

# Prior Authorization Detail December 2022

#### **GENERAL DISCLAIMER:**

Bright Health does not recognize the use of drug samples to meet clinical criteria requirements for prior drug use for drugs covered under the pharmacy benefit or drugs administered in the physician office or other outpatient setting. A physician's statement that samples have been used cannot be used as documentation of prior drug use.

### **ABALOPARATIDE**

### **Products Affected**

TYMLOS

PA Criteria	Criteria Details
<b>Covered Uses</b>	Postmenopausal osteoporosis
Exclusion Criteria	Patient has received a total of 24 months cumulative treatment with any parathryoid hormone therapy
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Up to 24 months
Other Criteria	Patient meets one of the following:1) High risk for fractures defined as ONE of the following: a) History of osteoporotic fractures, b) 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin) or 3) No prior treatment for osteoporosis AND FRAX score at least 20% for any major fracture OR at least 3% for hip fracture2) Unable to use oral thrapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)3) The patient has a trial of, intolerance to, or a contraindication to bisphosphonates (e.g., Fosamax, Actonel, Boniva)

### **ABEMACICLIB**

### **Products Affected**

VERZENIO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 year of age or older for monotherapy
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has not experienced disease progression following prior CDK inhibitor therapy

### **ABIRATERONE**

### **Products Affected**

• abiraterone oral tablet 250 mg, 500 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	One of the following: (1) Previous bilateral orchiectomy, (2) Castrate level of testosterone (i.e., less than 50 ng/dL), or (3) Concurrent use with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix) Yonsa only: Trial of or contraindication to Zytiga (abiraterone acetate)

### **ABOBOTULINUMTOXINA**

#### **Products Affected**

DYSPORT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	CERVICAL DYSTONIA OR SPASMODIC TORTICOLLIS, LOWER OR UPPER LIMB SPASTICITY: No contraindications including (1) pregnancy OR (2) sensitivity or allergic reaction to other botulinum toxins OR (3) allergy to cows milk protein OR (4) Not being used for treatment of moderate to severe glabellar lines
Required Medical Information	None
Age Restrictions	Cervical dystonia, Spasmodic torticollis: 18 years of age or older.Lower or upper limb spasticity: 2 years of age or older
Prescriber Restrictions	None
Coverage Duration	6 months. IL: 12 months
Other Criteria	A. CERVICAL DYSTONIA OR SPASMODIC TORTICOLLIS: The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patients medical records. B. LOWER OR UPPER LIMB SPASTICITY: Patient does not have spasticity caused by cerebral palsy. CAUTION (1) Potency of units between different preparations of botulinum toxin products is not interchangeable AND (2) Spread of toxin effects may cause swallowing and breathing difficulties AND (3) Re-treatment should not occur in intervals of less than 12 weeks

### **ACITRETIN**

#### **Products Affected**

• acitretin

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL:PregnancyPatients with severely impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values. Hypersensitivity to other retinoids. Concurrent use with methotrexate, tetracyclines.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist
Coverage Duration	INITIAL: 3 months. RENEWAL: 1 year. IL: 12 months
Other Criteria	INITIAL:Patient has a documented diagnosis of severe psoriasis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to a minimum 90-day trial of high dose topical steroid (i.e. betamethasone augmented, halobetasol); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to, 90-day trial of Methotrexate.  RENEWAL:Prescriber attests to a positive therapeutic response to therapy.Quantity Limit: Maximum of 2 capsules per day

### **ACYCLOVIR OINTMENT**

### **Products Affected**

• acyclovir topical ointment

PA Criteria	Criteria Details
<b>Covered Uses</b>	FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	GENITAL HERPES:Patient has diagnosis of Genital Herpes caused by the herpes simplex virus; AND Patient has had a trial and failure, intolerance, or contraindication to TWO of the following: oral acyclovir, valacyclovir, or famciclovir.

### **ADALIMUMAB**

- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS
- HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML
- HUMIRA(CF)

- HUMIRA(CF) PEDI CROHNS STARTER
- HUMIRA(CF) PEN
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PEDIATRIC UC
- HUMIRA(CF) PEN PSOR-UV-ADOL HS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	UVEITIS: Isolated anterior uveitis
Required Medical Information	None
Age Restrictions	RHEUMATOID ARTHRITIS (RA), PSORIATIC ARTHRITIS (PsA), ANKYLOSING SPONDYLITIS (AS), PSORIASIS (PsO): 18 years of age or olderPOLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), UVEITIS: 2 years of age or olderCROHNS DISEASE (CD): 6 years of age or olderULCERATIVE COLITIS: 5 years of age or older HIDRADENITIS SUPPURATIVA (HS): 12 years of age or older
Prescriber Restrictions	RA/PJIA/AS: Prescribed by or given in consultation with a rheumatologist.PsA: Prescribed by or given in consultation with a rheumatologist or dermatologist. PsO: Prescribed by or given in consultation with a dermatologist. CD/UC: Prescribed by or given in consultation with a gastroenterologist.UVEITIS: Prescribed by or in consultation with an ophthalmologist
Coverage Duration	INITIAL: 6 months, RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: Trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine. PJIA: (1) Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. (2) Documentation of patients current weight. PsA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. AS: Patient had a previous trial of or contraindication to an NSAID. PsO: (1) Psoriatic lesions involving greater than or equal to 3% or more of body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face. (2) Trial of or contraindication to one or more forms of conventional therapies such as PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine.CD/UC: Trial of or contraindication to one conventional agent such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine.UVEITIS: Documentation of patients current weight if between 2 to 17 years of age.RENEWAL: RA: (1) Patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. (2) If request is for Humira 40mg dosed every week OR Humira 80mg dosed every other week, patient had a trial of at least a 3-month regimen of Humira 40mg dosed every week OR Humira 80mg dosed every other week, patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy AS: Patient experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on ther
	of new inflammatory chorioretinal or retinal vascular lesions, (2) A 2-step increase from baseline in anterior chamber cell grade or vitreous haze grade, (3) A worsening of best-corrected visual acuity (BCVA) by at least 15 letters relative to best state achieved.

### **ADEFOVIR**

### **Products Affected**

adefovir

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease physician, gastroenterologist, hepatologist, or transplant physician
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of chronic hepatitis B; AND Patient has evidence of active viral replication; AND Patient has elevated ALT or AST or histologically active disease; AND Patient has had a trial and failure, intolerance, or contraindication to therapy with generic entecavir.

### **AFATINIB**

### **Products Affected**

• GILOTRIF

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	1. Metastatic squamous NSCLC: The patient has disease progression after platinum-based chemotherapy (i.e., cisplatin, carboplatin, oxaliplatin)2. Metastatic NSCLC: a) the tumor has non-resistant EGFR mutations and b) Giolotrif will NOT be used concurrently with an EGFR tyrosine kinase inhibitor (e.g., Tarceva, Tagrisso, Iressa)

### **ALBENDAZOLE**

### **Products Affected**

albendazole

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None.
Required Medical Information	None.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by, or in consultation with, an Infectious Disease specialist.
Coverage Duration	Hydatid Disease: 6 monthsNeurocysticercosis: 1 month
Other Criteria	Patient has a confirmed diagnosis of one of the following (1) Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm (Taenia solium) (2) Cystic hadatid disease of the liver, lung, and peritoneum caused by larval form of the dog tapeworm (Echinococcus granulosus).

### **ALCAFTADINE**

### **Products Affected**

LASTACAFT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	2 years and older
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	Patient has a diagnosis of allergic conjunctivitis; AND Patient has had a trial and failure, intolerance, or contraindication to at least TWO (2) of the following: azelastine 0.05% ophthalmic solution, cromolyn sodium solution 4%, OR epinastine 0.05% ophthalmic solution.

### **ALOSETRON HCL**

### **Products Affected**

alosetron

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Male patients. Constipation. History of chronic or severe constipation or with a history of sequelae from constipation. History of intestinal obstruction, stricture, toxic megacolon, gastrointestinal perforation, and/or adhesions. History of ischemic colitis, impaired intestinal circulation, thrombophlebitis, or hypercoagulable state. Crohns disease, ulcerative colitis, and/or diverticulitis. Severe hepatic impairment. Concomitant administration with fluvoxamine
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Duration of therapy: ONE MONTH. Renewal: 6 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL:Patient has a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) defined by documentation of at least ONE of the following: (1) frequent and severe abdominal pain/discomfort,(2) frequent bowel urgency or fecal incontinence,(3) disability or restriction of daily activities due to IBS; AND Patient has chronic IBS symptoms generally lasting 6 months or longer; AND Patient has had anatomic or biochemical abnormalities of the gastrointestinal tract ruled out; AND Patient has not responded adequately to conventional therapy including a trial and therapeutic failure of: (1) dietary changes (including fiber), stress reduction, and other behavioral changes, (2) antidiarrheals (e.g., loperamide, diphenoxylate and atropine), (3) antidepressants (e.g., desipramine, imipramine), (4) antispasmodics (e.g., dicyclomine, hyoscyamine).RENEWAL: Prescriber attests to clinical notes demonstrating adequate control of IBS symptoms

### **AMINOCAPROIC ACID**

#### **Products Affected**

• aminocaproic acid oral tablet

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	Patients with active intravascular clotting process or disseminated intravascular coagulation (DIC) without concomitant heparin.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Documented diagnosis of hemorrhage caused by hyperfibrinolysis secondary to various disorders including APLASTIC ANEMIA, ABRUPTIO PLACENTAE, HEPATIC CIRRHOSIS, and NEOPLASTIC DISEASES; OR aminocaproic acid is being used to enhance hemostasis when fibrinolysis contributes to bleeding in conditions such as: a) Bleeding in the urinary tract due to various etiologies b) SICKLE CELL ANEMIA with hematuria (sickling in the vas recta or renal papillary necrosis) c) Hemorrhagic cystitis d) surgery.

# ANABOLIC STEROIDS

### **Products Affected**

oxandrolone

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Anadrol-50: Fanconis anemia, cachexia associated with AIDS. Oxandrin: Cachexia associated with AIDS, Turners syndrome
Exclusion Criteria	INITIAL: Contraindication to anabolic steroid therapy: a) Known or suspected carcinoma of the prostate or breast in male patients b) Known or suspected carcinoma of the breast in females with hypercalcemia c) Known or suspected nephrosis (the nephrotic phase of nephritis) d) Known or suspected hypercalcemia e) Severe hepatic dysfunction
Required Medical Information	INITIAL:CACHEXIA ASSOCIATED WITH AIDS:1) Patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months. 2) Patient meets one of the following: a) 10% unintentional weight loss over 12 months b) 7.5% unintentional weight loss over 6 months c) 5% body cell mass (BCM) loss within 6 months d) Body cell mass (BCM) of less than 35% (men) and a body mass index (BMI) of less than 27 kg per meter squared e) Body cell mass (BCM) of less than 23% (women) of total body weight and a body mass index (BMI) of less than 27 kg per meter squaredf) BMI of less than 18.5 kg per meter squared.RENEWAL: 1) Patient has a documented viral load (with date) of less than 200 copies per mL within the past 3 months 2) Patient has responded to therapy as measured by at least a 10% increase in weight from baseline (current weight must have been measured within the last 4 weeks, document date of measurement)
Age Restrictions	None
Prescriber Restrictions	CACHEXIA ASSOCIATED WITH AIDS: Prescribed by or in consultation with a gastroenterologist, nutritional Support Specialist (SBS) or Infectious Disease specialist
Coverage Duration	ANM: 6 mo and IL: 12 mo For PROT CTB, BONE PAIN OP, TRNRS: 6 mo CCHX AIDS, WT GN: 12 wk.

PA Criteria	Criteria Details
Other Criteria	INITIAL: ANEMIA: 1) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes, 2) The request is for Anadrol-50. CACHEXIA ASSOCIATED WITH AIDS:1) Patient is on anti-retroviral therapy, 2) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changesADJUNCTIVE THERAPY FOR WEIGHT GAIN, ADJUNCTIVE THERAPY TO OFFSET PROTEIN CATABOLISM, BONE PAIN ACCOMPANYING OSTEOPOROSIS, TURNERS SYNDROME: 1) Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes, 2) The request is for Oxandrin RENEWAL: CACHEXIA ASSOCIATED WITH AIDS: 1) Patient is on anti-retroviral therapy 2) Patient has not received more than 24 weeks of therapy in a calendar year

### **APOMORPHINE**

- APOKYN
- apomorphine

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Concomitant use with 5HT2 antagonists, including antiemetics (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron). Hypersensitivity to sodium metabisulfite.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in conjunction with, a neurologist
Coverage Duration	12 months
Other Criteria	INITIAL(1) Patient has diagnosis of Advanced Parkinsons Disease with acute, intermittent hypomobility (off) episodes; AND (2) Apokyn will be used in combination with a levodopa containing product AND another anti-Parkinsons agent (i.e. dopamine agonist or COMT inhibitor). RENEWAL(1) Apokyn will be used in combination with a levodopa containing product AND another anti-Parkinsons agent (i.e. dopamine agonist or COMT inhibitor); AND (2) Patient has experienced a reduction in hypomobility (off) episodes.

### **APREMILAST**

- OTEZLA
- OTEZLA STARTER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a rheumatologist or dermatologist PLAQUE PSORIASIS (PsO): Prescribed by or in consultation with a dermatologist.ORAL ULCERS ASSOCIATED WITH BEHCETS DISEASE: Prescribed by or in consultation with a rheumatologist
Coverage Duration	INITIAL: 6 months, RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: PsA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.Mild PsO: (1) Trial or contraindication to one conventional systemic agent (e.g., methotrexate, calcipotriene, acitretin, cyclosporine) AND one conventional topical agent (e.g., PUVA, UVB, topical corticosteroids).(2) One of the following: Psoriasis covering 2% of body surface area (BSA), Static Physician Global Assessment (sPGA) score of 2, OR Psoriasis Area and Severity Index (PASI) score of 2 to 9.Moderate to Severe PsO: (1) Psoriasis covering 3% or more of body surface area or psoriatic lesions affecting the hands, feet, genital area, or face. (2) Trial of or contraindication to one or more forms of conventional therapies such as a PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine.ORAL ULCERS ASSOCIATED WITH BEHCETS DISEASE: Trial of or contraindication to ONE or more conservative treatments (e.g., colchicine, topical corticosteroid, oral corticosteroid, etc.).RENEWAL: PsA: Patient experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy. Mild PsO: Patient achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more OR a decrease in sPGA (static Physician Global Assessment) by at least a 2-point reduction from baseline.Moderate PsO: Patient achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.ORAL ULCERS ASSOCIATED WITH BEHCETS DISEASE: Patient achieved or maintained clinical benefit compared to baseline (e.g., pain scores, number of ulcers, etc.).

### **ARIPIPRAZOLE**

- ABILIFY MAINTENA
- aripiprazole oral solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	History of a hypersensitivity reaction to aripiprazole.
Required Medical Information	Medication usage (trial and failure, intolerance, contraindication) must be supported by documentation from the patient's chart notes/medical records/electronic claim history.
Age Restrictions	SCHIZOPHRENIA: (1) aripiprazole oral solution:13 years of age and older, (2) Abilify Maintena:18 years of age and older. ACUTE BIPOLAR MANIA (aripiprazole oral solution):10 years of age and older. BIPOLAR I DISORDER MAINTENANCE MONOTHERAPY (Abilify maintena): 18 years of age or older. MDD: 18 years of age and older. AUTISTIC DISORDER: 6 years of age and older.
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	A. SCHIZOPHRENIA: (1) Patient has a diagnosis of Schizophrenia, AND (2) Patient has had a trial and failure, intolerance, or contraindication of the formulary alternative, risperidone, AND (3) Patient has had a trial and failure, intolerance or contraindication of the formulary alternative, aripiprazole tablet. B. ACUTE BIPOLAR MANIA: (1) Patient has a diagnosis of Acute bipolar mania, including manic and mixed episodes associated with bipolar disorder, AND (2) Patient has had a trial and failure, intolerance or contraindication of the formulary alternative, risperidone, AND (3) Tried and failed, intolerance or contraindication of the formulary alternative, aripiprazole tablet. C. MAJOR DEPRESSIVE DISORDER: (1) Patient has a diagnosis of Major Depressive Disorder, AND (2) Patient has had a trial and failure, intolerance or contraindication of the formulary alternatives, fluoxetine, paroxetine, sertraline, citalopram, venlafaxine and bupropion (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history), AND (3) Patient has had a trial and failure, intolerance or contraindication of the formulary alternatives, escitalopram and desvenlafaxine (Pristiq) (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history), AND (4) Patient has had a trial and failure, intolerance or contraindication of the formulary alternative, risperidone, AND (5) Patient has had a trial and failure, intolerance or contraindication of the formulary alternative, aripiprazole tablet, AND (6) Requested medication must be used as adjunctive or add-on treatment to ADT and not as monotherapy. D. AUTISTIC DISORDER (1) Patient has a diagnosis of autistic disorder, AND (2) Patient has had a trial and failure, intolerance or contraindication of the formulary alternative, risperidone, AND (3) Patient has had a trial and failure, intolerance or contraindication of the formulary alternative, risperidone, AND (4) Patient has h
	amphetamine/dextroamphetamine (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history).

### **ASENAPINE**

### **Products Affected**

• asenapine maleate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	Known hypersensitivity to asenapine
Required Medical Information	None
Age Restrictions	Bipolar I disorder, Monotherapy - 10 years of age and olderAll other indications: 18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	(1) Patient has diagnosis of bipolar disorder, schizophrenia, or other psychotic disorder; AND (2) Patient is unable to ingest solid oral dosage forms due to one of the following: (i) oral/motor difficulties (ii) dysphagia; AND (3) Patient has had a trial and failure, intolerance or contraindication to at least ONE formulary alternative including risperidone ODT, risperidone, quetiapine, olanzapine, ziprasidone (medication usage must be supported by documentation from the patient's chart notes/medical records/electronic claim history).

# **ATOVAQUONE**

### **Products Affected**

atovaquone

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Treatment of more severe episodes of PCP. Patients who are failing therapy with TMP-SMX for PCP.
Required Medical Information	INITIAL/RENEWAL: PROPHYLAXIS OF PCP: Patients with HIV have documentation of one of the following: Must have a documented CD4 count of less than 200 cells/mm3 within the last 3 months; OR documentation the member had an episode of PCP that occurred at a CD4 count greater than 200cells/mm3 while the member was on antiretroviral therapy
Age Restrictions	13 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an Infectious Disease specialist, oncologist, or HIV specialist.
Coverage Duration	INITIAL: PCP treatment: 21 days. PCP prophyl: 12 mos. RENEWAL: PCP prophly: 12 mos.
Other Criteria	INITIAL:TREATMENT OF PCP: Patient has a diagnosis of mild-to-moderate PCP; AND Patient has a documented trial and intolerance or contraindication to trimethoprim/sulfamethoxazole (TMP-SMX); AND Patient has a documented trial and treatment failure, intolerance, or contraindication to dapsone. PROPHYLAXIS OF PCP: Documentation of member that is immunocompromised that requires prevention of Pneumocystis carinii pneumonia (PCP); AND Patient has a documented trial and intolerance or contraindication to trimethoprim/sulfamethoxazole (TMP-SMX); AND Patient has a documented trial and treatment failure, intolerance, or contraindication to dapsone. RENEWAL: PROPHYLAXIS OF PCP: Prescriber attests that patient is responding positively to therapy; AND Prescriber provides documentation of patient compliance

### **AXITINIB**

### **Products Affected**

INLYTA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **AZATHIOPRINE**

### **Products Affected**

• azathioprine oral tablet 100 mg, 75 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to azathioprineUse in pregnant women for treating rheumatoid arthritis.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure to generic azathioprine.

### AZELASTINE/FLUTICASONE

#### **Products Affected**

• azelastine-fluticasone

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of seasonal allergic rhinitis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO (2) generic intranasal steroid products, one of which must be intranasal generic fluticasone; AND Patient must have a minimum 2-week trial of an intranasal steroid in combination with azelastine

### **AZITHROMYCIN**

### **Products Affected**

AZASITE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	Patient has a diagnosis of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms: CDC coryneform group G, Haemophilus influenzae, Staphylococcus aureus, Streptococcus mitis group, Streptococcus pneumoniae
Age Restrictions	1 year of age and older
Prescriber Restrictions	None
Coverage Duration	7 days
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to a trial of at least TWO of the following: ciprofloxacin ophthalmic solution, gatifloxacin ophthalmic solution, levofloxacin ophthalmic solution, moxifloxacin ophthalmic solution, ofloxacin ophthalmic solution, tobramycin ophthalmic solution sulfacetamide solution 10% ophthalmic solution, polymyxin B sultrimethoprim ophthalmic solution

### **BECAPLERMIN**

#### **Products Affected**

REGRANEX

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Treatment of pressure ulcers and venous stasis ulcers. Treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue [Stage I or II, International Association of Enterostomal Therapy (IAET) staging classification] or ischemic diabetic ulcers. Use in wounds that close by primary intention. Patients with known neoplasm(s) at the site(s) of application.
Required Medical Information	None
Age Restrictions	16 years of age and older
Prescriber Restrictions	None
Coverage Duration	5 months
Other Criteria	Patient has a diagnosis of Diabetic Neuropathic Ulcer; AND Ulcer(s) must be on lower extremity with adequate blood supply; AND Ulcer(s) is confirmed full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues; AND Patients wound is free from infection.Note: If complete healing has not occurred in 20 weeks of treatment, continued treatment with REGRANEX should be reassessed

# BEDAQUILINE FUMARATE

#### **Products Affected**

• SIRTURO ORAL TABLET 100 MG

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications and pulmonary extensively drug resistant tuberculosis (XDR-TB)
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	PULMONARY MULTI-DRUG RESISTANT TUBERCULOSIS (MDR-TB), USED IN COMBINATION WITH AT LEAST 3 OTHER ANTIBIOTICS: 5 years of age or older PULMONARY MDR-TB OR PULMONARY XDR-TB, USED IN COMBINATION WITH PRETOMANID AND LINEZOLID: 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	PULM MDR-TB, CMBO W/ 3 ANTIBX: 24 wkPULM MDR-TB, XDR-TB, CMBO W/ PRETOMANID AND LINEZOLID: 26 wk
Other Criteria	PULMONARY MDR-TB: (1) Sirturo will be used in combination with (a) at least 3 other antibiotics OR (b) pretomanid and linezolid. (2) If patient is 5 to less than 18 years of age and Sirturo will be used with at least 3 other antibiotics, patient must weigh at least 15kg.PULMONARY XDR-TB: Sirturo will be used in combination with pretomanid and linezolid

### **BEPOTASTINE**

### **Products Affected**

• bepotastine besilate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	Patient has had a trial and therapeutic failure to at least TWO of the following: azelastine ophthalmic solution, cromolyn sodium ophthalmic solution, or epinastine ophthalmic solution.

### **BESIFLOXACIN**

### **Products Affected**

• BESIVANCE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	1 year of age and older
Prescriber Restrictions	Prescribed by or in conjunction with an optometrist or ophthalmologist
Coverage Duration	7 days
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to a trial of at least TWO of the following ophthalmic agents: ciprofloxacin, ofloxacin, erythromycin, gentamycin, polymyxin B sulfate-trimethoprim ophthalmics

### **BETAINE**

- betaine
- CYSTADANE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, a physician specializing in metabolic disorders and genetics
Coverage Duration	12 months
Other Criteria	None

### **BETAXOLOL**

### **Products Affected**

#### • BETOPTIC S

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with sinus bradycardia, greater than a first degree atrioventricular block, cardiogenic shock, or patients with overt cardiac failure.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of chronic open-angle glaucoma or ocular hypertension; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO of the following: betaxolol hel ophthalmic solution, carteolol hel ophthalmic solution, levobunolol hel ophthalmic solution, timolol maleate ophthalmic solution.

### **BEXAROTENE**

#### **Products Affected**

• bexarotene oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **BOSUTINIB**

#### **Products Affected**

• BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	CHRONIC, ACCELERATED, OR BLAST PHASE PHILADELPHIA CHROMOSOME-POSITIVE (PH+) CHRONIC MYELOGENOUS LEUKEMIA (CML): The patient had a mutaitonal analysis prior to initiation and Bosulif is appropriate per the NCCN guideline table for treamtent recommendations based on BCR-ABL 1 mutation profile.
Age Restrictions	18 year of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	CHRONIC, ACCELERATED, OR BLAST PHASE PH+ CML: 1) Trial of or contraindication to other tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]

### **BREXPIPRAZOLE**

#### **Products Affected**

• REXULTI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	SCHIZOPHRENIA: Patient has diagnosis of Schizophrenia; Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least THREE (3) formulary alternative antipsychotics including, but not limited to, risperidone, olanzapine, aripiprazole, ziprasidone, and quetiapine. MAJOR DEPRESSIVE DISORDER: Patient has diagnosis of Major Depressive Disorder; AND Patient will be using Rexulti in combination with other medication(s) used to treat MDD; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO formulary alternative antidepressants including, but not limited to fluoxetine, paroxetine, sertraline, citalopram, venlafaxine, bupropion, escitalopram, desvenlafaxine; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least ONE formulary alternative antipsychotics including, but not limited to olanzapine, aripiprazole, quetiapine ER.

### **BRIMONIDINE**

#### **Products Affected**

• MIRVASO TOPICAL GEL WITH PUMP

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	Hypersensitivity to brimonidine
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Diagnosis of persistent (nontransient) erythema of rosacea; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to generic topical metronidazole.

### **BUPRENORPHINE PAIN**

#### **Products Affected**

- BUPRENEX
- buprenorphine buprenorphine hcl injection

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Use as an as-needed (prn) analgesic. (Butrans only)Significant respiratory depression. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment. Known or suspected gastrointestinal obstruction, including paralytic ileus. Hypersensitivity to buprenorphine.
Required Medical Information	None
Age Restrictions	18 years of age or older prior to approval of Butrans 2 years of age or older prior to approval of Buprenex
Prescriber Restrictions	Prescribed by, or in consultation with, a pain management specialist.
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: (1) Butrans: Patient has a documented diagnosis of chronic, severe pain requiring long-term daily, around-the-clock opioid treatment; AND Patient has had a trial and failure, intolerance, or contraindication to alternative treatment options including non-opioid analgesics (e.g., NSAIDs) AND Patient has had a trial and failure, intolerance, or contraindication to an immediate-release opioid/opioid combination product. (2) Buprenex: Patient has a documented diagnosis of pain severe enough to require an opioid analgesic; AND Patient has had a trial and failure, intolerance, or contraindication to alternative treatment options including non-opioid analgesics (e.g., NSAIDs); AND Patient has had a trial and failure, intolerance, or contraindication to an immediate-release opioid/opioid combination product. RENEWAL: (1) Prescriber attests that patient continues to meet initial criteria.

### **BUSULFAN**

#### **Products Affected**

• busulfan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	History of hypersensitivity to busulfan or any of its components
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of chronic myelogenous leukemia and is undergoing a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation; AND patient is prescribed cyclophosphamide as part of conditioning regimen.

