syndrome (DS). For LGS: documentation of an inadequate response, intolerance, contraindication, or is concomitantly receiving one of the following: valproate, lamotrigine, rufinamide, cannabidiol (Epidiolex), felbamate. For refractory seizures/epilepsy: documentation of an inadequate response, intolerance, contraindication, or is concomitantly receiving two antiepileptics such as: felbamate, lamotrigine, levetiracetam, topiramate, valproate, zonisamide. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

CRESEMBA

MEDICATION(S)
CRESEMBA 186 MG CAP, CRESEMBA 74.5 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Subject to Part B vs D review for ESRD related use, if applicable. For Invasive aspergillosis (IA): Documentation of a diagnosis of invasive aspergillosis. Confirmation of one of the following: (1) Documentation of an inadequate response, intolerance, or contraindication to voriconazole (2) Documentation showing infection or disease is refractory or resistant to treatment with voriconazole. For invasive mucormycosis (MC): Documentation of a diagnosis of invasive mucormycosis. For all other medically accepted indications: Documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an infectious disease specialist, transplant specialist, hematologist or oncologist.

COVERAGE DURATION
6 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

CYSTARAN

MEDICATION(S)
CYSTARAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of cystinosis. Documentation showing patient has corneal cystine crystal accumulation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist or ophthalmologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

DEFERASIROX

MEDICATION(S)
DEFERASIROX 125 MG TAB SOL, DEFERASIROX 180 MG TAB, DEFERASIROX 250 MG TAB SOL, DEFERASIROX 360 MG TAB, DEFERASIROX 500 MG TAB SOL, DEFERASIROX 90 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Estimated glomerular filtration rate (GFR) less than 40 mL/min or serum creatinine more than 2 times the age-appropriate upper normal limit, platelet counts less than 50,000/mL, high-risk myelodysplastic syndromes (MDS), and advanced malignancies.

REQUIRED MEDICAL INFORMATION
For the treatment of chronic iron overload caused by blood transfusions: Documentation of serum ferritin levels consistently greater than 300 mcg/L. For chronic iron overload in nontransfusion-dependent thalassemia syndromes: Documentation of liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) AND documentation of serum ferritin level greater than 300 mcg/L on 2 consecutive measurements 1 month apart.

AGE RESTRICTION
Treatment of chronic iron overload caused by blood transfusions: 2 years of age and older. Chronic iron overload in nontransfusion-dependent thalassemia syndromes: 10 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist, oncologist, or hepatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

DENOSUMAB

MEDICATION(S)
WYOST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients currently being treated with a denosumab containing product.

REQUIRED MEDICAL INFORMATION
Subject to Part B vs Part D review. Documentation denosumab will be used for one the following: prevention of skeletal-related events in patients with multiple myeloma and patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity or hypercalcemia of malignancy refractory to bisphosphonates. For the prevention of skeletal-related events in patients with multiple myeloma and patients with bone metastases from solid tumors: documentation showing a trial of, intolerance to, or contraindication to zoledronic acid. For a diagnosis hypercalcemia of malignancy that is refractory to bisphosphonates: documentation of albumin-corrected calcium greater than 12.5 mg/dL. Documentation must be attached. Documentation of a trial of, intolerance to, or contraindication to IV bisphosphonates. For all diagnoses: documentation showing calcium levels were checked and will be monitored. Documentation showing calcium levels were corrected prior to therapy. Documentation showing the patient will be receiving supplementation with calcium and vitamin D. Documentation showing that an oral exam was done, and appropriate preventive dentistry was done prior to starting. Documentation showing that the patient is not pregnant or planning to become pregnant while on denosumab, if applicable. Documentation showing the patient will be using highly effective contraception during treatment and for at least 5 months after the last dose of denosumab, if applicable.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: For diagnosis of hypercalcemia of malignancy that is refractory to bisphosphonates: documentation that the corrected serum calcium is less than 11.5 mg/dL. All diagnoses: documentation showing improvement or stabilization of disease.

PART B PREREQUISITE
YES

PREREQUISITE THERAPY REQUIRED
YES

DIACOMIT

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of Dravet Syndrome. Documentation of an inadequate response, intolerance, or contraindication to at least two of the following: clobazam, valproic acid derivatives, topiramate, levetiracetam, zonisamide, clonazepam, ethosuximide, pharmaceutical grade cannabidiol. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

DIHYDROERGOTAMINE NASAL SPRAY

MEDICATION(S)
DIHYDROERGOTAMINE MESYLATE 4 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Uncontrolled hypertension. Use as management of hemiplegic basilar migraine. Ischemic heart disease (e.g. angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm including Prinzmetal's variant angina. Concomitant use or use within 24 hours of ergotamine containing or ergot type medications or methysergide. Coadministration with strong CYP3A4 inhibitors and peripheral and central vasoconstrictors. Peripheral arterial disease, sepsis, following vascular surgery, and severely impaired hepatic or renal function. Hypersensitivity to ergot alkaloids.

REQUIRED MEDICAL INFORMATION
Documentation to confirm diagnosis of acute treatment of migraine headaches with or without aura. Confirmation that drug will not be used for prophylactic migraine therapy. Documentation of an inadequate response, intolerance, or contraindication to two generic triptans (such as sumatriptan, zolmitriptan, rizatriptan) OR an inadequate response, intolerance, or contraindication to one generic triptan AND a gepant.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DOPTELET

MEDICATION(S)
DOPTELET, DOPTELET SPRINKLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of one of the following: (1) thrombocytopenia with chronic liver disease, (2) chronic immune thrombocytopenia (ITP), (3) persistent thrombocytopenia. For thrombocytopenia with chronic liver disease: Documentation that baseline platelet count is less than 50,000/mcL. Documentation that the patient is scheduled to undergo a procedure. For ITP and persistent thrombocytopenia: Documentation that baseline platelet count is less than 30,000/mcL. Documentation of inadequate response, intolerance, or contraindication to one of the following: glucocorticoids (prednisone, dexamethasone, or methylprednisolone), immunoglobulins, or splenectomy.

AGE RESTRICTION
For ITP and persistent thrombocytopenia: 1 year of age and older. For thrombocytopenia with chronic liver disease: 18 years of age or older.

PRESCRIBER RESTRICTION
For ITP and persistent thrombocytopenia: Prescribed by or in consultation with a hematologist. For thrombocytopenia in patients with chronic liver disease: Prescribed by or in consultation with a hematologist, hepatologist, or infectious disease specialist.

COVERAGE DURATION
Chronic liver disease: 1 month. ITP and persistent thrombocytopenia: 12 months.

OTHER CRITERIA
For reauthorization for ITP and persistent thrombocytopenia: Confirmation that the patient had a positive clinical response and remains at risk for bleeding complications. For reauthorization for

thrombocytopenia with chronic liver disease: Documentation that baseline platelet count is less than 50,000/mcL. Documentation that the patient is scheduled to undergo a procedure.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DRIZALMA SPRINKLE

MEDICATION(S)
DRIZALMA SPRINKLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing that administration via nasogastric tube is required or documentation showing inability to or difficulty with swallowing solid dosage forms. Documentation of diagnosis. For major depressive disorder (MDD): documentation of inadequate response, intolerance, or contraindication to one liquid antidepressant (e.g., fluoxetine solution, citalopram solution, escitalopram solution, sertraline oral concentrate, paroxetine suspension). For generalized anxiety disorder (GAD): documentation of inadequate response, intolerance, or contraindication to one liquid antidepressant (e.g., escitalopram solution, paroxetine suspension). For diabetic peripheral neuropathic pain (DPNP): documentation of inadequate response, intolerance, or contraindication to gabapentin solution. For fibromyalgia (FM): documentation of inadequate response, intolerance, or contraindication to gabapentin solution. Applies to new starts only.

AGE RESTRICTION
For MDD, DPNP, FM, chronic musculoskeletal pain: 18 years of age and older. For GAD: 7 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

DRONABINOL

MEDICATION(S)
DRONABINOL 10 MG CAP, DRONABINOL 2.5 MG CAP, DRONABINOL 5 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: Documented diagnosis of anorexia associated with weight loss in patients with AIDS OR documented diagnosis of chemotherapy-induced nausea and vomiting in patients with inadequate response to conventional antiemetic treatments [such as 5-HT3 (serotonin) receptor antagonists, NK1 (neurokinin-1) receptor antagonists, glucocorticoids]. Medication may be covered under Medicare Part B or D depending upon the circumstances. Information to be submitted describing the use and setting of the drug to make the determination.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

DROXIDOPA

MEDICATION(S)
DROXIDOPA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of neurogenic orthostatic hypotension (nOH) caused by one of the following: (1) primary autonomic failure (e.g. Parkinson's disease, multiple system atrophy, and pure autonomic failure), (2) dopamine beta-hydroxylase deficiency, or (3) non-diabetic autonomic neuropathy. Documentation of an inadequate response, intolerance, or contraindication to fludrocortisone or midodrine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist or a neurologist.

COVERAGE DURATION
3 months.

