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

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

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.

AGE RESTRICTION
12 years of age and older for Nayzilam (midazolam). 6 years of age and older for Valtoco (diazepam).

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

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ADALIMUMAB-AACF AGENTS

MEDICATION(S)

ADALIMUMAB-AACF (2 PEN), IDACIO, IDACIO FOR CROHNS DISEASE/UC, IDACIO FOR PLAQUE PSORIASIS

PENDING CMS APPROVAL

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
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 3 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. For all diagnosis: Confirmation treatment plan is in place.

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
N/A

PART B PREREQUISITE

N/A

ALPHA1-PROTEINASE INHIBITORS

MEDICATION(S)
ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

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. Confirmation that the member does not have selective IgA deficiencies with known antibodies against IgA (anti-IgA antibodies).

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

APOMORPHINE INJECTION

MEDICATION(S)
APOMORPHINE HCL 30 MG/3ML SOLN CART

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with 5-HT3 antagonists (e.g. ondansetron, granisetron, palonosetron, alosetron).

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Parkinson's disease (PD) with intermittent off episodes. Documentation showing an inadequate response, intolerance, or contraindication to at least two conventional oral therapies (e.g carbidopa-levodopa, pramipexole, ropinirole, bromocriptine, amantadine, selegiline, rasagaline, trihexyphenidyl, benztropine, entacapone, tolcapone).

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

ARCALYST

MEDICATION(S)
ARCALYST

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmed diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA). For DIRA: Patient weighs at least 10 kg. Documentation showing need for maintenance of remission. For recurrent pericarditis (RP): Documentation showing a trial of, intolerance to, 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

AUSTEDO

MEDICATION(S)
AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT TITRATION

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 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: Improvement in symptoms of Chorea with medical records attached.

PART B PREREQUISITE

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
Subcutaneous Injection: 18 years or older. Intravenous infusion for SLE and LN: 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

BESREMI

MEDICATION(S)
BESREMI

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.

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

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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Dermatologist, hematologist, oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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. IN ADDITION: FOR INITIAL REQUESTS: (1)For OAB with symptoms of urge urinary incontinence, urgency, and frequency: documentation of inadequate response or intolerance to an anticholinergic medication, dose no more than 100 units/treatment. (2)For urinary incontinence due to detrusor overactivity associated with a neurologic condition: inadequate response or intolerance to an anticholinergic medication, dose no more than 200 units/treatment. (3)For prophylaxis of headaches in adult patients with chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer): documentation of inadequate response or intolerance to at least 2 different classes of prophylactic medications (i.e., beta blockers [such as propranolol, metoprolol], amitriptyline, topiramate, valproic acid or its derivatives, verapamil), dose no more than 155 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: dose no more than 200 units/treatment. (7)For strabismus associated with dystonia: dose no more than 25 units per muscle per injection. (8)For sialorrhea associated with disorders of the nervous system or neurologic dysfunction, documentation of diagnosis and inadequate response or intolerance to at least 1 anticholinergic medication (e.g., glycopyrrolate). (9)For cervical dystonia: dose no more than 300 units/treatment. FOR RENEWAL REQUESTS: Dose consistent with total units for diagnosis (per initial request criteria). Documentation supporting the need for repeat treatment(s) occurring no sooner than every 3 months.

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

Urologist: OAB, urinary incontinence. Neurologist: Migraine headaches. Neurologist/Physiatrist: Upper limb spasticity, cervical dystonia. Ophthalmologist: Blepharospasm, strabismus. Dermatologist/Neurologist/Physiatrist: Severe primary axillary hyperhidrosis.

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

BRONCHITOL

MEDICATION(S)
BRONCHITOL

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Confirmation that patient has passed a Bronchitol Tolerance Test. Confirmation that Bronchitol will be used in conjunction with standard therapies (e.g., bronchodilators, inhaled antibiotics) to improve pulmonary function. For reauthorization, confirmation of improvement in condition.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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. Documentation showing use for maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency. Documentation showing use as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to priopionic acidemia (PA) or methylmalonic acidemia (MMA).

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

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 or a physician who specializes in the treatment of cystic fibrosis.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
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 F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data.

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

CGRP ANTAGONISTS

MEDICATION(S)
AIMOVIG, AJOVY, EMGALITY, EMGALITY (300 MG DOSE)

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Notes showing diagnosis and patient having at least 4 migraine days per month. For migraine: Confirmation of intolerance or inadequate response to a trial with at least one preventive medication from two of the following classes: beta blockers, antidepressants, anticonvulsants. For episodic cluster headaches (Emgality only): Confirmation of a history of inadequate response, intolerance, or contraindication to at least one other preventative medication recommended by current consensus guidelines for episodic cluster headache (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

CINRYZE

MEDICATION(S)
CINRYZE

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 Part D review. Documentation of a diagnosis of hereditary angioedema (HAE).

AGE RESTRICTION
6 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist or immunologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of reduction in severity or duration of attacks.

PART B PREREQUISITE
N/A

CORTICOTROPIN GEL

MEDICATION(S)
ACTHAR, CORTROPHIN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, sensitivity to proteins of porcine origin, congenital infections suspected in children under 2 years old, or administration of a live or live attenuated vaccine in a patient receiving immunosuppressive doses of corticotropin gel.

REQUIRED MEDICAL INFORMATION
Documented diagnosis of an FDA-approved indication not otherwise excluded from Part D. Cover under Medicare Part B, if the medication will be furnished by the prescriber/office, administered in the prescribers office or ambulatory setting, and will be billed by the prescriber/office. Cover under Medicare Part D, if the prescriber wants to have the medication provided by a pharmacy.

AGE RESTRICTION
Infantile Spasms: Less than 2 years of age. Multiple Sclerosis: Greater than or equal to 18 years of age. Other FDA-approved indications not otherwise excluded from Part D: Greater than 2 years of age.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Infantile Spasms: 12 months. Other FDA-approved indications: 1 month.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

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
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DEFERASIROX

MEDICATION(S)
DEFERASIROX, DEFERASIROX GRANULES

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

DEFERIPRONE

MEDICATION(S)
DEFERIPRONE, FERRIPROX 100 MG/ML SOLUTION

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of transfusional iron overload due to thalassemia syndromes, sickle cell disease or other anemias. Documentation of Absolute Neutrophil Count (ANC) greater than or equal to 1.5 x 1000000000 (10 to the ninth power) per liter.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with hematologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

DIACOMIT

MEDICATION(S)
DIACOMIT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documented diagnosis of Dravet syndrome (DS). Documentation of an inadequate response, intolerance, or contraindication to at least two of the following: clobazam, valproic acid derivatives, topiramate, levetiracetam, cannabidiol (pharmaceutical).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with neurologist or epileptologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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

DRONABINOL

MEDICATION(S)
DRONABINOL

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

DUPIXENT

MEDICATION(S)
DUPIXENT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Active helminth infection.