### **CALCITONIN SALMON**

#### **Products Affected**

• calcitonin (salmon) injection

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	Hypersensitivity of calcitonin-salmon or any component of the product Asymptomatic Pagets disease.
Required Medical Information	Pagets Disease of Bone: Patient has moderate to severe disease characterized by polyostotic involvement with elevated serum alkaline phosphatase and urinary hydroxyproline excretionHypercalcemia: Patients corrected total serum calcium is greater than or equal to 12 mg/dl (must provide documentation) OR greater than or equal to corrected total serum calcium of 6 mEq/L (must provide documentation).
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	Hypercalcemia: 1 month, All others: 12 months. IL: 12 months
Other Criteria	Pagets Disease of Bone: Patient has a diagnosis of symptomatic Pagets disease of bone; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO (2) oral bisphosphonates. Hypercalcemia: Patient has a documented diagnosis of hypercalcemia Postmenopausal osteoporosis: Patient has a diagnosis of postmenopausal osteoporosis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to a bisphosphonate or selective estrogen- receptor modulator (SERM); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to calcitonin(salmon) nasal spray; AND Patient has a history of vertebral compression fractures, or fractures of the hip or distal radius resulting from minimal trauma, or T score of -2.5 or less.

### **CALCITRIOL OINTMENT**

#### **Products Affected**

• calcitriol topical

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with known or suspected disorders of calcium metabolism.
Required Medical Information	None
Age Restrictions	2 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	MILD TO MODERATE PLAQUE PSORIASIS:Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to a generic topical steroid (e.g., betamethasone dipropionate, clobetasol propionate, desoximetasone, or fluocinonide); AND Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to topical calcipotriene.

### **CALCIUM ACETATE**

#### **Products Affected**

PHOSLYRA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with hypercalcemia.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a nephrologist
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of hyperphosphatemia associated with chronic kidney disease, dialysis, end stage renal disease (ESRD), or renal failure; AND Patient is on a phosphate-restricted diet; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to calcium acetate AND sevelamer carbonate. NOTE: Therapeutic failure would be defined as phosphorus level greater than 4.5 mg/dl or calcium levels above 9.6 as documented by lab test for 2 to 3 consecutive months.

### **CAPECITABINE**

#### **Products Affected**

• capecitabine oral tablet 150 mg, 500 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Metastatic colorectal cancer: Use as monotherapy or in combination with oxaliplatin (CapeOX or XELOX)

### **CERITINIB**

#### **Products Affected**

ZYKADIA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **CERTOLIZUMAB PEGOL**

#### **Products Affected**

- CIMZIA
- · CIMZIA POWDER FOR RECONST
- · CIMZIA STARTER KIT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA): ONE of the following objective signs of inflammation: C-reactive protein (CRP) levels above the upper limit of normal OR Sacroiliitis on magnetic resonance imaging (MRI)
Age Restrictions	18 year of age or older
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA)/ANKYLOSING SPONDYLITIS (AS)/ (NR-AXSPA): prescribed by or given in consultation with a rheumatologistPSORIATIC ARTHRITIS (PSA): prescribed by or given in consultation with a rheumatologist or dermatologist CROHNS DISEASE (CD): prescribed by or given in consultation with a gastroenterologist(PSO): prescribed by or given in consultation with a dermatologist
Coverage Duration	INITIAL: 6 months, RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INIT: RA: 1) Trial of or contraindication (C/I) to at least 3 mo. of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate (MTX) dose greater than or equal to 20mg per wk or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine 2) Patient meets ONE of the following: (a) Pregnant, breastfeeding, or trying to become pregnant (b) Trial of or C/I to any TWO of the following: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) (c) Trial of any TNF inhibitor (e.g., Humira, Enbrel) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq, Xeljanz IR/XR) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular eventsPSA: 1) Trial of or C/I to ONE DMARD, such as MTX, leflunomide, hydroxychloroquine, or sulfasalazine 2) Patient meets ONE of following: a) Pregnant, breastfeeding, or trying to become pregnant OR b) Trial of or C/I to any TWO of the following: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla, Tremfya, Rinvoq, Skyrizi. AS: 1) Trial of or C/I to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.) 2) Patient meets ONE of the following: a) Pregnant, breastfeeding, or trying to become pregnant OR b) Trial of or C/I to any TWO of the following: Cosentyx, Enbrel, Humira, Xeljanz (IR/XR), Rinvoq, CD: 1) Trial of or C/I to ONE conventional therapy, (e.g., budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate, or mesalamine) 2) Patient meets ONE of the following: (a) Pregnant, breastfeeding, or trying to become pregnant (b) Trial of or C/I to Humira.PSO: 1) Psoriasis covering 3% or more of body surface area (BSA) OR psoriatic lesions affecting the hands, feet, genital area, or face 2) Trial of or C/I to ONE or more conventional therapies, such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, MTX, or cyclosporine 3) Patient meets ONE of the following: (a) Pregnant, breastfeeding, or tryin

PA Criteria	Criteria Details
	meets ONE of the following: (a) C-reactive protein (CRP) levels above the upper limit of normalt (b) Sacroiliitis on magnetic resonance imaging (MRI).RNWL: RA/PSA: Patient experienced or maintained 20% or more improvement in tender joint count or swollen joint count while on therapy.AS/NR-AXSPA: Patient experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.PSO: Patient achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.CD: Diagnosis of moderate to severe Crohns disease.

### **CETIRIZINE**

#### **Products Affected**

• ZERVIATE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to cetirizine hydrochloride
Required Medical Information	None
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and failure, intolerance, or contraindication to at least TWO (2) of the following: azelastine ophthalmic solution, cromolyn sodium ophthalmic solution, epinastine ophthalmic solution.

### **CEVIMELINE**

#### **Products Affected**

• cevimeline

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with uncontrolled asthma. When miosis is undesirable, e.g., in acute iritis and in narrow-angle (angle-closure) glaucoma.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a documented trial and failure, intolerance, or contraindication to pilocarpine tablets.

## chlorambucil

### **Products Affected**

· LEUKERAN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients whose disease has demonstrated a prior resistance to the Leukeran. Patients who have demonstrated hypersensitivity to chlorambucil and other alkylating agents.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist.
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of chronic lymphatic (lymphocytic) leukemia, malignant lymphomas including lymphosarcoma, giant follicular lymphoma, or Hodgkins disease; AND Leukeran is being used as palliative treatment.

### **CHLORZOXAZONE**

#### **Products Affected**

• chlorzoxazone oral tablet 500 mg

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications.
Exclusion Criteria	Hypersensitivity to chlorzoxazone
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and failure, contraindication, or intolerance to at least TWO other muscle relaxants (e.g., baclofen 10mg, 20mg tablet, carisoprodol 350mg tablet, methocarbamol 500mg, 750mg tablets, or diazepam 2mg, 5mg, 10mg tablets).

## **CINACALCET**

#### **Products Affected**

cinacalcet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Serum calcium level less than the lower limit of the normal range. Use in patients with CKD who are NOT on dialysis.
Required Medical Information	INITIAL: SECONDARY HYPERPARATHYROIDISM: Patients iPTH levels are greater than 300pg/mL AND serum calcium levels greater than or equal to 8.4 mg/dL prior to start of therapy AND Intact parathyroid hormone (iPTH) is greater than or equal to 300 pg/ml prior to start of therapyHYPERCALCEMIA DUE TO PARATHYROID CARCINOMA AND SEVERE HYPERCALCEMIA DUE TO PRIMARY HYPERPARATHYROIDISM: Serum calcium greater than or equal to 12.5 mg/dL prior to start of therapy.RENEWAL: ALL INDICATIONS: iPTH levels must be greater than 150 pg/ml and calcium must be greater than or equal to 8.4 mg/dL.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	INITIAL: 3 mo, FIRST RENEWAL: 6 mo, ADD RENEWALS: 12 mo. IL: 12 mo

PA Criteria	Criteria Details
Other Criteria	INITIAL: SECONDARY HYPERPARATHYROIDISM Patient has a documented diagnosis of secondary hyperparathyroidism due to chronic kidney disease; AND Patient is currently on dialysis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to calcium acetate or a sevelamer carbonate; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to Vitamin D/Vitamin D analog (i.e., calcitriol, Hectorol, etc.). (Medication usage must be supported by documentation from the patients chart notes/medical records).INITIAL: PARATHYROID CARCINOMA Patient has a documented diagnosis of hypercalcemia due to parathyroid carcinoma.INITIAL: PRIMARY HYPERPARATHYROIDISM Patient has s documented diagnosis of severe hypercalcemia due to primary hyperparathyroidism; AND Patient is unable to undergo parathyroidectomy.

## CIPROFLOXACIN/HYDROCORTISONE

#### **Products Affected**

· CIPRO HC

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	1 year of age and older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO of the following: neomycin-polymyxin-HC otic suspension or otic solution, ofloxacin otic solution, ciprofloxacin 0.2% otic solution

### **CLOBAZAM**

#### **Products Affected**

• clobazam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	Lennox-Gastaut syndrome: Documentation supporting the diagnosisRefractory partial onset seizures: 1) Documentation supporting the diagnosis
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	12 months
Other Criteria	Lennox-Gastaut syndrome: 1) The patient is currently receiving treatment with at least one other antiepileptic medication 2) Patient has had a trial and therapeutic failure, intolerance or contraindication to one of the following: lamotrigine, topiramate, or valproate Refractory partial onset seizures: 1) The patient is currently being treated with at least one other antiepileptic medication 2) The patient has a history of trial and therapeutic failure, intolerance, or contraindication to at least TWO antiepileptic drugs (e.g., lamotrigine, topirmate, or valproate)

# Colistin/Hydrocortisone/Neomycin/Thonzonium

### **Products Affected**

· CORTISPORIN-TC

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	The external auditory canal disorder is suspected or known to be due to cutaneous viral infection (e.g., herpes simplex virus or varicella zoster virus). Hypersensitivity to any of the individual components (colistin sulfate, neomycin sulfate, thonzonium bromide and hydrocortisone acetate)
Required Medical Information	None
Age Restrictions	1 year of age and older
Prescriber Restrictions	None
Coverage Duration	10 days
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO (2) of the following: ciprofloxacin-dexamethasone otic suspension 0.3-0.1%, neomycin-polymyxin-hc otic solution, neomycin-polymyxin-hc, ofloxacin otic solution acetic acid otic solution.

### **CRIZOTINIB**

#### **Products Affected**

XALKORI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	ANAPLASTIC LARGE CELL LYMPHOMA (ALCL) and UNRESECTABLE, RECURRENT, OR REFRACTORY INFLAMMATORY MYOFIBROBLASTIC TUMOR: 1 year of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	1. Metastatic NSCLC: a) The patient's tumors are ALK-1 positive as detected by an FDA-approved test OR b) The patient's tumors are ROS-1 positive as detected by an FDA-approved test2. Relapsed or refractory ALCL: The patient's tumors are ALK-1 positive3. unresectable, recurrent, or refractory IMT: The patient's tumors are ALK-positive

### **CYCLOSPORINE SOLUTION**

#### **Products Affected**

SANDIMMUNE ORAL SOLUTION

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with a hypersensitivity to Sandimmune (cyclosporine) and/or Cremophor EL (polyoxyethylated castor oil).
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to BOTH of the following: cyclosporine capsule (generic Sandimmune capsule) AND Gengraf Solution 100mg/mL.

### **CYSTEAMINE**

#### **Products Affected**

CYSTAGON

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	Contraindicated in patients who have developed hypersensitivity to cysteamine or penicillamine.
Required Medical Information	Patient has a diagnosis of nephropathic cystinosis confirmed by one of the following: Leukocyte cystine measurements greater than normal (nl range normal values are less than 0.2 nmol half-cystine/mg protein) OR DNA testing (two mutations in the CTNS gene, the only gene).
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **DABRAFENIB**

#### **Products Affected**

TAFINLAR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	ADJUVANT TREATMENT OF MELANOMA: Taflinar has been used for more than one year.
Required Medical Information	None
Age Restrictions	Unresectable or metastatic solid tumors: 6 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Unresectable or metastatic melanoma: 1) The patient has BRAF V600E mutation as detected by an FDA-approved test AND the requested medication will be used as a single agent or 2) The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test AND the requested medication will be used in combination with Mekinist (trametinib)Melanoma: 1) The patient has BRAF V600E or V600K mutations as detected by an FDA-approved test 2) The requested medication has not previously been used for more than one year 3) The requested medication will be used in combination with Mekinist (trametinib) for adjuvant treatment AND 4) There is involvement of lymph node(s) following complete resectionMetastatic non-small cell lung cancer (NSCLC): 1) The patient has BRAF V600E mutation as detected by an FDA-approved test AND 2) The requested medication will be used in combination with Mekinist (trametinib)Locally advanced or metastatic anaplastic thyroid cancer (ATC): 1) The patient has BRAF V600E mutation 2) The requested medication will be used in combination with Mekinist (trametinib) AND 3) The patient has no satisfactory locoregional treatment options availableUnresectable or metastatic solid tumors: 1) The patient is 6 years of age or older 2) The patient has BRAF V600E mutation 3) The requested medication will be used in combination with Mekinist (trametinib) AND 4) The patient has progressed following prior treatment and have no satisfactory alternative treatment options

### **DACARBAZINE**

#### **Products Affected**

dacarbazine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to dacarbazine or any of its components.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in collaboration with an oncologist
Coverage Duration	12 months
Other Criteria	A.Melanoma: Patient has diagnosis of metastatic malignant melanoma.B.Hodgkins Disease: Patient has a diagnosis of Hodgkins disease AND medication is given in combination with other effective drugs.

### **DALFAMPRIDINE**

### **Products Affected**

• dalfampridine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Ampyra will not be covered in patients with any of the following exclusion criteria (1) The patient has a seizure disorder, OR (2) The patient has moderate renal impairment (defined as a creatinine clearance (CrCl) of 30-50 mL/min) or severe renal impairment (defined as a CrCl less than or equal to 50 mL/min), OR (3) The patient has a history of hypersensitivity to AMPYRA or 4-aminopyridine.
Required Medical Information	None
Age Restrictions	18 years of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with a neurologist.
Coverage Duration	INITIAL/RENEWAL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: (1) Patient has a diagnosis of Indication of multiple sclerosis (MS); AND (2) Medical records/chart notes from neurology consultation documenting the deterioration of walking ability confirmed by gait assessment (e.g., MS Walking Scale 12 (MSWS-12), Timed 25-foot Walk (T25FW), 6-minute Walk Test, Expanded Disability Status Scale (EDSS), AND Documentation of past or current physical therapy AND (3) History of or current treatment with immune modulating therapies for MS. RENEWAL: (1) Medical records/chart notes from neurology consultation documenting the improvement of walking ability confirmed by gait assessment. NOTE-The Expanded Disability Status Score (EDSS) quantifies disability in eight functional systems: pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral, and other. EDSS scores 1.0 to 4.5 refer to people with multiple sclerosis who are fully ambulatory. EDSS scores 5.0 to 9.5 are defined by increasing impairment to ambulation.

### **DANAZOL**

#### **Products Affected**

danazol

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	Undiagnosed abnormal genital bleedingMarkedly impaired hepatic, renal, or cardiac functionPregnancyBreast feedingPorphyria-Danazol capsules can induce ALA synthetase activity and hence porphyrin metabolismAndrogen-dependent tumorActive thrombosis or thromboembolic disease and history of such events
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	ENDOMETRIOSIS: Prescribed by, or in consultation with, a gynecologist.HEREDITARY ANGIOEDEMA: Prescribed by or in consultation with an allergist/immunologist.
Coverage Duration	12 months
Other Criteria	ENDOMETRIOSIS AMENABLE TO HORMONE MANAGEMENT: Patient has a diagnosis of endometriosis confirmed by laparoscopy; AND If the diagnosis is not confirmed by surgery, then chart documentation of an adequate work-up and the clinical rationale for the diagnosis must be provided; AND Patient has had an adequate trial of oral contraceptives and/or progestins with an inadequate response or significant side effects or must have a contraindication to these therapies.HEREDITARY ANGIOEDEMA: Patient has a diagnosis of hereditary angioedema; AND Danazol will be used as prophylactic therapy for the prevention of hereditary angioedema attacks.

### **DAROLUTAMIDE**

#### **Products Affected**

• NUBEQA

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Non-metastatic castration resistant prostate cancer (nmCRPC): 1) The patient has high risk prostate cancer and 2) One of the following: a) Patient previously received bilateral orchiectomy, b) Patient has a castrate level of testosterone (i.e., less than 50 ng/dL), or c) The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)Metastatic hormone-sensitive prostate cancer (mHSPC): The requested medication will be used in combination with docetaxel.

### **DASATINIB**

#### **Products Affected**

· SPRYCEL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older if the patient meets one of the following: 1) Newly diagnosed with Philadelpha chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase 2) Diagnosed with Ph+ CML in chronic accelerated, or myeloid lymphoid blast phase 3) Diagnosed with Ph+ acute lymphoblastic leukemia (ALL)1 to 17 years of age if the patient meets one of the following: 1) Diagnosed with Ph+ CML in chronic phase 2) Newly diagnosed with Ph+ ALL
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Diagnosis of Philadelpha chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic, accerlated, or myeloid or lymphoid blast phase: (1) The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec). (2) The patient must have a mutational analysis prior to initiation and Sprycel is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL 1 mutation profile. Diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) in patients not newly diagnosed: The patient has a resistance or intolerance to prior therapy (e.g., imatinib [Gleevec], or nilotinib [Tasigna]) Diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) in newly diagnosed patients: The patient is using Sprycel in combination with chemotherapy

### **DEFERASIROX**

#### **Products Affected**

• deferasirox oral tablet, dispersible

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL:CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: 2 lab values in the previous 3 months showing the patients serum ferritin levels are consistently greater than 1000mcg/L.CHRONIC IRON OVERLOAD RESULTING FROM NTDT: 2 lab values in the previous 3 months showing the patients serum ferritin levels are consistently greater than 300mcg/LRENEWAL:CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: 2 lab values in the previous 3 months showing the patients serum ferritin levels are consistently greater than 500mcg/L.CHRONIC IRON OVERLOAD RESULTING FROM NTDT: One of the following (1) 2 lab values in the previous 3 months showing serum ferritin levels are consistently greater than 300mcg/L OR (2) patients liver iron concentration (LIC) is at least 3mg Fe/g dry weight.
Age Restrictions	CHRONIC IRON OVERLOAD DUE TO BLOOD TRANSFUSIONS: 2 years of age or older.CHRONIC IRON OVERLOAD RESULTING FROM NTDT: 10 years of age or older
Prescriber Restrictions	Prescribed by or given in consultation with a hematologist or hematologist-oncologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: Requests for Jadenu sprinkle packets require a trial of equivalent generic Exjade or Jadenu tablets.

# **DEFERIPRONE** (Solution)

#### **Products Affected**

• FERRIPROX ORAL SOLUTION

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	RENEWAL: 2 lab values in the previous 3 months showing serum ferritin levels consistently greater than 500mcg/L
Age Restrictions	INITIAL/RENEWAL:Solution: 3 years of age or older.
Prescriber Restrictions	Prescribed by or given in consultation with a hematologist or hematologist/oncologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: (1) Trial of or contraindication to one of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine). (2) Patient is experiencing intolerable toxicities or clinically significant adverse effects, or has a contraindication to current chelators

# **DEFERIPRONE** (Tablet)

#### **Products Affected**

• deferiprone oral tablet 500 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	RENEWAL: 2 lab values in the previous 3 months showing serum ferritin levels consistently greater than 500mcg/L
Age Restrictions	INITIAL/RENEWAL:Tablets: 8 years of age or older.
Prescriber Restrictions	Prescribed by or given in consultation with a hematologist or hematologist/oncologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: (1) Trial of or contraindication to one of the following: Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine). (2) Patient is experiencing intolerable toxicities or clinically significant adverse effects, or has a contraindication to current chelators

## **DELAFLOXACIN**

#### **Products Affected**

- BAXDELA INTRAVENOUS
- BAXDELA ORAL

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Any other indication prescribed by or in consultation with an Infectious Disease (ID) specialist.
Exclusion Criteria	ACUTE BACTERIAL SKIN OR SKIN STRUCTURE INFECTION (ABSSSI): Diagnosis of animal or human bite, necrotizing fasciitis, diabetic foot infection, decubitis ulcer formation, myonecrosis or ecthyma gangrenosum
Required Medical Information	ABSSSI: One of the following: 1) Prescribed by or in consultation with an Infectious Disease (ID specialist) OR 2) Antimicrobial susceptibility testing shows susceptibility to delafloxacin and resistance to one standard of care agent for ABSSSI OR 3) If susceptibility results are unavailable, trial of or contraindication to one of the following agents for ABSSSI: gram positive targeting antibiotic (e.g., linezolid, clindamycin, doxycycline, Bactrim, vancomycin), penicillin antibiotic (e.g., amoxicillin), fluoroquinolone antibiotic (e.g., levofloxacin, ciprofloxacin, moxifloxacin), or cephalosporin antibiotic (e.g., ceftriaxone, cephalexin, cefazolin)COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP): One of the following:1) Therapy is prescribed by or in consultation with an Infectious Disease (ID specialist) OR 2) Antimicrobial susceptibility testing shows susceptibility to delafloxacin and resistance to at least two standard of care agents for community-acquired bacterial pneumonia (CABP) OR 3) If susceptibility results are unavailable, trial of or contraindication to at least two standard of care agents for community-acquired bacterial pneumonia (CABP) (e.g., macrolide, doxycycline, alternative fluoroquinolone, beta-lactam, linezolid)
Age Restrictions	ABSSSI/CABP: 18 year of age or older
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	ABSSI / OTHER INDICATION: 14 daysCABP: 10 days
Other Criteria	None

## **DENOSUMAB**

## **Products Affected**

PROLIA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypocalcemia. Pregnancy.
Required Medical Information	OSTEOPOROSIS IN MEN AND WOMEN:Patient has a documented diagnosis of osteoporosis indicated by at least ONE of the following: (1) Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius, (2) T-score less than or equal to -1 or low bone mass and a history of fragility fracture to the hip or spine, (3) T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 3%.TREATMENT OF BONE LOSS IN MEN WITH PROSTATE CANCER:Patient has a documented Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -1 OR Patient has a documented diagnosis of osteoporosis indicated by at least ONE of the following: (1) Hip DXA (femoral neck or total hip) or lumbar spine T-score less than or equal to -2.5 and/or forearm DXA 33% (one-third) radius, (2) T-score less than or equal to -1 or low bone mass and a history of fragility fracture to the hip or spine, (3) T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture greater than or equal to 20% or hip fracture greater than or equal to 3%.
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	ALL INDICATIONS:Patient must be at high risk for fracture defined as one or more of the following: (1) History of an osteoporotic fracture as an adult, (2) Parental history of hip fracture, (3) Low BMI, (4) Rheumatoid arthritis, (5) Alcohol intake (3 or more drinks per day), (5) Current smoking, (6) History of oral glucocorticoids greater than or equal to 5 mg/d of prednisone (or equivalent) for greater than 3 months (ever).OSTEOPOROSIS IN MEN AND WOMEN:Patient is post-menopausal (Women ONLY); AND Patient has had a documented trial and therapeutic failure to a minimum (12) month trial with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; OR Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid. GLUCOCORTICOID-INDUCED OSTEOPOROSIS:Patient will be initiating or is continuing systemic glucocorticoid therapy at a daily dosage equivalent to greater than or equal to 7.5 mg of prednisone and is expected to remain on glucocorticoid therapy for at least 6 months; AND Patient has had a documented trial and therapeutic failure to a minimum (12) month trial with bisphosphonates (oral or IV) such as alendronate, risedronate, ibandronate, or zoledronic acid; OR Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; OR Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid; OR Patient has a documented contraindication or intolerance to BOTH oral bisphosphonates AND intravenous (IV) bisphosphonates such as alendronate, risedronate, ibandronate, or zoledronic acid. TREATMENT OF BONE LOSS IN MEN WITH PROSTATE CANCER:Patient is receiving adjuvant aromatase inhibitor therapy for breast ca
	Barretts esophagus, esophageal stricture, dysmotility, or achalasia.

## **DESMOPRESSIN SOLUTION**

## **Products Affected**

• desmopressin injection

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	Known hypersensitivity to desmopressin acetate. Patients with moderate to severe renal impairment (defined as a creatinine clearance below 50 mL/min). Patients with hyponatremia or a history of hyponatremia. Treatment of nephrogenic diabetes insipidus. Treatment of severe classic von Willebrands disease (Type I) and when there is evidence of an abnormal molecular form of factor VIII antigen. Treatment of hemophilia A with factor VIII coagulant activity levels equal to or less than 5%, or treatment of hemophilia B, or patients who have factor VIII antibodies.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Patient has a diagnosis of Central Cranial Diabetes Insipidus; AND Desmopressin is being used as antidiuretic replacement therapy; OR desmopressin is being used to treat temporary polyuria and polydipsia following head trauma or surgery in the pituitary region. Patient has a diagnosis of mild to moderate classic von Willebrands disease (Type I); AND (1) Patient has factor VIII levels greater than 5%; AND (2) Patient is undergoing a surgical procedure; OR Patient is experiencing an episode of bleeding due to spontaneous or trauma-induced injury such as hemarthroses, intramuscular hematomas or mucosal bleeding. Patient has a diagnosis of hemophilia A; AND (1) Patient has factor VIII coagulant activity levels greater than 5%; AND (2) Patient is undergoing a surgical procedure; OR Patient is experiencing an episode of bleeding due to spontaneous or trauma-induced injury such as hemarthroses, intramuscular hematomas or mucosal bleeding.

## **DIFENOXIN/ATROPINE**

#### **Products Affected**

MOTOFEN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	Patients with diarrhea associated with organisms that penetrate the intestinal mucosa (toxigenic E. coli, Salmonella species, Shigella) and pseudomembranous colitis associated with broad spectrum antibiotics. Patients with a known hypersensitivity to different atropine, or any of the inactive ingredients. Patients who are jaundiced.
Required Medical Information	None
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of acute nonspecific diarrhea Or is experiencing an acute exacerbation of chronic functional diarrhea; AND Motofen is being used as adjunctive treatment; AND Patient has had a trial and therapeutic failure or intolerance to both of the following: loperamide (Capsule or Tablet) AND diphenoxylate/atropine (generic Lomotil).

## **DIMETHYL FUMARATE**

#### **Products Affected**

• dimethyl fumarate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Brand Tecfidera requires trial of generic dimethyl fumarate

## **DOCETAXEL**

#### **Products Affected**

docetaxel intravenous solution 160 mg/16 ml (10 mg/ml), 160 mg/8 ml (20 mg/ml), 20 mg/2 ml (10 mg/ml), 20 mg/ml (1 ml), 80 mg/4 ml (20 mg/ml), 80 mg/8 ml (10 mg/ml)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Neutrophil count less than 1500 cells/mm(3). History of severe hypersensitivity to products containing docetaxel.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	BREAST CANCER a. Patient has a diagnosis of locally advanced or metastatic breast cancer; AND has failed of prior chemotherapy. b. Patient has a diagnosis of operable node-positive breast cancer; AND docetaxel will be used in combination with doxorubicin and cyclophosphamide as adjuvant treatment.NON-SMALL CELL LUNG CANCER (NSCLC)a. Patient has a diagnosis of locally advanced or metastatic NSCLC; And patient has failed prior platinum-based chemotherapy; AND docetaxel will be used as a single agent.b. Patient has a diagnosis of unresectable, locally advanced, or metastatic NSCLC; AND patient has not previously received chemotherapy for this condition; AND docetaxel will be used in combination with cisplatin.PROSTATE CANCER Patient has a diagnosis of androgen independent (hormone refractory) metastatic prostate cancer; AND docetaxel will be used in combination with prednisone. GASTRIC ADENOCARCINOMA Patient has a diagnosis of advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction; AND patient has not received prior chemotherapy for advanced disease; AND docetaxel will be used in combination with cisplatin and fluorouracil.HEAD AND NECK CANCER Patient has a diagnosis of locally advanced squamous cell carcinoma of the head and neck (SCCHN); AND docetaxel will be used in combination with cisplatin and fluorouracil (5FU).