OTHER CRITERIA
For reauthorization: the patient has had a positive clinical response with improvement in symptoms.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

DUPIXENT

MEDICATION(S)
DUPIXENT 200 MG/1.14ML SOLN A-INJ, DUPIXENT 200 MG/1.14ML SOLN PRSYR, DUPIXENT 300 MG/2ML SOLN A-INJ, DUPIXENT 300 MG/2ML SOLN PRSYR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For moderate-to-severe atopic dermatitis when disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable: For patients under age 2, documentation of inadequate response, intolerance, or contraindication to at least one topical steroid. For patients over age 2, documentation of inadequate response, intolerance, or contraindication to at least one topical corticosteroid or at least one topical calcineurin inhibitor. For add on maintenance therapy for the treatment of moderate to severe asthma with eosinophilic type: Documentation showing a diagnosis of eosinophilic asthma including eosinophil count greater than or equal to 150 cells per microliter (lab results required). Documentation of inadequate response, intolerance, or contraindication to both of the following medications: 1) medium-to-high-dose inhaled corticosteroid, AND 2) additional controller (i.e., LABA, LAMA, leukotriene modifier, or theophylline). For add on maintenance therapy for the treatment of oral corticosteroid dependent asthma: Documentation showing oral corticosteroid dependent asthma. Documentation of inadequate response, intolerance, or contraindication to both of the following medications: 1) high-dose inhaled corticosteroid AND 2) additional controller (i.e., long acting beta2-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene modifier, or theophylline). For patients with chronic rhinosinusitis with nasal polyposis (CRSwNP): Documentation of a diagnosis of CRSwNP. Documentation of inadequate response, intolerance, or contraindication to at least one intranasal corticosteroid and at least one systemic corticosteroid. Documentation showing the patient will be treated with Dupixent in combination with intranasal corticosteroids. Continued in OTHER CRITERIA.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with pulmonologist, allergist, immunologist, dermatologist, otolaryngologist, gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For patients with eosinophilic esophagitis: Documentation of a diagnosis of eosinophilic esophagitis. Documentation of inadequate response, intolerance, or contraindication to at least one proton pump inhibitor. Documentation of inadequate response, intolerance, or contraindication to one topical corticosteroid (swallowed inhaled fluticasone propionate, swallowed budesonide). For prurigo nodularis: Documentation of diagnosis. For chronic obstructive pulmonary disease (COPD), eosinophilic phenotype: Documentation showing a diagnosis of COPD with an eosinophilic phenotype including eosinophil count greater than 300 cells per microliter (lab results required). Notes showing COPD is inadequately controlled. Documentation of inadequate response, intolerance, or contraindication to at least one inhaled combination therapy (including LAMA/LABA or LAMA/LABA/ICS combination therapies). For chronic spontaneous urticaria (CSU): Documentation of diagnosis including notes ruling out other forms of urticaria. Chart notes that show patient remains symptomatic despite treatment with at least one H1 antihistamine or has an intolerance or contraindication to at least one H1 antihistamine treatment. For bullous pemphigoid (BP): Documentation of diagnosis. Documentation of inadequate response, contraindication, or intolerance to one systemic corticosteroid OR inadequate response, contraindication, or intolerance to one immunosuppressive agent (i.e., azathioprine, cyclophosphamide, mycophenolate mofetil). For allergic fungal rhinosinusitis: Documentation of diagnosis. Documentation of a history of sino-nasal surgery. For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Active non-radiographic axial spondyloarthritis (nr-axSpA).

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (pJIA), or juvenile psoriatic arthritis (jPsA): Documentation of inadequate response, intolerance, or contraindication to at least one conventional DMARD (e.g., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine). For ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA): Documentation of inadequate response, intolerance, or contraindication to at least two NSAIDs. For moderate to severe plaque psoriasis (PsO): Documentation that the patient is a candidate for systemic therapy or phototherapy. Documentation of inadequate response, intolerance, or contraindication to one of the following: methotrexate, UVB therapy, or acitretin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a rheumatologist or dermatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ENDOTHELIN RECEPTOR ANTAGONISTS

MEDICATION(S)
AMBRISENTAN, BOSENTAN 125 MG TAB, BOSENTAN 62.5 MG TAB, MACITENTAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnancy. For ambrisentan, a diagnosis of idiopathic pulmonary fibrosis. For bosentan, use with glyburide and/or cyclosporine A.

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC). PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than 20 mmHg, pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 2 Wood units. RHC results must be provided. Confirmation that hemoglobin, liver function tests, and bilirubin are being monitored. If female of childbearing age, documentation showing reliable contraception will be used during and after treatment and confirmation of negative pregnancy test prior to starting medication.

AGE RESTRICTION
For ambrisentan and macitentan: 18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist, pulmonologist, or practitioner at a Pulmonary Hypertension Association-Accredited center.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response or stabilization.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

EPCLUSA

MEDICATION(S)
EPCLUSA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure or calculate FIB-4 score), Hepatitis B surface antigen (HBsAg), and HIV antigen/antibody test. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 to 24 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

OTHER CRITERIA
Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

EPIDIOLEX

MEDICATION(S)
EPIDIOLEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Hypersensitivity to cannabidiol or any of the ingredients in the product.

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Dravet syndrome (DS), Lennox-Gastaut syndrome (LGS) or Tuberous Sclerosis Complex (TSC). Documentation showing the patient has failed to become seizure-free with at least 2 antiepileptic drugs (specify drugs tried) indicated to treat the patient's diagnosis. Confirmation that Epidiolex is being used as adjunctive therapy including documentation of antiepileptic drug(s) with which Epidiolex will be used. Request is within FDA approved labeled dosing for treatment of seizures associated with the patient's diagnosis. Applies to new starts only.

AGE RESTRICTION
1 year of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

EUCRISA

MEDICATION(S)
EUCRISA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing a diagnosis of mild to moderate atopic dermatitis. Documentation of inadequate response, intolerance, or contraindication to at least one of the following: topical tacrolimus, topical pimecrolimus, or a prescription medium potency or higher topical steroid.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

FASENRA

MEDICATION(S)
FASENRA, FASENRA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For add-on maintenance treatment of severe asthma: Documentation showing confirmation of the following: diagnosis of severe asthma with an eosinophil count greater than or equal to 150 cells per microliter (lab results required) AND inadequate response, intolerance or contraindication to one agent from both of the following: a) medium-to-high-dose inhaled corticosteroid AND b) additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or theophylline). For eosinophilic granulomatosis with polyangiitis (EGPA): Documentation showing history of asthma. Documentation of absolute blood eosinophil count greater than or equal to 1000 cells per microliter or blood eosinophil level greater than 10% of the total leukocyte count (lab results required). Documentation showing inadequate response, intolerance, or contraindication to one systemic glucocorticoid. For severe EGPA including organ involvement or life-threatening disease: documentation of inadequate response, intolerance, or contraindication to either rituximab or cyclophosphamide. For hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause: Chart notes documenting a diagnosis of HES including notes showing there is no identifiable non-hematologic secondary cause. Blood eosinophil count greater than or equal to 1000 cells per microliter (lab results required). Documentation showing inadequate response, intolerance, or contraindication to one of the following: 1) oral corticosteroid, 2) immunosuppressive, or 3) cytotoxic therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with pulmonologist, allergist, immunologist. EGPA: Prescribed by or in

consultation with pulmonologist, allergist, immunologist, rheumatologist. HES: Prescribed by or in consultation with an allergist, immunologist, pulmonologist, rheumatologist, gastroenterologist, or hematologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

FILGRASTIM AGENTS

MEDICATION(S)
ZARXIO

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation or chart notes supporting medication is being used for a medically accepted indication not otherwise excluded from Part D. For all diagnoses, chart notes that show that lab work (complete blood count with differential including ANC) is being monitored prior to initiation of medication and during therapy based on recommendation for that specific diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

FINTEPLA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Hypersensitivity to fenfluramine or any of the components of Fintepla. Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors.

REQUIRED MEDICAL INFORMATION
Confirmation that the patient will have required echocardiogram monitoring. Documented diagnosis of Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS). For Dravet Syndrome (DS): Documentation showing an inadequate response or intolerance to at least two of the following: clobazam, valproic acid derivatives, topiramate, levetiracetam, cannabidiol (pharmaceutical), or stiripentol (include dates, duration, and outcome of drugs tried). For Lennox-Gastaut syndrome: Documentation showing inadequate response or intolerance to at least two of the following: lamotrigine, rufinamide, topiramate, cannabidiol (pharmaceutical), clobazam, felbamate (include dates, duration, and outcome of drugs tried). Applies to new starts only.

AGE RESTRICTION
2 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

FYCOMPA

MEDICATION(S)
FYCOMPA 0.5 MG/ML SUSPENSION, PERAMPANEL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of partial-onset seizures or generalized tonic-clonic seizures. Documentation of an inadequate response, intolerance, or contraindication to two of the following: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproate, zonisamide. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

GATTEX

MEDICATION(S)
GATTEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing a diagnosis of short bowel syndrome and patient is dependent on parenteral support. For continuation: Documentation of reduction in parenteral support.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

GLP-1 AGONISTS

MEDICATION(S)
MOUNJARO, OZEMPIC, OZEMPIC (0.25 OR 0.5 MG/DOSE) 2 MG/3ML SOLN PEN, OZEMPIC (1 MG/DOSE), OZEMPIC (2 MG/DOSE), RYBELSUS, TRULICITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Excluded if used for weight loss only. Concomitant use with another GLP-1 agonist containing drug or DPP4 inhibitor.

REQUIRED MEDICAL INFORMATION
Documentation such as medical records or chart notes showing that the member is diagnosed with type 2 diabetes mellitus. Prior authorization does not apply to patients whose claim is submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

HAEGARDA

MEDICATION(S)
HAEGARDA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of hereditary angioedema (HAE). Confirmation that Haegarda is being used for prophylaxis against HAE attacks. Not to be used in combination with other approved treatments for prophylaxis against HAE attacks.

AGE RESTRICTION
6 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or prescriber who specializes in the management of HAE.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

HIGH-RISK MEDICATION - ANTIDEPRESSANTS

MEDICATION(S)

AMITRIPTYLINE HCL 100 MG TAB, AMITRIPTYLINE HCL 10 MG TAB, AMITRIPTYLINE HCL 150 MG TAB, AMITRIPTYLINE HCL 25 MG TAB, AMITRIPTYLINE HCL 50 MG TAB, AMITRIPTYLINE HCL 75 MG TAB, AMOXAPINE, CLOMIPRAMINE HCL 25 MG CAP, CLOMIPRAMINE HCL 50 MG CAP, CLOMIPRAMINE HCL 75 MG CAP, CLOMIPRAMINE HCL 25 MG CAP, CLOMIPRAMINE HCL 50 MG CAP, CLOMIPRAMINE HCL 75 MG CAP, DESIPRAMINE HCL 100 MG TAB, DESIPRAMINE HCL 10 MG TAB, DESIPRAMINE HCL 150 MG TAB, DESIPRAMINE HCL 25 MG TAB, DESIPRAMINE HCL 50 MG TAB, DESIPRAMINE HCL 75 MG TAB, DOXEPIN HCL 100 MG CAP, DOXEPIN HCL 10 MG CAP, DOXEPIN HCL 10 MG/ML CONC, DOXEPIN HCL 150 MG CAP, DOXEPIN HCL 25 MG CAP, DOXEPIN HCL 50 MG CAP, DOXEPIN HCL 75 MG CAP, IMIPRAMINE HCL 10 MG TAB, IMIPRAMINE HCL 25 MG TAB, IMIPRAMINE HCL 50 MG TAB

PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

OFF LABEL USES

N/A

EXCLUSION CRITERIA

N/A

REQUIRED MEDICAL INFORMATION

Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For all indications: If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). For depression: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives medically accepted for the patient’s diagnosis such as a SSRI, SNRI, bupropion, mirtazapine, or trazodone. For OCD or panic disorder: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives (such as SSRIs) medically accepted for the patient’s diagnosis. For fibromyalgia or neuropathic pain (from spinal cord injury, antineoplastic therapy, post-herpetic

neuralgia, or neuropathy due to diabetes mellitus): Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives medically accepted for the patient's diagnosis such as duloxetine, gabapentin, or pregabalin. For insomnia: Documentation of inadequate response, intolerance, or contraindication to at least two safer alternatives medically accepted for the patient's diagnosis such as trazodone, mirtazapine, doxepin 3 mg or 6 mg, or ramelteon. Continued in OTHER CRITERIA.