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 showing a trial of, intolerance to, or contraindication to at least one topical steroid. For patients over age 2, documentation showing a trial of, intolerance to, or contraindication to at least one topical corticosteroid and 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 showing a trial of, intolerance to, or contraindication to at least one combination therapy (inhaled steroids, long acting beta-agonists, antileukotrienes, theophylline). For add on maintenance therapy for the treatment of oral corticosteroid dependent asthma: Documentation showing oral corticosteroid dependent asthma. Documentation showing trial of, intolerance to, or contraindication to at least one combination therapy (inhaled steroids, long acting beta-agonists, antileukotrienes, theophylline). For patients with chronic rhinosinusitis with nasal polyposis (CRSwNP): Documentation of a diagnosis of CRSwNP. Documentation showing a trial of, intolerance to, 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. For patients with eosinophilic esophagitis: Documentation of a diagnosis of eosinophilic esophagitis. Documentation showing a trial of, intolerance to, or contraindication to at least one proton pump inhibitor. Documentation showing a trial of, intolerance to, or contraindication to inhaled fluticasone propionate. Continued in OTHER CRITERIA.

AGE RESTRICTION
6 months of age or older for atopic dermatitis. 6 years of age and older for eosinophilic phenotype or

oral corticosteroid dependent asthma.18 years of age and older for CRSwNP and prurigo nodularis. 1 year of age and older for EOE.

PRESCRIBER RESTRICTION
Pulmonologist, allergist, immunologist, dermatologist, otolaryngologist, gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For prurigo nodularis: Documentation of diagnosis. Documentation showing a trial, intolerance, or contraindication to one high potency topical steroid. For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

ENBREL

MEDICATION(S)
ENBREL, ENBREL MINI, ENBREL SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of the results of PPD test and treatment plan to address latent or active infection. Confirmation of diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), plaque psoriasis (PsO), polyarticular juvenile idiopathic arthritis (JIA), or ankylosing spondylitis (AS). For RA or PsA: Documentation of inadequate response, intolerance, or contraindication to at least one or more DMARDs. For PsO (moderate to severe disease): Documentation that patient is a candidate for systemic therapy or phototherapy and documentation of inadequate response, intolerance, or contraindication to methotrexate OR UVB therapy OR Acitretin. For PsO (limited disease): Documentation of inadequate response, intolerance, or contraindication to one topical steroid (high or very high potency) AND calcipotriene. For moderately to severely active polyarticular JIA: Documentation of inadequate response, intolerance, or contraindication to one or more DMARDs. For AS: Documentation of inadequate response, intolerance, or contraindication to at least two non-steroidal anti-inflammatory drugs OR is intolerant to non-steroidal anti-inflammatory drugs.

AGE RESTRICTION
For RA, AS: 18 years of age and older. For PsO: 4 years of age and older. For JIA, PsA: 2 years of age and older.

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

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

ENDARI

MEDICATION(S)
ENDARI

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 request is to reduce acute complications of sickle cell disease. Documentation of inadequate response to maximum tolerated dose of hydroxyurea therapy OR documented intolerance or contraindication to hydroxyurea therapy. Request is within the FDA labeled dose.

AGE RESTRICTION
5 years of age and older.

PRESCRIBER RESTRICTION
Hematologist or oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ENDOTHELIN RECEPTOR ANTAGONISTS

MEDICATION(S)
AMBRISENTAN, BOSENTAN, OPSUMIT, TRACLEER 32 MG TAB SOL

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 3 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
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: documentation showing treatment response and monitoring.

PART B PREREQUISITE

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 of baseline serum transaminases (ALT and AST) and total bilirubin levels prior to initiation of treatment and confirmation that these labs will be monitored periodically during treatment. Documentation showing that patient has failed to become seizure-free with at least 2 antiepileptic drugs (specify drugs tried). Confirmation that Epidiolex is adjunctive therapy with documentation of antiepileptic drug(s) with which Epidiolex will be used.

AGE RESTRICTION
1 year of age and older.

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

COVERAGE DURATION
12 months.

OTHER CRITERIA
Request is within FDA approved labeled dose not exceeding 20 mg/kg/day for treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome or dose not exceeding 25 mg/kg/day for treatment of seizures associated with Tuberous Sclerosis Complex.

PART B PREREQUISITE
N/A

FASENRA

MEDICATION(S)
FASENRA 30 MG/ML SOLN PRSYR, FASENRA PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
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 treatment with an inhaled ICS/LABA (inhaled corticosteroid/long-acting beta-agonist) with or without other controllers, including systemic steroids, antileukotrienes.

AGE RESTRICTION
6 years of age and older.

PRESCRIBER RESTRICTION
Pulmonologist, allergist, immunologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

FENTANYL CITRATE TRANSMUCOSAL LOZENGE

MEDICATION(S)
FENTANYL CITRATE 1200 MCG LOZ HANDLE, FENTANYL CITRATE 1600 MCG LOZ HANDLE, FENTANYL CITRATE 200 MCG LOZ HANDLE, FENTANYL CITRATE 400 MCG LOZ HANDLE, FENTANYL CITRATE 600 MCG LOZ HANDLE, FENTANYL CITRATE 800 MCG LOZ HANDLE

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Prescribers and patients not enrolled in TIRF REMs Access Program. Must not be used in opioid non-tolerant patients.

REQUIRED MEDICAL INFORMATION
For use in the management of breakthrough pain in cancer patients (documentation must be attached) who are already receiving and have become tolerant to around-the-clock opioid therapy for persistent cancer pain. Opioid tolerant is defined as patients taking at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg oral oxyocodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid daily for 1 week or longer. Patients must remain on around-the-clock opioids when taking fentanyl citrate transmucosal lozenges. For renewal: assessment of pain severity and functional ability, progress towards achieving therapeutic goals, presence of adverse effects, plan of care including duration of treatment. Chart notes that assess the patient for possible aberrant drug-related behaviors, substance use, and psychological issues. Patients remain on around-the-clock opioids when taking fentanyl citrate transmucosal lozenges.