## **DORNASE ALFA**

## **Products Affected**

PULMOZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## **DOXEPIN CREAM**

## **Products Affected**

• doxepin topical

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved Indications.
Exclusion Criteria	Patients with untreated narrow angle glaucoma Patient with a tendency to urinary retention
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	1 month. IL: 12 months
Other Criteria	Patient has a diagnosis of moderate pruritis associated with atopic dermatitis OR lichen simplex chronicus; AND Patient has tried and failed previous treatment with at least TWO (2) topical steroid creams.

## **DOXERCALCIFEROL**

## **Products Affected**

doxercalciferol oral

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of secondary hyperparathyroidism associated with one of the following diagnoses: Stage 3 or 4 chronic kidney disease not yet requiring dialysis (pre-dialysis) AND Patient has had a clinical trial and failure, intolerance, or contraindication to calcitriol; OR Stage 5 chronic kidney disease requiring dialysis AND Patient has a serum intact parathyroid hormone (iPTH) level greater than 10 pg/mL

## **DUPILUMAB**

#### **Products Affected**

- DUPIXENT PEN
- DUPIXENT SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Atopic Dermatitis: Concurrent use with other systemic biologics or JAK inhibitors (e.g., Adbry, Rinvoq, Cibinqo) for the treatment of atopic dermatitisAsthma: Concurrent use with Xolair or an anti-IL5 biologic (such as Nucala, Cinqair, Fasenra) when these are used for the treatment of asthma
Required Medical Information	ATOPIC DERMATITIS: INITIAL: Prescriber attests that patient has greater than or equal to 10% body surface area (BSA) involvement OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas AND the patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily livingASTHMA: INITIAL: Documentation that the patient has an eosinophilic phenotype (blood eosinophil level of at least 150 cells/mcL within the past 12 months)CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS: Documentation (patient's chart notes/medical records) supporting the patient's diagnosis with the presence of nasal polyps (by direct examination, endoscopy, or sinus CT scan)EOSINOPHILIC ESOPHAGITIS: Diagnosis is confirmed by an esophagogastroduodenoscopy (EGD) with biopsy
Age Restrictions	ASTHMA: 6 years of age or olderATOPIC DERMATITIS: 6 months of age or olderRHINOSINUSITIS WITH NASAL POLYPS: 18 years of age or olderEOSINOPHILIC ESOPHAGITIS: 12 years of age or olderPRURIGO NODULARIS: 18 years of age or older
Prescriber Restrictions	MODERATE TO SEVERE ATOPIC DERMATITIS, ASTHMA, CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS: Pulmonologist, allergist, immunologist, asthma specialist, dermatologist, or otolaryngologistEOSINOPHILIC ESOPHAGITIS: Gastroenterologist, allergist, or immunologist

PA Criteria	Criteria Details
Coverage Duration	INITIAL: AD, CRSwNP: 6 mo; ASTHMA, EE, and PRURIGO NODULARIS: 12 mo; RENEWAL: 12 mo. IL: 12 mo
Other Criteria	ATOPIC DERMATITIS: INITIAL: 1) Documentation (e.g., chart notes) supporting the diagnosis AND 2) History of failure or contraindication to a 6-month trial to ONE of the following options: a) topical corticoteroid (e.g., betamethasone diproprionate) OR b) topical calcineurin inhibitor (e.g., Elidel or Protopic), OR c) topical PDE-4 inhibitor (e.g., Eucrisa), OR d) topical JAK inhibitor (e.g., Opzelura), OR e) phototherapy RENEWAL: (1) Documentation that the patient has responded to Dupixent therapy as determined by the prescribing physician AND the patient is NOT using dupilumab concurrently with another biologic medication. ASTHMA: INITIAL: 1) Documentation (e.g., chart notes) supporting the diagnosis of moderate to severe eosinophilic or corticotsteroid-dependent asthma AND 2) The paitent is being treated with a medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) AND at least one other maintenance medication such as long-acting beta2-agonist (e.g., salmeterol), long-acting muscarinic antagonist (e.g., tiotropium), or a leukotriene antagonist (e.g., montelukast) AND 3) At least ONE of the following is true: a) Within the past 12 months the patient has experienced at least one asthma exacerbation requiring systemic corticosteroid for at least 3 days OR at least ONE serious exacerbation requiring hospitalization or emergency room visit OR b) The patient has poor symptom control depsite current therapy as evidenced by at least THREE of the following within the past 4 weeks: i) Daytime asthma symptoms more than twice per week OR ii) Night waking due to asthma OR iii) Use of rescue treatment (e.g., albuterol) for symptoms more than twice per week OR iv) Activity limitation due to asthmaRENEWAL: Documentation that the treatment has resulted in clinical benefit defined as one or more of the following: a) Decreased use of systemic corticosteroids b) Increase in Forced Expiratory Volume (FEV1) from pretreatment baseline c) Decreased use of ICS use for at least 3 days d) Decrease in hospitalizations e)

PA Criteria	Criteria Details
	steroids in the past 2 years or b) Endoscopic sinus surgery AND 2) Dupixent will be used as add-on maintenance treatment AND 3) Previous 90-day trial of ONE intranasal corticosteroid 4) Dupixent will be add-on maintenance treatmentRENEWAL: Documentation that the patient has responded to Dupixent.EOSINOPHILIC ESOPHAGITIS: INITIAL: 1) If patient age is 12-17 years, weight is at least 40 kg 2) Patient has a history of failure or contraindication to dietary therapy, proton pump inhibitor (e.g., omeprazole), and topical glucocorticosteroid (e.g., swallowed budesonide) or systemic glucocorticosteroidRENEWAL: The patient has shown improvement while on therapy

## **ELTROMBOPAG**

#### **Products Affected**

• PROMACTA ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	RENEWAL: CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (cITP): A clinical response, as defined by an increase in platelet count to at least 50,000 per microliter.
Age Restrictions	CHRONIC IMMUNE (IDIOPATHIC) THROMBOCYTOPENIA (cITP): 1 year of age or older.APLASTIC ANEMIA: 12 years of age or older.
Prescriber Restrictions	cITP: Prescribed by or in consultation with a hematologist or immunologist.
Coverage Duration	INITIAL: cITP: 2 mo. RENEWAL: cITP: 12 mo. INITIAL/RENEWAL: All others: 12 mo. IL: 12 mo
Other Criteria	INITIAL: cITP: Trial of or contraindication to corticosteroids or immunoglobulins, or an insufficient response to splenectomy.

## **ENASIDENIB**

#### **Products Affected**

• IDHIFA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# ENDOTHELIN RECEPTOR ANTAGONISTS (LETAIRIS)

#### **Products Affected**

• ambrisentan

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications
Exclusion Criteria	Idiopathic pulmonary fibrosis
Required Medical Information	INITIAL: 1) Mean pulmonary artery pressure greater than 20 mm Hg 2) Pulmonary capillary wedge pressure less than or equal to 15 mm Hg 3) Pulmonary vascular resistance of at least 3 Wood units 4) NYHA-WHO Function Class II to IV symptoms
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist for pulmonologist
Coverage Duration	12 months
Other Criteria	INITIAL: Documented confirmatory PAH diagnosis RENEWAL: PAH 1) Patient must show improvement from baseline in the 6-minute walk distance test or 2) Patient must show they are stable from baseline in the 6-minute walk distance test AND the WHO functional class has remained stable or improved

# ENDOTHELIN RECEPTOR ANTAGONISTS (OPSUMIT)

## **Products Affected**

OPSUMIT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	INITIAL: PAH: 1) Mean pulmonary artery pressure greater than 20 mm Hg 2) Pulmonary capillary wedge pressure less than or equal to 15 mm Hg 3) Pulmonary vascular resistance of at least 3 Wood units 4) NYHA-WHO Function Class II to IV symptoms
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist for pulmonologist
Coverage Duration	12 months
Other Criteria	INITIAL: Documented confirmatory PAH diagnosis RENEWAL: PAH 1) Patient must show improvement from baseline in the 6-minute walk distance test or 2) Patient must show they are stable from baseline in the 6-minute walk distance test AND the WHO functional class has remained stable or improved

# ENDOTHELIN RECEPTOR ANTAGONISTS (TRACLEER)

#### **Products Affected**

• bosentan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH): (1) Idiopathic pulmonary fibrosis (2) Concurrently taking cyclosporine A or glyburide.
Required Medical Information	INITIAL: PAH: (1) NYHA-WHO Functional Class II to IV symptoms AND (2) Right heart catheterization with the following parameters: (1) Mean pulmonary artery pressure (PAP) greater than 20 mmHg and (2) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg and (3) Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units.
Age Restrictions	3 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	INITIAL: Documented confirmatory PAH diagnosis RENEWAL: PAH: APPROVAL FOR TRACLEER AND PATIENT IS 3 TO 17 YEARS OLD REQUIRES EITHER (1) improvement in pulmonary vascular resistance OR (2) patient has remained stable or shown improvement in exercise ability (e.g., 6-minute walk test, World Health Organization [WHO] functional class symptoms). APPROVAL FOR ALL OTHERS REQUIRES EITHER (1) improvement from baseline in the 6-minute walk distance test OR (2) patient is stable from baseline in the 6-minute walk distance test AND WHO functional class has remained stable or has improved.

## **ENZALUTAMIDE**

## **Products Affected**

XTANDI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER (CRPC): Patient has high risk prostate cancer (i.e. rapidly increasing prostate specific antigen [PSA] levels)CRPC (NON-METASTATIC AND METASTATIC) OR METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (MCSPC): Patient meets one of the following: (1) Previously received a bilateral orchiectomy, or (2) Patient has a castrate level of testosterone (i.e., less than 50 ng/dL) or (3) Concurrent use with a gonadotropin releasing hormone (GNRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)RENEWAL: Diagnosis of CRPC (non-metastatic and metastatic) or MCSPC.

## **EPOETIN ALFA-EPBX**

#### **Products Affected**

RETACRIT

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Anemia due to concurrent hepatitis C treatment with ribavirin plus an interferon alfa or peginterferon alfa will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	INITIAL: A. ANEMIA DUE TO CHRONIC KIDNEY DISEASE (CKD), ANEMIA DUE TO ZIDOVUDINE THERAPY, OR ANEMIA DUE TO CONCURRENT HEPATITIS C TREATMENT: (1) Hemoglobin level of less than 10g/dL. B. ANEMIA DUE TO CANCER CHEMOTHERAPY: (1) Hemoglobin level of less than 11g/dL OR (2) Hemoglobin level has decreased at least 2g/dL below baseline level. C. ELECTIVE, NONCARDIAC, NONVASCULAR SURGERY: (1) Hemoglobin level of less than 13g/dL. RENEWAL: A. ANEMIA DUE TO CKD: One of the following: (1) hemoglobin level of less than 10g/dL if not on dialysis OR (2) hemoglobin level of less than 11g/dL if on dialysis OR (3) hemoglobin level has reached 10g/dL (if not on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions, OR (4) hemoglobin level has reached 11g/dL (if on dialysis) and dose reduction/interruption is required to reduce the need for blood transfusions. B. ANEMIA DUE TO CANCER CHEMOTHERAPY, DUE TO ZIDOVUDINE THERAPY, OR DUE TO CONCURRENT HEPATITIS C TREATMENT: (1) Hemoglobin level between 10g/dL and 12g/dL.
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	ANMIA CKD, CANCER CHEM, ZDV: 12 mo. ANMIA HEP C: 6 mo INIT: SURGERY: 1 mo. IL: 12 mo chronic

PA Criteria	Criteria Details
Other Criteria	INITIAL: A. ANEMIA DUE TO CONCURRENT HEPATITIS C TREATMENT: (1) Trial of or contraindication to ribavirin dose reduction.

## **ERENUMAB-AOOE**

#### **Products Affected**

AIMOVIG AUTOINJECTOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	The medication wil be used concurrently with other CGRP inhibitors (e.g., Ajovy, Emgality, Vyepti, Nurtec ODT, Qulipta) for migraine prevention.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL: 6 months, RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: EPISODIC MIGRAINES: Trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadololCHRONIC MIGRAINES: Trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable]RENEWAL: ONE of the following: (1) Patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Aimovig therapy OR (2) Patient has experienced a reduction in migraine severity with Aimovig therapy OR (3) Patient has experienced a reduction in migraine duration with Aimovig therapy

## **ERGOLOID MESYLATES ORAL**

## **Products Affected**

ergoloid

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Known hypersensitivity to ergoloid mesylates or in patients with known ergot alkaloid hypersensitivity. Ergoloid mesylate should not be used in patients acute or chronic psychosis regardless of etiology.
Required Medical Information	None
Age Restrictions	INITIAL/RENEWAL: 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL 1.Diagnosis of Alzheimers disease, vascular dementia, or primary progressive dementia supported by documentation. 2.Patient intolerance to, or adequate trial of TWO of the following: galantamine, donepezil or rivastigmine. RENEWAL 1.Documented positive clinical response to ergoloid therapy.

## **ERLOTINIB**

## **Products Affected**

• erlotinib oral tablet 100 mg, 150 mg, 25 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	1. Metastatic NSCLC: a) The patient's tumor has EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test and b) Tarceva will NOT be used concurrently with an EGFR tyrosine kinase inhibitor (e.g., Gilotrif, Tagrisso, Iressa, Vizimpro)2. Locally advanced, unresectable, or metastatic pancreatic cancer: a) Tarceva will be used in combination with gemcitabine and b) Tarceva will be used as a first line treatment

## **ESLICARBAZEPINE**

## **Products Affected**

APTIOM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to eslicarbazepine acetate or oxcarbazepine
Required Medical Information	None
Age Restrictions	4 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of Partial-Onset Seizures; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO other formulary treatments (carbamazepine, oxcarbazepine, phenytoin, topiramate, pregabalin, valproic acid, zonisamide, divalproex, gabapentin, lamotrigine, levetiracetam, etc.)

## ESTRAMUSTINE PHOSPHATE SODIUM

#### **Products Affected**

• EMCYT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with known hypersensitivity to either estradiol or to nitrogen mustard. Active thrombophlebitis or thromboembolic disorders, except in those cases where the actual tumor mass is the cause of the thromboembolic phenomenon.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of metastatic and/or progressive prostate cancer; AND Emcyt (extramustine phosphate sodium) is being used for palliative treatment.

## **ETANERCEPT**

#### **Products Affected**

- ENBREL
- ENBREL MINI
- ENBREL SURECLICK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RHEUMATOID ARTHRITIS (RA), PSORIATIC ARTHRITIS (PsA), ANKYLOSING SPONDYLITIS (AS): 18 years of age or olderPOLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA): 2 years of age or olderPSORIASIS (PsO): 4 years of age or older
Prescriber Restrictions	RA/PJIA/AS: Prescribed by or in consultation with a rheumatologistPsA: Prescribed by or in consultation with a rheumatologist or dermatologistPsO: Prescribed by or in consultation with a dermatologist
Coverage Duration	INITIAL: 6 months, RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: Trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine. PJIA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. PsA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. AS: Trial of or contraindication to an NSAID (e.g., naproxen, ibuprofen, diclofenac).PsO: (1) Psoriasis covering 3% or more of body surface area (BSA) or psoriatic lesions affecting the hands, feet, genital area, or face. (2) Trial of or contraindication at least one conventional therapy such as a PUVA (phototherapy ultraviolet light A), UVB (ultraviolet light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine.RENEWAL: RA/PJIA/PsA: Patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. AS: Patient experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.PsO: Patient achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.

## ETHACRYNIC ACID

## **Products Affected**

• ethacrynic acid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Patients with anuria. Patients that have experienced severe, watery diarrhea with previous treatment with ethacrynic acid
Required Medical Information	None
Age Restrictions	1 year of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	INITIAL: Patient has a documented diagnosis of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome, ascites due to malignancy, idiopathic edema, or lymphedema; AND Patient has a documented sulfa allergy; OR Patient had a trial and therapeutic failure of a 30-day trial of furosemide, bumetanide, AND torsemide.RENEWAL:Prescriber attests that patient is responding positively to therapy; ANDPatient has not experienced an increasing electrolyte imbalance, azotemia, and/or oliguria occur during treatment of severe, progressive renal disease; AND Patient has not experienced severe, watery diarrhea.

## **EVEROLIMUS**

#### **Products Affected**

• everolimus (antineoplastic) oral tablet 2.5 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Afinitor Disperz:SEGA-TSC: 1 year of age or older.TSC-associated partial-onset seizures: 2 years of age or older.Afinitor: HR-positive, HER2-negative breast cancer: postmenopausal.NET: 18 years of age or older.RCC: 18 years of age or older.Renal angiomyolipoma-TSC: 18 years of age or older.SEGA-TSC: 1 year of age or older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## **EVEROLIMUS - ZORTRESS**

#### **Products Affected**

• everolimus (immunosuppressive) oral tablet 0.25 mg, 0.5 mg, 0.75 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Zortress is contraindicated in patients with known hypersensitivity to everolimus and sirolimus. Kidney transplant patients at high immunologic riskRecipients of transplanted organs other than kidney and liver
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a transplant specialist
Coverage Duration	12 months
Other Criteria	At least ONE of the following: (i) Has had a trial and failure on an anti-rejection regiment containing at least two of the following: (a) cyclosporine (b) tacrolimus (c) azathioprine (d) mycophenolate mofetil/sodium AND has one of the following indications: (i) kidney transplant rejection prophylaxis in patients at low-moderate immunologic risk OR (ii) liver transplant rejection prophylaxis

## FENTANYL TRANSDERMAL PATCH

#### **Products Affected**

• fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Requests for every 48 hours dosing requires a trial of every 72 hours dosing

## **FIDAXOMICIN**

## **Products Affected**

• DIFICID

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	Patient has diagnosis of C. difficile-associated diarrhea (CDAD) confirmed by a positive stool assay
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	3 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to oral vancomycin after a trial of at least 10 days.QTY LIMIT 20 per 10-day supply

# **FILGRASTIM**

### **Products Affected**

NIVESTYM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Granix: 1 month of age or older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Neupogen, Zarxio, Granix: Trial of or contraindication to Nivestym where indications align.

# **FINGOLIMOD**

### **Products Affected**

• fingolimod

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	(1) recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure, (2) history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker, (3) baseline QTC interval 500 msec or above, or (4) Current treatment with Class Ia (quinidine, procainamide, or disopyramide) or Class III anti-arrhythmic drugs (amiodarone, dofetilide, dronedarone, ibutilide, or sotalol)
Required Medical Information	None
Age Restrictions	10 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **FLUCYTOSINE**

### **Products Affected**

• flucytosine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	12 months
Other Criteria	Patient has a documented and confirmed diagnosis of Cryptococcus Meningitis or pulmonary infection OR Candida septicemia, endocarditis or urinary system infection AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to least one first-line agent (e.g. fluconazole, itraconazole, voriconazole, amphotericin B, or an echinocandin); AND for systemic candidiasis or cryptococcosis ONLY Patient will be using flucytosine in combination with amphotericin B.

# **FLURANDRENOLIDE**

- flurandrenolide topical cream flurandrenolide topical lotion

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Patient has a diagnosis of corticosteroid responsive dermatoses and meets ALL of the following criteria: (1) Patient has had a trial and therapeutic failure, intolerance, or contraindication to ALL of the formulary preferred medium potency topical steroid alternatives: betamethasone valerate 0.1% cream and lotion, fluocinolone 0.025% cream and ointment, fluticasone 0.05% cream, hydrocortisone butyrate 0.1% solution and ointment, mometasone 0.1% cream and ointment, and triamcinolone 0.1% cream, lotion and ointment (2) If the preferred medium potency alternative trials are completed AND do not yield adequate relief, a clinical reason is provided for requesting flurandrenolide (a non-preferred alternative with the same potency) instead of trying a formulary high potency topical steroid alternative: (a) Medium to high potency: betamethasone dipropionate 0.05% cream and fluticasone 0.05% ointment (b) High potency: betamethasone dipropionate 0.05% ointment, betamethasone valerate 0.1% ointment, desoximetasone 0.25% cream, diflorasone 0.05% cream, triamcinolone 0.5% cream and ointment, and fluocinonide 0.05% gel, ointment and cream (c) Ultra high potency: betamethasone dipropionate augmented 0.05% cream, gel, lotion and ointment, clobetasol 0.05% solution, diflorasone 0.05% ointment (3) If requesting Cordran 0.025% cream, the patient needs to have a history of trial and failure, contraindication, or intolerance to Cordran 0.05% cream

# **FONDAPARINUX**

### **Products Affected**

• fondaparinux

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Severe renal impairment (creatinine clearance [CrCl] less than 30 mL/min) Active major bleeding.Bacterial endocarditis.Thrombocytopenia associated with a positive in vitro test for anti-platelet antibody in the presence of fondaparinux sodium.Body weight less than 50 kg (venous thromboembolism [VTE] prophylaxis only)
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Prophylaxis of Deep Vein ThrombosisFondaparinux will be used as prophylaxis of deep vein thrombosis (DVT); AND patient is undergoing hip fracture surgery, including extended prophylaxis; OR patient is undergoing hip replacement surgery; OR patient is undergoing knee replacement surgery; OR patient is undergoing abdominal surgery who are at risk for thromboembolic complications. Treatment of Acute Deep Vein ThrombosisPatient has a diagnosis of acute deep vein thrombosis; AND fondaparinux will be administered in conjunction with warfarin sodium. Treatment of Acute Pulmonary EmbolismPatient has a diagnosis of acute pulmonary embolism; AND fondaparinux will be administered in conjunction with warfarin sodium; AND initial therapy will be administered in the hospital.

# **FORMOTEROL**

### **Products Affected**

• formoterol fumarate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Treatment of asthma
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD); AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to ALL of the following: Serevent, Spiriva, Stiolto Respimat, and Anoro Ellipta.

# **FULVESTRANT**

### **Products Affected**

• fulvestrant

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist
Coverage Duration	12 months
Other Criteria	MonotherapyPatient has a diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer; AND Patient is a postmenopausal woman; AND Patient has not received prior endocrine therapy; ORPatient has a diagnosis of hormone receptor (HR)-positive advanced breast cancer; AND Patient is a postmenopausal woman; AND Patient has experienced disease progression following endocrine therapy. Combination TherapyPatient has a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer; AND Patient is a postmenopausal woman; AND Patient will be using fulvestrant in combination with ribociclib as initial endocrine based therapy or following disease progression on endocrine therapy; ORPatient has a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer; AND fulvestrant will be used in combination with palbociclib or abemaciclib; AND Patient has had disease progression after endocrine therapy.

# **GALCANEZUMAB-GNLM**

- EMGALITY PEN
- EMGALITY SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	The medication wil be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Vyepti, Nurtec ODT, Qulipta) for migraine prevention) for migraine prevention.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INIT: EPISODIC/CHRONIC MIG: 6 mo, EPISODIC CLUSTER HEAD: 3 mo. RNWL: 12 mo. IL: 12 mo
Other Criteria	INITIAL: EPISODIC MIGRAINES: Trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol CHRONIC MIGRAINES: Trial of ONE of the following preventative migraine treatments: valproic acid/divalproex sodium, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol, or Botox [Note: For Botox, previous trial of only NDCs # 00023-1145-01 or 00023-3921-02 are allowable] RENEWAL: EPISODIC/CHRONIC MIGRAINES: ONE of the following: (1) Patient has experienced a reduction in migraine or headache frequency of at least 2 days per month with Emgality therapy OR (2) Patient has experienced a reduction in migraine severity with Emgality therapy OR (3) Patient has experienced a reduction in migraine duration with Emgality therapy EPISODIC CLUSTER HEADACHE: Improvement in episodic cluster headache frequency as compared to baseline.

# **GANCICLOVIR**

### **Products Affected**

· ZIRGAN

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	2 years age and older
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Patient has a documented diagnosis of herpetic keratitis; AND Patient has a documented intolerance, contraindication, or treatment failure with an adequate trial of trifluridine eye drops AND acyclovir oral tablets

# **GEMCITABINE IV**

### **Products Affected**

• gemcitabine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patient with known hypersensitivity to products containing gemcitabine.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist.
Coverage Duration	12 months
Other Criteria	OVARIAN CANCER:Patient has a diagnosis of advanced ovarian cancer; AND Patient has relapsed at least 6 months after completion of platinum-based therapy; AND Patient will be using gemcitabine in combination with carboplatin.BREAST CANCER:Patient has a diagnosis of metastatic breast cancer; AND Patient has previously failed anthracycline-containing adjuvant chemotherapy unless anthracyclines were clinically contraindicated; AND Patient will be using gemcitabine in combination with paclitaxel as first-line treatment.NON-SMALL CELL LUNG CANCER:Patient has a diagnosis of inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer; AND Patient will be using gemcitabine in combination with cisplatin as first-line treatment.PANCREATIC CANCER: Patient has a diagnosis of locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas; AND Patient has been previously treated with 5-FU; AND gemcitabine is being used as first-line treatment.

# **GLATIRAMER ACETATE**

- glatiramer
- glatopa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Patients with known hypersensitivity to glatiramer acetate or mannitol. Concurrent use of glatiramer acetate with interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia) or natalizumab (Tysabri)
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in consultation with, a neurologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: Patient has a diagnosis of a relapsing form of MS including relapsing-remitting, secondary progressive with relapses, and progressive relapsing or clinically isolated RENEWAL: (1) Patient has a diagnosis of a relapsing form of MS including relapsing-remitting, secondary progressive with relapses, and progressive relapsing or clinically isolated (2) Medical records/chart notes from neurology consultation documenting the improvement of the relapsing rate OR that the patients clinical condition is stabilized with the current therapy with no significant adverse effects.