AGE RESTRICTION

Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

For anxiety: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives medically accepted for the patient's diagnosis such as an SSRI, SNRI, or buspirone. For preventive treatment of episodic migraine: Documentation of inadequate response, intolerance, or contraindication to at least one non-high risk alternative medically accepted for the patient's diagnosis such as venlafaxine, metoprolol, propranolol, or topiramate. For a medically accepted indication not listed within criteria, no trial of alternatives is required. Prior authorization applies to greater than cumulative 30 days of therapy per year. For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

HIGH-RISK MEDICATION - ANTIEMETICS

MEDICATION(S)
PROMETHAZINE HCL 12.5 MG/10ML SOLUTION, PROMETHAZINE HCL 12.5 MG TAB, PROMETHAZINE HCL 25 MG TAB, PROMETHAZINE HCL 50 MG TAB, PROMETHAZINE HCL 6.25 MG/5ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For allergic conditions: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives such as levocetirizine, desloratadine, azelastine nasal spray, fluticasone propionate nasal spray, or mometasone nasal spray. For nausea and vomiting: Cancer diagnosis or documentation of inadequate response, intolerance, or contraindication to ondansetron or granisetron tablet. For all indications: If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). Prior authorization applies to greater than cumulative 30 days of therapy per year.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

HIGH-RISK MEDICATION - ANTIHISTAMINES

MEDICATION(S)
CYPROHEPTADINE HCL 4 MG TAB, HYDROXYZINE HCL 10 MG/5ML SYRUP, HYDROXYZINE HCL 10 MG TAB, HYDROXYZINE HCL 25 MG TAB, HYDROXYZINE HCL 50 MG/25ML SYRUP, HYDROXYZINE HCL 50 MG TAB, HYDROXYZINE PAMOATE 100 MG CAP, HYDROXYZINE PAMOATE 25 MG CAP, HYDROXYZINE PAMOATE 50 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For anxiety: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives medically accepted for the patient’s diagnosis such as buspirone, SSRI, SNRI. For allergic conditions: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives medically accepted for the patient’s diagnosis such as levocetirizine, desloratadine, azelastine nasal spray, fluticasone propionate nasal spray, or mometasone nasal spray. For appetite stimulation: Documentation of inadequate response, intolerance, or contraindication to at least one non-high risk alternative medically accepted for the patient’s diagnosis such as megestrol acetate. For an FDA-approved indication not listed within criteria, no trial of alternatives is required. For all indications: If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). Prior authorization applies to greater than cumulative 30 days of therapy per year.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in

older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

HIGH-RISK MEDICATION - ANTIPARKINSONS

MEDICATION(S)
TRIHEXYPHENIDYL HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For extrapyramidal disease: Documentation of inadequate response, intolerance, or contraindication to at least one non-high risk formulary alternative, such as amantadine. For Parkinson’s: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk formulary alternatives, such as amantadine, carbidopa/levodopa, pramipexole, or ropinirole. For an FDA-approved indication not listed within criteria, no trial of alternatives is required. For all indications: If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). Prior authorization applies to greater than cumulative 30 days of therapy per year.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

HIGH-RISK MEDICATION - ANTISPASMODICS

MEDICATION(S)
DICYCLOMINE HCL 10 MG/5ML SOLUTION, DICYCLOMINE HCL 10 MG CAP, DICYCLOMINE HCL 20 MG TAB, DIPHENOXYLATE-ATROPINE 2.5-0.025 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For diarrhea: Documentation of inadequate response, intolerance, or contraindication to at least one non-high risk formulary alternative, such as loperamide. For nausea and vomiting: Documentation of inadequate response, intolerance, or contraindication to at least one non-high risk formulary alternative, such as ondansetron or granisetron tablet. For a medically accepted indication not listed within criteria, no trial of alternatives is required. For all indications: If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). Prior authorization applies to greater than cumulative 30 days of therapy per year.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

HIGH-RISK MEDICATION - DIAZEPAM

MEDICATION(S)
DIAZEPAM 10 MG TAB, DIAZEPAM 2 MG TAB, DIAZEPAM 5 MG/5ML SOLUTION, DIAZEPAM 5 MG/ML CONC, DIAZEPAM 5 MG TAB, DIAZEPAM INTENSOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient has an FDA labeled contraindication to the requested drug.

REQUIRED MEDICAL INFORMATION
Prior authorization does not apply to patients receiving hospice care, palliative care, diagnosed with cancer or sickle-cell disease, or patients receiving cancer-related pain treatment. Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication with concurrent opioid therapy. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For anxiety disorder: The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety OR documentation of inadequate response, intolerance, or contraindication to at least one agent from each the following classes: SSRIs and SNRIs. For skeletal muscle spasms: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk formulary alternatives, such as tizanidine tablet, baclofen, dantrolene, methocarbamol 500 mg or 750 mg. For an FDA-approved indication not listed within criteria, no trial of alternatives is required. Prior authorization applies for greater than 15 day supply of medication with concurrent opioid use. Applies to new starts only.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication with concurrent opioid therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

HIGH-RISK MEDICATION - LORAZEPAM

MEDICATION(S)
LORAZEPAM 0.5 MG TAB, LORAZEPAM 1 MG TAB, LORAZEPAM 2 MG/ML CONC, LORAZEPAM 2 MG TAB, LORAZEPAM INTENSOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient has an FDA labeled contraindication to the requested drug.

REQUIRED MEDICAL INFORMATION
Prior authorization does not apply to patients receiving hospice care, palliative care, diagnosed with cancer or sickle-cell disease, or patients receiving cancer-related pain treatment. Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication with concurrent opioid therapy. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For anxiety disorder: The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety OR Documentation of inadequate treatment response, intolerance, or contraindication to at least one agent from each of the following classes: SSRIs and SNRIs. For insomnia: Documentation of inadequate response, intolerance, or contraindication to two non-high risk alternatives, such as trazodone, mirtazapine, doxepin 3 mg or 6 mg, ramelteon. For an FDA-approved indication not listed within criteria, no trial of alternatives is required. Prior authorization applies to greater than 15 day supply of medication with concurrent opioid use. Applies to new starts only.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication with concurrent opioid therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

HIGH-RISK MEDICATION - MECLIZINE

MEDICATION(S)
MECLIZINE HCL 12.5 MG TAB, MECLIZINE HCL 25 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, paroxetine, amitriptyline, dicyclomine etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). Prior authorization applies to greater than cumulative 30 days of therapy per year.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

HIGH-RISK MEDICATION - NON-BENZODIAZEPINE SEDATIVE HYPNOTICS

MEDICATION(S)
ZALEPLON, ZOLPIDEM TARTRATE 10 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of the patient's diagnosis. Confirmation that a risk-versus-benefit assessment has been completed for use of the high-risk medication. Confirmation that the benefit outweighs the potential risk of the high-risk medication. Prescriber attestation of intent to monitor and address treatment-related adverse events. Documentation of inadequate response, intolerance, or contraindication to at least one safer formulary alternative, such as trazodone, mirtazapine, ramelteon, or doxepin 3 mg or 6 mg.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

HIGH-RISK MEDICATION - SKELETAL MUSCLE RELAXANTS

MEDICATION(S)
CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For skeletal muscle spasms: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk formulary alternatives, such as tizanidine tablet, baclofen, dantrolene, methocarbamol 500 mg or 750 mg. For fibromyalgia: Documentation of inadequate response, intolerance, or contraindication to at least two non-high risk alternatives medically accepted for the patient’s diagnosis such as duloxetine, gabapentin, or pregabalin. For all indications: If the patient is taking one or more additional anticholinergic medications (e.g., oxybutynin, meclizine, paroxetine, amitriptyline, dicyclomine, etc.) with the requested drug, the prescriber provides an explanation that taking multiple anticholinergic medications is medically necessary for the patient (Note: Use of multiple anticholinergic medications in older adults is associated with an increased risk of cognitive decline). Prior authorization applies to greater than cumulative 30 days of therapy per year.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

HIGH-RISK MEDICATION - TEMAZEPAM

MEDICATION(S)
TEMAZEPAM 15 MG CAP, TEMAZEPAM 30 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patient has an FDA labeled contraindication to the requested drug.

REQUIRED MEDICAL INFORMATION
Prior authorization does not apply to patients receiving hospice care, palliative care, diagnosed with cancer or sickle-cell disease, or patients receiving cancer-related pain treatment. Chart notes documenting patient's diagnosis. Chart notes documenting an explanation of the risk versus benefit profile which shows the benefit outweighs the potential risk for the use of the high-risk medication with concurrent opioid therapy. The prescriber provides attestation of intent to monitor and address treatment-related adverse events. For insomnia: Documentation of inadequate response, intolerance, or contraindication to two non-high risk alternatives, such as trazodone, mirtazapine, doxepin 3 mg or 6 mg, ramelteon. Prior authorization applies for greater than 15 day supply of medication with concurrent opioid use.