AGE RESTRICTION
16 years of age and older.

PRESCRIBER RESTRICTION
Pain management specialist or oncologist.

COVERAGE DURATION
6 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

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

FINTEPLA

MEDICATION(S)
FINTEPLA

PA INDICATION INDICATOR
1 - All FDA-Approved 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).

AGE RESTRICTION
2 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation neurologist or epileptologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

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

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).

AGE RESTRICTION
6 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an allergist or immunologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of reduction in severity or duration of attacks.

PART B PREREQUISITE
N/A

HARVONI

MEDICATION(S)
HARVONI

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

HIGH RISK MEDICATION

MEDICATION(S)
DIPYRIDAMOLE 25 MG TAB, DIPYRIDAMOLE 50 MG TAB, DIPYRIDAMOLE 75 MG TAB, DISOPYRAMIDE PHOSPHATE, ERGOLOID MESYLATES 1 MG TAB, GUANFACINE HCL

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. 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. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication.

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HIGH RISK MEDICATION - BUTALBITAL COMBINATIONS

MEDICATION(S)
BAC, BUTALBITAL-APAP-CAFF-COD 50-325-40-30 MG CAP, BUTALBITAL-APAP-CAFFEINE 50-325-40 MG TAB, BUTALBITAL-ASPIRIN-CAFFEINE 50-325-40 MG CAP

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. Confirmation that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Confirmation that there is specific benefit established and that the benefit outweighs the potential risk. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication.

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HIGH RISK MEDICATION - FIRST GENERATION ANTIHISTAMINES

MEDICATION(S)
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
Confirmation of patient's diagnosis and indication for use of the High Risk Medication. Confirmation that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Confirmation of the specific benefit established and that the benefit outweighs the potential risk. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication. For allergic conditions, confirmation of an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as levocetirizine, desloratadine, azelastine nasal spray, fluticasone propionate nasal spray, or mometasone nasal spray.

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

HIGH RISK MEDICATION - NON-BENZODIAZEPINE SEDATIVE HYPNOTICS

MEDICATION(S)
ESZOPICLONE, ZALEPLON, ZOLPIDEM TARTRATE 10 MG TAB, ZOLPIDEM TARTRATE ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. 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. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication. Confirmation of an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as temazepam, ramelteon, or doxepin (generic Silenor).

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HIGH RISK MEDICATION - NON-COX-SELECTIVE NSAIDS

MEDICATION(S)
INDOMETHACIN 25 MG CAP, INDOMETHACIN 50 MG CAP, INDOMETHACIN ER

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. 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. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication. Confirmation of an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as ibuprofen, naproxen, nabumetone, etodolac, diclofenac, meloxicam, or topical diclofenac 1% gel.

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HIGH RISK MEDICATION - SKELETAL MUSCLE RELAXANTS

MEDICATION(S)
CARISOPRODOL 350 MG TAB, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, METHOCARBAMOL 500 MG TAB, METHOCARBAMOL 750 MG TAB, VANADOM

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. 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. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication.

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

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

HUMIRA

MEDICATION(S)
HUMIRA, HUMIRA (2 PEN), HUMIRA (2 SYRINGE), HUMIRA PEDIATRIC CROHNS START, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, HUMIRA PEN-PEDIATRIC UC START, HUMIRA PEN-PSOR/UVEIT STARTER, HUMIRA-CD/UC/HS STARTER, HUMIRA-PS/UV/ADOL HS STARTER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of PPD test results and treatment plan for active or latent infection. Confirmation of diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), plaque psoriasis (PsO), polyarticular juvenile idiopathic arthritis (JIA), ankylosing spondylitis (AS), Crohn’s disease (CD), ulcerative colitis (UC), hidradenitis suppurativa (HS), uveitis. For RA, PsA: Documentation of inadequate response, intolerance or contraindication to at least 1 DMARD (e.g. methotrexate, hydroxychloroquine, sulfasalazine). For JIA: Documentation of inadequate response, intolerance, or contraindication to 1 or more DMARDs (e.g.methotrexate). For AS: Documentation of inadequate response, intolerance, or contraindication to at least 2 NSAIDs. For PsO (moderate to severe disease): Documentation that patient is a candidate for systemic therapy or phototherapy and documentation of inadequate response, intolerance, or contraindication to methotrexate OR UVB therapy OR Acitretin. For PsO (limited disease): Documentation of inadequate response, intolerance, or contraindication to 1 topical steroid (high or very high potency) AND calcipotriene. For active CD: Documentation of inadequate response, intolerance or contraindication to corticosteroids and methotrexate or azathioprine, or lost response to or intolerant to infliximab. For active UC: Documentation of inadequate response, intolerance, or contraindication to corticosteroids, azathioprine, OR 6-MP. For HS: Documentation of inadequate response, intolerance, or contraindication to 2 of the following: topical antibiotics (e.g. clindamycin), oral antibiotics (e.g. doxycycline, minocycline, amoxicillin-clavulanic acid, clindamycin, rifampin, dapsone), intralesional triamcinolone injections. For Uveitis: Documentation of inadequate response, intolerance, or contraindication to 1 or more oral or topical glucocorticoids (e.g. prednisone), immunosuppressant agent, or periocular or intraocular injection (e.g. triamcinolone).

AGE RESTRICTION

RA, PsA, AS, PsO, adult CD: 18 years of age and older. UC: 5 years of age and older. HS: 12 years of age and older. JIA and Uveitis: 2 years of age and older. Pediatric CD: 6 years of age and older.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a rheumatologist, dermatologist, gastroenterologist, or ophthalmologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

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).

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with allergist or immunologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Documentation of reduction in severity or duration of attacks.

PART B PREREQUISITE
N/A

INGREZZA

MEDICATION(S)
INGREZZA 40 & 80 MG CAP THPK, INGREZZA 40 MG CAP, INGREZZA 60 MG CAP, INGREZZA 80 MG CAP

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Congenital long QT syndrome. Cardiac arrhythmias associated with prolonged QT interval. Concurrent use of MAO inhibitors or strong CYP3A4 inducers. For a diagnosis of Chorea associated with Huntington’s Disease: suicidal patients and patients with untreated or inadequately treated depression.