# **GOLIMUMAB - IV (NSA)**

### **Products Affected**

SIMPONI ARIA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RA, AS: 18 years of age or olderPsA, PJIA: 2 years of age or older
Prescriber Restrictions	RA/AS/PJIA: Prescribed by or in consultation with a rheumatologistPsA: Prescribed by or in consultation with a rheumatologist or dermatologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: (1) Concurrently using or has a contraindication to methotrexate, (2) Trial of or contraindication to at least 3 months of treatment with at least ONE of the following DMARDs (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, AND (3) One of the following: (a) Trial of or contraindication to any TWO of the following preferred agents: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) (b) Trial of any TNF inhibitor (e.g., Humira, Enbrel) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq, Xeljanz IR/XR) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events.PsA: (1) Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, AND (2) One of the following (a) Patient 2 to 5 years of age: trial or contraindication to Cosentyx, (b) Patient 6 to 17 years of age: trial or contraindication to BOTH Cosentyx and Stelara, (c) Patients 18 years or older: Trial or contraindication to any TWO of the following agents: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla, Tremfya, Rinvoq, Skyrizi.AS: (1) Trial of or contraindication to TWO of the following preferred agents: Cosentyx, Enbrel, Humira, Xeljanz (IR/XR), Rinvoq.PJIA: (1) Trial of or contraindication to TWO of the following preferred agents: Cosentyx, Enbrel, Humira, Xeljanz (IR/XR), Rinvoq.PJIA: (1) Trial of or contraindication to any TWO of the following preferred agents: Cosentyx, Enbrel, Humira, Actemra, Xeljanz IR.[NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify for trials]RENEWAL: RA: (1) Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy, AND (2) Concurrently using or has a contraindication to methotrexate.PsA/PJIA:
	an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.

# **GOLIMUMAB - SQ**

### **Products Affected**

· SIMPONI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS): Prescribed by or in consultation with a rheumatologistPSORIATIC ARTHRITIS (PSA): Prescribed by or in consultation with a rheumatologist or dermatologistULCERATIVE COLITIS (UC): Prescribed by or in consultation with a gastroenterologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: (1) Trial of or contraindication to at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, (2) Concurrent use or contraindication to methotrexate, AND 3) One of the following (a) Trial of or contraindication to any TWO of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) (b) Trial of any TNF inhibitor (e.g., Humira, Enbrel) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq, Xeljanz IR/XR) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events. PsA: (1) Trial of or contraindication to at least ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, AND (2) Trial of or contraindication to any TWO of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Stelara, Xeljanz (IR/XR), Otezla, Tremfya, Rinvoq, Skyrizi. AS: (1) Trial of or contraindication to an NSAID, AND (2) Trial of or contraindication to any TWO of the following preferred immunomodulators: Cosentyx, Enbrel, Humira, Xeljanz (IR/XR), Rinvoq. UC: (1) Trial of or contraindication to at least ONE conventional therapy (e.g., budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate, or mesalamine) AND (2) Trial of or contraindication to the preferred immunomodulator Humira. [NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify for trials]RENEWAL: RA: (1) Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy AND (2) Concurrent use or contraindication to methotrexate. PsA: Experienced or maintained a 10% or greater improvement in tender joint count or swollen joint count while on therapy.AS: Experienced or maintained an improvement o
	Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapy.UC: Diagnosis of moderate to severe ulcerative colitis.

# GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (LEUPROLIDE)

### **Products Affected**

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)

• leuprolide subcutaneous kit

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications and gender dysphoria will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	CENTRAL PRECOCIOUS PUBERTY (CPP): (1) Elevated levels of follicle-stimulating hormone (level greater than 4.0 mIU/mL for females or greater than 5.0 mIU/mL for males) AND luteinizing hormone (level greater than 0.2 to 0.3 mIU/mL) at diagnosis.
Age Restrictions	CENTRAL PRECOCIOUS PUBERTY: 2 years of age or older.
Prescriber Restrictions	CPP: Prescribed by or in consultation with a pediatric endocrinologist
Coverage Duration	INIT/RNWL: GENDER DYSPHORIA, PROSTATE CANCER, or CPP: 12 m
Other Criteria	INITIAL: CPP (1) Younger than 8 years of age (females) or 9 years of age (males) at the onset of CPP AND (2) Documentation of pubertal staging using the Tanner scale for breast development (females) or genital development (males) (stage 2 or above) AND pubic hair growth (stage 2 or above). RENEWAL: CPP: (1) Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year AND (2) Patient has not reached actual age which corresponds to current pubertal age.

# GONADOTROPIN RELEASING HORMONE (GNRH) AGONIST (NSA)

### **Products Affected**

- CAMCEVI (6 MONTH)
- · LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)

• LUPRON DEPOT (6 MONTH)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications and gender dysphoria (Lupron only) will also be considered for approval.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	ENDOMETRIOSIS: Prescribed by or in consultation with an obstetrician/gynecologist.
Coverage Duration	INIT: UTERINE LEIOMY: 3 mo. GENDR DYSPH, PROST CNCR: 12 mo. ENDOMTRSIS: 6 mo. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: A. ENDOMETRIOSIS (Lupron only): (1) The diagnosis is confirmed via surgical or direct visualization (e.g., pelvic ultrasound) OR histopathological confirmation (e.g., laparoscopy or laparotomy) in the last 10 years (2) Trial of or contraindication to a nonsteroidal anti-inflammatory drug (NSAID) AND a progestin-containing contraceptive preparation (e.g., combination hormonal contraceptive preparation, progestin-only contraceptive preparation) AND (3) The requested medication will NOT be used concurrently with another GnRH-modulating agent (e.g., elagolix, relugolix).B. Anemia cuased by uterine leiomyomata (Lupron only): The requested medication needs to be used concomitantly with iron therapy. RENEWAL: A. ENDOMETRIOSIS (Lupron only): (1) Improvement of pain related to endometriosis while on therapy AND (2) Patient is receiving concomitant add-back therapy (i.e., combination estrogen-progestin or progestin-only contraceptive preparation) (3) patient has NOT received a total course of therapy exceeding 12 months AND (4) The requested medication will NOT be used concurrently with another GnRH-modulating agent (e.g., elagolix, relugolix).

# **GUSELKUMAB**

### **Products Affected**

TREMFYA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	PSORIASIS (PsO): Prescribed by or in consultation with a dermatologist.PSORIATIC ARTHRITIS (PsA): Prescribed by or in consultation with a rheumatologist or dermatologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: PsO: (1) Psoriasis covering 3% or more of body surface area, OR psoriatic lesions affecting the hands, feet, genital area, or face, AND (2) Trial of or contraindication at least one conventional therapy such as a PUVA (phototherapy ultraviolet light a), UVB (ultraviolet light b), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine.PsA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.RENEWAL: PsO: Achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.PsA: Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count

# HEREDITARY ANGIOEDEMA (PA)

- icatibant
- sajazir

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Takhyzryo: History of anaphylactic or life-threatening hypersensitivity reactions to lanadelumab or any component of the formulation. Icatibant or Sajazir: History of anaphylactic or life-threatening hypersensitivity reactions to icatibant or any component of the formulation.
Required Medical Information	INITIAL: HAE ACUTE (ICATIBANT or SAJAZIR), HAE PROPHYLAXIS (TAKHZYRO):(1) The patient has a diagnosis of Type I or Type II hereditary angioedema (HAE) evidenced by ONE of the following: a) Mutation in the C1-INH gene altering protein synthesis and/or function b) TWO separate low measurements for BOTH of the following tests defined as below the testing laboratory's lower limit of the normal range: i) Low serum complement factor 4 [C4] level AND ii) Either low C1-INH antigenic level OR low C1-INH functional level
Age Restrictions	Takhzyro: 12 years and older; Icatibant, Sajazir: 18 years and older
Prescriber Restrictions	Prescribed by or in consultation with medical geneticist, allergist, immunologist, or hematologist
Coverage Duration	Initial: 6 months. Renewal: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: HAE ACUTE (ICATIBANT or SAJAZIR):(1) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, estrogens) AND(2) Patient is experiencing at least one (1) symptom of moderate to severe HAE attack (i.e. airway swelling, severe abdominal pain, facial swelling, nausea/vomiting, painful facial distortion) AND (3) Patient is receiving only ONE agent indicated for treatment of acute HAE attack OR the other agent being used for acute HAE attacks will be discontinued before starting requested agent INITIAL: HAE PROPHYLAXIS (TAKHZYRO):(1) The requested agent will be used for prophylaxis against HAE attacks ANDa. The patient is receiving only ONE agent indicated for prophylaxis will be discontinued before starting the requested agent ANDc. The patient has had at least 2 acute severe attacks per month (i.e. swelling of the throat, cutaneous or incapacitating abdominal swelling) AND(2) Medications known to cause angioedema have been evaluated and discontinued if appropriate (i.e. ACE-I, ARBs, and estrogens) AND (3) Member has tried and failed, intolerant to, or has a contraindication to danazol(4) The prescribed dosage follows Food and Drug Administration label unless there is documented clinical reasoning for higher dosageRENEWAL: HAE ACUTE (ICATIBANT or SAJAZIR): (1) Member has experienced a significant improvement in severity and duration of attacks yet continues to have occurrence of acute attacks AND (2) The patient continues to have occurrence of acute attacks AND (2) The patient continues to have occurrence of acute attacks (3) The prescriber has communicated (via any means) with the patient does not have greater than 1 month supply (sufficient for 2 acute attacks) currently onhand. icatibant 6 syringes/30 days (4) The requested drug will not be used concurrently with alternative acute treatment for HAE attacks (e.g., Berinert, Kalbitor, Ruconest, icatibant).RENEWAL: HAE PROPHYLAXIS (TAKHZYRO): (1) Documented decrease in HAE attacks (frequency AND (2) Decrea
	attacks (Note to prescriber: Consider increasing dosing interval to every 4 weeks if patient attack free for 6 months)(3) The requested drug will not be used concurrently with alternative prophylactic treatment for HAE (e.g., Cinryze, Takhzyro, Haegarda, Orladeyo, danazol)

# **HYDROCODONE ER**

### **Products Affected**

• hydrocodone bitartrate oral capsule, oral only, er 12hr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Significant respiratory depressionAcute or severe bronchial asthma or hypercarbiaPatient has or is suspected of having paralytic ileusHypersensitivity to any components of Hysingla ER or the active ingredient, hydrocodone bitartrate
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	AROUND-THE-CLOCK SEVERE-CHRONIC PAIN IN OPIOID TOLERANT PATIENTS: (1) Prescriber attests patient has diagnosis of Around-the-clock severe-chronic pain, in opioid-tolerant patients (2) The patient is 18 years of age or older (3) The patient must have severe pain enough to require daily, around-the clock, long-term opioid treatment (4) Patient has had inadequate pain control or intolerance to a two-week trial of at least 1 non-opioid and a 2-week trial of 1 short-acting opioid (5) Not indicated as an as-needed (PRN) analgesic

# **HYDROMORPHONE ER**

### **Products Affected**

• hydromorphone oral tablet extended release 24 hr 12 mg, 16 mg, 32 mg, 8 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Dosages above 16mg require recommendation from a pain specialist
Coverage Duration	12 months
Other Criteria	None

### **IBRUTINIB**

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	cGVHD: 1 year of age or olderMCL, CLL, SLL, WM, MZL: 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	MANTLE CELL LYMPHOMA (MCL): The patient has received at least one prior therapy for MCLMARGINAL ZONE LYPHOMA (MZL): The patient requires systemic therapy, and the patient has received at least one prior anti-CD20-based therapy (e.g., Rituxan)CHRONIC GRAFT VERSUS HOST DISEASE (cGVHD): The patient has failed one or more lines of systemic therapy (e.g., corticosteroids)Requests for 140 mg or 280 mg tablets: Patient must have tried or have a contraindication to ibrutinib 140 mg capsulesRequests for ibrutinib 70 mg/mL oral suspension: The patient must be unable to swallow capsules or tablets

# **ILOPROST**

### **Products Affected**

VENTAVIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL:(1) Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters: (a) Mean pulmonary artery pressure (PAP) greater than 20 mmHg, (b) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg, and (c) Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units (WU).(2) Patient has NYHA/WHO Functional Class III-IV symptoms.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL:One of the following:(1) WHO Functional Class III symptoms with trial of or contraindication to two of the following agents from different drug classes: (a) Oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan), (b) Oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil), (c) Oral cGMP inhibitor (e.g., riociguat), OR(2) WHO Functional Class III symptoms with evidence of rapid progression/poor prognosis or WHO Functional Class IV symptoms, with trial of or contraindication to one IV/SQ prostacyclin (e.g., epoprostenol or treprostinil).RENEWAL: One of the following: (1) Patient had improvement from baseline in the 6-minute walk distance test, OR (2) Patient remained stable from baseline in the 6-minute walk distance test and the patients WHO functional class remained stable or has improved.

# **IMATINIB**

### **Products Affected**

• imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RELAPSED OR REFRACTORY PHILADELPHIA CHROMOSOME POSITIVE ACUTE LYMPHOBLASTIC LEUKEMIA (PH+ ALL); MYELODYSPLASTIC/MYELOPROLIFERATIVE; AGGRESSIVE SYSTEMIC MASTOCYTOSIS (ASM); HYPEREOSINOPHILIC SYNDROME (HES) AND/OR CHRONIC EOSINOPHILIC LEUKEMIA (CEL); DERMATOFIBROSARCOMA PROTUBERANS (DFSP); ADJUVANT GASTROINTESTINAL STROMAL TUMOR TREATMENT: 18 years of age or older.
Prescriber Restrictions	None
Coverage Duration	ADJUV GASTROINTESTINAL STROMAL TUMOR: 36 mo. ALL OTHER DIAGNOSES: 12 mo
Other Criteria	PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): No previous treatment with another tyrosine kinase inhibitor.

# **IMMUNE GLOBULIN**

### **Products Affected**

HYQVIA

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Primary Immunodeficiency Disease (PID).
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Subcutaneous Use Only. Primary immunodeficiency disease only.

# **INSULIN GLULISINE**

- APIDRA SOLOSTAR U-100 INSULIN
- APIDRA U-100 INSULIN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Use during episodes of hypoglycemia
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of Diabetes Mellitus; AND Patient has had a previous trial and failure, intolerance, or contraindication to all of the following: (i) Novolin (ii) Novolog (iii) Fiasp

# **INTERFERON GAMMA-1B**

### **Products Affected**

ACTIMMUNE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	CHRONIC GRANULOMATOUS DISEASE (CGD): Prescribed by or given in consultation with a hematologist, infectious disease specialist, or immunologistSEVERE MALIGNANT OSTEOPETROSIS (SMO): Prescribed by or given in consultation with an endocrinologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	RENEWAL: CGD, SMO: 1) Patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections) 2) Patient has not received hematopoietic cell transplantation

# INTERFERONS FOR MULTIPLE SCLEROSIS (AVONEX)

### **Products Affected**

AVONEX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# INTERFERONS FOR MULTIPLE SCLEROSIS (PLEGRIDY, BETASERON, EXTAVIA)

- BETASERON
- EXTAVIA
- PLEGRIDY

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **ISAVUCONAZONIUM**

### **Products Affected**

· CRESEMBA ORAL

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Coadministration with strong CYP3A4 inhibitors, such as ketoconazole or high-dose ritonavir. Coadministration with strong CYP3A4 inducers, such as rifampin, carbamazepine, St. Johns wort, or long-acting barbiturates. Use in patients with familial short QT syndrome
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an Infectious Disease specialist
Coverage Duration	3 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to therapy with amphotericin B, posaconazole, or voriconazole.

### **ISOTRETINOIN**

### **Products Affected**

• accutane

mg, 40 mg

amnesteem

myorisan

• claravis

• zenatane

• isotretinoin oral capsule 10 mg, 20 mg, 30

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	INITIAL/RENEWAL: 12 years of age and older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL:Patient has a diagnosis of severe recalcitrant nodular acne, treatment-resistant or scarring acne; AND Patient has had a trial and therapeutic failure with at least TWO (2) topical acne medications AND a trial of an oral tetracycline or tetracycline derivative. RENEWAL:Patient has had a relapse of severe recalcitrant nodular acne, treatment-resistant or scarring acne requiring a second treatment course; AND there is a gap of at least 2 months since completing the initial treatment course.QUANTITY RESTRICTION, Maximum 60 capsules / 30 days

# ITRACONAZOLE ORAL

### **Products Affected**

itraconazole

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Concomitant administration of itraconazole with drugs metabolized by CYP3A4: oral midazolam, pimozide, quinidine, dofetilide, triazolam, lovastatin, and simvastatin. Treatment of onychomycosis to pregnant patients or to women contemplating pregnancy. Patients who have shown hypersensitivity to itraconazole. Itraconazole capsules should not be administered for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF.
Required Medical Information	ONYCHOMYCOSIS OF THE FINGERNAILS/TOENAILS:Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	Fingernl Onycho: 5 wk. Toenl Onycho: 12 wk. Histoplas/Blasto: 12 mo. Asperg: 6 mo. Candids: 2 mo

PA Criteria	Criteria Details
Other Criteria	ORAL CAPSULES ONLYOnychomycosis of the fingernails/toenails:Patient is not immunocompromised; AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to 6 weeks of oral terbinafine for the fingernails OR 12 weeks of oral terbinafine for toenails. ORAL SOLUTION ONLYEsophageal Candidiasis:Patient has diagnosis of candidiasis of the esophagus with or without HIV; AND Patient has trial and failure, contraindication, or intolerance to 21-day trial of fluconazole. Oropharyngeal Candidiasis:Patient has diagnosis of oropharyngeal candidiasis with or without HIV. AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to a 14-day treatment with fluconazole; AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to a 14-day trial of nystatin suspension or clotrimazole troches.

### **IVABRADINE**

### **Products Affected**

· CORLANOR ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Acute decompensated heart failure, Clinically significant hypotension (e.g., blood pressure less than 90/50 mm Hg), Sick sinus syndrome, sinoatrial block, or third-degree atrioventricular (AV) block (unless a functioning demand pacemaker is present), Clinically significant bradycardia (e.g., resting heart rate less than 60 bpm prior to treatment), Severe hepatic impairment, Pacemaker dependence (heart rate maintained exclusively by the pacemaker), Concomitant use with strong CYP3A4 inhibitors
Required Medical Information	INITIAL:A. STABLE, SYMPTOMATIC HEART FAILURE (NYHA II-IV)(1) Left ventricular ejection fraction less than or equal to 35% AND (2) Resting heart rate greater than or equal to 70 beats per minute. B. SYMPTOMATIC NYHA CLASS II-IV HEART FAILURE DUE TO DILATED CARDIOMYOPATHY(1) Patient has a resting heart rate of greater than or equal to 70 beats per minute
Age Restrictions	Stable, symptomatic heart failure (NYHA II-IV): 18 years of age or older, Symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy: 6 months of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL:A. STABLE, SYMPTOMATIC HEART FAILURE (NYHA II-IV) (1) Patient has a diagnosis of stable, symptomatic heart failure (NYHA II-IV) AND (2) In sinus rhythm AND (3) Have symptoms despite maximal beta-blocker therapy or have documented contraindication to beta-blocker use AND (4) Trial, failure, or contraindication to ACE-inhibitor or ARB therapyB. SYMPTOMATIC NYHA CLASS II-IV HEART FAILURE DUE TO DILATED CARDIOMYOPATHY (1) Patient has diagnosis of symptomatic NYHA class II-IV heart failure due to dilated cardiomyopathy AND (2) In sinus rhythm. RENEWAL CRITERIA: (1) patient continues to meet initial criteria AND (2) patient has experienced disease stabilization or improvement with medication as determined by the prescriber.

# **LACOSAMIDE**

### **Products Affected**

• lacosamide oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	4 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to a trial of at least TWO (2) formulary anticonvulsants.

# **LACTULOSE**

- KRISTALOSE
- lactulose oral packet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients who require a low galactose diet.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of constipation; AND Patient has had a trial and failure, intolerance, or contraindication to generic lactulose solution.

# **LANREOTIDE**

- lanreotide
- SOMATULINE DEPOT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: ACROMEGALYPrescriber must provide the following baseline documentation from patients medical record: 1) Elevated serum IGF-1 level for patients age range and gender, 2) Elevated growth hormone level defined by a GH level greater than or equal to 1 ng/mL during oral glucose tolerance test (OGTT).RENEWAL: ACROMEGALYPatient has documented disease response confirmed by reduction of growth hormone (GH) and/or IGF-I blood levels from baseline. AND Serum insulin-like growth factor-I (IGF-I) levels remain outside normal limits.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	INITIAL: ACROMEGALYPatient has a documented diagnosis of Acromegaly; AND Patient has had an inadequate response to surgery and/or radiation therapy; OR Documentation has been provided to confirm surgery and radiation therapy are not appropriate.

# **LAPATINIB**

### **Products Affected**

• lapatinib

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **LASMIDITAN**

### **Products Affected**

REYVOW

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL: 6 months, RENEWAL: 12 months
Other Criteria	INITIAL: Trial of or contraindication to ONE triptan (e.g., sumatriptan, rizatriptan). RENEWAL: The patient has experienced an improvement from baseline in a validated acute treatment patient-reported outcome questionnaire OR the patient has experienced clinical improvement as defined by one of the following: (1) Ability to function normally within 2 hours of dose, (2) Headache pain disappears within 2 hours of dose, (3) Therapy works consistently in majority of migraine attacks.

# LEDIPASVIR/SOFOSBUVIR

### **Products Affected**

HARVONI

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	(1) Currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, rosuvastatin, simeprevir, (Sovaldi), elvitegravir/cobicistat/emtricitabine/tenofovir (Stribild), tipranavir/ritonavir, pibrentasvir/glecaprevir (Mavyret), velpatasvir/sofosbuvir (Epclusa), elbasvir/grazoprevir (Zepatier), or velpatasvir/sofosbuvir/voxilaprevir (Vosevi).(2) Limited life expectancy (less than 12 months) due to non-liver related comorbid conditions (e.g., physician attestation).
Required Medical Information	Recent HCV infection documented by at least ONE detectable HCV RNA level within the last 6 months
Age Restrictions	3 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	Coverage duration will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	(1) Criteria will be applied consistent with current AASLD/IDSA guidance.(2) Requests for Harvoni 45mg/200mg pellets require that the patient is unable to swallow tablets.

### **LENALIDOMIDE**

- lenalidomide oral capsule 10 mg, 15 mg, 2.5 mg, 20 mg, 25 mg, 5 mg
- REVLIMID ORAL CAPSULE 10 MG, 15 MG, 25 MG, 5 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	MULTIPLE MYELOMA: Revlimid (lenalidomide) will be used as induction treatment

### **LENVATINIB**

#### **Products Affected**

LENVIMA ORAL CAPSULE 10
 MG/DAY (10 MG X 1), 12 MG/DAY (4
 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24
 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RENAL CELL CARCINOMA (RCC): 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# LEVOFLOXACIN OPHTHALMIC

#### **Products Affected**

• levofloxacin ophthalmic (eye) drops  $0.5\,\%$ 

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Patients with a history of hypersensitivity to levofloxacin or other quinolones
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	1 month
Other Criteria	Patient has diagnosis of Bacterial Conjunctivitis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO (2) of the following: ciprofloxacin 0.3% ophthalmic solution, tobramycin 0.3% ophthalmic solution, ofloxacin 0.3% ophthalmic solution

# **LIDOCAINE PATCH 5%**

#### **Products Affected**

• lidocaine topical adhesive patch,medicated 5 %

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications and Diabetic peripheral neuropathy
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	POSTHERPETIC NEURALGIAPatient has a diagnosis of postherpetic neuralgia (shingles or herpes zoster); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to Xylocaine (Lidocaine 2.5% or 4.0% solution, Lidocaine 2.5% or 3% cream, Lidocaine 2% gel) OR Capsaicin 0.025%, 0.075%, 0.1% cream (medication usage must be supported by documentation from the patients chart notes/medical records); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to gabapentin (medication usage must be supported by documentation from the patients chart notes/medical records) DIABETIC PERIPHERAL NEUROPATHYPatient has had a diagnosis of diabetic peripheral neuropathy; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to Xylocaine (Lidocaine 2.5% or 4.0% solution, Lidocaine 2.5% or 3% cream, Lidocaine 2% gel) OR Capsaicin 0.025%, 0.075%, 0.1% cream (medication usage must be supported by documentation from the patients chart notes/medical records); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to a one month trial of ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records): At least TWO (2) tricyclic antidepressants (amitriptyline, desipramine, imipramine, and nortriptyline) AND a traditional anticonvulsant (eg., carbamazepine, sodium valproate) AND venlafaxine AND duloxetine.

# **LODOXAMIDE**

### **Products Affected**

· ALOMIDE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	2 years of age and older
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	Patient has a diagnosis of vernal keratoconjunctivitis, vernal conjunctivitis, and/or vernal keratitis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO of the following azelastine ophthalmic solution, cromolyn sodium ophthalmic solution, or epinastine ophthalmic solution.

# **LOMUSTINE**

### **Products Affected**

• GLEOSTINE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	PRIMARY AND METASTATIC BRAIN TUMORS: 1) Requested medication will be used as a part of the PCV regimen (procarbazine, lomustine, and vincristine) OR 2) Patient had trial of IV carmustine

# **LUMACAFTOR-IVACAFTOR**

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: Documentation that the patient is homozygous for the F508del-CFTR gene mutation
Age Restrictions	1 year of age or older
Prescriber Restrictions	Prescribed by or given in consultation with a pulmonologist or CF expert
Coverage Duration	INITIAL: 24 weeks. RENEWAL: Lifetime. IL: Initial 12 mo, Renewal: Lifetime
Other Criteria	RENEWAL: Improvement in clinical status as shown by one of the following: (a) Patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume), (b) Patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index), or (c) Reduction in rate of pulmonary exacerbations.

# **LURASIDONE**

### **Products Affected**

LATUDA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.). Strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. Johns wort, phenytoin, carbamazepine, etc.).
Required Medical Information	None
Age Restrictions	Bipolar depression: 10 years of age and olderSchizophrenia: 13 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a psychiatrist.
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of major depressive episode associated with bipolar I disorder (bipolar depression) or schizophrenia; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least THREE (3) of the following (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history): risperidone, quetiapine, olanzapine, ziprasidone, aripiprazole.

# **MECASERMIN**

### **Products Affected**

INCRELEX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	2 years to less than 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a pediatric endocrinologist or a pediatric nephrologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: (1) Height standard deviation score of less than or equal to -3.0, (2) Basal IGF-1 standard deviation score of less than or equal to -3.0, (3) Normal or elevated growth hormone (GH), [serum growth hormone level of greater than equal to 10ngm/mL to at least two stimuli (insulin, levodopa, arginine, clonidine, or glucagon)], AND (4) Epiphyses (bone growth plates) is open (as confirmed by radiograph of the wrist and hand).RENEWAL: Shown response in the first 6 months of IGF-1 therapy (i.e., increase in height, increase in height velocity)

# **MELPHALAN**

- melphalan melphalan hcl

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Patients whose disease has demonstrated a prior resistance to this agent. Patients who have demonstrated hypersensitivity to melphalan
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	ORAL TABLET:Patient has a diagnosis of multiple myeloma OR non-resectable epithelial carcinoma of the ovary; AND diagnosis is supported by chart notes/documentation; AND melphalan is being used for palliative treatment.INTRAVENOUS INJECTION:Patient has a diagnosis of multiple myeloma; AND diagnosis is supported by chart notes/documentation; AND melphalan is being used for palliative treatment; AND oral melphalan therapy is not appropriate (dysphagia, difficulty swallowing, etc.).

# **MEMANTINE ORAL SOLUTION**

#### **Products Affected**

• memantine oral solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Known hypersensitivity to memantine hydrochloride
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to generic memantine tablets; AND Patient is unable to ingest solid oral dosage forms due to one of the following: Oral/motor difficulties; OR Dysphagia.