AGE RESTRICTION
Apply if patient is 65 years of age or older to ensure safe use of a potentially high-risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: The prescriber provides an explanation that the benefit continues to outweigh the potential risk of the high-risk medication with concurrent opioid therapy.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ICATIBANT

MEDICATION(S)
ICATIBANT ACETATE, SAJAZIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of hereditary angioedema (HAE). Confirmation that icatibant is being used for the treatment of acute HAE attacks. Not to be used in combination with other approved treatments for acute HAE attacks.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with allergist, immunologist, pulmonologist, or prescriber who specializes in the management of HAE.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Notes showing a favorable clinical response as documented by the prescriber.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

INBRIJA

MEDICATION(S)
INBRIJA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Parkinson’s disease. Documentation that patient is experiencing OFF episodes. Confirmation that patient is currently being treated with carbidopa/levodopa.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

INCRELEX

MEDICATION(S)
INCRELEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Closed epiphyses.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of severe primary IGF1 deficiency confirmed by all of the following: 1) Height standard deviation score of -3.0 or less, 2) Basal IGF-1 standard deviation score of -3.0 or less, and 3) Normal or elevated growth hormone (GH). OR, Documentation of diagnosis of growth hormone (GH) gene deletion with neutralizing antibodies to GH.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of a positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

INJECTABLE TESTOSTERONE PRODUCTS

MEDICATION(S)
TESTOSTERONE CYPIONATE 100 MG/ML SOLUTION, TESTOSTERONE CYPIONATE 200 MG/ML SOLUTION, TESTOSTERONE ENANTHATE 200 MG/ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation confirming diagnosis. For hypogonadism: Confirmed low testosterone levels in comparison to lab reference values on two separate occasions. Explanation of symptoms experienced as a result of testosterone deficiency.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Evaluation of response to testosterone therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

INTRAVENOUS IMMUNE GLOBULIN (IVIG)

MEDICATION(S)
BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD, GAMMAGARD ERC, GAMMAGARD S/D LESS IGA, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist, immunologist, hematologist, neurologist, cardiologist, or oncologist.

COVERAGE DURATION
6 months.

OTHER CRITERIA
Subject to Part B vs D review. Documentation showing confirmation that one of the following is present: (1) Autoimmune mucocutaneous blistering disease pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, benign mucous membrane pemphigoid, epidermolysis bullosa acquisita AND one of the following: (a) documentation of inadequate response, intolerance, or contraindication to 1 conventional therapy (e.g., steroid, immunosuppressant) OR (b) rapidly progressive disease in conjunction with 1 conventional therapy (such as steroid, immunosuppressant), (2) Erythema multiforme major (SJS, TEN) AND SCORTEN level 3 or greater, (3) Acute idiopathic thrombocytopenia purpura (ITP) AND ONE of the following: (a) management of acute bleeding, (b) used to increase platelet count prior to surgical procedures, (c) severe

thrombocytopenia (platelets less than 20,000 per uL), OR (d) high risk for intracerebral hemorrhage, (4) Chronic ITP AND ALL of the following: (a) documentation of inadequate response, intolerance, or contraindication to 1 steroid, (b) duration of illness greater than 6 months, (c) platelets persistently less than 20,000 per uL, (5) Chronic B-cell lymphocytic leukemia with IgG less than 600 mg/dL AND recurrent, serious bacterial infections requiring antibiotic therapy, (6) Hematopoietic stem cell transplant AND IgG less than 400 mg/dL, (7) HIV and all of the following: (a) less than 14 years of age, (b) evidence of qualitative or quantitative humoral immunologic defects, AND (c) current bacterial infection despite antimicrobial prophylaxis, (8) Solid organ transplant, (9) Chronic inflammatory demyelinating polyneuritis confirmed by electrodiagnostic testing or nerve biopsy AND, an documentation of inadequate response, intolerance, or contraindication to 1 steroid, (10) Dermatomyositis or polymyositis diagnosed by laboratory testing (antinuclear or myositis specific antibodies, biopsy, EMG, or MRI) AND, documentation of inadequate response, intolerance, or contraindication to either 1 steroid or 1 immunosuppressant, (11) Guillain Barre syndrome with impaired function (ie unable to stand or walk without aid), (12) Lambert Eaton myasthenic syndrome refractory to 1 of the following: steroid, immunosuppressant, or cholinesterase inhibitor, (13) Multifocal motor neuropathy diagnosed by electrodiagnostic studies, (14) Acute exacerbations of multiple sclerosis unresponsive to 1 steroid, (15) Myasthenia gravis refractory to 8 weeks of 1 standard therapy (steroid, immunosuppressant, cholinesterase inhibitor), (16) Myasthenic crisis, (17) Stiff person syndrome refractory to 1 standard therapy (muscle relaxant, benzodiazepine, gabapentin), (18) Severe, active SLE unresponsive to 1 steroid, (19) Kawasaki disease. FOR REAUTHORIZATION: Documentation of clinical improvement using objective monitoring as appropriate to the diagnosis such as, but not limited to, Rankin score and Activities of Daily Living (ADL) scores.

PART B PREREQUISITE

YES

PREREQUISITE THERAPY REQUIRED

YES

IVABRADINE

MEDICATION(S)
IVABRADINE HCL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
One of the following: 1) Documentation of diagnosis of chronic heart failure (CHF). Stable symptomatic NYHA class II to IV heart failure with reduced left ventricular ejection fraction (EF). Documentation of EF less than or equal to 35 percent. Patient is in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute. Patient has intolerance, contraindication, or is on maximally tolerated doses of beta-blockers. Or, 2) Documentation of diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (CHF-DC). Patient is in sinus rhythm with an elevated heart rate.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

KERENDIA

MEDICATION(S)
KERENDIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin). Adrenal insufficiency. Estimated glomerular filtration rate (GFR) less than 25 mL/min. Baseline (prior to initiation of finerenone) serum potassium greater than 5 mEq/L.

REQUIRED MEDICAL INFORMATION
For chronic kidney disease associated with type 2 diabetes: Documented diagnosis of chronic kidney disease associated with type 2 diabetes (CKD with T2D). Documentation of concomitant therapy with an angiotensin-converting enzyme (ACE) inhibitor (e.g., lisinopril, ramipril) or angiotensin II receptor blocker (ARB) (e.g., losartan, irbesartan, valsartan) at maximally tolerated dose for diabetic nephropathy unless there is an intolerance or contraindication to these therapies. For heart failure with left ventricular ejection fraction of 40 percent or greater: Documented diagnosis of heart failure with left ventricular ejection fraction of 40 percent or greater determined by one of the following tests with results attached (echocardiography, cardiac MRI, nuclear medicine scans (MUGA), cardiac catheterization). Documentation of concomitant therapy with one sodium-glucose co-transporter 2 (SGLT2) inhibitor at a maximally tolerated dose unless there is an intolerance or contraindication to these drugs.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

KESIMPTA

MEDICATION(S)
KESIMPTA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Active HBV infection.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Documentation to show inadequate response, contraindication, or intolerance to two different agents used to treat multiple sclerosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

LANREOTIDE EXTENDED RELEASE

MEDICATION(S)
LANREOTIDE ACETATE, SOMATULINE DEPOT 60 MG/0.2ML SOLUTION, SOMATULINE DEPOT 90 MG/0.3ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of acromegaly. Baseline insulin-like growth factor-1 (IGF-1) level for age and/or gender is above the upper limit of normal based on laboratory reference range. The patient has had an inadequate response to surgery or radiation therapy OR there is a clinical reason why the patient has not had surgery or radiation therapy. Documented diagnosis of unresectable, well or moderately differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors. Documented diagnosis of carcinoid syndrome with symptoms of flushing and/or diarrhea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: the patient has had a positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

L-GLUTAMINE ORAL POWDER

MEDICATION(S)
L-GLUTAMINE 5 GM PACKET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of sickle cell disease confirmed by chart notes (must be attached). Documentation that the request is to reduce acute complications of sickle cell disease. Documentation of inadequate response, intolerance, or contraindication to hydroxyurea OR documentation showing L-glutamine will be used in combination with hydroxyurea. Request is within the FDA labeled dose.

AGE RESTRICTION
5 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hematologist or oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

LIDOCAINE PATCHES

MEDICATION(S)
LIDOCAINE 5 % PATCH, LIDOCAN

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Diabetic peripheral neuropathy, cancer-related neuropathic pain.

EXCLUSION CRITERIA
Patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

REQUIRED MEDICAL INFORMATION
Documentation to confirm the diagnosis of pain associated with post-herpetic neuralgia, diabetic peripheral neuropathy, or cancer-related neuropathic pain.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

LIVTENCITY

MEDICATION(S)
LIVTENCITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of ganciclovir or valganciclovir.

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of active cytomegalovirus (CMV) infection or disease. Confirmation that the patient has undergone hematopoietic stem cell transplant or solid organ transplant. Confirmation of one of the following: (1) Documentation showing infection or disease is refractory or resistant to treatment with one of the following: ganciclovir, valganciclovir, cidofovir, foscarnet, (2) Documentation of an inadequate response, intolerance, or contraindication to one of the following: ganciclovir, valganciclovir, cidofovir, foscarnet, (3) Documentation showing only Livtencity will be effective for CMV infection or disease.

AGE RESTRICTION
12 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a transplant specialist, infectious disease specialist, hematologist, or oncologist.

COVERAGE DURATION
2 months.

OTHER CRITERIA
For reauthorization: Confirmation that the patient has had a positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

LYBALVI

MEDICATION(S)
LYBALVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of schizophrenia or bipolar I disorder. One of the following: 1) therapeutic failure, intolerance or contraindication to two generic atypical antipsychotics OR 2) currently stable and responding to olanzapine but experiencing weight gain from the medication. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

MAVYRET

MEDICATION(S)
MAVYRET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of acute or chronic Hepatitis C (CHC) without cirrhosis or with compensated cirrhosis. Lab results must be attached: Hepatitis C virus (HCV) genotype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure or calculate FIB-4 score), Hepatitis B surface antigen (HBsAg), and HIV antigen/antibody test. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
8 to 16 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

OTHER CRITERIA
Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

METYROSINE

MEDICATION(S)
METYROSINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Documentation of inadequate response, intolerance, or contraindication to a selective alpha-blocker (e.g., doxazosin, prazosin, terazosin).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

MIFEPRISTONE

MEDICATION(S)
MIFEPRISTONE 300 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use of lovastatin, simvastatin, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinine, sirolimus, tacrolimus. Concurrent use of systemic corticosteroids for life-saving purposes such as immunosuppression following organ transplant.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

NEXLETOL AND NEXLIZET

MEDICATION(S)
NEXLETOL, NEXLIZET

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Documentation of prior treatment with statin therapy. Documentation discussing statin-associated side effects (rhabdomyolysis, muscle pain, muscle weakness associated with statin use) or contraindication (active liver disease, persistent elevation of serum transaminases) if statin therapy cannot be used. Documentation of prior treatment with ezetimibe therapy or intolerance/contraindication to ezetimibe. Documentation of baseline labs (lipid profile).