REQUIRED MEDICAL INFORMATION
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: Documented diagnosis of Chorea associated with Huntington’s Disease with documentation attached. Documentation showing that other movement disorders (such Tardive Dyskinesia, or Parkinson’s disease) have been excluded 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: Improvement in symptoms of Tardive Dyskinesia with an updated AIMS assessment. Documentation must be attached. For Chorea associated with Huntington’s Disease: Improvement in symptoms of Chorea with medical records attached.

PART B PREREQUISITE

N/A

INJECTABLE TESTOSTERONE PRODUCTS

MEDICATION(S)
DEPO-TESTOSTERONE, 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

INTRAVENOUS IMMUNE GLOBULIN (IVIG)

MEDICATION(S)
BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD, 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
3 months.

OTHER CRITERIA
Subject to Part B vs D review. Documentation showing confirmation of 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) inadequate response or inability to tolerate conventional therapy (ie steroids, immunosuppressants) OR (b) rapidly progressive disease in conjunction with conventional therapy (such as steroids, immunosuppressants) (2) erythema multiforme major (SJS, TEN) and SCORTEN level 3 or greater (3) scleromyxedema (4) 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 (5) chronic ITP and ALL of the following (a) inadequate response or inability to tolerate corticosteroids (b) duration of illness greater than 6 months (c) platelets persistently less than 20,000 per uL (6) chronic B-cell lymphocytic leukemia with IgG less than 600 mg/dL and recurrent, serious bacterial infections requiring antibiotic therapy (7) hematopoetic stem cell transplant and IgG less than 400 mg/dL (8) 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 (9) solid organ transplant (10) chronic inflammatory demyelinating polyneuritis confirmed by electrodiagnostic testing or nerve biopsy and an inadequate response or inability to tolerate corticosteroids (11) dermatomyositis or polymyositis diagnosed by laboratory testing (antinuclear or myositis specific antibodies, biopsy, EMG, or MRI) and inadequate response or inability to tolerate steroids or immunosuppressants (12) Guillain Barre syndrome with impaired function (ie unable to stand or walk without aid) (13) Lambert Eaton myasthenic syndrome refractory to steroids, immunosuppressants, or cholinesterase inhibitors (14) multifocal motor neuropathy diagnosed by electrodiagnostic studies (15) acute exacerbations of multiple sclerosis unresponsive to steroids (16) myasthenia gravis refractory to at least 8 weeks of standard therapy (steroids, immunosupressants, cholinesterase inhibitors) (17) myasthenic crisis (18) stiff person syndrome refractory to standard therapy (muscle relaxants, benzodiazepines, gabapentin) (19) severe, active SLE unresponsive to steroids (20) Kawasaki disease. CONTINUATION OF THERAPY CRITERIA: 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

N/A

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.

REQUIRED MEDICAL INFORMATION
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. Documentation of inadequate response, intolerance, or contraindication to one sodium-glucose co-transporter 2 (SGLT2) inhibitor used for chronic kidney disease (e.g., Farxiga).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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 to show inadequate response, contraindication, or intolerance to 2 different agents used to treat MS.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Neurologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

KORLYM

MEDICATION(S)
KORLYM, MIFEPRISTONE 300 MG TAB

PA INDICATION INDICATOR
3 - All Medically-Accepted 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
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

LIDOCAINE PATCHES

MEDICATION(S)
LIDOCAINE 5 % PATCH, LIDOCAN

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

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 or diabetic peripheral neuropathy.

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

LUCEMYRA

MEDICATION(S)
LUCEMYRA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of acute opioid withdrawal documented by an opioid withdrawal scale (such as Objective Opioid Withdrawal Scale [OOWS], Clinical Opioid Withdrawal Scale [COWS], Subjective Opioid Withdrawal Scale [SOWS]). Documentation must be attached. Documentation of an inadequate response, inability to tolerate, or contraindication to clonidine.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
14 days.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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 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
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

MYALEPT

MEDICATION(S)
MYALEPT

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with general obesity not associated with congenital leptin deficiency. Patients with HIV-related lipodystrophy. Patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy.

REQUIRED MEDICAL INFORMATION
Documentation showing confirmation of a diagnosis of congenital or acquired generalized lipodystrophy. Documentation of baseline labs (hemoglobin A1c, fasting plasma glucose, triglycerides). For members who have been previously approved, documentation showing benefit of treatment (as evidenced by decrease in at least one of the following: hemoglobin A1c, fasting glucose, and/or triglycerides).

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

NATPARA

MEDICATION(S)
NATPARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with a documented risk for osteosarcoma (including Pagets disease or unexplained elevation of alkaline phosphatase, open epiphyses, hereditary disorders predisposed to osteosarcoma, or a history of external beam or implant radiation therapy).

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis. Documentation showing uncontrolled hypocalcemia despite treatment with calcium supplements and active forms of vitamin D. Labs showing serum calcium is above 7.5 mg/dL and serum 25-hydroxyvitamin D level is within normal range prior to starting Natpara.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with an endocrinologist or parathyroid specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
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
For primary hyperlipidemia with heterozygous familial hypercholesterolemia (HeFH): Documentation of either genetic confirmation or Dutch Lipid Network Criteria score greater than 6 with documentation attached. For primary hyperlipidemia with atherosclerotic cardiovascular disease (ASCVD): Documentation of diagnosis. For HeFH and ASCVD: 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 as adjunct to statin 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

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
Endocrinologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
RENEWAL REQUESTS: chart notes (for children include documentation of growth chart, height velocity, chronological age, bone age, and linear growth potential remaining with open epiphyses) and for children and adults, 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.

PART B PREREQUISITE
N/A

NUCALA

MEDICATION(S)
NUCALA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation showing confirmation of the following: (1) 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 treatment with an inhaled ICS/LABA (inhaled corticosteroid/long-acting beta-agonist) with or without other controllers, including systemic steroids, antileukotrienes. (2) Documented diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA). (3) Documented diagnosis of hypereosinophilic syndrome for greater than or equal to 6 months without an identifiable non-hematologic secondary cause. (4) Documented diagnosis of rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to nasal corticosteroids.