# **MESALAMINE**

### **Products Affected**

• mesalamine rectal suppository

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with known or suspected hypersensitivity to salicylates or aminosalicylates
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and failure, intolerance, or contraindication to all of the following: Mesalamine 1.2gm DR, Mesalamine 800mg DR and Mesalamine 4gm Enema.

# **MESNA**

### **Products Affected**

MESNEX ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a Hematologist or Oncologist
Coverage Duration	12 months
Other Criteria	None

# **METAXALONE**

### **Products Affected**

• metaxalone oral tablet 800 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Known tendency to drug induced, hemolytic, or other anemias. Significantly impaired renal or hepatic function.
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	3 months
Other Criteria	Patient has diagnosis of acute musculoskeletal pain; AND Patient has had a trial and therapeutic failure, contraindication, or intolerance to THREE of the following: (i) cyclobenzaprine (ii) orphenadrine (iii) chlorzoxazone (iv) methocarbamol

# **METHOXSALEN**

### **Products Affected**

methoxsalen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients exhibiting idiosyncratic reactions to psoralen compounds. Patients possessing a specific history of light-sensitive disease states (e.g., lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism) Patients with melanoma or with a history of melanoma. Patients with invasive squamous cell carcinomas. Patients with aphakia because of the significantly increased risk of retinal damage due to the absence of lenses.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a dermatologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of severe, recalcitrant, disabling psoriasis; AND Patients diagnosis is supported by biopsy (submission of supporting chart notes required); AND Patients disease is not adequately responsive to other forms of therapy; AND methoxsalen will be used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation.

# **MILNACIPRAN**

### **Products Affected**

SAVELLA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Use of MAOIs intended to treat psychiatric disorders with Savella or within 5 days of stopping treatment with Savella. Use of Savella within 14 days of stopping an MAOI intended to treat psychiatric disorders
Required Medical Information	FIBROMYALGIA: Patient has a documented diagnosis of Fibromyalgia confirmed by all of the following: (1) Physical exam indicating presence of 11 of 18 tender points, and (2a) Widespread Pain Index (WPI) greater than or equal to 7 and Symptom Severity (SS) scale score greater than or equal to 5, OR (2b) WPI is between 3 and 6 and SS scale score greater than or equal to 9.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, physiatrist, neurologist, or pain management specialist.
Coverage Duration	12 months
Other Criteria	FIBROMYALGIA: Symptoms have been present for at least 3 months; AND Other conditions mistaken for fibromyalgia have been ruled out (e.g. rheumatoid arthritis, peripheral neuropathies, infection); AND Patient has had a trial and failure, intolerance, or contraindication to a tricyclic antidepressant (i.e. amitriptyline) AND duloxetine.

# **MILTEFOSINE**

#### **Products Affected**

IMPAVIDO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	Leishmaniasis species is identified via ONE of the following CDC recommended tests:(1) Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings(2) Culture medium(3) Polymerase chain reaction (PCR)(4) Serologic testing (e.g. rK39 Rapid Test)
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **MIRABEGRON**

#### **Products Affected**

• MYRBETRIQ ORAL TABLET EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Known hypersensitivity to mirabegron.
Required Medical Information	None
Age Restrictions	3 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	Quantity limit: 1 tablet per day.INITIAL:1.Diagnosis of overactive bladder, neurogenic detrusor overactivity or other FDA approved indication supported by chart notes/documentation. 2.Documented trial and failure of, or contraindication to, adequate treatment with at least THREE (3) antimuscarinic agents (i.e. darifenacin, solifenacin, oxybutynin, tolterodine, or trospium)RENEWAL:Patient has documented positive clinical response to Myrbetriq therapy.

# **MITOTANE**

#### **Products Affected**

LYSODREN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an Oncologist
Coverage Duration	12 months
Other Criteria	None

### **MODAFINIL AND ARMODAFINIL**

- armodafinil
- modafinil

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	1. Hypersensitivity to modafinil or armodafinil. 2. Concurrently on modafinil and armodafinil.
Required Medical Information	Chart notes confirming the diagnosis of narcolepsy, shift work sleep disorder, or obstructive sleep apnea.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	None.
Coverage Duration	12 months
Other Criteria	NARCOLEPSY: Chart notes confirm that the diagnosis is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication). SHIFT WORK DISORDER: Chart notes confirm the patient is experiencing excessive sleepiness and working a minumum of five (or more) overnight shifts per month and that the diagnosis is not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition.

# NALDEMEDINE TOSYLATE

#### **Products Affected**

SYMPROIC

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with a history of a hypersensitivity reaction to naldemedine.  Patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of OIC with chronic non-cancer pain, including patients with chronic pain related to prior cancer treatment who do not require frequent (weekly) opioid dose escalation; AND Patient has been on opioid for at least 30 days; AND Patient has a documented intolerance, contraindication, or treatment failure with, an adequate trial of ONE agent from each of the following TWO classes while on opioid therapy: stimulant laxative (e.g., bisacodyl, senna) AND osmotic laxative (e.g., lactulose, polyethylene glycol).

# **NALOXEGOL**

#### **Products Affected**

MOVANTIK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction. Patients concomitantly using strong CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole)
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has been taking an opioid analgesic for at least 4 weeks immediately prior to the request (as evidenced by pharmacy claims) AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least one agent from within each of the following laxative types: (1) Fiber laxatives (psyllium, methylcellulose, calcium polycarbophil) AND (2) Stimulant laxatives (bisacodyl, senna) AND (3) Osmotic laxatives (Polyethylene glycol, milk of magnesia, sorbitol, lactulose)

# NALTREXONE MICROSPHERES

#### **Products Affected**

VIVITROL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients receiving opioid analgesics. Patients with current physiologic opioid dependence. Patients in acute opioid withdrawal. Any individual who has failed the naloxone challenge test or has a positive urine screen for opioids. Patients who have previously exhibited hypersensitivity to naltrexone, PLG, carboxymethylcellulose, or any other components of the diluent
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	ALCOHOL DEPENDENCE Patient must have already abstained from drinking alcohol; AND Vivitrol will be used as part of a comprehensive treatment program for alcohol dependence that should include a psychosocial support systemOPIOID DEPENDENCE Patient must be opioid free for a minimum of 7-10 days; AND Patient does not have a current need for opioid analgesics; AND Patient is using Vivitrol as part of a comprehensive treatment program for opioid dependence that should include a psychosocial support system

# **NEDOCROMIL**

### **Products Affected**

· ALOCRIL

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to at least TWO of the following: azelastine ophthalmic solution, cromolyn sodium ophthalmic solution, or epinastine ophthalmic solution.

# **NILOTINIB**

#### **Products Affected**

TASIGNA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications
Exclusion Criteria	None
Required Medical Information	RESISTANT PHILADELPHIA CHROMOSOME POSITIVE CHRONIC MYELOID LEUKEMIA (Ph+ CML): BCR-ABL mutational analysis negative based on NCCN treatment recommendations for BCR-ABL1 mutation profile (CML-5)
Age Restrictions	NEWLY DIAGNOSED Ph+ CML IN CHRONIC PHASE: 1 year of age or older.Ph+ CML IN ACCELERATED PHASE: 18 years of age or older.Ph+ CML IN CHRONIC PHASE: Patient is between 1 and 17 years of age.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Ph+ CML IN ACCELERATED PHASE: 1) Patient is resistant or intolerant to prior therapy that included Gleevec. 2) Patient has had a mutational analysis prior to initiation AND Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL 1 mutation profile.Ph+ CML IN CHRONIC PHASE: 1) Patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)] 2) Patient had a mutational analysis prior to initation and Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL 1 mutation profile.

# **NILUTAMIDE**

### **Products Affected**

• nilutamide

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with severe hepatic impairment (baseline hepatic enzymes should be evaluated prior to treatment). Patients with severe respiratory insufficiency
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist.
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of metastatic prostate cancer (Stage D2) AND Patient is undergoing surgical castration AND Patient will begin nilutamide therapy on the same day as or on the day after surgical castration.

### **NITAZOXANIDE**

- ALINIA ORAL SUSPENSION FOR RECONSTITUTION
- nitazoxanide

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Prior hypersensitivity to nitazoxanide
Required Medical Information	None
Age Restrictions	Tablets: 12 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	Giardiasis or Cryptosporidiosis: 3 days
Other Criteria	A. GIARDIASIS (1) Prescriber attests patient has a diagnosis of diarrhea caused by Giardia lamblia (giardiasis) and (2) Patient is immunocompetent and is not infected with HIV and (3) Patient has had a trial and failure, contraindication, or intolerance to metronidazole. B. CRYPTOSPORIDIOSIS (1) Prescriber attests patient has a diagnosis of diarrhea caused by Cryptosporidium parvum (cryptosporidiosis) AND (2) Patient is immunocompetent and not infected with HIV

### **OCTREOTIDE**

#### **Products Affected**

octreotide acetate

#### **RECON**

 SANDOSTATIN LAR DEPOT INTRAMUSCULAR SUSPENSION, EXTENDED REL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: ACROMEGALYBaseline growth hormone (GH) and/or IGF-I blood levels are submitted for documentation.RENEWAL: ACROMEGALYPatient has documented disease response confirmed by reduction of growth hormone (GH) and/or IGF-I blood levels from baseline AND Serum insulin-like growth factor-I (IGF-I) levels remain outside normal limits.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: ACROMEGALY: Patients has had an inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.ALL DIAGNOSES: REQUESTS FOR SANDOSTATIN LAR: Patient must have responded to and tolerated octreotide injection.

## **OLAPARIB**

#### **Products Affected**

LYNPARZA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	ADVANCED STAGES OF OVARIAN CANCER, EPITHELIAL OVARIAN, FALLOPIAN TUBE, PRIMARY PERITONEAL CANCER; OR HER2-NEGATIVE HIGH RISK EARLY BREAST CANCER, HER2-NEGATIVE METASTATIC BREAST CANCER, METASTATIC PANCREATIC ADENOCARCINOMA, METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: FDA-approved companion diagnostic
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: (1) Requested medication will be used for maintenance treatment. (2) The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin). (3) ONE of the following: a) Deleterious or suspected deleterious germline or somatic BRCA mutation or b) The patient's cancer is associated with a homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability AND Lynparza will be used in combination with bevacizumab. RECURRENT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER: (1) The patient is in complete or partial response to their most recent platinum based-chemotherapy. (2) Completed two or more lines of platinum based chemotherapy. (3) Requested medication will be used as monotherapy for maintenance treatment. HER2-NEGATIVE HIGH RISK EARLY BREAST CANCER: (1) Requested medication will be used as adjuvant treatment. (2) Cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm). (3) Previous treatment with neoadjuvant or adjuvant chemotherapy. HER2-NEGATIVE METASTATIC BREAST CANCER: (1) Cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (2) Previous treatment with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. (3) ONE of the following has been met (3a) Patient does NOT have hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Patient has a hormone receptor (HR)-positive breast cancer or (3b) Pati

PA Criteria	Criteria Details
	regimen.METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (MCRPC): (1) Cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation. (2) Disease has progressed following prior treatment with enzalutamide or abiraterone. (3) ONE of the following has been met: (3a) Previously had a bilateral orchiectomy. (3b) Castrate testosterone level (less than 50 ng/dL). (3c) Concurrent use with a gonadotropin releasing hormone (GNRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix).

## **OLSALAZINE**

#### **Products Affected**

DIPENTUM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Known or suspected hypersensitivity to salicylates, aminosalicylates, or their metabolites
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by, or in conjunction with, a gastroenterologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of mild to moderate ulcerative colitis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history): sulfasalazine (immediate-release/delayed-release), balsalazide, mesalamine ER capsules 0.37g (maintenance of remission)

## **OMALIZUMAB**

#### **Products Affected**

XOLAIR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	NASAL POLYPS: 18 years of age or older.ASTHMA: 6 years of age or older.CIU: 12 years of age or older
Prescriber Restrictions	Asthma/CIU: Prescribed by a physician specializing in allergy or pulmonary medicineNasal Polyps: Prescribed by or in consultation with an otolaryngologist or allergist/immunologist
Coverage Duration	Asthma: initial 4 mo, RNWL 12 moNasal Polyps: 6 mo, RNWL 12 moCIU: 6 moIL: 12 mo

PA Criteria	Criteria Details
Other Criteria	Nasal polyps:INITIAL:1. Xolair will be utilized as add-on maintenance treatment2. The patient had a previous 90-day trial of ONE intranasal corticosteroidRENEWAL:1. The patient has had a clinical benefit compared to baselineChronic idiopathic uticariaINITIAL:1. The patient still experiences hives on most days of the week for at least 6 weeks2. The patient has tried a high dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) AND leukotriene antagonist (such as montelukast, zafirlukast) for at least 2 weeksRENEWAL:1. The patient has a diagnosis of chronic spontaneous urticaria and is under the care of the appropriate specialist. Moderate-to-severe, persistent asthmaINITIAL requires BOTH of the following (1 AND 2):1. All of the followinga. Patient has a positive skin prick or blood test (eg., ELISA, FEIA) to a perennial aeroallergenb. Patient has a documented baseline IgE serum level of at least 30 IU/mLc. The patient is concurrently treated with a medium, high-dose, or maximally tolerated inhaled corticosteroid AND at least one other maintenance medicationd. Xolair will NOT be used concurrently with Dupixent or an anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra) when these ar eused for the treatment of asthma2. ONE of the following:a. The patient has experienced at least ONE asthma exacerabation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least one serious exacerbation requiring hospitalization or emergency room visit within the past 12 monthsb. The patient has poor symptoms control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks: i) daytime asthma symptoms more than twice per week ii) Any night waking due to asthma iii) Use of a short-acting reliever for symptoms more than twice per week and iv) Any activity limitation due to asthma RENEWAL:a. The patient will continue to use an inhaled corticosteroid and least one other maintenance medicationb. Xolair will NOT be used concomitantly with Dupixen

## **OXICONAZOLE NITRATE CREAM**

#### **Products Affected**

oxiconazole

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of one of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, or Epidermophyton floccosum or tinea (pityriasis) versicolor due to Malassezia furfur AND Patient has a documented intolerance to, contraindication, or treatment failure to TWO of the following: clotrimazole 1% cream, econazole nitrate 1% cream, ciclopirox olamine 0.77% cream, or ketoconazole 2% cream.

### **OXYCODONE EXTENDED RELEASE**

#### **Products Affected**

• oxycodone oral tablet,oral only,ext.rel.12 hr 10 mg, 20 mg, 40 mg 20 MG, 30 MG, 40 MG

 OXYCONTIN ORAL TABLET, ORAL ONLY, EXT. REL. 12 HR 10 MG, 15 MG,

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	SEVERE PAIN THAT REQUIRES AN OPIOID ANALGESIC OR CHRONIC SEVERE PAIN IN OPIOID-TOLERANT PATIENTS REQUIRING A LONG-TERM DAILY AROUND-THE-CLOCK OPIOID ANALGESIC: (1) Prescriber attests patient has diagnosis of Severe pain that requires an opioid analgesic or Chronic, severe pain in opioid-tolerant patients requiring a long-term daily around-the-clock opioid analgesic (2) One of the following: (i) Member has had a trial and inadequate clinical response or intolerance to TWO preferred short acting agents (Oxycodone tablet, morphine sulfate tablet, oxycodone/APAP, hydromorphone) (ii) Patient has a need for an abuse-deterrent formulation based upon a history of substance abuse disorder by dissolving in order to inject or snorting (iii) Patient has a need for an abuse-deterrent formulation based upon household resident has active substance abuse disorder or a history of substance use disorder. NOTE: Some plans may require a history of inadequate responsee or intolerance to morphine sulfate ER tablets. For requests for Oxycodone 60mg or 80mg ER tablets, approval also requires: The patient been taking the lower strength Oxycodone ER tablets (10mg, 15mg, 20mg, 30mg, 40mg) and now requires an increase in dose to the 60mg and 80mg tablets? (Patient is tolerant to the lower strength.)

## **OXYMORPHONE EXTENDED RELEASE**

#### **Products Affected**

• oxymorphone oral tablet extended release 12 hr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Moderate and severe hepatic impairment, Paralytic ileus
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. CHRONIC PAIN (1) used for management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time AND (2) not intended for use as a prn analgesic AND (3) trial/failure to ALL of the opioids (hydrocodone/APAP, morphine IR, oxycodone IR, hydromorphone IR, morphine ER) (documentation required) AND (4) An inadequate response, intolerance, or contraindication to both of the following (documentation required): Hysingla ER AND Oxycontin AND (5) Patient has been warned that: Co-administration with alcohol may increase oxymorphone plasma levels and the risk of potentially fatal toxicity AND Opana should be taken on an empty stomach since food can increase the rate of absorption by 50%

## **PALBOCICLIB**

#### **Products Affected**

• IBRANCE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has not experienced disease progression following prior CDK inhibitor therapy

## **PALIPERIDONE**

#### **Products Affected**

INVEGA SUSTENNA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to risperidone
Required Medical Information	None
Age Restrictions	12 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of schizophrenia or schizoaffective disorder; AND Patient has had a trial and failure, intolerance, or contraindication to at least TWO (2) of the following: risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole. For Invega Sustenna, patient has documented issues with compliance and longacting injection is clinically necessary.

## PALIPERIDONE TAB ER

#### **Products Affected**

• paliperidone

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to risperidone
Required Medical Information	None
Age Restrictions	12 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of schizophrenia or schizoaffective disorder; AND Patient has had a trial and failure, intolerance, or contraindication to at least TWO (2) of the following: risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole.

## **PALIVIZUMAB**

#### **Products Affected**

SYNAGIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	1.Any indication other than those listed in Other Criteria due to insufficient evidence of therapeutic value2.Infants with cardiac lesions adequately corrected by surgery (unless pharmacological management is required for CHF)3.Infants with CLD not requiring medical support in the 2nd year of life4.Infants with mild cardiomyopathy, which does not require pharmacotherapy5.Synagis use as routine prophylaxis for any of the following conditions:a.Down syndrome (unless qualifying heart disease, CLD/BPD, airway clearance issues or prematurity [less than 29 weeks, 0 days gestation] is present)b.Nosocomial disease preventionc.Primary asthma prevention (or for reduction of subsequent wheezing episodes) in infants and children6.Synagis use as prophylaxis in any of the following scenarios:a.Outside of RSV "season" as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departmentsb.Dosing in excess of 5 doses per single RSV "season" as defined by Centers for Disease and Prevention (CDC) surveillance reports or state or local health departmentsc.Monthly Synagis administration as prophylaxis post breakthrough RSV hospitalization during the current season (if child had met criteria for palivizumab) 7.Treatment of symptomatic RSV disease
Required Medical Information	See Other Criteria
Age Restrictions	See Other Criteria
Prescriber Restrictions	None
Coverage Duration	Max 5 months of Synagis (15 mg/kg body weight per dose) w/ last dose given in March or per CDC

PA Criteria	Criteria Details
Other Criteria	Synagis is approved for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients who meet at least one of the following criteria:1. Early Preterm Infants a. Infants born before 29 weeks, 0 days gestation and younger than 12 months of age at the start of RSV season 2. Chronic Lung Disease of Prematurity (CLD)/Bronchopulmonary dysplasia (BPD)a. Infants younger than 12 months of age at the start of RSV season:i. Preterm infants who develop CLD/BPD of prematurity (defined as gestational age less than 32 weeks, 0 days AND a requirement for greater than 21% of oxygen for at least the first 28 days after birth)b. Infants between 12: 24 months of age at the start of RSV season: i. Preterm infants who develop CLD/BPD of prematurity (defined as gestational age less than 32 weeks, 0 days AND a requirement for greater than 21% of oxygen for at least the first 28 days after birth) AND continue to require medical intervention (e.g., chronic corticosteroid therapy, diuretic therapy, supplemental oxygen) within the 6-month period before the start of the childs second RSV season3. Hemodynamically significant Congenital Heart Disease (CHD) a. Infants younger than 24 months of age at the start of RSV season with one of the following: i. Acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) AND will require cardiac surgical procedures ii. Cyanotic heart defects iii. Moderate to severe pulmonary hypertension iv. Will undergo cardiac transplantation during RSV season4. Anatomic Pulmonary Abnormalities or Neuromuscular Disorder a. Infants younger than 12 months of age at the start of RSV season with a neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough/swallow5. Immunocompromised statusa. Infants younger than 24 months of age at the start of RSV season and are profoundly immunocompromised during the RSV season i. Examples of severe immunodef

PA Criteria	Criteria Details
	Chemotherapy5. Solid organ or hematopoietic stem cell transplant recipients6. Cystic Fibrosis:a. Infants younger than 12 months of age at the start of RSV season: i. With clinical evidence of CLD/BPD and/or nutritional compromise b. Infants between 12:24 months of age at the start of RSV season: i. For second year treatment, infant has manifestations of severe lung disease including one of the following: 1. Previous hospitalization for pulmonary exacerbation in the first year of life 2. Abnormalities on chest radiography or chest computed tomography that persist when stable3. Weight for length less than the 10th percentile on a pediatric growth chart

## **PANOBINOSTAT**

#### **Products Affected**

FARYDAK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	RENEWAL: Tolerated the first 8 cycles of therapy without any severe or medically significant toxicity

# **PARICALCITOL**

#### **Products Affected**

• paricalcitol oral

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL:HypercalcemiaVitamin D toxicity
Required Medical Information	SECONDARY HYPERPARATHYROIDISMINITIAL:Patients intact parathyroid hormone (iPTH) levels are greater than 240 pg/mL, corrected serum calcium less than 10.5 mg/dL, corrected serum Ca x (times) serum phosphorus less than 70RENEWAL:(1) iPTH greater than 120 pg/mL (or 2 times the upper limit of normal) (2) Corrected serum calcium less than 11.5 mg/dL (3) Corrected serum Ca x (times) serum phosphorus less than 75
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	SECONDARY HYPERPARATHYROIDISMINITIALPatient has a documented diagnosis of secondary hyperparathyroidism due to chronic kidney disease (CKD); AND Patients with CKD stage 5 are currently receiving hemodialysis (HD) or peritoneal dialysis (PD); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to calcitriol or Hectorol oral or injection therapy by demonstrating iPTH level greater than 180 pg/mL; AND Patient development of hypercalcemia (serum calcium greater than 11.5 mg/dL) despite adequate therapy and discontinuance of calcium based phosphate binders.

## PAROXETINE SUSPENSION

#### **Products Affected**

• paroxetine hcl oral suspension

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Patients taking, or within 14 days of stopping, MAOIs (including the MAOIs linezolid and intravenous methylene blue). Concurrent use of thioridazine or pimozide. Known hypersensitivity to paroxetine.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to generic oral paroxetine; AND Patient is unable to ingest solid oral dosage forms due to one of the following: Oral/motor difficulties; OR Dysphagia.

## PASIREOTIDE DIASPARTATE

#### **Products Affected**

SIGNIFOR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	INITIAL: 6 MONTHS. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL: Trial of or contraindication to oral ketoconazole. RENEWAL: (1) Continued improvement of Cushings disease (e.g., clinically meaningful reduction in 24-hour urinary free cortisol and/or improvements in signs and symptoms of disease). (2) Maintains tolerability to Signifor.

## PASIREOTIDE PAMOATE

#### **Products Affected**

SIGNIFOR LAR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	12 months
Other Criteria	ACROMEGALY: Patient has had an inadequate response to surgery OR surgery is not an option; AND Patient has had an inadequate response, intolerance, or contraindication to Lanreotide depot injection (Somatuline Depot) AND a dopamine agonist (e.g., bromocriptine, cabergoline). CUSHINGS DISEASE: Patient has had an inadequate response to surgery OR surgery is not an option.

### **PAZOPANIB**

#### **Products Affected**

VOTRIENT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patient has adipocytic soft tissue sarcoma (STS) or gastrointestinal stromal tumors (GIST)
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### PCSK9

#### **Products Affected**

- PRALUENT PEN
- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None

PA Criteria	Criteria Details
Required Medical Information	INITIAL:HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH):Patient has diagnosis of HeFH confirmed by [documentation req]: A. Simon Broome criteria: Prescriber reports total cholesterol greater than 290mg/dL or greater than 260mg/dL in patients less than 16 yrs, OR LDL cholesterol greater than 190mg/dL or greater than 155mg/dL in patients less than 16 yrs, ANDB. History of tendon xanthomas in ONE of the following: (i) the patient, (ii) patients 1st degree relative (i.e. parent, sibling, or child), or (iii) patients 2nd degree relative (i.e. grandparent, uncle, or aunt) OR C. ONE of the following:(i) Family history of myocardial infarction (MI) in a 1st degree relative less than 60 yrs old, or (iii) Family history of LDL-C greater than 190mg/dL in a 1st or 2nd degree relative ORD. history of arcus cornealis before age of 45 in ONE of the following: (i) the patient or (ii) first or second degree relative B. HeFH diagnosis confirmed by genetic testing of an LDL receptor mutation, familiar defective apoB, or a PCSK9 mutation. HOMOZYGOUS FAMILIAL HYPERCHOLESTSEROLEMIA (HoFH): Clinical diagnosis confirmed ANY one the following: (i) Patient has a documented history of untreated LDL-C greater than 400 mg/dL and 1 or both parents have clinical diagnosed familial hypercholesterolemia (FH) or treated LDL-C greater than 300mg/dL (ii) Prescriber attests genetic evidence of a LDL receptor mutation, familial defective apo B-100, or a PCSK9 mutation or autosomal recessive FH or (iii) LDL-C greater than 400mg/dL with aortic valve disease or (v) LDL-C greater than 400mg/dL with aortic valve disease or (v) LDL-C greater than 400mg/dL with xanthomata at less than 20 yrs of age.CLINICAL ASCVD OR PRIMARY HYPERLIPIDEMIA AT HIGH RISK FOR ASCVD: (1) Prescriber reports: baseline and current LDL-C, AND (2) One of the following: (a) baseline LDL-C is between 70-189mg/dL OR (b) patient requires greater than 25 percent additional lowering of LDL-C.
Age Restrictions	PRALUENT: CVD, HeFH, HoFH: 18 years of age or older.REPATHA: CVD: 18 years of age or older, HeFH and HoFH: 10 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	INITIAL: 12 months, RENEWAL: 12 months

DA Cuitania	Cuitoria Dotoila
PA Criteria	Criteria Details
Other Criteria	INITIAL:HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (HeFH):Prescriber attests that PCSK-9 will be used in combination with a maximally tolerated statin OR prescriber attests that member is statin intolerant and can provide rationale to intolerance or contraindication. HOMOZYGOUS FAMILIAL HYPERCHOLESTSEROLEMIA (HoFH): Prescriber attests that PCSK-9 will be used in combination with a maximally tolerated statin OR prescriber attests that member is statin intolerant and can provide rationale to intolerance or contraindication. CLINICAL ASCVD OR PRIMARY HYPERLIPIDEMIA AT HIGH RISK FOR ASCVD: (1a) Patient has a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) as defined as ONE of the following: a. History of or current acute coronary syndrome, b. myocardial infarction (MI), c. coronary or other arterial revascularization, d. stroke, e. transient ischemic stroke (TIA), f. stable/unstable angina, g. peripheral arterial disease presumed to be atherosclerotic region OR (1b) Patient is at high risk for ASCVD or CV event based on 10-year risk score use by ONE of the following tools: i. ASCVD pooled cohort risk assessment: score greater than or equal to 7.5 percent OR ii. Framingham Risk Score: score greater than or equal to 20 percent, AND (2) (a) Prescriber attests PCSK-9 will be used in combination with a maximally tolerated high-intensity statin OR (b) Prescriber attests that member is statin intolerant, as demonstrated by experiencing: i. Documented statin-associated rhabdomyolysis OR ii. Documented myositis or myalgia related symptoms with either, rosuvastatin, atorvastatin OR another maximally tolerated statin AND (3) Requires LDL-C reduction after at least a 90-day trial of BOTH of the following: (a) high-intensity statin (atorvastatin 40-80mg OR rosuvastatin 20-40mg) or documentation of maximally tolerated statin AND (b) in combination with ezetimibe RENEWAL: ALL INDICATIONS: (1) Documented response, defined as ONE of the following: (a) Prescriber reports percentage reduction of LDL is greater th
	Prescriber reports absolute LDL is less than 70 mg/dL AND (2) Patient is tolerating the medication AND (3) Patient will continue to be used in combination with a maximally tolerated statin or is statin intolerant demonstrated by experiencing (a) Documented statin- associated rhabdomyolysis OR (b) Documented myositis or myalgia related symptoms with either, rosuvastatin, atorvastatin OR another maximally tolerated statin.