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Documentation of updated labs (lipid profile).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

NORDITROPIN

MEDICATION(S)
NORDITROPIN FLEXPRO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For children: (1) Growth failure due to growth hormone deficiency (GHD) diagnosed via clinical assessment of appropriate auxological findings documented and attached (such as growth chart, height, height velocity, chronological and bone age) and at least 1 of the following: (a) Subnormal response to at least 2 provocative growth hormone (GH) stimulation tests (resulting in peak GH levels less than 10ng/mL) OR (b) Subnormal response to at least 1 provocative GH stimulation test (resulting in peak GH level less than 10ng/mL) AND subnormal insulin-like growth factor-1 (IGF-1) level OR (c) Subnormal IGF-1 level AND panhypopituitarism, pituitary disease, hypothalamic disease, hypothalamic/pituitary surgery, radiation therapy, or trauma. (2) Short stature associated with Noonan Syndrome, Prader-Willi Syndrome, or Turner Syndrome with attached documentation of appropriate genetic testing and assessment of characteristic clinical manifestations. (3) For short stature born small for gestational age with no catch-up growth by age 2-4 years, chart notes confirming diagnosis. (4) Idiopathic Short Stature (ISS) with (a) documentation of a height standard deviation score (SDS) less than -2.25 and associated with growth rates unlikely to allow one to reach normal adult height and (b) documentation of growth chart, growth potential, impaired height velocity for age group, and bone age. For adults: (5) Diagnosis of adult GHD (a) as a result of childhood onset of GHD due to organic disease (attach documentation) or (b) adult onset as a result of pituitary or hypothalamic disease, panhypopituitarism, hypothalamic/pituitary surgery, radiation therapy, or trauma, (c) confirmation of adult GHD via subnormal IGF-1 prior to or while off of GH, and (d) If IGF-1 is questionable or uncertain, confirmation of adult GHD via a subnormal GH response to provocative testing prior to or while off of GH therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: For all patients: Documentation that the patient has tolerated the medication and has a normal IGF-1 level or will have their growth hormone dose adjusted to attain a normal IGF-1 concentration. For children: Documentation of growth chart, height velocity, chronological age, bone age, and linear growth potential remaining with open epiphyses.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

NUEDEXTA

MEDICATION(S)
DEXTROMETHORPHAN-QUINIDINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with quinidine, quinine, or mefloquine. Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. Use with an MAOI or within 14 days of stopping an MAOI. Prolonged QT interval, congenital long QT syndrome, torsades de pointes, heart failure, or complete atrioventricular (AV) block without implanted pacemaker. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of pseudobulbar affect (PBA). For patients at risk of QT prolongation and torsades de pointes, baseline ECG and an ECG evaluation 3-4 hours after the first dose.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

NUPLAZID

MEDICATION(S)
NUPLAZID

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Parkinson’s disease. Documentation of symptoms of psychosis with at least one of the following: hallucinations or delusions. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

OCTREOTIDE

MEDICATION(S)
OCTREOTIDE ACETATE 1000 MCG/ML SOLUTION, OCTREOTIDE ACETATE 100 MCG/ML SOLN PRSYR, OCTREOTIDE ACETATE 100 MCG/ML SOLUTION, OCTREOTIDE ACETATE 200 MCG/ML SOLUTION, OCTREOTIDE ACETATE 500 MCG/ML SOLN PRSYR, OCTREOTIDE ACETATE 500 MCG/ML SOLUTION, OCTREOTIDE ACETATE 50 MCG/ML SOLN PRSYR, OCTREOTIDE ACETATE 50 MCG/ML SOLUTION

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Subject to Part B vs D review. Documented diagnosis of acromegaly. Baseline insulin-like growth factor-1 (IGF-1) level for age and/or gender is above the upper limit of normal based on laboratory reference range. The patient has had an inadequate response to surgery or radiation therapy OR there is a clinical reason why the patient has not had surgery or radiation therapy. Documented diagnosis of metastatic carcinoid tumor. Patient requiring symptomatic treatment of severe diarrhea or flushing episodes. Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: the patient has had a positive clinical response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

OFEV

MEDICATION(S)
NINTEDANIB ESYLATE, OFEV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing a diagnosis of idiopathic pulmonary fibrosis by biopsy or high-resolution computed tomography (HRCT) OR documentation showing a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype by HRCT study OR documentation showing that the medication will be used to slow the rate of decline in pulmonary function in patients with a diagnosis of systemic sclerosis-associated interstitial lung disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist or rheumatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

OPIPZA

MEDICATION(S)
OPIPZA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing inability to or difficulty with swallowing solid dosage forms. Documentation of diagnosis. For schizophrenia and adjunctive treatment of major depressive disorder (MDD): documentation of inadequate response, intolerance or contraindication to generic aripiprazole and documentation of inadequate response, intolerance or contraindication to at least one other generic atypical antipsychotic indicated for the patient's condition. For treatment of Tourette's disorder and irritability associated with autistic disorder: documentation of inadequate response, intolerance or contraindication to generic aripiprazole. Applies to new starts only.

AGE RESTRICTION
For treatment of Tourette's disorder and irritability associated with autistic disorder: 6 years of age and older. For schizophrenia: 13 years of age and older. For adjunctive treatment of major depressive disorder (MDD): 18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

ORAL ONCOLOGY AGENTS

MEDICATION(S)

ABIRATERONE ACETATE, ABIRTEGA, AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO, AVMAPKI FAKZYNJA CO-PACK, AYVAKIT, BALVERSA, BEQALZI, BEQALZI STARTER PACK, BEXAROTENE 75 MG CAP, BOSULIF 100 MG CAP, BOSULIF 100 MG TAB, BOSULIF 500 MG TAB, BOSULIF 50 MG CAP, BOSUTINIB 400 MG TAB, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE 100 MG TAB, CAPRELSA, COMETRIQ (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE), COPIKTRA, COTELLIC, DANZITEN, DASATINIB, DAURISMO, ENSACOVE, ERIVEDGE, ERLEADA, ERLOTINIB HCL, ETCAMAH, EULEXIN, EVEROLIMUS 10 MG TAB, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, GLEOSTINE, GOMEKLI, HERNEXEOS, HYRNUO, IBRANCE, IBTROZI, ICLUSIG, IDHIFA, IMATINIB MESYLATE 100 MG TAB, IMATINIB MESYLATE 400 MG TAB, IMBRUVICA 140 MG CAP, IMBRUVICA 140 MG TAB, IMBRUVICA 280 MG TAB, IMBRUVICA 420 MG TAB, IMBRUVICA 70 MG CAP, IMBRUVICA 70 MG/ML SUSPENSION, IMKELDI, INLURIYO, INLYTA, INQOVI, INREBIC, ITOVEBI, IWILFIN, JAKAFI, JAKAFI XR, JAYPIRCA, JIDEYTRO, KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE), KOMZIFTI, KOSELUGO, KRAZATI, LAPATINIB DITOSYLATE, LAZCLUZE, LENALIDOMIDE, LENVIMA (10 MG DAILY DOSE), LENVIMA (12 MG 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), LIFYORLI (125 MG DOSE), LIFYORLI (150 MG DOSE), LOMUSTINE, LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE), MEKINIST, MEKTOVI, MODEYSO, NERLYNX, NILOTINIB D-TARTRATE, NILOTINIB HCL, NINLARO, NUBEQA, ODOMZO, OGSIVEO, OJEMDA, OJJAARA, ONUREG, ORGOVYX, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PHYRAGO, PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE), POMALIDOMIDE, POMALYST, QINLOCK, RASONQUE, RETEVMO 120 MG TAB, RETEVMO 160 MG TAB, RETEVMO 40 MG TAB, RETEVMO 80 MG TAB, REVUFORJ, REZLIDHIA, ROMVIMZA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB TOSYLATE, STIVARGA, SUNITINIB MALATE, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TEPMETKO, THALOMID 100 MG CAP, THALOMID 50 MG CAP, TIBSOVO, TORPENZ, TRUQAP, TUKYSA, TURALIO 125 MG CAP, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VORANIGO, WELIREG, XALKORI, XOSPATA, XPOVIO (100 MG ONCE WEEKLY), XPOVIO (40 MG ONCE WEEKLY), XPOVIO (40 MG TWICE WEEKLY), XPOVIO (60 MG ONCE WEEKLY), XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY), XPOVIO (80 MG TWICE

WEEKLY), XTANDI, YONSA, YULITHIRA, ZEJULA 100 MG TAB, ZEJULA 200 MG TAB, ZEJULA 300 MG TAB, ZELBORAF, ZENBEXUS, ZOLINZA, ZYDELIG, ZYKADIA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

PANRETIN

MEDICATION(S)
PANRETIN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist or oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

PART D INSULIN SUPPLIES

MEDICATION(S)
BD ALCOHOL PADS, GAUZE PADS & DRESSINGS - PADS 2 X 2, INSULIN PEN NEEDLE (NOVO/BD/EMBECTA/ULTIMED/TRIVIDIA), INSULIN SYRINGE (DISP) U-100 0.3 ML (BD/EMBECTA/ULTIMED/ALLISON/TRIVIDIA/MHC), ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD, NEEDLES, INSULIN DISP., SAFETY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing that the member is diagnosed with diabetes mellitus. Documentation showing the patient will be using the requested product for the purpose of delivering insulin to the body. Prior authorization does not apply to patients who have filled insulin in the last 180 days.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

PART D INSULIN SYRINGES

MEDICATION(S)
INSULIN SYRINGE (DISP) U-100 1/2 ML (BD/EMBECTA/ULTIMED/ALLISON/TRIVIDIA/MHC), INSULIN SYRINGE (DISP) U-100 1 ML (BD/EMBECTA/ULTIMED/ALLISON/TRIVIDIA/MHC)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing that the member is diagnosed with diabetes mellitus. Documentation showing the patient will be using the requested product for the purpose of delivering insulin to the body. Prior authorization does not apply to patients who have filled insulin in the last 180 days. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

PART D VS PART B

MEDICATION(S)

ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, AMINOSYN II, AMINOSYN-PF, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, APREPITANT, ARFORMOTEROL TARTRATE, AVASTIN, AZACITIDINE, AZATHIOPRINE 50 MG TAB, BORTEZOMIB 3.5 MG RECON SOLN, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CINACALCET HCL, CISPLATIN 100 MG/100ML SOLUTION, CISPLATIN 200 MG/200ML SOLUTION, CISPLATIN 50 MG/50ML SOLUTION, CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINISOL SF, CLINOLIPID, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOPHOSPHAMIDE (25 MG CAP, 50 MG CAP), CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE MODIFIED, ELIGARD, ENGERIX-B, ENVARSUS XR, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB, FIRMAGON, FIRMAGON (240 MG DOSE), FLUOROURACIL 1 GM/20ML SOLUTION, FLUOROURACIL 2.5 GM/50ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FLUOROURACIL 5 GM/100ML SOLUTION, FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, FULVESTRANT, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPLISAV-B, HERCEPTIN HYLECTA, INFLECTRA, INTRALIPID, IPRATROPIUM-ALBUTEROL, IPRATROPIUM BROMIDE 0.02 % SOLUTION, JYNNEOS, KADCYLA, KANJINTI, KEYTRUDA, LEUPROLIDE ACETATE 1 MG/0.2ML KIT, LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, LUPRON DEPOT (1-MONTH), LUPRON DEPOT (3-MONTH), LUPRON DEPOT-PED (1-MONTH), LUPRON DEPOT-PED (3-MONTH), LUPRON DEPOT-PED (6-MONTH), MVASI, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, NULOJIX, NUTRILIPID, OGIVRI, ONDANSETRON 4 MG TAB DISP, ONDANSETRON 8 MG TAB DISP, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 8 MG TAB, ONDANSETRON HCL ORAL SOLN 4 MG/5ML, PENTAMIDINE ISETHIONATE, PENTAMIDINE ISETHIONATE FOR NEBULIZATION SOLN 300 MG, PLENAMINE, PREMASOL, PROCRIT, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, PULMOZYME, RECOMBIVAX HB, RENFLEXIS, RETACRIT, RUXIENCE, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG/ML

SOLUTION, SIROLIMUS 1 MG TAB, SIROLIMUS 2 MG TAB, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TPN ELECTROLYTES, TRAVASOL, TRAZIMERA, TROPHAMINE, TRUXIMA, YUPELRI, ZIRABEV, ZOLEDRONIC ACID 4 MG/5ML CONC, ZOLEDRONIC ACID 5 MG/100ML SOLUTION

DETAILS

This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

PEGFILGRASTIM AGENTS

MEDICATION(S)
FULPHILA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For primary prophylaxis of febrile neutropenia: Documentation that shows that patient is receiving myelosuppressive chemotherapy. Documentation that shows that patient is at increased risk for febrile neutropenia. Documentation that shows that patient is receiving dose-dense or high-dose chemotherapy. For secondary prophylaxis of febrile neutropenia: documentation that shows the patient is receiving myelosuppressive chemotherapy with a history of febrile neutropenia during previous course of chemotherapy (for which primary prophylaxis was not received). Documentation or chart notes supporting medication is being used for a medically accepted indication not otherwise excluded from Part D. For all diagnoses, chart notes that show lab work (complete blood count with differential including ANC) is being monitored.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

PHOSPHODIESTERASE 5 INHIBITORS

MEDICATION(S)
ALYQ, SILDENAFIL CITRATE 20 MG TAB, TADALAFIL (PAH)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant organic nitrates. Concomitant guanylate cyclase (GC) Stimulators.

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC). PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than 20 mmHg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 2 Wood units (RHC results must be provided). For Raynaud’s phenomenon: Confirmation of an inadequate response or intolerance to one calcium channel blocker.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist, pulmonologist, practitioner at a Pulmonary Hypertension Association-Accredited center, or rheumatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response or stabilization.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

PIRFENIDONE

MEDICATION(S)
PIRFENIDONE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity, Hermansky-Pudlak syndrome, familial idiopathic pulmonary fibrosis, and chronic hypersensitivity pneumonitis).

REQUIRED MEDICAL INFORMATION
INITIAL REQUEST: Documented diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by usual interstitial pneumonia (UIP) pattern present on high resolution computed tomography (HRCT) in patients without lung biopsy, or the combination of HRCT and biopsy pattern in patients with lung biopsy. Documented baseline liver function tests (ALT, AST, and bilirubin) and documentation that liver function tests (ALT, AST, and bilirubin) will be monitored periodically throughout the course of treatment as clinically necessary.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a pulmonologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For ongoing therapy and/or reauthorization: Documentation of rationale for continued IPF therapy (e.g., stability or improvement in the rate of decline for FVC, IPF symptoms, or other prescriber-assessed benefit of therapy). Confirmation that liver function tests (ALT, AST, and bilirubin) are being monitored periodically throughout the course of treatment as clinically indicated.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

POSACONAZOLE

MEDICATION(S)
POSACONAZOLE 100 MG TAB DR, POSACONAZOLE 40 MG/ML SUSPENSION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with known hypersensitivity to posaconazole or other azole antifungal agents. Concurrent use with sirolimus, CYP3A4 substrates (pimozide, quinidine), HMG-CoA reductase inhibitors primarily metabolized through CYP3A4, ergot alkaloids, or venetoclax.

REQUIRED MEDICAL INFORMATION
For tablet or oral suspension: Documentation of use for prophylaxis of invasive Aspergillus and Candida infections in severely immunocompromised patients (hematopoietic stem cell transplant (HSCT) recipients with graft-versus host-disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy). Documentation of use for the treatment of invasive Aspergillus with oral tablet. Documentation of use of oral suspension for a treatment of oropharyngeal candidiasis (OC). For OC: inadequate response, intolerance, or contraindication to itraconazole or fluconazole.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Aspergillus/Candida Prophylaxis: 6 months. OC: 30 days. Aspergillus treatment: 12 weeks.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

PREVYMIS

MEDICATION(S)
PREVYMIS 120 MG PACKET, PREVYMIS 20 MG PACKET, PREVYMIS 240 MG TAB, PREVYMIS 480 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high-risk recipient of kidney transplant where donor is CMV seropositive.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
7 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

PYRIMETHAMINE

MEDICATION(S)
PYRIMETHAMINE 25 MG TAB

PA INDICATION INDICATOR
4 - All FDA-Approved Indications, Some Medically-Accepted Indications

OFF LABEL USES
Primary and secondary prophylaxis of toxoplasmosis in patients with HIV, Prophylaxis of pneumocystis jirovecii pneumonia in patients with HIV. Treatment and secondary prophylaxis of cyclosporiasis in patients with HIV.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For all diagnoses: Documentation of an inadequate response, intolerance, or contraindication to trimethoprim-sulfamethoxazole. For acute treatment of toxoplasmosis: Confirmation of severe or prolonged symptoms that warrants treatment. For primary prophylaxis of toxoplasmosis gondii (T. gondii) infection all of the following: (1) Confirmed diagnosis of HIV, (2) Documentation of CD4 count less than 100 cells/mm3, AND (3) T. gondii IgG positive. For secondary prophylaxis of toxoplasmosis gondii infection all of the following: (1) Confirmed diagnosis of HIV, (2) CD4 count less than 200 cells/mm3. For primary prophylaxis of Pneumocystis jirovecii pneumonia: (1) Confirmed diagnosis of HIV, (2) CD4 count less than 200 cells/mm3. For treatment of cystoisosporiasis: (1) Confirmed diagnosis of HIV. For secondary prophylaxis of cystoisosporiasis: (1) Confirmed diagnosis of HIV. (2) CD4 count less than 200 cells/mm3 within the past 6 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with infectious disease specialist.

COVERAGE DURATION
For acute treatment of toxoplasmosis: 1 month. For all other diagnoses: 12 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

QUININE

MEDICATION(S)
QUININE SULFATE 324 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment or prevention of leg cramps.

REQUIRED MEDICAL INFORMATION
One of the following: Documentation of diagnosis of uncomplicated Plasmodium falciparum malaria with confirmation of chloroquine resistance. Or, documentation of diagnosis of babesiosis and quinine will be used in combination with clindamycin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

REPATHA

MEDICATION(S)
REPATHA, REPATHA SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

REVCOVI

MEDICATION(S)
REVCOVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Subject to Part B vs D review. Documentation of diagnosis. One of the following: 1) documentation of absent or very low adenosine deaminase activity in red blood cells (less than 1 percent of normal) OR 2) molecular genetic testing confirming diagnosis. Documentation of severely impaired immune function (e.g., lymphopenia, extensive dermatitis, persistent diarrhea, recurrent pneumonia, life threatening illness caused by opportunistic infections). Notes showing the patient has failed or is not a candidate for hematopoietic cell transplantation (HCT).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an immunologist, hematologist, oncologist, or specialist in inherited metabolic disorders.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Documentation showing stabilization or improvement in immune status (such as infection rate, incidence and duration of hospitalization, performance status).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

REZDIFFRA

MEDICATION(S)
REZDIFFRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of metabolic dysfunction-associated steatohepatitis (MASH)/noncirrhotic nonalcoholic steatohepatitis (NASH) confirmed by liver biopsy or imaging (such as ultrasound, Fibroscan CAP, or MRI-PDFF). Results confirming steatosis must be attached. Documentation of moderate to advanced liver fibrosis (stage F2 or F3) confirmed by one of the following tests performed within the last 6 months: liver biopsy or non-invasive tests (such as transient elastography (Fibroscan), shear wave elastography, or magnetic resonance elastography). Confirmation that the medication will be used in combination with diet and exercise. Confirmation that patient will abstain from alcohol consumption. Patient does not have evidence of cirrhosis, hepatic decompensation, or hepatocellular carcinoma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a hepatologist or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response or stabilization. Confirmation that the medication will be used in combination with diet and exercise. Confirmation that patient will abstain from alcohol consumption. Patient does not have evidence of cirrhosis, hepatic decompensation, or

hepatocellular carcinoma.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

REZUROCK

MEDICATION(S)
REZUROCK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Pregnancy.

REQUIRED MEDICAL INFORMATION
If female of childbearing age or male with female partners of reproductive potential, confirmation that effective contraception will be used during treatment. Confirmation of a trial and failure of at least 2 conventional systemic treatments for chronic graft-versus-host disease.