AGE RESTRICTION
6 years of age and older.

PRESCRIBER RESTRICTION
Pulmonologist, allergist, immunologist, rheumatologist, hematologist, otolaryngologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

NUEDEXTA

MEDICATION(S)
NUEDEXTA

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. Patients with known hypersensitivity to dextromethorphan. Use with an MAOI or within 14 days of stopping an MAOI. Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block. 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. For patients at risk of QT prolongation and torsades de pointes, baseline EKG and an EKG 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

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. Documentation of an inadequate response, intolerance, or contraindication to at least one of the following: quetiapine or clozapine.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

OCALIVA

MEDICATION(S)
OCALIVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients with decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event. Patients with compensated cirrhosis who have evidence of portal hypertension. Complete biliary obstruction.

REQUIRED MEDICAL INFORMATION
Chart notes that document the patient's diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following: a positive antimitochondrial antibody test, elevated serum alkaline phosphatase level, liver biopsy, or ultrasound scan of the liver. Confirmation that the patient was taking UDCA for at least one year without response and will continue treatment with UDCA while on Ocaliva or is unable to tolerate UDCA. Labs documenting liver function (AST/ALT, alkaline phosphatase, total bilirubin) and lipid panel. For renewals, updated labs documenting liver function and lipid panel and confirmation showing disease improvement while on therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Hepatologist or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

OFEV

MEDICATION(S)
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 OR documentation showing a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype 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.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

ORAL ONCOLOGY AGENTS

MEDICATION(S)

ABIRATERONE ACETATE, AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO, AYVAKIT, BALVERSA, BEXAROTENE 75 MG CAP, BOSULIF, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE), COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLEADA, ERLOTINIB HCL, EVEROLIMUS 10 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB, EXKIVITY, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, 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, INLYTA, INQOVI, INREBIC, IWILFIN, JAKAFI, JAYPIRCA, KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE), KISQALI FEMARA(200 MG DOSE), KOSELUGO, KRAZATI, LAPATINIB DITOSYLATE, 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), LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE), MEKINIST, MEKTOVI, NERLYNX, NINLARO, NUBEQA, ODOMZO, OGSIVEO, OJJAARA, ONUREG, ORGOVYX, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE), POMALYST, QINLOCK, RETEVMO, REVLIMID, REZLIDHIA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB TOSYLATE, SPRYCEL, STIVARGA, SUNITINIB MALATE, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, THALOMID, TIBSOVO, TRUQAP, TUKYSA, TURALIO 125 MG CAP, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, VOTRIENT, WELIREG, XALKORI, XOSPATA, XPOVIO (100 MG ONCE WEEKLY) 50 MG TAB THPK, XPOVIO (40 MG ONCE WEEKLY) 40 MG TAB THPK, XPOVIO (40 MG TWICE WEEKLY) 40 MG TAB THPK, XPOVIO (60 MG ONCE WEEKLY) 60 MG TAB THPK, XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY) 40 MG TAB THPK, XPOVIO (80 MG TWICE WEEKLY), XTANDI, YONSA, ZEJULA, ZELBORAF, 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.

AGE RESTRICTION

N/A

PRESCRIBER RESTRICTION

N/A

COVERAGE DURATION

12 months.

OTHER CRITERIA

N/A

PART B PREREQUISITE

N/A

OTEZLA

MEDICATION(S)
OTEZLA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other disease-modifying antirheumatic drugs (DMARDs).

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis. For active psoriatic arthritis and plaque psoriasis: Documentation showing a trial of, intolerance to, or contraindication to at least one DMARD indicated for the diagnosis. For oral ulcers associated with Behets Disease: Documentation showing a trial of, intolerance to, or contraindication to colchicine.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Psoriatic arthritis: dermatologist or rheumatologist. Plaque psoriasis: dermatologist. Behets Disease: rheumatologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE
N/A

OXERVATE

MEDICATION(S)
OXERVATE

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
Ophthalmologist.

COVERAGE DURATION
8 weeks.

OTHER CRITERIA
N/A

PART B PREREQUISITE
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.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Dermatologist, oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PART D VS PART B

MEDICATION(S)

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ADRIAMYCIN 2 MG/ML SOLUTION, ADRUCIL, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, 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, ALIQOPA, ALYMSYS, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, APREPITANT, ARFORMOTEROL TARTRATE, ARSENIC TRIOXIDE 10 MG/10ML SOLUTION, ATGAM, AVASTIN, AVSOLA, AZACITIDINE, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE SODIUM, BAVENCIO, BENDAMUSTINE HCL 100 MG RECON SOLN, BENDAMUSTINE HCL 25 MG RECON SOLN, BLEOMYCIN SULFATE, BORTEZOMIB 3.5 MG RECON SOLN, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CARBOPLATIN, CINACALCET HCL, CISPLATIN 100 MG/100ML SOLUTION, CISPLATIN 200 MG/200ML SOLUTION, CISPLATIN 50 MG/50ML SOLUTION, CLADRIBINE, CLINIMIX E/DEXTROSE (2.75/5), CLINIMIX E/DEXTROSE (4.25/10), CLINIMIX E/DEXTROSE (4.25/5), CLINIMIX E/DEXTROSE (5/15), CLINIMIX E/DEXTROSE (5/20), CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINISOL SF, CLINOLIPID, CLOFARABINE, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE 50 MG/ML SOLUTION, CYCLOSPORINE MODIFIED, CYRAMZA, CYTARABINE, CYTARABINE (PF), DACTINOMYCIN, DARZALEX, DAUNORUBICIN HCL, DECITABINE, DOCETAXEL 160 MG/16ML SOLUTION, DOCETAXEL 160 MG/8ML CONC, DOCETAXEL 20 MG/2ML SOLUTION, DOCETAXEL 20 MG/ML CONC, DOCETAXEL 80 MG/4ML CONC, DOCETAXEL 80 MG/8ML SOLUTION, DOXORUBICIN HCL 2 MG/ML SOLUTION, DOXORUBICIN HCL LIPOSOMAL, ELIGARD, EMEND 125 MG/5ML RECON SUSP, EMPLICITI, ENGERIX-B, ENVARSUS XR, EPIRUBICIN HCL, 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 5 GM/100ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, FREAMINE III, FULVESTRANT, GEMCITABINE HCL 1 GM RECON SOLN, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPLISAV-B, HERCEPTIN HYLECTA, HERZUMA, IDARUBICIN HCL, IMFINZI, INFLECTRA, INTRALIPID, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, JYNNEOS, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LEUPROLIDE ACETATE 1 MG/0.2ML