# PDE5 INHIBITORS FOR PULMONARY ARTERIAL HYPERTENSION

#### **Products Affected**

- alyq
- sildenafil (pulm.hypertension) oral tablet
- tadalafil (pulm. hypertension)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters: 1) Mean pulmonary artery pressure (PAP) of greater than 20 mmHg, 2) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg, and 3) Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units
Age Restrictions	REVATIO/SILDENAFIL: 18 years of age or older.
Prescriber Restrictions	Prescribed by or given in consultation with a cardiologist or pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: (1) Has NYHA-WHO Functional Class II to IV symptoms, (2) Not concurrently or intermittently taking oral erectile dysfunction agents (e.g. Cialis, Viagra) or any organic nitrates in any form, and (3) Not concurrently taking guanylate cyclase stimulators (e.g. Adempas). RENEWAL: One of the following: 1) Improvement from baseline in the 6-minute walk distance test OR 2) Stable 6-minute walk distance test with a stable or improved World Health Organization functional class.

## **PEGFILGRASTIM**

#### **Products Affected**

- NYVEPRIA
- ZIEXTENZO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	NEULASTA, FULPHILA, UDENYCA, ZIEXTENZO: Trial of or contraindication to Nyvepria where indications align.NEULASTA ONPRO: Patient has barrier to access (e.g., travel barriers, or patient is unable to return to clinic for Neulasta injections)

# PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

#### **Products Affected**

 PEGASYS SUBCUTANEOUS SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL: HEPATITIS B: Cirrhosis
Required Medical Information	INITIAL:HEPATITIS B: (1) Serum HBeAg positive chronic hepatitis B, AND (2) Evidence of viral replication with elevated serum ALT.HEPATITIS C: Detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)
Age Restrictions	HEPATITIS B: 3 years of age or olderHEPATITIS C: 3 to 11 years of age
Prescriber Restrictions	HEPATITIS B: Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model.HEPATITS C: Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
Coverage Duration	INIT/RNWL: HEP B: 24 wk; HEP C: GT 2 or 3: max tot of 24 wk. GT 1, 4, 5, 6: tot of 48 wk

PA Criteria	Criteria Details
Other Criteria	INITIAL: HEPATITIS B: Request is for Pegasys vial, kit, or syringes.HEPATITIS C: (1) Extrahepatic manifestations of hepatitis C such as cryoglobulinemia, rashes, and glomerulonephritis - as well as advanced fibrosis that requires urgent HCV treatment to minimize future morbidity and mortality, AND (2) Use with ribavirin or has a contraindication to ribavirin.RENEWAL: HEPATITIS B: Request is for PegasysHEPATITIS C: (1) Request is for PegIntron, AND (2) Requested medication is being used with ribavirin or has a contraindication to combination therapy with ribavirin

## **PEGVISOMANT**

#### **Products Affected**

SOMAVERT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	ACROMEGALY: INITIAL: Prescriber must provide the following baseline documentation from patient's medical record: (i) Elevated serum IGF-1 level for patients age range and gender ACROMEGALY: RENEWAL: Patient has documented disease response confirmed by reduction of IGF-I blood levels from baseline. AND Serum insulin-like growth factor-I (IGF-I) levels remain outside normal limits.
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	ACROMEGALY: INITIAL: Patient has a diagnosis of Acromegaly; AND Patient has had an inadequate response to surgery or radiation therapy, or documentation that these therapies are not appropriate.

### **PEMETREXED**

### **Products Affected**

• pemetrexed disodium intravenous recon soln

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	History of severe hypersensitivity reaction to pemetrexed. Diagnosis of squamous cell non-small cell lung cancer.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	A. Non-Squamous Non-Small Cell Lung Cancer (NSCLC): 1) The patient has a diagnosis of metastatic non-squamous NSCLC and meets all of the following: a) Pemetrexed will be used in combination with pembrolizumab and platinum chemotherapy for initial treatment and b) The patient does not have EGFR or ALK genomic tumor aberrations; 2) The patient has a diagnosis of locally advanced or metastatic, NSCLC and meets ONE of the following: a) Pemetrexed will be used as initial treatment in combination with cisplatin or carboplatin OR b) Pemetrexed will be used as a single agent for maintenance therapy AND the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy; 3) The patient has a diagnosis of recurrent, metastatic, non-squamous, NSCLC and meets ALL of the following: a) Pemetrexed will be used as a single agent and b) The patient has received prior chemotherapy. B. Malignant mesothelioma: Patient has a diagnosis of malignant mesothelioma AND the patient's disease is unresectable or patient is not a candidate for curative surgery; AND Pemetrexed will be used in combination with cisplatin or carboplatin.

# **PENICILLAMINE**

### **Products Affected**

• penicillamine oral tablet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL:WILSONS DISEASE: One of the following: (1) Plasma copper-protein ceruloplasmin less than 20mg/dL, (2) Liver biopsy positive for abnormally high amount of copper (greater than 250 mcg/d dry weight) or presence of Kayser-Fleischer rings, OR (3) Diagnosis confirmed by genetic testing for ATP7B mutationsCYSTINURIA: Daily cystine output greater than 300mg per 24 hours following urine cystine excretion testing RENEWAL: WILSONS DISEASE: Free serum copper level less than 10 mcg/dLCYSTINURIA: Cystine excretion of less than 200 mg/day
Age Restrictions	None
Prescriber Restrictions	WILSONS DISEASE: Prescribed by or given in consultation with a hepatologist CYSTINURIA: Prescribed by or given in consultation with a nephrologistRHEUMTATOID ARTHRITIS (RA): Prescribed by or given in consultation with a rheumatologist
Coverage Duration	INITIAL: 12 monthsRENEWAL: Lifetime

PA Criteria	Criteria Details
Other Criteria	INITIAL:Request for D-Penamine may be approved without additional criteria met if patient has an active prior authorization approval for Depen: [Note: D-Penamine is temporarily available to address a critical drug shortage of Depen. Patients previously approved for Depen will be allowed access without additional criteria during this shortage.]WILSONS DISEASE: (1) Maintained a low copper diet (less than 2 mg copper per day).(2) Requests for Cuprimine require trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine)CYSTINURIA: (1) Presence of nephrolithiasis and one of the following: (a) Stone analysis positive for cystine, (b) Urinalysis positive for pathognomonic hexagonal cystine crystals, (c) Family history of cystinuria with positive cyanide-nitroprusside screen. (2) Failure to respond to an adequate trial of or contraindication to all of the following conventional therapies: increased fluid intake, modest reductions in sodium and protein intake, and urinary alkalinization.(3) Requests for Cuprimine require trial of or contraindication to Depen (penicillamine) or D-Penamine (penicillamine) AND Thiola (tiopronin)RA: (1) No history of or other evidence of renal insufficiency,(2) Failure to respond to an adequate trial of at least 3 months of conventional therapy including at least ONE of the following DMARD (disease-modifyingantirheumatic drug) agents: methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine. (3) Requests for Cuprimine require trial of or contraindication to Depen or D-PenamineRENEWAL: RA: 1) No history of or other evidence of renal insufficiency 2) Experienced or maintained improvement in tender joint count or swollen joint count while on therapy compared to baseline

## PENTOSAN POLYSULFATE

### **Products Affected**

• ELMIRON

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	INITIAL: 6 months. RENEWAL: Lifetime IL: Initial: 12 months Renewal: Lifetime
Other Criteria	INITIAL: Interstitial cystitis/bladder pain syndrome ongoing for at least six weeks. RENEWAL: Clinical improvement from baseline secondary to treatment

### **PERAMPANEL**

#### **Products Affected**

FYCOMPA ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Primary Generalized Tonic-Clonic Seizures: 12 years of age or older, Partial-onset seizures: 4 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of partial-onset seizures; AND (2) Patient has had a trial and failure, intolerance, or contraindication to at least TWO (2) antiepileptic drugs; OR History Vagal Nerve Stimulator (VNS) implantation or lobectomy; OR Patient has a diagnosis of primary generalized tonic-clonic seizures; AND Patient has had a trial and failure, intolerance, or contraindication to valproate (Depakote, Depakote ER, Depakene); AND Patient will be using Fycompa in combination with other antiepileptic medications

## **PHENOXYBENZAMINE**

#### **Products Affected**

• phenoxybenzamine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, an endocrine surgeon, or a hematologist/oncologist
Coverage Duration	21 days
Other Criteria	(1) Requested for treatment of pheochromocytoma prior to pheochromocytoma resection/removal. (2) Trial of or contraindication to an alpha-1 selective adrenergic receptor blocker (such as doxazosin, terazosin, or prazosin).

## PHOSPHATE BINDERS

#### **Products Affected**

- lanthanum
- sevelamer carbonate oral powder in packet
- sevelamer hcl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Sevelamer carbonate/sevelamer HCl/lanthanum carbonate: Patients with bowel obstruction. Sevelamer carbonate ONLY: Patients with known hypersensitivity to sevelamer carbonate or sevelamer hydrochloride.
Required Medical Information	None
Age Restrictions	Sevelamer carbonate: 6 years of age and older. All others: 18 years of age and older.
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	For sevelamer carbonate powder packet/sevelamer HCL/Velphoro: patient has a diagnosis of chronic kidney disease (CKD); AND Patient is on dialysis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to sevelamer carbonate tablets. For lanthanum carbonate: patient has a diagnosis of end-stage renal disease (ESRD); AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to sevelamer carbonate tablets.

## **PIMECROLIMUS**

### **Products Affected**

• pimecrolimus

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	2 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	(1) Diagnosis of mild to moderate atopic dermatitis AND (2) Patient is not immunocompromised AND (3) Patient had a documented trial and failure, intolerance, or contraindication to at least ONE formulary topical corticosteroid (e.g., hydrocortisone, amcinonide, betamethasone, clobetasol, desoximetasone, fluocinolone, triamcinolone) OR (4) Elidel will be used on the face, body skin folds, genital area, armpit, or around the eyes AND (5) Patient has had a documented trial and failure, intolerance, or contraindication to tacrolimus ointment.

## **PIRFENIDONE**

#### **Products Affected**

- ESBRIET ORAL CAPSULE
- pirfenidone oral tablet 267 mg, 801 mg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: (1) Usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT. (2) Predicted forced vital capacity (FVC) of at least 50% at baseline
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INTIAL: (1) No other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer). (2) Patient does not currently smoke cigarettes. RENEWAL: Clinically meaningful improvement or maintenance in annual rate of decline

### **PKU**

#### **Products Affected**

- MSUD EXPRESS15
- PHENYLADE 40
- PHENYLADE AMINO ACIDS
- PHENYLADE MTE AMINO ACIDS
- PKU AIR20
- PKU COOLER 10
- PKU COOLER 15
- PKU COOLER 20

- PKU EXPRESS15
- PKU EXPRESS20
- PKU GEL POWDER
- PKU GO
- PKU SPHERE15
- PKU SPHERE20 ORAL POWDER IN PACKET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Male: 21 years of age or younger, Female: 35 years of age or younger
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	PHENYLKETONURIA (1) Patient has diagnosis of Phenylketonuria

## **PLECANATIDE**

#### **Products Affected**

TRULANCE

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	SEVERE CHRONIC IDIOPATHIC CONSTIPATION AND IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (1) Prescriber attests patient has diagnosis of Severe Chronic Idiopathic Constipation or Irritable Bowel Syndrome with Constipation (2) Trial and failure, intolerance, or contraindication to Linzess (3) An inadequate response to at least one agent from within each of the following laxative types: (i) Fiber laxatives (psyllium, methylcellulose, calcium polycarbophil) (ii) Stimulant laxatives (bisacodyl, Senna) (iii) Osmotic laxatives (polyethylene glycol, milk of magnesia, sorbitol, lactulose)

## **POMALIDOMIDE**

### **Products Affected**

POMALYST

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## **PONATINIB**

#### **Products Affected**

• ICLUSIG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	CML and Ph+ ALL: 18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	T315I-Positive CML (chronic phase, accelerated phase, or blast phase): The patinet has had a mutational analysis prior to initiation and Iclusig is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL 1 mutation profileCHRONIC PHASE CML: The patient has a resistance or intolerance to at least two prior kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)].ACCELERATED OR BLAST PHASE CML: No other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] are indicated for the patient. Ph+ ALL: 1) Patient's cancer is positive for the T315l mutation and 2) No other kinase inhibitors [e.g., Tasigna (nilotinib), Sprycel (dasatinib), Bosulif (bosutinib), Gleevec (imatinib)] are indicated for the patient

## **POSACONAZOLE**

### **Products Affected**

posaconazole

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Known hypersensitivity to posaconazole or other azole antifungal agents. Concomitant administration of sirolimus, ergot alkaloids (ergotamine and dihydroergotamine), HMG-CoA reductase inhibitors (e.g., atorvastatin, lovastatin, and simvastatin), CYP3A4 substrates that prolong the QT interval (e.g., pimozide and quinidine).
Required Medical Information	TREATMENT OF INVASIVE ASPERGILLUSPatient has diagnosis of clinically documented invasive aspergillosis, that is susceptible to posaconazole confirmed by fungal culture and other relevant laboratory studies (including histopathology) with isolated and identified causative organisms
Age Restrictions	INVASIVE ASPERGILLOSIS: 13 years of age and olderPROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS: adults and pediatric patients 2 years of age and older who weigh greater than 40 kg
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	6 months
Other Criteria	TREATMENT OF INVASIVE ASPERGILLUS: Patient has had a trial and therapeutic failure of voriconazole AND amphotericin B.PROPHYLAXIS OF INVASIVE ASPERGILLUS AND CANDIDA INFECTIONS: Patient is recipient of hematopoetic stem cell transplant (HSCT) with Graft-vs-Host Disease (GVHD) and who is at risk of developing invasive Aspergillus fumigatus and/or Candida infections OR (2) Patient has hematological malignancies causing prolonged neutropenia from chemotherapy and who is at risk of developing Aspergillus fumigatus and/or Candida infections

## **PRAMLINTIDE**

#### **Products Affected**

- SYMLINPEN 120
- SYMLINPEN 60

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypoglycemia unawareness.Confirmed gastroparesis.
Required Medical Information	Hgb A1C
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	12 months
Other Criteria	Patient utilizes both basal and short-acting insulin OR Patient uses an insulin pump; AND Patient has failed to achieve desired glucose control despite optimal insulin therapy.

## **PRASTERONE**

#### **Products Affected**

INTRAROSA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Undiagnosed abnormal genital bleeding.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	INITIAL: 3 months. RENEWAL: 12 months IL: 12 months
Other Criteria	INITIAL:Patient has a diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause; AND Patient has tried and failed two vaginal lubricants or vaginal moisturizers; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to a 4 week trial of two vaginal estrogen products (e.g., Estrace vaginal cream, Premarin vaginal cream, Vagifem, Estring).RENEWAL: Patient has had a response to therapy (decrease in symptoms of dyspareunia) as determined by prescriber.INITIAL/RENEWAL: Dose must not exceed 1 vaginal insert daily

# **PRAZIQUANTEL**

### **Products Affected**

praziquantel

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with ocular cysticercosis. Patients taking strong Cytochrome P450 (CYP450) inducers, such as rifampin.
Required Medical Information	None
Age Restrictions	1 year of age and older.
Prescriber Restrictions	Prescribed by, or in consultation with, an infectious disease specialist.
Coverage Duration	7 days.
Other Criteria	Patient has a documented diagnosis of Schistosomiasis due to a species of schistosoma (for example, Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni and Schistosoma hematobium); OR Patient has a documented diagnosis of Clonorchiasis or Opisthorchiasis due to the liver flukes, Clonorchis sinensis/Opisthorchis viverrini.

## **PROCARBAZINE**

### **Products Affected**

MATULANE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with inadequate marrow reserve as demonstrated by bone marrow aspiration.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, a Hematologist or Oncologist
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of Stage III and IV Hodgkins disease; AND Matulane will be used as part of the MOPP (nitrogen mustard, vincristine, procarbazine, prednisone) regimen.

# **PROGESTERONE (4%)**

### **Products Affected**

· CRINONE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL:12 months
Other Criteria	INITIAL:SECONDARY AMENORRHEA: (1) Prescriber attests to diagnosis of secondary amenorrhea AND (2) Clinical trial and failure to one alternative progestin (e.g., medroxyprogesterone, norethindrone) unless contraindicated or clinically significant adverse effects are experienced. RENEWAL:SECONDARY AMENORRHEA: (1) Currently receiving medication via health plan benefit or member has previously met initial approval criteria AND (2) Prescriber attests to a positive response to therapy.

# **PROGESTERONE (8%)**

### **Products Affected**

· CRINONE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications unless otherwise excluded from benefit . Prevention of preterm birth will also be considered for approval.
Exclusion Criteria	Diagnoses excluded from benefit.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL:12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL:SECONDARY AMENORRHEA: (1) Prescriber attests to diagnosis of secondary amenorrhea (2) Clinical trial and failure to one alternative progestin (e.g., medroxyprogesterone, norethindrone) unless contraindicated or clinically significant adverse effects are experienced PREVENTION OF PRETERM BIRTH: (1) Prescriber attests that this is used in prevention of preterm birth (2) Documentation of one of the following (2a) short cervix OR (2b) Singleton pregnancy and a history of spontaneous preterm birthLUTEAL PHASE SUPPORT (I.E. HISTORY OF SPONTANEOUS ABORTIONS): (1) Prescriber attests to this being used in luteal phase support RENEWAL:Currently receiving medication via health plan benefit or member has previously met initial approval criteria AND (2) Request is for Crinone 8% AND (3) Prescriber attests to a positive response to therapy FERTILITY COVERAGE DEPENDENT UPON BENEFIT COVERAGE (Not covered by plan if fertility is an excluded benefit): ASSISTED REPRODUCTIVE TECHNOLOGY (ART) TREATMENT: (1) Must meet one of the following (1a) Use as ART treatment for infertile women with progesterone deficiency OR (1b) Use in ART treatment in patients with partial or complete ovarian failure OR (1c) For support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an ART treatment program for infertile women

### **PYRAZINAMIDE**

### **Products Affected**

• pyrazinamide

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Patients with severe hepatic damagePatients with acute gout
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, an Infectious Disease specialist
Coverage Duration	2 months
Other Criteria	Patient has a documented diagnosis of active tuberculosis; AND pyrazinamide will be used in combination with other antituberculous agents; AND prescribed dosing and duration are within the current CDC and American Thoracic Society guidelines

## **PYRIDOSTIGMINE**

### **Products Affected**

• pyridostigmine bromide oral syrup

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Mechanical intestinal or urinary obstruction
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of myasthenia gravis; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to pyridostigmine oral tablets.

## **PYRIMETHAMINE**

#### **Products Affected**

• pyrimethamine

PA Criteria	Criteria Details
Covered Uses	Toxoplasmosis (Treatment and prophylaxis). Pneumocystis Pneumonia (primary and secondary prophylaxis).
Exclusion Criteria	Patients with documented megaloblastic anemia due to folate deficiency
Required Medical Information	TOXOPLASMOSIS Chart notes/medical records required for all of the below.PRIMARY PROPHYLAXIS FOR TOXOPLASMIC ENCEPHALITIS:(1a) patient is Toxoplasma IgG positive; AND (1b) Patient has a documented CD4 less than or equal to 100 cells/mm3 if initiating prophylaxis OR CD4 less than 100-200 cells/mm3 if reinstituting prophylaxis
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	PRIMARY PROPHYLAXIS: 6 mo.TREATMENT AND SECONDARY PROPHYLAXIS: 12 mo.

PA Criteria	Criteria Details
Other Criteria	TOXOPLASMOSIS Chart notes/medical records required for all of the below.(1) Patient has a documented diagnosis of active severe acquired toxoplasmosis (including toxoplasmic encephalitis and congenital toxoplasmosis); OR(2) Pyrimethamine is being used for secondary prophylaxis of toxoplasmic encephalitis; OR (3) Pyrimethamine is being used for primary prophylaxis for toxoplasmic encephalitis; AND 3a) pyrimethamine will be used in combination with dapsone or atovaquone; AND 3b) Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX); AND 3c) Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate; OR 3d) Patient has experienced a moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome).PNEUMOCYSTIS PNEUMONIA (PCP)(1a) Pyrimethamine is being used as primary Pneumocystis Pneumonia (PCP) prophylaxis in an HIV infected patient; OR (1b) pyrimethamine is being used as secondary prophylaxis in an HIV infected patient who has been treated for an acute episode of Pneumocystis Pneumonia; AND (2) Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX); AND (3a) Patient has been rechallenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate; OR (3b) Patient has experienced a moderately severe or life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome).

## **RANOLAZINE**

### **Products Affected**

ranolazine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Concurrent use with strong inhibitors of CYP3A and inducers of CYP3A Patients with clinically significant hepatic impairment
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, a cardiologist
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of Chronic Angina; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to ALL of the following at maximum tolerated dosages (medication usage must be supported by documentation from the patients chart notes/medical records/electronic claim history): calcium channel blocker, betablocker, nitrate.

### **RETAPAMULIN**

### **Products Affected**

ALTABAX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	9 months of age and older.
Prescriber Restrictions	None
Coverage Duration	12 months.
Other Criteria	Patient has a diagnosis of impetigo; AND Patient has a documented intolerance, contraindication, or treatment failure with, an adequate trial of mupirocin 2% ointment

### **RIBOCICLIB**

#### **Products Affected**

KISQALI ORAL TABLET 200
 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	none
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	KISQALI-FEMARA CO-PACK:Patient has not experienced disease progression following prior CDK inhibitor therapyIf request is for post-menopausal patient: Trial of Ibrance (palbociclib) or Verzenio (abemaciclib) is required. KISQALI: Patient has not experienced disease progression following prior CDK inhibitor therapyIf request is for use in combination with an aromatase inhibitor in post-menopausal patient: Trial of Ibrance (palbociclib) or Verzenio (abemaciclib) is required. If request is for use in combination with Faslodex (fulvestrant) after disease progression on endocrine therapy in post-menopausal patient: Trial of Ibrance (palbociclib) or Verzenio (abemaciclib) is required.

## **RIFABUTIN**

### **Products Affected**

• rifabutin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Hypersensitivity to rifabutin or to any other rifamycins.
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	Initial:Patient has diagnosis of advanced HIV infection; Patient requires MAC prophylaxis confirmed by documented CD4+ count remains less than 100 cells/mcL; AND For primary prophylaxis patient has had a trial and failure, intolerance, or contraindication to both clarithromycin and azithromycin; OR For secondary prophylaxis, rifabutin will be used in combination with ethambutol plus clarithromycin or azithromycin. Renewal:Patients CD4+ count remains less than 100 cells/mcL

# RIFAXIMIN (200 mg)

#### **Products Affected**

• XIFAXAN ORAL TABLET 200 MG

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Xifaxan 200mg: Hepatic encephalopathy (HE), Clostridium difficile infection (CDI)
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	TRAVELERS DIARRHEA: 12 years of age or older
Prescriber Restrictions	CLOSTRIDIUM DIFFICILE INFECTION: Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	INIT:HE: 200mg: 10 d TRVLRS DIARR: 3 dC.DIFF: 20 d
Other Criteria	INITIAL: HEPATIC ENCEPHALOPATHY: Concurrent use with lactulose AND request is for Xifaxan 200mg tablets.TRAVELERS DIARRHEA: (1) Trial of or contraindication to oral azithromycin, ciprofloxacin, ofloxacin, or levofloxacin, AND (2) Request is for Xifaxan 200mg tablets.CLOSTRIDIUM DIFFICILE INFECTION: (1) Had at least one previous occurrence of Clostridium difficile infection, AND (2) Use in combination with vancomycin.RENEWAL: Refer to Initial Criteria.

# RIFAXIMIN (550 mg)

#### **Products Affected**

• XIFAXAN ORAL TABLET 550 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	HEPATIC ENCEPHALOPATHY: Xifaxan 550mg: 18 years of age or older.IRRITABLE BOWEL SYNDROME WITH DIARRHEA: 18 years of age or older
Prescriber Restrictions	HEPATIC ENCEPHALOPATHY: Prescribed by or in consultation with a hepatologist.IRRITABLE BOWEL SYNDROME WITH DIARRHEA: Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	INIT:HE: 550mg: 12 m IBS: 8 wRNWL:HE, IBS: 12 m
Other Criteria	INITIAL: HEPATIC ENCEPHALOPATHY: One of the following: 1) Trial of lactulose or currently on lactulose monotherapy AND request is for Xifaxan 550mg tabletsIRRITABLE BOWEL SYNDROME WITH DIARRHEA: (1) Trial of or contraindication to tricyclic anti-depressants or dicyclomine, AND (2) Request is for Xifaxan 550mg tablets.RENEWAL: HEPATIC ENCEPHALOPATHY: Patient is being treated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence.IRRITABLE BOWEL SYNDROME WITH DIARRHEA: 1) At least 6 weeks have passed since the last treatment course of rifaximin AND 2) Patient has experienced at least 30% decrease in abdominal pain (on a 0-10 point pain scale), AND 3) Patient has experienced at least 50% reduction in the number of days per week with a stool consistency of mushy stool (Bristol Stool scale type 6) or entirely liquid stool (Bristol Stool scale type 7) AND 4) Request is for Xifaxan 550mg tablets

### **RILONACEPT**

### **Products Affected**

ARCALYST

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	CAPS/Recurrent Pericarditis: 12 years of age or older. DIRA: 18 years of age or older OR weighs at least 10 kg
Prescriber Restrictions	CAPS/DIRA: Prescribed by, or in consultation with, a rheumatologist or immunologistRecurrent Pericarditis: Prescribed by or in consultation with a rheumatologist, immunologist, or cardiologist
Coverage Duration	12 months
Other Criteria	None

### **RIMEGEPANT**

#### **Products Affected**

NURTEC ODT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	PREVENTION: The medication will be used concurrently with other CGRP inhibitors (e.g., Ajovy, Aimovig, Emgality, Vyepti, Qulipta) for migraine prevention).
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INIT. 6 mo, RENWL: 12 mo. IL: Initial Acute Migraine Tx: 6 mo, all others: 12 mo
Other Criteria	INITIAL: ACUTE MIGRAINE TREATMENT: Trial of or contraindication to ONE triptan (e.g., sumatriptan, rizatriptan). EPISODIC MIGRAINE PREVENTION: Trial of or contraindication to ONE preventive migraine treatment (e.g., divalproex sodium/sodium valproate, topiramate, propranolol, timolol, metoprolol, amitriptyline, venlafaxine, atenolol, nadolol)RENEWAL: ACUTE MIGRAINE TREATMENT: 1) Improvement from baseline in a validated acute treatment patient-reported outcome questionnaire OR 2) Clinical improvement as defined by ONE of the following: a) Ability to function normally within 2 hours of dose, b) Headache pain disappears within 2 hours of dose, or c) Therapy works consistently in majority of migraine attacks. EPISODIC MIGRAINE PREVENTION: 1) Reduction in migraine or headache frequency of at least 2 days per month, OR 2) Reduction in migraine severity or migraine duration.