AGE RESTRICTION
12 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist, hematologist, or transplant specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

RINVOQ

MEDICATION(S)
RINVOQ, RINVOQ LQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD), a targeted synthetic DMARD, JAK inhibitors, or with potent immunosuppressants such as azathioprine and cyclosporine.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For rheumatoid arthritis (RA), psoriatic arthritis (PsA), active ankylosing spondylitis (AS), active non-radiographic axial spondyloarthritis (nr-axSpA), or polyarticular juvenile idiopathic arthritis (pJIA): Documentation of inadequate response, intolerance, or contraindication to at least one TNF blocker. For moderately to severely active ulcerative colitis (UC) or moderately to severely active Crohn’s disease (CD): one of the following (1) documentation of inadequate response or intolerance to at least one TNF blocker, (2) documentation of inadequate response or intolerance to at least one approved systemic therapy if TNF blockers are not clinically appropriate, OR contraindication to both TNF blockers and approved systemic therapies consistent with current clinical treatment guidelines. For atopic dermatitis (AD): Documentation of inadequate response, intolerance, or contraindication to at least one other systemic drug (including biologics) used to treat refractory, moderate to severe AD.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a gastroenterologist, rheumatologist, or dermatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

RUFINAMIDE

MEDICATION(S)
RUFINAMIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Lennox-Gastaut Syndrome (LGS). Documentation showing rufinamide will be used as adjunctive therapy. Documentation of an inadequate response, intolerance, or contraindication to at least one of the following: valproic acid derivatives, lamotrigine, clobazam, topiramate, cannabidiol (pharmaceutical). Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

SAPROPTERIN

MEDICATION(S)
JAVYGTOR, SAPROPTERIN DIHYDROCHLORIDE, ZELVYSIA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of phenylketonuria confirmed by blood phenylalanine concentrations with labs attached.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months. Reauthorization: 12 months.

OTHER CRITERIA
For reauthorization: The patient has had a positive clinical response, such as cognitive and/or behavioral improvements.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

SIGNIFOR

MEDICATION(S)
SIGNIFOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of Cushing’s disease and ONE of the following: patient is not a candidate for pituitary surgery OR pituitary surgery has not been curative.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: confirmation of decrease in urinary free cortisol levels from baseline.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

SIRTURO

MEDICATION(S)
SIRTURO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of pulmonary tuberculosis resistant to rifampin and isoniazid.
Documentation that Sirturo is being used in combination with at least 2 other anti-tuberculosis agents.

AGE RESTRICTION
2 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an infectious disease specialist.

COVERAGE DURATION
24 weeks.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

SKYRIZI

MEDICATION(S)
SKYRIZI, SKYRIZI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For moderate to severe plaque psoriasis (PsO): Documentation of inadequate response, intolerance, or contraindication to at least one of the following: methotrexate, UVB therapy, or acitretin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a dermatologist, rheumatologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

SODIUM OXYBATE

MEDICATION(S)
SODIUM OXYBATE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with sedative hypnotics. Concomitant use with Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium, and sodium oxybates), Lumryz (sodium oxybate), Wakix (pitolisant), or Sunosi (solriamfetol). Succinic semialdehyde dehydrogenase deficiency.

REQUIRED MEDICAL INFORMATION
For narcolepsy with excessive daytime sleepiness (EDS): documentation of diagnosis. Results of sleep testing (such as polysomnography, multiple sleep latency test) confirming diagnosis. In patients 18 and older: documentation of an inadequate response, intolerance, or contraindication to a stimulant and one of the following: modafinil or armodafinil. In patients under the age of 18: documentation of an inadequate response, intolerance, or contraindication to modafinil. For narcolepsy with cataplexy: documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or sleep specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: documentation of reduction in frequency of cataplexy attacks OR documentation of reduction in symptoms of excessive daytime sleepiness.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

SODIUM PHENYLBUTYRATE

MEDICATION(S)
SODIUM PHENYLBUTYRATE 3 GM/TSP POWDER, SODIUM PHENYLBUTYRATE 500 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Treatment of acute hyperammonemia in urea cycle disorders.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of urea cycle disorder involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) confirmed by enzymatic, biochemical, or genetic testing. Confirmation showing sodium phenylbutyrate will be used for chronic management.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with prescriber experienced in metabolic disorders.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

SOMAVERT

MEDICATION(S)
SOMAVERT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of acromegaly. Baseline insulin-like growth factor-1 (IGF-1) level for age and/or gender is above the upper limit of normal based on laboratory reference range. The patient has had an inadequate response to surgery or radiation therapy OR there is a clinical reason why the patient has not had surgery or radiation therapy. Documentation of an inadequate response, intolerance, or contraindication to octreotide.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: the patient has had a positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

SOTYKTU

MEDICATION(S)
SOTYKTU

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD), a targeted synthetic DMARD, or potent immunosuppressants such as azathioprine and cyclosporine.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For moderate to severe plaque psoriasis (PsO): Documentation that the patient is a candidate for systemic therapy or phototherapy. Documentation of inadequate response, intolerance, or contraindication to at least one of the following: methotrexate, UVB therapy, or acitretin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a rheumatologist or dermatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

SYMPAZAN

MEDICATION(S)
SYMPAZAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of inadequate response, intolerance, or contraindication to both generic clobazam tablet and generic clobazam suspension. Documentation showing that Sympazan will be used as adjunctive therapy to other antiepileptic drugs. Applies to new starts only.

AGE RESTRICTION
2 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

TADALAFIL BPH

MEDICATION(S)
TADALAFIL 2.5 MG TAB, TADALAFIL 5 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant organic nitrates. Concomitant Guanylate Cyclase (GC) Stimulators. Treatment of erectile dysfunction (ED) in the absence of benign prostatic hyperplasia (BPH).

REQUIRED MEDICAL INFORMATION
Documentation showing a diagnosis of benign prostatic hyperplasia (BPH). Documentation of inadequate response, intolerance, or contraindication to at least one alpha blocker AND documentation of inadequate response, intolerance, or contraindication to at least one 5-alpha-reductase inhibitor.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

TASIMELTEON

MEDICATION(S)
TASIMELTEON

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Non-24-Hour Sleep-Wake Disorder (Non-24): Documentation of diagnosis of complete blindness. Documentation of diagnosis of Non-24 indicated by actigraphy or sleep log or diary. Documentation of baseline nighttime sleep time and daytime naptime per sleep log or diary. For nighttime sleep disturbances in Smith-Magens Syndrome (SMS): Documentation of diagnosis confirmed by genetic testing. Documentation of sleep disturbances.

AGE RESTRICTION
16 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a sleep specialist, psychiatrist, or neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization for Non-24: Documentation of response indicated by improvement in nighttime sleep time or reduction in daytime naptime compared to baseline per sleep log or diary. For reauthorization for nighttime sleep disturbances in Smith-Magens Syndrome (SMS): Documentation of response indicated by improvement in sleep disturbances including difficulty falling asleep, problems staying asleep, and frequent awakenings at night as documented per chart notes.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TAVNEOS

MEDICATION(S)
TAVNEOS

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]). Used in combination with standard therapy (e.g., rituximab, cyclophosphamide, mycophenolate, azathioprine, and/or glucocorticoids).

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.

COVERAGE DURATION
Initial: 6 months. Reauthorization: 12 months.

OTHER CRITERIA
For reauthorization: confirmation of disease stability or improvement. Documentation showing the patient will continue to take in combination with standard therapy (e.g., rituximab, cyclophosphamide, mycophenolate, azathioprine, and/or glucocorticoids).

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

TERIPARATIDE

MEDICATION(S)
BONSITY, TERIPARATIDE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of osteoporosis (glucocorticoid induced, primary or hypogonadal in men, or postmenopausal in women). Baseline labs (T-score). Documentation of an inadequate response or inability to tolerate at least ONE of the following: bisphosphonates, hormone replacement therapy, selective-estrogen receptor modulators (SERMs) or Denosumab (Prolia).

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization, one of the following: Cumulative lifetime therapy does not exceed 2 years OR member remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

TETRABENAZINE

MEDICATION(S)
TETRABENAZINE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Congenital long QT syndrome. History of cardiac arrhythmias. Hepatic impairment. Concurrent use of MAO inhibitors. Concurrent use of reserpine, deutetrabenazine, or valbenazine. Actively suicidal patients and patients with untreated or inadequately treated depression.

REQUIRED MEDICAL INFORMATION
Documentation showing that other movement disorders (such as Tardive Dyskinesia or Parkinsons disease) have been excluded with documentation attached. Documentation showing confirmation of a diagnosis of Chorea associated with Huntingtons Disease with documentation attached.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or psychiatrist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Documented improvement in symptoms of Chorea with medical records attached.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

TOCILIZUMAB

MEDICATION(S)
TYENNE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA): Documentation of inadequate response, intolerance, or contraindication to at least one conventional DMARD (e.g. methotrexate, hydroxychloroquine, leflunomide, sulfasalazine).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a rheumatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

TOLVAPTAN (JYNARQUE)

MEDICATION(S)
TOLVAPTAN 15 MG TAB (GENERIC JYNARQUE), TOLVAPTAN (15 MG TAB THPK, 30 & 15 MG TAB THPK, 45 & 15 MG TAB THPK, 60 & 30 MG TAB THPK, 90 & 30 MG TAB THPK – GENERIC JYNARQUE), TOLVAPTAN 30 MG TAB (GENERIC JYNARQUE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). Must have eGFR greater than or equal to 25 mL/min/1.73 m2 AND meet one of the following criteria: (1) Mayo Imaging Classification 1C, 1D, or 1E, (2) Predicting Renal Outcome in Polycystic Kidney Disease [PROPKD] score greater than 6, (3) Family history with onset of kidney replacement therapy at less than 60 years in greater than or equal to 2 first-line family members, or (4) Historical rate of eGFR decline of greater than or equal to 3 mL/min/1.73 m2 per year. Documentation showing that other acute or chronic causes of eGFR decline have been assessed (if eGFR loss has likely alternative explanations and/or acute kidney injury).

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a nephrologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of stabilization or positive clinical response.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

N/A

TOPICAL RETINOIDS

MEDICATION(S)
TAZAROTENE 0.1 % CREAM, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.1 % CREAM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

TOPICAL TESTOSTERONE PRODUCTS

MEDICATION(S)
TESTOSTERONE 12.5 MG/ACT (1%) GEL, TESTOSTERONE 20.25 MG/ACT (1.62%) GEL, TESTOSTERONE 25 MG/2.5GM (1%) GEL, TESTOSTERONE 50 MG/5GM (1%) GEL, TESTOSTERONE TD GEL PUMP 20.25 MG/ACT (1.62%)

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Men with carcinoma of the breast or known or suspected prostate cancer. Women who are pregnant.