KIT, LEUPROLIDE ACETATE (3 MONTH), 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 (4-MONTH), LUPRON DEPOT (6-MONTH), LUPRON DEPOT-PED (1-MONTH), LUPRON DEPOT-PED (3-MONTH), LUPRON DEPOT-PED (6-MONTH), MELPHALAN, MELPHALAN HCL, MVASI, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG RECON SOLN, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE MOFETIL HCL, MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, MYLOTARG, NIPENT, NULOJIX, NUTRILIPID, OGIVRI, ONDANSETRON, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 8 MG TAB, ONDANSETRON HCL ORAL SOLN 4 MG/5ML, ONTRUZANT, OPDIVO, OXALIPLATIN 100 MG RECON SOLN, OXALIPLATIN 100 MG/20ML SOLUTION, OXALIPLATIN 50 MG RECON SOLN, OXALIPLATIN 50 MG/10ML SOLUTION, PACLITAXEL, PACLITAXEL PROTEIN-BOUND PART, PARAPLATIN, PEMETREXED DISODIUM 100 MG RECON SOLN, PEMETREXED DISODIUM 1000 MG RECON SOLN, PEMETREXED DISODIUM 500 MG RECON SOLN, PEMETREXED DISODIUM 750 MG RECON SOLN, PENTAMIDINE ISETHIONATE FOR NEBULIZATION SOLN 300 MG, PLENAMINE, PREHEVBRIO, PREMASOL, PROCRIT, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, PULMOZYME, RECOMBIVAX HB, RENFLEXIS, RETACRIT, RIABNI, RITUXAN HYCELA, RUXIENCE, SANDIMMUNE 100 MG/ML SOLUTION, SIMULECT 20 MG RECON SOLN, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SYNRIBO, SYNTHAMIN 17, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TECENTRIQ, THYMOGLOBULIN, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TOPOTECAN HCL 4 MG RECON SOLN, TPN ELECTROLYTES, TRAVASOL, TRAZIMERA, TRELSTAR MIXJECT, TROPHAMINE, TRUXIMA, VECTIBIX 100 MG/5ML SOLUTION, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, VYXEOS, YUPELRI, ZANOSAR, 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)
NYVEPRIA, ZIEXTENZO

PA INDICATION INDICATOR
1 - All FDA-Approved 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). For Ziextenzo only: diagnosis of hematopoietic subsyndrome of acute radiation syndrome: documentation of exposure to myelosuppressive doses of radiation. For all diagnoses, confirmation that lab work (complete blood count with differential including ANC) is being monitored.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Oncologist or hematologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

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 3 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
N/A

PART B PREREQUISITE
N/A

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 forced vital capacity (FVC) greater than or equal to 50%. 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. For ongoing therapy: 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.

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

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
Documentation of use for treatment of invasive Aspergillosis OR 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) OR diagnosis of oropharyngeal candidiasis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

PREGABALIN ER

MEDICATION(S)
PREGABALIN ER

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation to confirm the diagnosis of pain associated with post-herpetic neuralgia (PHN) or diabetic peripheral neuropathy (DPN). Documentation of an inadequate response or inability to tolerate gabapentin and immediate release Lyrica. Dosage prescribed within package insert requirements (maximum of 330 mg per day for DPN, maximum of 660 mg per day for PHN).

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

PROMACTA

MEDICATION(S)
PROMACTA

PA INDICATION INDICATOR
3 - All Medically-Accepted Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis: 1) chronic immune thrombocytopenia (ITP), 2) thrombocytopenia in patients with chronic hepatitis C, or 3) severe aplastic anemia. For ITP: 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 that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For severe aplastic anemia: Documentation of inadequate response, intolerance or contraindication to immunosuppressive therapy or being used in combination with standard immunosuppressive therapy

AGE RESTRICTION
For ITP: 1 year or older. For thrombocytopenia in patients with chronic hepatitis C: 18 years or older. For severe aplastic anemia: 2 years or older.

PRESCRIBER RESTRICTION
For ITP and severe aplastic anemia: hematologist. For thrombocytopenia in patients with chronic hepatitis C: hematologist, hepatologist, or infectious disease specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

RAVICTI

MEDICATION(S)
RAVICTI

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Not indicated for the treatment of acute hyperammonemia in patients with UCDs nor for the treatment of N-acetylglutamate synthase (NAGS) deficiency. Concomitant use with another phenylbutyrate product (like sodium phenylbutyrate).

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis by enzymatic, biochemical, or genetic testing attached. Documentation of inadequate response, intolerance, or contraindication to sodium phenylbutyrate. Confirmation that ammonia concentration and serum amino acids are and will continue to be monitored to ensure positive clinical treatment response.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a metabolic or medical genetic specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RECORLEV

MEDICATION(S)
RECORLEV

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 Syndrome. Notes showing the member is being treated for endogenous hypercortisolemia (e.g. pituitary tumor, ectopic tumor, adrenal adenoma or carcinoma). Notes showing one of the following: a) the member is not a candidate for surgery or b) the member has recurrent hypercortisolism after initial surgery. Documentation showing a trial of, intolerance to, or contraindication to ketoconazole.

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 positive clinical response.

PART B PREREQUISITE
N/A

REGRANEX

MEDICATION(S)
REGRANEX

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation to confirm the diagnosis for use on lower extremity diabetic neuropathic ulcers.

AGE RESTRICTION
16 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
5 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

REPATHA

MEDICATION(S)
REPATHA, REPATHA PUSHTRONEX SYSTEM, REPATHA SURECLICK

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Homozygous Familial Hypercholesterolemia (HoFH): Genetic confirmation of 2 mutant alleles in the LDL receptor, Apo B-100 PCSK9 gene OR untreated LDL-C greater than 500 mg/dL OR treated LDL-C greater than or equal to 300 mg/dL with cutaneous or tendonous xanthoma before the age of 10 OR untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia (HeFH) in both parents with documentation attached. Dosing as 420 mg once a month. For HeFH: Documentation of either genetic confirmation OR Dutch Lipid Network Criteria score greater than 6 with documentation attached. For patients with clinical atherosclerotic cardiovascular disease (ASCVD) or primary hyperlipidemia: Documentation of diagnosis. For all diagnoses: Documentation of prior treatment of at least one high intensity statin therapy (such as atorvastatin 40 mg or 80 mg or rosuvastatin 20 mg or 40 mg) with failure to reach target LDL-C levels. 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. Baseline labs (lipid profile) required for all indications.