## **RIOCIGUAT**

#### **Products Affected**

ADEMPAS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP I: INITIAL: Confirmatory diagnosis based on right heart catheterization with the following parameters: 1) Mean pulmonary artery pressure (PAP) greater than 20 mmHg, 2) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg, 3) Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units. NYHA-WHO functional class II-IV symptoms. CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH) WHO GROUP 4: INITIAL: NYHA-WHO functional class II-IV Symptoms.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: PAH: Not concurrently taking nitrate or nitric oxide donors, phosphodiesterase inhibitors, or non-specific phosphodiesterase inhibitors. CTEPH: (1) Not concurrently taking nitrate or nitric oxide donors, phosphodiesterase inhibitors, or non-specific phosphodiesterase inhibitors. (2) Patient has persistent or recurrent disease after surgical treatment OR is not a candidate for surgery or has inoperable CTEPH. RENEWAL: PAH/CTEPH: (1) Improvement from baseline in the 6-minute walk distance, OR (2) Stable 6-minute walk distance and a stable or improved World Health Organization (WHO) functional class.

### RISANKIZUMAB-RZAA

#### **Products Affected**

SKYRIZI

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	PsO: Prescribed by or in consultation with a dermatologist.PsA: Prescribed by or in consultation with a rheumatologist or dermatologistCD: Prescribed by or in consultation with a gastroenterologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months IL: 12 months
Other Criteria	INITIAL: PsO: Psoriasis covering 3% or more of body surface area or psoriatic lesions affecting the hands, feet, genital area, or face. Previous trial of or contraindication at least one conventional therapy such as a PUVA (phototherapy ultraviolet light a), UVB (ultraviolet light b), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. CD: The patient must have had a trial of or contraindication to ONE conventional agent such as corticosteroids (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine. PsA: trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazineRENEWAL: PsO: Achieved or maintained clear or minimal disease, OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy. PsA: Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

## **ROLAPITANT**

### **Products Affected**

VARUBI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients taking CYP2D6 substrates with a narrow therapeutic index, such as thioridazine and pimozide.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	6 months IL: 12 months
Other Criteria	Patient is using Varubi for prevention of delayed nausea and vomiting AND Patient is receiving highly or moderately emetogenic chemotherapy (see HEC/MEC list below); AND Patient is using Varubi in combination with a 5-HT3 receptor antagonist such as ondansetron or granisetron; AND Patient is using Varubi in combination with a corticosteroid such as dexamethasone. Highly Emetogenic Chemotherapy (HEC) includes: Carboplatin, Carmustine, Cisplatin, Cyclophosphamide, Dacarbazine, Doxorubicin, Epirubicin, Ifosfamide, Mechlorethamine, Streptozocin. Moderately Emetogenic Chemotherapy (MEC) includes: Aldesleukin, Amifostine, Arsenic Trioxide, Azacitidine, Bendamustine, Busulfan, Clofarabine, Cytarabine, - Dactinomycin, Daunorubicin, Dinutuximab, Idarubicin, Interferon alfa, Irinotecan, Melphalan, Methotrexate, Oxaliplatin, Temozolomide, TrabectedinThe following regimens can be considered HEC: FOLFOX.

## **ROTIGOTINE**

#### **Products Affected**

NEUPRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a diagnosis of Parkinsons disease OR restless leg syndrome; AND one of the following: 1) Patient has had a trial and therapeutic failure, intolerance, or contraindication to generic oral pramipexole AND oral ropinirole; OR 2) Patient is unable to ingest solid oral dosage forms due to one of the following: Oral/motor difficulties; OR Dysphagia.

## **RUXOLITINIB**

### **Products Affected**

JAKAFI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	INTERMEDIATE OR HIGH-RISK MYELOFIBROSIS, POLYCYTHEMIA VERA: 18 years of age or older.STEROID- REFRACTORY ACUTE GRAFT-VERSUS-HOST DISEASE, CHRONIC GRAFT-VERSUS-HOST DISEASE: 12 years of age or older
Prescriber Restrictions	None
Coverage Duration	MYELOFIBROSIS: INIT: 6 mo. RNWL: 12 mo. PV, ACUTE GvHD, CHRONIC GvHD: 12 mo. IL: 12 mo
Other Criteria	POLYCYTHEMIA VERA: INITIAL: Trial of or contraindication to hydroxyurea.MYELOFIBROSIS: RENEWAL: Patient shows symptom improvement by meeting ONE of the following: (1) 50% or greater reduction in total symptom score (such as Myeloproliferative Neoplasm Symptom Assessment Form [MPN-SAF TSS], modified Myelofibrosis Symptom Assessment Form [MFSAF] v2.0), (2) 50% or greater reduction in spleen length, OR (3) spleen volume reduction of 35% or greater from baseline.

## SARGRAMOSTIM

#### **Products Affected**

• LEUKINE INJECTION RECON SOLN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	ACUTE MYELOID LEUKEMIA FOLLOWING INDUCTION CHEMOTHERAPY: 55 years of age or older.AUTOLOGOUS PERIPHERAL BLOOD PROGENITOR CELL MOBILIZATION AND COLLECTION: 18 years of age or older.AUTOLOGOUS PERIPHERAL BLOOD PROGENITOR CELL AND BONE MARROW TRANSPLANTATION: 2 years of age or older.ALLOGENEIC OR AUTOLOGOUS BONE MARROW TRANSPLANTATION: 2 years of age or older.
Prescriber Restrictions	None
Coverage Duration	3 months or requested duration of treatment up to 1 year
Other Criteria	Leukine requests prescribed by or given in consultation with a hematologist or oncologist are excepted from the PA criteria.

### **SECUKINUMAB**

#### **Products Affected**

- · COSENTYX
- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA): ONE of the following objective signs of inflammation: (1) C-reactive protein (CRP) levels above the upper limit of normal OR (2) Sacroiliitis on magnetic resonance imaging (MRI)
Age Restrictions	PLAQUE PSORIASIS (PsO): 6 years of age or olderPSORIATIC ARTHRITIS (PsA): 2 years of age or older ANKYLOSING SPONDYLITIS (AS), NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (nr-axSpA): 18 years of age or olderENTHESITIS-RELATED ARTHRITIS (ERA): 4 years of age or older
Prescriber Restrictions	PsO: Prescribed by or in consultation with a dermatologist.PsA: Prescribed by or in consultation with a rheumatologist or dermatologistAS/nr-axSpA, ERA: Prescribed by or in consultation with a rheumatologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: PsO: Moderate to severe plaque psoriasis covering 3% or more of body surface area or psoriatic lesions affecting the hands, feet, genital area, or face. Trial of or contraindication to at least one conventional therapy such as a PUVA (phototherapy ultraviolet light a), UVB (ultraviolet light b), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. PsA: (1) Trial of or contraindication to one DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine. (2) Request of 300mg dosing schedule requires trial of 150mg dosing schedule AND patient continue to have active psoriatic arthritisAS: (1) Trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.). (2) Request of 300mg dosing schedule requires trial of 150mg dosing schedule AND patient continue to have active psoriatic arthritis.nr-axSpA: Trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.) ERA: Trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.), sulfasalazine, OR methotrexateRENEWAL: PsO: Patient achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more while on therapy.PsA: Patient experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.AS/nr-axSpA: Patient experienced or maintained an improvement of at least 50% or 2 units (scale of 1 - 10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) while on therapyERA: Patient has experienced or maintained an improvement in global assessment of disease activity, functional ability, number of joints with active arthritis, OR number of joints with limited range of motion

### **SELEXIPAG**

### **Products Affected**

• UPTRAVI ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: (1) Documented confirmatory pulmonary arterial hypertension (PAH) diagnosis based on right heart catheterization with the following parameters: a) Mean pulmonary artery pressure (PAP) greater than 20 mmHg, b) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg, and c) Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units. (2) NYHAWHO Functional Class II-IV symptoms.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	INITIAL/RENEWAL: 12 months
Other Criteria	INITIAL: WHO FUNCTIONAL CLASS II OR III SYMPTOMS: Trial or contraindication to TWO agents from the following different drug classes: 1) Oral endothelin receptor antagonist, 2) Oral phosphodiesterase-5 inhibitor, 3) Oral cGMP stimulator. WHO FUNCTIONAL CLASS III SYMPTOMS WITH EVIDENCE OF RAPID PROGRESSION/POOR PROGNOSIS, OR WHO FUNCTIONAL CLASS IV SYMPTOMS: Trial or contraindication to ONE intravenous or subcutaneous prostacyclin. RENEWAL: (1) Improvement from baseline in the 6-minute walk distance, OR (2) Stable 6-minute walk distance and a stable or improved World Health Organization (WHO) functional class.

### **SELINEXOR**

#### **Products Affected**

 XPOVIO ORAL TABLET 60MG TWICE WEEK (120 MG/WEEK)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## SERTACONAZOLE NITRATE

### **Products Affected**

ERTACZO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has a documented diagnosis of interdigital tinea pedis caused by Trichophyton rubrum, Trichophyton mentagrophytes, or Epidermophyton floccosum; AND Patient is not immunocompromised; AND Patient has had a trial and therapeutic failure, intolerance, or contraindication to TWO (2) of the following: clotrimazole 1% cream, econazole nitrate 1% cream, or ketoconazole 2% cream

## **SILODOSIN**

#### **Products Affected**

• silodosin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Severe renal impairment (CCr less than 30 mL/min)Severe hepatic impairment (Child-Pugh score greater than 10)Concomitant administration with strong Cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ketoconazole, clarithromycin, itraconazole, ritonavir)
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of Benign Prostatic Hyperplasia (BPH); AND Patient has had a trial and failure, contraindication, or intolerance to at least TWO of the following: (i) tamsulosin (ii) doxazosin (iii) alfuzosin (iv) terazosin.

## **SIROLIMUS**

#### **Products Affected**

• sirolimus

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	LYMPHANGIOLEIOMYOMATOSIS (LAM): Prescriber attests patient has diagnosis of Lymphangioleiomyomatosis (LAM) confirmed by lung biopsy or HRCT showing cystic lung disease
Age Restrictions	LAM: 18 years of age or older
Prescriber Restrictions	RENAL TRANSPLANT: Prescribed by or in consultation with a transplant specialist.LAM: Prescribed by, or in consultation with, a pulmonologist.
Coverage Duration	12 months
Other Criteria	PROPHYLAXIS OF ORGAN REJECTION IN RENAL TRANSPLANTS: The patient has had a trial and failure on an antirejection regimen containing at least two (2) of the following: (a) cyclosporine (b) tacrolimus (c) azathioprine (d) mycophenolate mofetil/sodium LYMPHANGIOLEIOMYOMATOSIS (LAM): Patient has one of the following conditions: (i) Diagnosis of Tuberous Sclerosis Complex (TSC) (ii) Chylous Pleural Effusion (iii) Angioleiomyoma

## SOFOSBUVIR/VELPATASVIR

#### **Products Affected**

• EPCLUSA

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	(1) Currently taking any of the following medications: amiodarone, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifampin, rifabutin, rifapentine, efavirenz-containing HIV regimens, rosuvastatin at doses above 10mg, tipranavir/ritonavir, topotecan, sofosbuvir (Sovaldi) (as a single agent), ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier), pibrentasvir/glecaprevir (Mavyret), or velpatasvir/sofosbuvir/voxilaprevir (Vosevi). (2) Has a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
Required Medical Information	Chronic HCV infection documented by at least ONE detectable HCV RNA level within the last 6 months
Age Restrictions	3 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	Coverage duration will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

### SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR

#### **Products Affected**

VOSEVI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	(1) Currently taking any of the following medications: amiodarone, rifampin, carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifapentine, HIV regimen containing atazanavir, lopinavir, tipranavir/ritonavir, or efavirenz, rosuvastatin, pitavastatin, pravastatin (at doses above 40mg), cyclosporine, methotrexate, mitoxantrone, imatinib, irinotecan, lapatinib, sulfasalazine, topotecan, sofosbuvir (Sovaldi) (as a single agent), velpatasvir/sofosbuvir (Epclusa), ledipasvir/sofosbuvir (Harvoni), elbasvir/grazoprevir (Zepatier), or pibrentasvir/glecaprevir (Mavyret). (2) Moderate to severe hepatitis impairment (Child-Pug B or C). (3) Has limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
Required Medical Information	Current HCV infection documented by at least ONE detectable HCV RNA level within the last 6 months
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist, infectious disease specialist, physician specializing in the treatment of hepatitis (for example, a hepatologist), or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
Coverage Duration	Coverage duration will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

## **SOLRIAMFETOL**

### **Products Affected**

• SUNOSI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, psychiatrist, or specialist in sleep medicine
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	EXCESSIVE DAYTIME SLEEPINESS (EDS) WITH NARCOLEPSY: INITIAL: (1) Narcolepsy is confirmed by ONE of the following: a) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND 2 or more early-onset rapid eye movement (REM) sleep test periods (SOREMPs), b) Multiple Sleep Latency Test (MSLT) showing both a mean sleep latency of 8 minutes or less AND one early-onset rapid eye movement (REM) sleep test period (SOREMP) AND additionally one SOREMP (within approximately 15 minutes) on a polysomnography the night preceding the MSLT, with the polysomnography ruling out non-narcolepsy causes of excessive daytime sleepiness (EDS), OR c) Low orexin (aka hypocretin) levels on a cerebrospinal fluid (CSF) assay. (2) Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10. (3) Trial of or contraindication to one amphetamine derivative (e.g., amphetamine sulfate, methylphenidate, etc.) AND modafinil or armodafinil. RENEWAL: Demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline. EXCESSIVE DAYTIME SLEEPINESS (EDS) WITH OBSTRUCTIVE SLEEP APNEA (OSA): INITIAL: (1) OSA confirmed by one of the following: a) polysomnography, b) home sleep apnea testing devices, or c) hospital-based bedside monitoring. (2) Excessive Daytime Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness (EDS) persisting for at least 3 months and Epworth Sleepiness Scale (ESS) score of more than 10. (3) Trial of or contraindication to modafinil or armodafinil. (4) Receiving ongoing treatment to address the obstructive causes of OSA, for at least one month since initiation, and has been counseled on weightloss intervention (if BMI greater than 30). RENEWAL: Demonstrated 25% or more improvement in Epworth Sleepiness Scale (ESS) scores compared to baseline

## **SOMATROPIN**

#### **Products Affected**

NORDITROPIN FLEXPRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: SEROSTIM, ZORBTIVE: Prescribed for athletic enhancement or anti-aging purposes. GENOTROPIN, HUMATROPE, NORTIDROPIN FLEXPRO, NUTROPIN AQ NUSPIN, OMNITROPE, SAIZEN, ZOMACTON: Prescribed for athletic enhancement, anti-aging purposes, or idiopathic short stature.
Required Medical Information	INITIAL:HIV WASTING/CACHEXIA:ONE of the following criteria for weight loss: 10% unintentional weight loss over 12 months7.5% unintentional weight loss over 6 months5% body cell mass (BCM) loss within 6 monthsBCM less than 35% (men) AND a body mass index (BMI) less than 27 kg per meter squaredBCM less than 23% (women) of total body weight AND a body mass index (BMI) less than 27 kg per meter squaredBMI less than 18.5 kg per meter squaredPEDIATRIC GROWTH HORMONE DEFICIENCY (GHD): (1) Epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), and (2) ONE of the following criteria for short stature: a) Height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender, b) Height velocity less than the 25th percentile for age, or c) Documented low peak growth hormone (less than 10ng/mL) on two GH stimulation tests or insulin-like growth factor 1 (IGF-1) greater than or equal to 2 SD below the mean for age and gender.TURNER SYNDROME, NOONAN SYNDROME, SMALL GESTATIONAL AGE (SGA), SHOX DEFICIENCY:(1) Epiphyses are NOT closed (as confirmed by radiograph of the wrist and hand), and (2) Height greater than or equal to 2 standard deviations (SD) below the mean height for normal children of the same age and gender. PRADER-WILLI SYNDROME (PWS): (1) Confirmed genetic diagnosis of PWS. GROWTH FAILURE SECONDARY TO CHRONIC KIDNEY DISEASE (CKD): (1) Height or growth velocity greater than or equal to 2 standard deviations (SD) below the mean for normal children of the same age and gender

PA Criteria	Criteria Details
Age Restrictions	None
Prescriber Restrictions	INIT: HIV WASTING/CACHEXIA: Prescribed by/in consult w/ gastroenterologist, nutritional support specialist, or infectious disease specialist.SHORT BOWEL SYND: Prescribed by/in consult w/ gastroenterologist.GROWTH FAILURE 2ND TO CKD: Prescribed by/in consult with nephrologist.INIT/RNWL: PEDIATRIC GHD, TURNER SYN, NOONAN SYN, PRADER-WILLI SYN, SMALL GESTATIONAL AGE, SHOX DEFICIENCY, ADULT GHD: Prescribed by/in consultation with endocrinologist
Coverage Duration	INIT/RNWL:SEROSTIM: 12 wkZORBTIVE: max 4 wk/lifetimeOthers: 12 mo

PA Criteria	Criteria Details
Other Criteria	INIT: HIV WASTING/CACHEXIA: (1) on HIV anti-retroviral, (2) inadequate response to prev. tx, (3) inadequate response to prev. pharm. tx incl. one: cyproheptadine, Marinol, or Megace, (4) Alt. causes of wasting ruled out, (5) Hypogonadal patients: a) Tot serum testosterone less than 300ng/dL (10.4 nmol/L), b) Low tot serum testosterone level (lab result), obtained w/ in 90 days, or c) Free serum testosterone level less than 5 pg/mL (0.17 nmol/L)]: Trial of testosterone, AND (6) Req. is for Serostim.SHORT BOWEL SYN: (1) On specialized nutritional support, AND (2) Req. is for Zorbtive.PEDIATRIC GHD: (1) Trial of/CI to Norditropin (unless req for Norditropin). (2) Req. is for Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen, ZomactonTURNER SYN: (1) Trial of/CI to Norditropin (unless req for Norditropin). (2) Req. is for Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, ZomactonPRADER-WILLI SYN: (1) Trial of/CI to Norditropin (unless req for Norditropin). (2) Req. is for Genotropin, Norditropin Flexpro, OmnitropeSMALL GESTATIONAL AGE: (1) Trial of/CI to Norditropin (unless req for Norditropin (unless req for Norditropin flexpro, Omnitrope, by age 2 to 4 (for Humatrope, Norditropin flexpro, Zomacton), and (3) Req. is for Genotropin, Humatrope, Norditropin Flexpro, Omnitrope, ZomactonNOONAN SYN: Req. is for NorditropinADULT GHD: (1) Trial of/CI to Norditropin (unless req for Norditropin), (2) Growth hormone deficiency alone or associated w/ multiple hormone deficiency, and (3) Req. is for Genotropin, Humatrope, Norditropin Flexpro, Norditropin, (2) Growth hormone deficiency, and (3) Req. is for Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen, ZomactonGROWTH FAILURE SECONDARY TO CKD: (1) Has NOT undergone a renal transplantation, and (2) Req. is for Nutropin AQ.RNWL: HIV WASTING/CACHEXIA: (1) Has NOT received

PA Criteria	Criteria Details
	greater than 24 wks of therapy within plan year, and (2) Has shown clinical benefit in muscle mass and weight (10+ percent increase in wt or BCM from baseline), (3) Taking HIV anti-retroviral therapySHORT BOWEL SYN: (1) Has NOT been on med for 4 wksPEDIATRIC GHD: (1) Epiphyses NOT closed. (2) ONE from: a) Annual growth velocity of 2+ cm, OR b) Annual growth velocity of 1+ cm for patients near terminal phase of puberty.TURNER SYN, SMALL GESTATIONAL AGE, SHOX DEFICIENCY, NOONAN SYNDROME: (1) Epiphyses NOT closed. (2) Growth velocity of 2+ cm or patient hasnt reached 50th percent of predicted adult ht.PRADER-WILLI SYN: (1) Improvement in body composition. GROWTH FAILURE SECONDARY TO CKD: (1) Has NOT undergone renal transplant. (2) Growth velocity of 2+ cm or patient has not reached 50th percent of predicted adult ht.

## **SORAFENIB**

#### **Products Affected**

• sorafenib

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## **SUCRALFATE**

#### **Products Affected**

• sucralfate oral suspension

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to sucralfate
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by, or in consultation with, a gastroenterologist
Coverage Duration	3 months. IL: 12 months
Other Criteria	Patient has had a trial and therapeutic failure, intolerance, or contraindication to generic oral sucralfate tablet.

### **SULCONAZOLE NITRATE**

#### **Products Affected**

- EXELDERM TOPICAL CREAM
- EXELDERM TOPICAL SOLUTION
- sulconazole topical cream
- sulconazole topical solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Diagnosis of Tinea pedis (athletes foot) (Topical solution only)
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	1 month.
Other Criteria	EXELDERM 1% EXTERNAL SOLUTION:Patient has a diagnosis of ONE of the following: a. Tinea crurisb. Tinea corporisc. Tinea versicolor; ANDPatient has experienced an inadequate treatment response, intolerance, or contraindication to TWO generic formulary alternatives indicated to treat tinea cruris, tinea corporis, and/or tinea versicolor (e.g. clotrimazole, ketoconazole, miconazole, naftifine).EXELDERM 1% EXTERNAL CREAM:Patient has a diagnosis of ONE of the following: a. Tinea crurisb. Tinea corporisc. Tinea pedisd. Tinea versicolor; ANDPatient has experienced an inadequate treatment response, intolerance, or contraindication to TWO generic formulary alternatives indicated to treat tinea cruris, tinea corporis, tinea pedis, and/or tinea versicolor (e.g. clotrimazole, ketoconazole, miconazole, naftifine).

### **SUMATRIPTAN**

#### **Products Affected**

- sumatriptan nasal spray,non-aerosol 20 mglactuation, 5 mglactuation
- sumatriptan succinate subcutaneous pen injector 6 mg/0.5 ml
- sumatriptan succinate subcutaneous solution

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Prevention of migraine or cluster headache attacks. Nasal Spray: treatment of cluster headache Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetals angina. Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders. History of stroke or transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke. Peripheral vascular disease. Ischemic bowel disease. Uncontrolled hypertension. Recent use (i.e., within 24 hours) of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine1 (5-HT1) agonist. Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor. Hypersensitivity to sumatriptan. Severe hepatic impairment.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	ACUTE TREATMENT OF MIGRAINES:Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to ALL of the following (medication usage must be supported by documentation from the patients chart notes/medical records electronic claim history): oral sumatriptan, rizatriptan, naratriptan, almotriptan; AND Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to Sumatriptan Nasal Spray (before injection).

## **SUNITINIB**

### **Products Affected**

• sunitinib

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 year of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	GASTROINTESTINAL STROMAL TUMOR (GIST): Trial of or contraindication to imatinib mesylate (Gleevec)

### **TADALAFIL**

#### **Products Affected**

• tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications unless otherwise excluded from benefit.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	BENIGN PROSTATIC HYPERPLASIA: Trial of TWO preferred formulary agents, including ONE agent from EACH of the following classes: (1) 5-alpha-reductase inhibitors: (e.g., finasteride or dutasteride), and (2) Alpha blockers: (e.g., doxazosin, terazosin, tamsulosin, or alfuzosin)

### **TAZAROTENE**

#### **Products Affected**

- tazarotene topical creamtazarotene topical gelTAZORAC TOPICAL GEL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	PregnancyUse on more than 20% body surface area
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	ACNE VULGARIS: Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to topical tretinoin. PLAQUE PSORIASIS: Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to at least TWO (2) topical corticosteroids (e.g., clobetasol, fluocinonide, mometasone, triamcinolone).NOTE: If requesting tazarotene gel, the patient must have a documented trial and therapeutic failure, contraindication, or intolerance to tazarotene 0.1% cream.

## **TEDIZOLID**

#### **Products Affected**

· SIVEXTRO ORAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	1 week
Other Criteria	Patient has had a trial and therapeutic failure to other antibiotics to which the organism is susceptible [documentation required]

## **TEMOZOLOMIDE**

#### **Products Affected**

- TEMODAR INTRAVENOUS
- temozolomide

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Metastatic melanoma, small cell lung cancer (SCLC).
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Metastatic melanoma: Temodar will not be used concurrently with an immunosuppressive therapy or a medical therapy for the treatment of melanoma.

## **TEMSIROLIMUS**

#### **Products Affected**

• temsirolimus

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

## TENOFOVIR ALAFENAMIDE

#### **Products Affected**

VEMLIDY

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: A. Patient has diagnosis of Chronic Hepatitis B (HBsAg positive or negative for at least 6 months); ANDB. There is documented evidence of active viral replication (HBeAG+ and HBV DNAgreater than 100,000 copies/mL); ANDC. There is documented evidence of active liver disease as demonstrated by persistent elevation in serum ALT (greater than 2 times normal) or moderate to severe hepatitis on biopsy.RENEWAL:A. Patient has compensated liver disease (no evidence of ascites, hepatic encephalopathy, variceal bleeding, INR less than 1.5x ULN, total bilirubin less than 2.5x ULN, and albumin greater than 3.0 g/dL), ANDB. Patient has been tested for and remains HIV-1 negative.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with a Gastroenterologist, Hepatologist, or Infectious Disease Specialist.
Coverage Duration	INITIAL/RENEWAL:12 months.
Other Criteria	INITIAL:A. The patient had a trial and failure of Viread or Baraclude/entecavir; ORB. The patient has documented resistance to Viread and/or entecavir (Baraclude).RENEWAL:A. Patient must have a documented diagnosis of chronic hepatitis b virus (HBV) infection, AND B. Prescriber is attesting that patient is responding positively to therapy.