REQUIRED MEDICAL INFORMATION
Documentation confirming diagnosis. For hypogonadism: Confirmed low testosterone levels in comparison to lab reference values on two separate occasions. Explanation of symptoms experienced as a result of testosterone deficiency.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Evaluation of response to testosterone therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

TREMFYA

MEDICATION(S)
TREMFYA, TREMFYA-CD/UC INDUCTION, TREMFYA ONE-PRESS, TREMFYA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For moderate to severe plaque psoriasis (PsO): Documentation that the patient is a candidate for systemic therapy or phototherapy. Documentation of inadequate response, intolerance, or contraindication to at least one of the following: methotrexate, UVB therapy, or acitretin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a rheumatologist, dermatologist, gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

UPTRAVI

MEDICATION(S)
UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent use with strong inhibitors of CYP2C8 (e.g., gemfibrozil).

REQUIRED MEDICAL INFORMATION
Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 confirmed by complete right catheterization (RHC) with results attached. Mean pulmonary artery pressure (mPAP) greater than 20 mmHg, pulmonary vascular resistance (PVR) greater than 2 wood units, and a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Chart notes documenting inadequate response, intolerance, or contraindication to ONE drug from TWO of the following classes: an endothelin receptor antagonists (e.g., bosentan, ambrisentan, macitentan), a phosphodiesterase-5 inhibitors (e.g., sildenafil, tadalafil), OR guanylate cyclase stimulators (e.g., riociguat). Chart notes that document required lab monitoring [hepatic impairment status (Child Pugh Class)] and dosing adjustments as needed.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist, pulmonologist, or practitioner at a Pulmonary Hypertension Association-Accredited center.

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response or stabilization.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

USTEKINUMAB

MEDICATION(S)
STELARA, USTEKINUMAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For moderate to severe plaque psoriasis (PsO): Documentation of an inadequate response, intolerance, or contraindication to one of the following: methotrexate, UVB therapy, or acitretin.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a dermatologist, rheumatologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

VALCHLOR

MEDICATION(S)
VALCHLOR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma. Documentation of an inadequate response, intolerance, or contraindication to at least one prior skin-directed therapy (e.g. topical corticosteroids, topical retinoids, topical imiquimod). Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

VELSIPITY

MEDICATION(S)
VELSIPITY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD) or a targeted synthetic DMARD.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of moderately to severely active ulcerative colitis with chart notes attached.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

VERQUVO

MEDICATION(S)
VERQUVO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of symptomatic chronic heart failure with NYHA Class II to IV. The patient has a left ventricular ejection fraction (LVEF) less than 45 percent. For initial therapy, the patient meets ONE of the following: (1) hospitalization for heart failure within the past 6 months OR (2) use of outpatient intravenous diuretics for heart failure within the past 3 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: patient has had a positive clinical response to therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

VIGABATRIN

MEDICATION(S)
VIGABATRIN, VIGADRONE, VIGAFYDE, VIGPODER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of refractory complex partial seizures or infantile spasms. For refractory complex partial seizures: documentation that vigabatrin is being used as adjunctive therapy AND documentation of an inadequate response, intolerance, or contraindication to two antiepileptic agents such as: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, topiramate, zonisamide. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

VORICONAZOLE

MEDICATION(S)
VORICONAZOLE 200 MG RECON SOLN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

VOSEVI

MEDICATION(S)
VOSEVI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure or calculate FIB-4 score), Hepatitis B surface antigen (HBsAg), and HIV antigen/antibody test. Documentation of previous treatment failure with sofosbuvir-based regimen, Zepatier, or Mavyret. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

OTHER CRITERIA
Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

N/A

VOWST

MEDICATION(S)
VOWST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Active Clostridioides difficile infection (CDI).

REQUIRED MEDICAL INFORMATION
Documentation to confirm Vowst is being used to prevent the recurrence of CDI. The patient has experienced at least 2 recurrent CDIs. The patient has or will complete CDI standard of care treatment (defined as 10-21 days of treatment with vancomycin and/or fidaxomicin) 2-4 days prior to initiating treatment with Vowst. The patient has or will complete a bowel prep and will not eat or drink for at least 8 hours prior to the first dose.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist or infectious disease specialist.

COVERAGE DURATION
30 days.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

WAKEFULNESS-PROMOTING AGENTS

MEDICATION(S)
ARMODAFINIL, MODAFINIL 100 MG TAB, MODAFINIL 200 MG TAB

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
A confirmed diagnosis of either narcolepsy (with sleep study attached), obstructive sleep apnea (with sleep study attached), or shift work disorder (with chart notes attached).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

WINREVAIR

MEDICATION(S)
WINREVAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC). PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than 20 mmHg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 2 Wood units (RHC results must be provided). Documentation showing that the patient is currently being treated with at least two PAH therapies from different pharmacologic categories unless there is a contraindication or intolerance (e.g., phosphodiesterase-5 inhibitor, endothelin receptor antagonist, prostacyclin agonist, guanylate cyclase stimulators). Confirmation patient will remain on background PAH therapies while on Winrevair.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a cardiologist, pulmonologist, or a practitioner at a Pulmonary Hypertension Association-Accredited center.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response or stabilization. Confirmation patient will remain on background PAH therapies while on Winrevair.

PART B PREREQUISITE

N/A

PREREQUISITE THERAPY REQUIRED

YES

XCOPRI

MEDICATION(S)
XCOPRI, XCOPRI (250 MG DAILY DOSE), XCOPRI (350 MG DAILY DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of partial-onset seizures. Documentation of an inadequate response, intolerance, or contraindication to two of the following drugs: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, topiramate. Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

XDEMVY

MEDICATION(S)
XDEMVY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an ophthalmologist, optometrist, or prescriber who specializes in the condition.

COVERAGE DURATION
6 weeks.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

XELJANZ

MEDICATION(S)
TOFACITINIB CITRATE 10 MG TAB, TOFACITINIB CITRATE 1 MG/ML SOLUTION, TOFACITINIB CITRATE 5 MG TAB, TOFACITINIB CITRATE ER, XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with another biologic Disease Modifying Anti-Rheumatic Drug (DMARD), a targeted synthetic DMARD, or with potent immunosuppressants such as azathioprine and cyclosporine.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis with chart notes attached. For all diagnoses: Documentation of an inadequate response or intolerance to at least one TNF blocker indicated to treat the diagnosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an appropriate specialist such as a rheumatologist or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

XERMELO

MEDICATION(S)
XERMELO

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of carcinoid syndrome diarrhea (CSD). Notes showing diarrhea is inadequately controlled by at least a 3-month trial of somatostatin analog therapy (SSA). Must provide documentation showing average of at least 4 bowel movements per day despite use of SSA therapy (e.g., lanreotide, octreotide). Must have records confirming concurrent SSA therapy.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response to therapy.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

XIFAXAN 550 MG

MEDICATION(S)
XIFAXAN 550 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of Hepatic Encephalopathy (HE), irritable bowel syndrome (IBS) with diarrhea, or small intestinal bacterial overgrowth (SIBO). For HE: Documentation of inadequate response, intolerance, or contraindication to lactulose. Documentation of dosing as 550 mg tablet 2 times a day. For IBS with diarrhea: Documentation of inadequate response, intolerance, or contraindication to one anti-diarrheal agent (loperamide). Documentation of dosing as 550 mg tablet 3 times a day. For SIBO: Results of glucose hydrogen or lactulose hydrogen breath tests OR small bowel aspirate and culture. Documentation of dosing as 550 mg tablet 3 times a day.

AGE RESTRICTION
18 years of age and older for IBS with diarrhea, HE or SIBO.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist.

COVERAGE DURATION
HE 12 months. IBS 3 treatments (14 days per tx) in 12 months. SIBO 1 treatment (14 days) in 30 days.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED

YES

XOLAIR

MEDICATION(S)
XOLAIR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For moderate to severe persistent asthma: Documentation of inadequate response, intolerance, or contraindication to both of the following: 1) Medium-to-high-dose inhaled corticosteroid, AND 2) Additional controller (i.e., LABA, LAMA, leukotriene modifier, or theophylline). Chart notes that show patient has daily asthma symptoms (coughing, wheezing, dyspnea), daily use of rescue inhalers (such as short acting beta2-agonist), asthma attacks/exacerbations two or more times per week, multiple emergency room visits within the past 12 months, or one or more nights of nocturnal asthma causing awakening. Chart notes that show positive skin test, RAST, or in vitro reactivity to at least one perennial aeroallergen AND IgE levels between 30-700 IU/mL for patients 12 years of age and older or IgE levels between 30-1,300 IU/mL for patients between the ages of 6 to less than 12 years. For chronic spontaneous urticaria (CSU): Documentation of diagnosis including notes ruling out other forms of urticaria. Chart notes that show patient remains symptomatic despite treatment with at least one H1 antihistamine or has an intolerance or contraindication to at least one H1 antihistamine treatment. For patients with chronic rhinosinusitis with nasal polyposis (CRSwNP): Documentation of a diagnosis of nasal polyps. Documentation of inadequate response, intolerance, or contraindication to at least one intranasal corticosteroid and at least one systemic corticosteroid. Documentation showing the patient will be treated with Xolair in combination with intranasal corticosteroids. For IgE mediated food allergy: Documentation of a diagnosis of IgE mediated food allergy. Documentation of IgE levels between 30 and 1850 IU/mL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist, allergist, immunologist, dermatologist, or otolaryngologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
YES

ZTALMY

MEDICATION(S)
ZTALMY

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Applies to new starts only.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A

ZURZUVAE

MEDICATION(S)
ZURZUVAE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Current pregnancy.

REQUIRED MEDICAL INFORMATION
Documentation of a diagnosis of postpartum depression with chart notes attached. Confirmation that medication will not be used for greater than 14 days. Applies to new starts only.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a psychiatrist or obstetrician/gynecologist.

COVERAGE DURATION
14 days of treatment in a 30-day approval duration.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREREQUISITE THERAPY REQUIRED
N/A