AGE RESTRICTION
HoFH and HeFH: 10 years of age and older. ASCVD: 18 years of age and older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization for all indications: updated lipid profile.

PART B PREREQUISITE

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 bone marrow transplant specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

RINVOQ

MEDICATION(S)
RINVOQ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Severe hepatic impairment. Active, serious infection. Live vaccines. Concomitant use with Janus kinase (JAK) inhibitor, biologic disease modifying anti-rheumatic drugs (DMARDs), potent immunosuppressant drugs, strong cytochrome P450 3A4 (CYP3A4) inducers, biologic immunomodulators, or biological therapies for ulcerative colitis.

REQUIRED MEDICAL INFORMATION
For a documented diagnosis of moderately to severely active rheumatoid arthritis, active psoriatic arthritis, moderately to severely active ulcerative colitis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, or moderately to severely active Crohn’s disease: attach documentation of inadequate response or intolerance to at least one TNF blocker. For a documented diagnosis of refractory, moderate to severe atopic dermatitis, attach a documented history of inadequate control with at least one other systemic drug (including biologics) used to treat refractory, moderate to severe atopic dermatitis OR documentation explaining why these drugs are inadvisable. For all diagnoses: confirmation that recent tuberculin testing is negative for latent tuberculosis infection or positive for latent tuberculosis with confirmation that treatment is completed or is receiving treatment for latent tuberculosis. Confirmation that liver function will be monitored with focus on elevated liver enzymes (ALT or AST). Confirmation that a complete blood count with differential does not show an absolute lymphocyte count less than 500 cells/mm3, absolute neutrophil count less than 1000 cells/mm3, or hemoglobin level less than 8g/dL.

AGE RESTRICTION
18 years of age and older for rheumatoid arthritis, psoriatic arthritis, active ankylosing spondylitis, active non-radiographic axial spondyloarthritis, ulcerative colitis, and Crohn's disease. 12 years of age and older for atopic dermatitis.

PRESCRIBER RESTRICTION

Prescribed by or in consultation with a gastroenterologist, rheumatologist or dermatologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with neurologist or epileptologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

SKYRIZI

MEDICATION(S)
SKYRIZI, SKYRIZI PEN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Active, serious infection. Live vaccines.

REQUIRED MEDICAL INFORMATION
For plaque psoriasis: Confirmed diagnosis of moderately to severely active plaque psoriasis supported by clinical documentation. Documentation of inadequate response, intolerance, or contraindication to methotrexate or UVB therapy (alone or in combination with other medications) or acitretin. For psoriatic arthritis: Confirmed diagnosis of active psoriatic arthritis supported by clinical documentation. Documentation of inadequate response, intolerance, or contraindication to at least one DMARD. For moderately to severely active Crohn's disease: Confirmed diagnosis of moderately to severely active Crohn's disease supported by clinical documentation. Documentation of inadequate response, intolerance, or contraindication to one of the following: corticosteroids, methotrexate, or azathioprine. For all diagnoses: Documentation of tuberculin testing that is negative for latent tuberculosis infection or positive for latent tuberculosis with documentation that treatment is completed or is receiving treatment for latent tuberculosis.

AGE RESTRICTION
18 years of age and older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

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

SOFOSBUVIR/VELPATASVIR

MEDICATION(S)
EPCLUSA, SOFOSBUVIR-VELPATASVIR

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

STELARA

MEDICATION(S)
STELARA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Active, serious infection. Live vaccines.

REQUIRED MEDICAL INFORMATION
For initial requests: Confirmation of diagnosis of moderate to severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease, moderately to severely active ulcerative colitis. For plaque psoriasis: (1) patient 6 to 17 years of age: documentation of an inadequate response, intolerance, or contraindication to Enbrel, (2) patient 18 years of age or older: documentation of an inadequate response, intolerance, or contraindication to two of the following: Enbrel, Humira, Skyrizi, Otelza. For psoriatic arthritis: documentation of an inadequate response, intolerance, or contraindication to two of the following: Enbrel, Humira, Xeljanz/Xeljanz XR, Otezla, Skyrizi. For Crohn's disease: documentation of an inadequate response, intolerance, or contraindication to Humira and Skyrizi. For ulcerative colitis: inadequate response, intolerance, or contraindication to Humira and Xeljanz/Xeljanz XR. For all indications: Documentation of tuberculosis (TB) testing that is negative for latent tuberculosis infection or positive for latent tuberculosis with documentation that treatment is completed or is receiving treatment for latent tuberculosis.

AGE RESTRICTION
For plaque psoriasis and psoriatic arthritis: 6 years of age or older. For Crohn's disease and ulcerative colitis: 18 years of age or older.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

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 an inadequate response or inability to tolerate generic clobazam. Documentation showing that Sympazan will be used as adjunctive therapy to other antiepileptic drugs.

AGE RESTRICTION
2 years of age and older.

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

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

TALTZ

MEDICATION(S)
TALTZ

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concurrent therapy with biologic DMARDs or tumor necrosis factor antagonists.

REQUIRED MEDICAL INFORMATION
Confirmation of diagnosis of moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. For PsO: in pediatric patients ages 6-17 years, documentation of an inadequate response, intolerance, or contraindication to Enbrel and in adults with PsO documentation of inadequate response, intolerance, or contraindication to Enbrel, Humira, or Skyrizi. For PsA and AS: documentation of inadequate response, intolerance, or contraindication to Enbrel, Humira, Rinvoq or Xeljanz/Xeljanz XR. For nr-axSpA: documentation of inadequate response, intolerance, or contraindication to Rinvoq. For all indications: Confirmation of tuberculosis (TB) screening results and treatment plan for active or latent infection.

AGE RESTRICTION
For moderate-to-severe PsO: 6 years of age or older. For active PsA, active AS and nr-axSpA: 18 years of age or older.