## **TERIFLUNOMIDE**

#### **Products Affected**

AUBAGIO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

### **TERIPARATIDE**

#### **Products Affected**

 FORTEO SUBCUTANEOUS PEN INJECTOR 20 MCG/DOSE (600MCG/2.4ML)

PA Criteria	Criteria Details
Covered Uses	Postmenopausal osteoporosis, primary or hypogonadal osteoporosis in a male patient, or glucocorticoid-induced osteoporosis
Exclusion Criteria	Patient has received a total of 24 months cumulative treatment with teriparatide and does not have high risk for fracture
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	Up to 24 months
Other Criteria	Patient meets one of the following:1) High risk for fractures defined as ONE of the following: a) History of osteoporotic fractures, b) 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs such as nafarelin) or 3) No prior treatment for osteoporosis AND FRAX score at least 20% for any major fracture OR at least 3% for hip fracture2) Unable to use oral thrapy (i.e., upper gastrointestinal [GI] problems unable to tolerate oral medication, lower GI problems unable to absorb oral medications, trouble remembering to take oral medications or coordinating an oral bisphosphonate with other oral medications or their daily routine)3) The patient has a trial of, intolerance to, or a contraindication to bisphosphonates (e.g., alendronate, risedronate, ibandronate)

### **TESTOSTERONE**

#### **Products Affected**

- testosterone transdermal gel in metereddose pump 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1.62 % (20.25 mg/1.25

gram), 1.62 % (40.5 mg/2.5 gram)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)
Exclusion Criteria	None
Required Medical Information	INITIAL: MALE HYPOGONADISM: Low testosterone levels confirmed by at least ONE of the following laboratory values: 1) Two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state or 2) Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
Age Restrictions	GENDER DYSPHORIA: 16 years of age or older ALL OTHER INDICATIONS: None
Prescriber Restrictions	None
Coverage Duration	INITIAL/RENEWAL: MALE HYPOGONADISM, GENDER DYSPHORIA: 12 mo.
Other Criteria	INITIAL: MALE HYPOGONADISM: Testosterone levels not required for the following patients: 1) Has a previously approved prior authorization for testosterone, OR 2) Receiving any form of testosterone replacement therapy per physician attestation or claims history. RENEWAL: MALE HYPOGONADISM: (1) Improved symptoms compared to baseline and tolerance to treatment, AND (2) Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline.

## **TESTOSTERONE - KYZATREX**

#### **Products Affected**

 KYZATREX ORAL CAPSULE 100 MG, 150 MG, 200 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	PA History, claims history, or physician attestation that the patient has been receiving testosterone replacement therapy OR The patient has AT LEAST ONE of the following laboratory values confirming low testosterone levels: 1) At least two total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occations or 2) Free serum testosterone level of less than 5 pg/ml (0.17 nmol/L)
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	INITIAL: If the patient is 40 years of age or older, the provider must attest that the patient's prostate specific antigen (PSA) has been evaluated for prostate cancer screening RENEWAL: 1) The patient has improved symptoms compared to baseline and tolerance to treatment, 2) There is documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline, 3) If the patient is 40 years of age or older, the patient's PSA has been evaluated for prostate cancer screening

## TESTOSTERONE ENANTHATE

#### **Products Affected**

• testosterone enanthate

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications. Gender dysphoria as supported by the compendia (e.g., DrugDex strength of recommendation Class I, IIa, or IIb)
Exclusion Criteria	None
Required Medical Information	INITIAL: MALE HYPOGONADISM: Low testosterone levels confirmed by at least ONE of the following laboratory values: 1) Two morning total serum testosterone levels of less than 300 ng/dL (10.4 nmol/L) taken on separate occasions while in a fasted state or 2) Free serum testosterone level of less than 5 pg/mL (0.17 nmol/L)
Age Restrictions	GENDER DYSPHORIA: 16 years of age or older ALL OTHER INDICATIONS: None
Prescriber Restrictions	None
Coverage Duration	HYPOGONADISM, GENDER DYSPHORIA: 12 mo.DELAYED PUBERTY, FEMALE METASTATIC BREAST CANCER: Lifetime
Other Criteria	INITIAL: MALE HYPOGONADISM: Testosterone levels not required for the following patients: 1) Has a previously approved prior authorization for testosterone, OR 2) Receiving any form of testosterone replacement therapy per physician attestation or claims history. RENEWAL: MALE HYPOGONADISM: (1) Improved symptoms compared to baseline and tolerance to treatment, AND (2) Documentation of normalized serum testosterone levels and hematocrit concentrations compared to baseline.

## **TETRABENAZINE**

#### **Products Affected**

• tetrabenazine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Patients who are actively suicidal, or in patients with untreated or inadequately treated depression. Patients with hepatic impairment. Patients taking monoamine oxidase inhibitors (MAOIs) or within a minimum of 14 days of discontinuing therapy with an MAOI. Concomitant therapy with reserpine (at least 20 days should elapse after stopping reserpine before starting tetrabenazine. Concomitant therapy with deutetrabenazine or valbenazine.
Required Medical Information	INITIAL: Patients who require doses of XENAZINE greater than 50 mg/day should be first tested and genotyped to determine if they are poor metabolizers (PMs) or extensive metabolizers (EMs) by their ability to express the drug metabolizing enzyme, CYP2D6; AND Patient is a confirmed extensive metabolizer (poor metabolizer should not exceed a daily dose of 50mg).
Age Restrictions	None
Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist that treats Huntingtons Disease
Coverage Duration	INITIAL/RENEWAL: 3 months. IL: 12 months
Other Criteria	INITIAL: Patient has had a documented trial and therapeutic failure of at least TWO (2) of the following: amantadine, an antipsychotic (fluphenazine, haloperidol, risperidone, ziprasidone, quetiapine, or olanzapine), riluzole, a benzodiazepine.RENEWAL: (1) Signs and symptoms of chorea must be decreased (2) Adverse reactions such as akathisia, restlessness, parkinsonism, depression, insomnia, anxiety, or sedation occur have not subsided with dose reduction.

## TEZACAFTOR/IVACAFTOR

#### **Products Affected**

SYMDEKO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: (1) Documentation that patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, OR (2) Documentation that patient has at least one mutation in the CFTR gene.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
Coverage Duration	INITIAL: 24 weeks. RENEWAL: Lifetime. IL: Initial: 12 months Renewal: Lifetime
Other Criteria	RENEWAL: Improvement in clinical status compared to baseline as shown by Improved, maintained, or demonstrated less than expected decline in ONE of the following: FEV1, or body mass index (BMI), or reduction in rate of pulmonary exacerbations.

## **THIOGUANINE**

#### **Products Affected**

TABLOID

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients whose disease has demonstrated prior resistance to mercaptopurine and thioguanine. Use during maintenance therapy or similar long-term continuous treatments for acute nonlymphocytic leukemias. Treatment of chronic lymphocytic leukemia, Hodgkins lymphoma, multiple myeloma, or solid tumors.
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	12 months
Other Criteria	None

## **TOBRAMYCIN INHALED**

#### **Products Affected**

- tobramycin in 0.225 % nacl
- tobramycin with nebulizer

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	Patients with a known hypersensitivity to any aminoglycoside. Patients with an FEV1 less than 25% or greater than 75% predicted Patients colonized with Burkholderia cepacia.
Required Medical Information	Patient has a documented diagnosis of lung infection due to Pseudomonas aeruginosa.
Age Restrictions	6 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months.
Other Criteria	None

# TOCILIZUMAB - IV (NSA)

#### **Products Affected**

ACTEMRA

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RHEUMATOID ARTHRITIS (RA), GIANT CELL ARTERITIS (GCA): 18 years of age or older.POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA), CYTOKINE RELEASE SYNDROME (CRS): 2 years of age or older.
Prescriber Restrictions	RA/PJIA: Prescribed by or in consultation with a rheumatologist.SJIA: Prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: (1) Trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, AND (2) Trial of or contraindication to the preferred immunomodulator Humira.PJIA: (1) Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, AND (2) Trial of or contraindication to the preferred immunomodulator Humira.SJIA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.[NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify for trials]RENEWAL: RA/PJIA: Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.SJIA: (1) Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy, OR (2) Maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

# TOCILIZUMAB - SQ

#### **Products Affected**

- ACTEMRA
- ACTEMRA ACTPEN

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD): Other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]
Required Medical Information	None
Age Restrictions	RHEUMATOID ARTHRITIS (RA), GIANT CELL ARTERITIS (GCA), SSc-ILD: 18 years of age or older POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA), SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA): 2 years of age or older
Prescriber Restrictions	RA/PJIA: Prescribed by or in consultation with a rheumatologistSSc-ILD: Prescribed by or in consultation with a pulmonologist or rheumatologistSJIA: Prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: (1) Trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine, AND (2) Trial of or contraindication to the preferred immunomodulator Humira.SSc-ILD: Diagnosis is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR).PJIA: (1) Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine, AND (2) Trial of or contraindication to the preferred immunomodulator Humira.SJIA: Trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.[NOTE: pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify for trials]RENEWAL: RA/PJIA: Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapyGCA: Diagnosis of GCA.SSc-ILD: Experienced a clinical meaningful improvement or maintenance in annual rate of decline. SJIA: (1) Experienced or maintained a 20% or greater improvement in tender joint count while on therapy, OR (2) Maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

# **TOFACITINIB**

#### **Products Affected**

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RHEUMATOID ARTHRITIS (RA), PSORIATIC ARTHRITIS (PsA), ULCERATIVE COLITIS (UC), ANKYLOSING APONDYLITIS (AS): 18 years of age or olderPOLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS (pcJIA): 2 years of age or older
Prescriber Restrictions	RA/pcJIA/AS: Prescribed by or in consultation with a rheumatologistPsA: Prescribed by or in consultation with a rheumatologist or dermatologist UC: Prescribed by or in consultation with a gastroenterologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: RA: Trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine AND the patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira, Enbrel).PsA/pcJIA: Trial of or contraindication to ONE DMARD such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine AND the patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira, Enbrel).AS: Trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen, meloxicam, diclofenac, etc.) AND the patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (TNF) blocker (e.g., Humira, Enbrel).UC: Trial of or contraindication to ONE conventional therapy (e.g., budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate, or mesalamine) AND the patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira).[NOTE: Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]RENEWAL: RA/PsA/pcJIA: Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.AS: Patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score while on therapy.UC: Diagnosis of moderate to severe UC.

# **TOLCAPONE**

### **Products Affected**

tolcapone

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	INITIAL/RENEWAL: Patients with liver disease, inpatients who were withdrawn from tolcapone because of evidence of tolcapone:induced hepatocellular injury or who have demonstrated hypersensitivity to the drug or its ingredients.Patients with a history of nontraumatic rhabdomyolysis or hyperpyrexia and confusion possibly related to medication.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	INITIAL: 3 months. RENEWAL: 12 months. IL: 12 months
Other Criteria	INITIAL:Patient will be taking tolcapone concurrently with levodopa/carbidopa; AND Patient is experiencing symptom fluctuations; AND Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to entacapone.RENEWAL:Documentation has been provided to confirm that therapy has shown substantial clinical benefits; AND Patient does not exhibit clinical evidence of liver disease or two SGPT/ALT or SGOT/AST values greater than the upper limit of normal.

# **TOREMIFENE**

### **Products Affected**

• toremifene

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# TRAMETINIB DIMETHYL SULFOXIDE

#### **Products Affected**

 MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	Unresectable or metastatic solid tumors: 6 years of age or older
Prescriber Restrictions	None
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Unresectable or metastatic solid tumors: 1) The patient has BRAF V600E or V600K mutations as detected by a FDA-approved test AND 2) The requested medication will be used in combination with Tafinlar (dabrafenib) OR as a single agent in a BRAF-inhibitor treatment-naive patientMetastatic non-small cell lung cancer (NSCLC): 1) The patient has BRAF V600E mutation as detected by an FDA-approved test AND 2) The requested medication will be used in combination with Tafinlar (dabrafenib)Melanoma: 1) The patient has BRAF V600E or V600K mutations as detected by a FDA-approved test 2) The requested medication will be used as an adjuvant therapy in combination with Tafinlar (dabrafenib) AND 3) There is involvement of lymph node(s), following complete resectionLocally advanced or metastatic anaplastic thyroid cancer (ATC): 1) The patient has BRAF V600E mutation 2) The requested medication will be used in combination with Tafinlar (dabrafenib) AND 3) The patient has no satisfactory locoregional treatment options available Unresectable or metastatic solid tumors: 1) The patient has BRAF V600E mutation 2) The requested medication will be used in combination with Tafinlar (dabrafenib) AND 3) The patient has progressed following prior treatment and has no satisfactory alternative treatment options

# **TRASTUZUMAB**

#### **Products Affected**

 HERCEPTIN INTRAVENOUS RECON SOLN 150 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	INITIAL: BREAST CANCER:(1) HER2 protein overexpression or HER2 gene amplification is confirmed by FDA-approved test.GASTRIC, ESOPHAGEAL OR ESOPHAGOGASTRIC JUNCTION CANCER:(1) HER2 protein overexpression or HER2 gene amplification is confirmed by FDA-approved test.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in collaboration with an oncologist.
Coverage Duration	INITIAL: Maximum of 6 months. RENEWAL: Maximum of 12 months.

PA Criteria	Criteria Details
Other Criteria	INITIAL:BREAST CANCER: (1) Documentation of human epidermal growth factor receptor 2 (HER2)-positive breast cancer diagnosis, AND (2) Requested medication is being used as adjuvant therapy for HER2 overexpressing node-negative (estrogen- or progesterone-receptor negative or with 1 high-risk feature) or node-positive breast cancer in a regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel OR as part of a regimen with docetaxel and carboplatin OR as a single agent following multi-modality anthracycline based therapy, OR (2) Requested medication is being used for metastatic HER-2 overexpressing breast cancer, AND is being used as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease OR as first-line therapy in combination with paclitaxel. GASTRIC, ESOPHAGEAL OR ESOPHAGOGASTRIC JUNCTION CANCER: (1) Documentation of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma diagnosis, AND (2) Requested drug is being used in combination with cisplatin and capecitabine or 5-fluorouracil, AND (3) Patient has not received prior treatment for metastatic disease. RENEWAL ALL:(1) Patient meets requirements for initial criteria, AND (2) Documented positive clinical outcome and continued requirement for use.

# **TREPROSTINIL**

### **Products Affected**

ORENITRAM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	ORENITRAM: Severe hepatic impairment
Required Medical Information	INITIAL: PULMONARY ARTERIAL HYPERTENSION (PAH) (WHO GROUP 1):Documented confirmatory PAH diagnosis based on right heart catheterization with the following parameters: (1) Mean pulmonary artery pressure (PAP) of greater than 20 mmHg, (2) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg, (3) Pulmonary vascular resistance (PVR) greater than or equal to 3 Wood units (WU)TYVASO TYVASO DPI: PULMONARY HYPERTENSION ASSOCIATED WITH INTERSTITIAL LUNG DISEASE (PH-ILD) (WHO Group 3): Diagnosis confirmed based on right heart catheterization with the following parameters: (1) Pulmonary vascular resistance (PVR) greater than or equal to 3 WU, (2) Mean pulmonary artery pressure (PAP) of greater than 20 mmHg, (3) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
Age Restrictions	None
Prescriber Restrictions	Prescribed by or given in consultation with a cardiologist or pulmonologist
Coverage Duration	INIT: REMODULIN/ORENITRAM, TYVASO PAH: 12 mo TYVASO PH G3: INIT: 6 mo RNWL: All: 12 mo IL: 12 mo

PA Criteria	Criteria Details
Other Criteria	INITIAL:REMODULIN1 of the following:(1) Cont. of Remodulin (treprostinil) therapy from hospital discharge AND patient has NYHA/WHO FC II, III, or IV symptoms OR(2) New request for Remodulin AND patient has NYHA-WHO FC III or IV symptoms OR (3) New request for Remodulin AND patient has NYHA-WHO FC III symptoms AND trial of or contraindication to TWO of the following from different drug classes: a) oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan), b) oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil), c) oral cGMP inhibitor (e.g., riociguat)TYVASO, TYVASO DPIPAH WHO GROUP 1: (1) NYHA-WHO FC III or IV symptoms. (2) One of the following: (a) WHO FC III symptoms AND trial of or contraindication to TWO of the following agents from different drug class: (i) oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan), (ii) oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil), (iii) oral cGMP inhibitor (e.g., riociguat) OR(b) WHO FC III symptoms with evidence of rapid progression/poor prognosis, or WHO FC IV symptoms AND trial of or contraindication to ONE IV/SQ prostacyclin (e.g., epoprostenol or treprostinil) ORENITRAMOne of the following: (1) Continuation of Orenitram (treprostinil) therapy from hospital discharge AND NYHA/WHO FC II, III, or IV symptoms OR (2) New start of Orenitram AND WHO FC III or III symptoms AND trial of or contraindication to TWO of the following agents from different drug classes: (a) oral endothelin receptor antagonist (e.g., ambrisentan, bosentan, or macitentan), (b) oral phosphodiesterase-5 inhibitor (e.g., sildenafil or tadalafil), (c) oral cGMP inhibitor (e.g., riociguat), AND trial of or contraindication to the preferred oral prostanoid: Uptravi. OR (3) New start of Orenitram AND WHO FC III symptoms with evidence of rapid progression/poor prognosis, or WHO FC IV symptoms AND trial of or contraindication to ONE IV/SQ prostacycline (e.g., epoprostenol or treprostinil) AND trial of or contraindication to the

PA Criteria	Criteria Details
	following: (1) Patient had improvement from baseline in the 6-minute walk distance test OR (2) Patient remained stable from baseline in the 6-minute walk distance test AND the patients World Health Organization (WHO) functional class has improved or remained stableTYVASO, TYVASO DPI: PAH WHO GROUP 1: One of the following: (1) Patient had improvement from baseline in the 6-minute walk distance test OR (2) Patient remained stable from baseline in the 6-minute walk distance test AND the patients World Health Organization (WHO) functional class has improved or remained stablePH-ILD WHO GROUP 3:One of the following:(1) Patient had improvement from baseline in the 6-minute walk distance test OR (2) Patient has stable 6-minute walk distance test

# TRETINOIN ORAL

#### **Products Affected**

• tretinoin (antineoplastic)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Patients with known hypersensitivity to tretinoin or other retinoids.
Required Medical Information	Patient has a documented diagnosis of acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant) confirmed by the presence of the t(15;17) translocation AND/OR the presence of the PML/RAR gene.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by, or in consultation with, an oncologist.
Coverage Duration	12 months
Other Criteria	Tretinoin will be used for the induction of remission only; AND Patient is refractory to, or has relapsed from, anthracycline chemotherapy, or anthracycline-based chemotherapy is contraindicated; Patient will receive an accepted form of remission consolidation and/or maintenance therapy for APL after completion of induction therapy with tretinoin.

# TRIAMCINOLONE AEROSOL

#### **Products Affected**

• triamcinolone acetonide topical aerosol

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has had a documented trial and therapeutic failure, contraindication, or intolerance to at least THREE of the following: mometasone 0.1% solution, fluocinonide 0.05% solution, fluocinolone 0.01% solution, clobetasol 0.05% shampoo, clobetasol 0.05% solution

# TRIFLURIDINE EYE DROPS

### **Products Affected**

• trifluridine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	21 Days
Other Criteria	Patient has diagnosis of primary keratoconjunctivitis or recurrent epithelial keratitis due to herpes simplex virus, types 1 or 2.

# **UBROGEPANT**

### **Products Affected**

UBRELVY

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	None
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months.
Other Criteria	INITIAL: Trial of or contraindication to ONE triptan. RENEWAL: 1) Improvement from baseline in a validated acute treatment patient- reported outcome questionnaire (e.g., Migraine Assessment of Current Therapy [Migraine-ACT]), OR 2) Clinical improvement as defined by ONE of the following: a) ability to function normally within 2 hours of dose, b) headache pain disappears within 2 hours of dose, or c) therapy works consistently in majority of migraine attacks

# **UPADACITINIB**

### **Products Affected**

· RINVOQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	RA/PSA/UC/AS: 18 years of age or olderAD: 12 years of age or older
Prescriber Restrictions	RA: Prescribed by or in consultation with a rheumatologistPSA: Prescribed by or in consultation with a rheumatologist or dermatologist AD: Prescribed by or in consultation with a dermatologist, allergist, or immunologistUC: Prescribed by or in consultation with a gastroenterologistAS: Prescribed by or in consultation wit a rheumatologist
Coverage Duration	INITIAL: RA/PSA/AS: 6 months. AD: 4 months. UC: 12 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: Rheumatoid Arthritis (RA):Trial of or contraindication to at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine AND the patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira or Enbrel). Psoriatic Arthritis (PSA): A trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine ANDthe patient had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira or Enbrel). Moderate to severe Atopic Dermatitis (AD): The patient has atopic dermatitis involving at least 10% of body surface area OR atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas, AND the patient has at least TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living, AND Rinvoq will NOT be used concurrently with other systemic biologics or JAK inhibitors (e.g., Adbry, Cibingo, Dupixent) for the treatment of atopic dermatitis, AND the patient must have a history of trial of or contraindication to ONE of the following: topical corticosteroid (e.g., hydrocortisone), topical calcineurin inhibitor (e.g., Elidel), topical PDE-4 inhibitor (e.g., Eucrisa), topical JAK inhibitor (Opzelura), or phototherapy. Moderate to severe Ulcerative Colitis (UC): The patient has a history of trial of or contraindication to ONE conventional therapy (e.g., corticosteroids [e.g., budesonide, methylprednisolone], azathioprine, mercaptopurine, methotrexate, mesalamine), AND the patient has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira). AS: The has had a trial of or contraindication to an NSAID (e.g., ibuprofen, naproxen,
	meloxicam), AND the patient has had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers (e.g., Humira, Enbrel).RENEWAL: RA/PSA: Experienced or maintained a

PA Criteria	Criteria Details
	20% or greater improvement in tender joint count or swollen joint count while on therapy. AD: The patient has shown improvement while on therapy, AND Rinvoq will NOT be usd concurrently with other systtemic biologics or JAK inhibitors (e.g., Adbry, Cibingo, Dupixent) for the treatment of atopic dermatitisAS: The patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score whle on therapy.

# **USTEKINUMAB**

#### **Products Affected**

• STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	PLAQUE PSORIASIS (PsO), PSORIATIC ARTHRITIS (PsA): 6 years of age or olderCROHNS DISEASE (CD), ULCERATIVE COLITIS (UC): 18 years of age or older
Prescriber Restrictions	PsO: prescribed by or in consultation with a dermatologistPsA: prescribed by or in consultation with a rheumatologist or dermatologistCD/UC: prescribed by or in consultation with a gastroenterologist
Coverage Duration	INITIAL: 6 months. RENEWAL: 12 months. IL: 12 months

PA Criteria	Criteria Details
Other Criteria	INITIAL: PsO: (1) Psoriasis covering 3% or more of body surface area or psoriatic lesions affecting the hands, feet, genital area, or face. (2) Trial of or contraindication at least one standard therapy such as a PUVA (phototherapy ultraviolet light a), UVB (ultraviolet light b), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine. (3) Documentation of patients weight.PsA: Trial of or contraindication to one DMARD (disease-modifying antirheumatic drug) such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine.CD/UC: (1) Trial of or contraindication to at least one standard therapy such as a corticosteroid (e.g., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine.RENEWAL: PsA WITHOUT PsO: Experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. PsO: (1) Achieved or maintained clear or minimal disease, OR a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more. (2) Documentation of patients current weight.

# VALGANCICLOVIR

### **Products Affected**

• valganciclovir

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Hypersensitivity to valganciclovir or ganciclovir.
Required Medical Information	PREVENTION OF CMV DISEASEDonor CMV seropositive/Recipient CMV seronegative [D+/R-]
Age Restrictions	Pediatric kidney transplant: 4 months of age and olderPediatric heart transplant: 1 month of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	CYTOMEGALOVIRUS (CMV) RETINITIS:Patient has a documented diagnosis of Cytomegalovirus (CMV) Retinitis; AND Patients has a documented diagnosis of acquired immunodeficiency syndrome (AIDS).PREVENTION OF CMV DISEASE:The patient is at high risk for CMV, the donor is CMV seropositive, and recipient is CMV seronegative [D+/R-] AND patients meets ONE of the following: (1) the patient is post kidney transplant and is 4 months of age or older, (2) the patient is post heart transplant and is 1 month of age or older, or (3) the patient is post kidney-pancreas transplant.NOTE: Requests for oral solution require a history of trial and failure, contraindication, or intolerance to oral valganciclovir tablets OR a documented inability to ingest solid oral dosage forms.

# **VANDETANIB**

#### **Products Affected**

 CAPRELSA ORAL TABLET 100 MG, 300 MG

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications OR for continuation of therapy if patient is stable on requested medication.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	None

# **VEMURAFENIB**

### **Products Affected**

ZELBORAF

PA Criteria	Criteria Details
<b>Covered Uses</b>	All FDA approved indications.
Exclusion Criteria	None
Required Medical Information	None
Age Restrictions	None
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Unresectable or metastatic melanoma: 1) The patient has a genetic mutation called BRAF V600E as detected by an FDA-approved test 2) Zelboraf will be used alone or in combination with Cotellic (cobimetinib) Erdheim-Chester Disease: 1) The patient has a genetic mutation called BRAF V600

# **VILAZODONE**

#### **Products Affected**

- VIIBRYD ORAL TABLETS,DOSE PACK 10 MG (7)- 20 MG (23)
- vilazodone

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue.
Required Medical Information	None
Age Restrictions	18 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	MAJOR DEPRESSIVE DISORDERPatient has had an adequate trial and failure, intolerance, or contraindication with at least ONE (1) generic SSRI; AND Patient has had had an adequate trial and failure, intolerance, or contraindication with at least ONE (1) generic SNRI. [Documentation Required]

# **VORICONAZOLE**

### **Products Affected**

• voriconazole oral

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Coadministration of cisapride, pimozide, quinidine, ivabradine, Sirolimus, rifampin, carbamazepine, and long-acting barbiturates, efavirenz doses of 400 mg every 24 hours or higher, ritonavir, rifabutin, ergot alkaloids (ergotamine and dihydroergotamine), St. Johns Wort, naloxegol, tolvaptan, venetoclax (at initiation and during the ramp-up phase).
Required Medical Information	Fungal culture and other relevant laboratory studies (including histopathology) need to be obtained to isolate and identify causative organisms
Age Restrictions	2 years of age and older
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	12 months
Other Criteria	TREATMENT OF INVASIVE ASPERGILLUSPatient has a diagnosis of clinically documented invasive aspergillosis, that is susceptible to voriconazole confirmed by fungal culture and other relevant laboratory studies (including histopathology) with isolated and identified causative organisms; AND Patient has had a trial and therapeutic failure of amphotericin B.ALL OTHER INDICATIONS:Patient has trial and failure, contraindication, or intolerance to fluconazole.

# **ZILEUTON**

### **Products Affected**

• zileuton

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications.
Exclusion Criteria	Use in the reversal of bronchospasm in acute asthma attacks. Patients with active liver disease or persistent hepatic function enzyme elevations greater than or equal to 3 times the upper limit of normal (greater than or equal to 3xULN). Patients with a history of allergic reaction to zileuton.
Required Medical Information	None
Age Restrictions	12 years of age and older
Prescriber Restrictions	None
Coverage Duration	12 months
Other Criteria	Patient has diagnosis of Asthma; Patient has had a trial and therapeutic failure, intolerance, or contraindication to ALL of the following: montelukast and zafirlukast (medication usage must be supported by documentation from the patients chart notes/medical records).

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