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

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

TASIMELTEON

MEDICATION(S)
HETLIOZ, HETLIOZ LQ, 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
Capsules: 16 years of age and older. Oral suspension: 3 to 15 years of age.

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 renewal 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

TERIPARATIDE

MEDICATION(S)
FORTEO, TERIPARATIDE, TERIPARATIDE (RECOMBINANT)

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 (primary or hypogonadal in men, glucocorticoid-induced or postmenopausal in women). Baseline labs [DXA scan, serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D)]. Documentation of an inadequate response or inability to tolerate at least one of the following: bisphosphonates, hormone replacement therapy, or selective-estrogen receptor modulators (SERMs).

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

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

TOPICAL RETINOIDS

MEDICATION(S)
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

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

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
Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 with New York Heart Association (NYHA) Functional Class II-III by complete right catheterization (RHC) with results attached. Mean pulmonary artery pressure (mPAP) greater than 20 mmHg, pulmonary vascular resistance (PVR) greater than 3 wood units, and a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Pharmacy records or chart notes documenting trial of or inadequate response to two alternatives (used alone or in combination) from the following list of medications: endothelin receptor antagonists (bosentan, ambrisentan, macitentan), phosphodiesterase-5 inhibitors (sildenafil, tadalafil), guanylate cyclase stimulators (riociguat). Clarify there is a treatment plan. 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

N/A

PART B PREREQUISITE

N/A

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).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

VENTAVIS

MEDICATION(S)
VENTAVIS

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. Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1 with New York Heart Association (NYHA) Functional Class III-IV. 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 3 Wood units. RHC results must be provided.

AGE RESTRICTION
N/A

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: documentation indicating improvement in condition.

PART B PREREQUISITE
N/A

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

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.

AGE RESTRICTION
17 years of age and older.

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

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XELJANZ

MEDICATION(S)
XELJANZ, XELJANZ XR

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with other biologic Disease Modifying Anti-Rheumatic Drugs (DMARDs) or potent immunosuppressants (such as azathioprine or cyclosporine).

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis. Documentation of tuberculosis screening results and treatment plan for active or latent infection. For rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis: Documentation of inadequate response or intolerance to at least one TNF blocker. For ulcerative colitis: Documentation of inadequate response, intolerance, or contraindication to at least one previous treatment tried (such as TNF blockers, oral or intravenous corticosteroids, azathioprine, 6-MP). For active polyarticular course juvenile idiopathic arthritis: documentation of inadequate response, intolerance, or contraindication to at least one first-line therapy (including full-dose NSAIDs).

AGE RESTRICTION
2 years and older for polyarticular course juvenile idiopathic arthritis. 18 years and older for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis.

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a rheumatologist, dermatologist or gastroenterologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

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. Sandostatin LAR Depot). 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

XGEVA

MEDICATION(S)
XGEVA

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Patients currently being treated with Prolia.

REQUIRED MEDICAL INFORMATION
Subject to Part B vs Part D review. INITIAL: Documentation Xgeva 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 Xgeva 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 Xgeva if applicable. RENEWALS: diagnosis of hypercalcemia of malignancy that is refractory to bisphosphonates: documentation that the corrected serum calcium is less than 11.5 mg/dL. Documentation must be attached. All diagnoses: documentation showing improvement or stabilization of disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Hematologist or oncologist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XIFAXAN

MEDICATION(S)
XIFAXAN

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any component of the formulation.

REQUIRED MEDICAL INFORMATION
Documentation of diagnosis of Traveler's Diarrhea (TD) caused by noninvasive strains of Escherichia coli, Hepatic Encephalopathy (HE), or Irritable Bowel Syndrome (IBS) with diarrhea. For TD: Documentation of inadequate response, intolerance, or contraindication to azithromycin or a fluoroquinolone (e.g., ciprofloxacin, levofloxacin). Documentation of dosing as 200 mg tablet 3 times a day. 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 antispasmodic agent (e.g., dicyclomine) or one anti-diarrheal agent (e.g., diphenoxylate/atropine, loperamide). Documentation of dosing as 550 mg tablet 3 times a day.

AGE RESTRICTION
12 years of age and older for TD. 18 years of age and older for IBS with diarrhea or HE.

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

COVERAGE DURATION
TD: 3 days. HE: 12 months. IBS with diarrhea: 3 treatments (14 days per treatment) per 1 year.

OTHER CRITERIA
N/A

PART B PREREQUISITE

N/A

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: Chart notes that show patient had at least a 3 month trial of OR intolerance to oral corticosteroids and/or combination therapies (inhaled steroids, long acting beta-agonists, antileukotrienes, 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 patient's FEV1 is greater than 40% and less than 80% of predicted normal pre-inhaled steroids. 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 6 and 12 years of age. For chronic idiopathic urticaria: Chart notes that show patient remained symptomatic despite H1 antihistamine treatment or has an intolerance or contraindication to H1 antihistamine treatment. For nasal polyps: Documentation of a diagnosis of nasal polyps. Documentation showing a trial of, intolerance to, 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
1 year of age and older.

PRESCRIBER RESTRICTION
Pulmonologist, allergist, immunologist, dermatologist, otolaryngologist.

COVERAGE DURATION

12 months.

OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

PART B PREREQUISITE

N/A

XYREM

MEDICATION(S)
XYREM

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with sedative hypnotics. Succinic semialdehyde dehydrogenase deficiency.

REQUIRED MEDICAL INFORMATION
Documentation showing a diagnosis of excessive daytime sleepiness or cataplexy with narcolepsy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Neurologist or sleep specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

XYWAV

MEDICATION(S)
XYWAV

PA INDICATION INDICATOR
1 - All FDA-Approved Indications

OFF LABEL USES
N/A

EXCLUSION CRITERIA
Concomitant use with sedative hypnotics. Succinic semialdehyde dehydrogenase deficiency.

REQUIRED MEDICAL INFORMATION
Documentation showing a diagnosis of excessive daytime sleepiness or cataplexy with narcolepsy or a diagnosis of idiopathic hypersomnia.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Neurologist or sleep specialist.

COVERAGE DURATION
12 months.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A

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).

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

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. Medical records must be attached.

AGE RESTRICTION
18 years of age or older.

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

COVERAGE DURATION
30 days.

OTHER CRITERIA
N/A

PART B PREREQUISITE
N/A