PriorityHealth
THINK SMART. LIVE SMART.

2021 Priority Health Optimized – Small Employer Group Prior Authorization Criteria

An alphabetical index by drug name appears after the drug criteria listings.

Accrufer (ferric maltol)

Products Affected

- **ACCRUFER**

PA Criteria	Criteria Details
Covered Uses	Iron deficiency anemia due to Irritable Bowel Disease (IBD) or non-dialysis dependent chronic kidney disease (CKD).
Exclusion Criteria	
Required Medical Information	1. Baseline (pre-treatment) hemoglobin and ferritin levels. 2. Must have an inadequate response to 2 different generic oral iron therapies. For intolerances to previously tried oral iron, the following strategies must have been attempted to improve tolerability: (1) increase interval to every other day dosing and (2) lifestyle and dietary changes (e.g., take iron with food, use a stool softener, etc.).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation of previously approved requests, must have documentation of improvement in condition from baseline (e.g., improved tolerance and/or increased hemoglobin and ferritin levels).

Acthar (corticotropin)

Products Affected

- **ACTHAR**

PA Criteria	Criteria Details
Covered Uses	Infantile spasms (West syndrome).
Exclusion Criteria	H.P. Acthar Gel is not considered medically necessary for the following corticosteroid-responsive conditions because it has not been proven to be more effective than corticosteroids for these conditions. 1. Acute exacerbations of multiple sclerosis. 2. Rheumatic disorders (psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis). 3. Collagen diseases (systemic lupus erythematosus, systemic dermatomyositis). 4. Dermatologic diseases (severe erythema multiforme, Stevens-Johnson syndrome). 5. Allergic states (serum sickness). 6. Ophthalmic diseases (keratitis, iritis, iridocyclitis, uveitis, choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation). 7. Respiratory diseases (symptomatic sarcoidosis). 8. Edematous state.
Required Medical Information	For a diagnosis of infantile spasms, H.P. Acthar Gel is authorized up to a dose of 75 units/m2 twice daily for two weeks, followed by a tapering schedule for an additional two weeks.
Age Restrictions	Less than 2 years of age.
Prescriber Restrictions	
Coverage Duration	One month
Other Criteria	

Actiq (fentanyl citrate lozenge)

Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
Covered Uses	To manage breakthrough pain in cancer patients.
Exclusion Criteria	
Required Medical Information	Must be receiving and tolerant to around-the-clock opioid therapy for persistent cancer pain.
Age Restrictions	Must be at least 16 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Quantity limit: 120 lozenges per 30 days.

Adempas (riociguat)

Products Affected

- **ADEMPAS**

PA Criteria	Criteria Details
Covered Uses	1. Chronic thromboembolic pulmonary hypertension (CTEPH), World Health Organization (WHO) Group 4, that is either recurrent or persistent after documented pulmonary endarterectomy (PEA), OR inoperable. 2. Pulmonary arterial hypertension (PAH), WHO Group 1. Documentation must be submitted to Priority Health.
Exclusion Criteria	
Required Medical Information	For chronic thromboembolic pulmonary hypertension (CTEPH), must be World Health Organization (WHO) Group 4, that is either recurrent or persistent after documented pulmonary endarterectomy (PEA), OR inoperable, WITH: a. Documentation confirming diagnosis, such as: i. Computed tomography (CT)/Magnetic resonance imaging (MRI) angiography or pulmonary angiography. ii. Pretreatment right heart catheterization with all the of the following results: 1. MPAP at least 25mmHg. 2. PCWP no greater than 15 mmHg. 3. PVR greater than 3 Wood units. For pulmonary arterial hypertension (PAH), World Health Organization Group 1, must meet all of the following: a. Member has WHO Functional Class II or III symptoms prior to initiation of Adempas therapy. b. Documentation confirming diagnosis such as pre-treatment right heart catheterization with the following results: i. MPAP at least 25mmHg. ii. PCWP no greater than 15 mmHg. iii. PVR greater than 3 Wood units. c. Patients not previously treated for pulmonary arterial hypertension must first try sildenafil (generic Revatio).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Ampyra (dalfampridine)

Products Affected

- *dalfampridine er*

PA Criteria	Criteria Details
Covered Uses	To improve walking in patients with multiple sclerosis (MS).
Exclusion Criteria	Patient must not have a spinal cord injury, myasthenia gravis, or demyelinating peripheral neuropathies (such as Guillain-Barre syndrome), Alzheimers disease, or Lambert Eaton myasthenic syndrome.
Required Medical Information	1. Must have diagnosis of multiple sclerosis (MS). 2. Must be receiving immunomodulatory therapy (unless immunomodulatory therapy is not indicated for patients MS type). 3. Must have significant and continuous walking impairment that impairs ability to complete normal daily activities (such as meal preparation, household chores, etc.) attributable to ambulation or functional status despite optimal treatment for MS. 4. Patient does not require the use of a wheelchair (bilateral assistance is acceptable, such as a brace, cane, or crutch, as long as the patient can walk 20 meters without resting). 5. Baseline timed 25-foot walk test (T25FW) is completed within 8 45 seconds OR patient has an Expanded Disability Status Scale (EDSS) score greater than or equal to 4.5 but less than 7.
Age Restrictions	Must be between ages 18-70 years.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, documentation that the patient has met all of the following requirements must be provided every 12 months: 1. The patient currently meets all of the initial criteria as shown above. 2. Must maintain an 85% adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient. 3. The patients functional impairment must resolve as a result of increased speed of ambulation resulting in the member being able to complete instrumental activities (meal preparation, household chores, etc.). 4. Requires at least a 20% improvement in timed walking speed as documented by the T25FW test from pre-treatment baseline.

Aptiom (eslicarbazepine)

Products Affected

- **APTIOM**

PA Criteria	Criteria Details
Covered Uses	Partial-onset seizure (documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Trial and failure with or intolerance to all of the following: 1. Oxcarbazepine. 2. One additional generic anti-seizure medication.
Age Restrictions	Must be at least 4 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Arikayce (amikacin oral inhalation)

Products Affected

- **ARIKAYCE**

PA Criteria	Criteria Details
Covered Uses	Mycobacterium avium complex (MAC) lung disease (documentation of sputum culture supporting the diagnosis must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Documentation of failure to obtain a negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy for MAC lung disease such as clarithromycin (or azithromycin), rifampin and ethambutol. 2. Arikayce must be used as part of a multi-drug regimen and will not be approved for use as a single agent treatment.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with infectious disease specialist.
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	1. Continuation requires documentation of negative sputum culture obtained within the last 30 days. (The ATS/IDSA guidelines state that patients should continue to be treated until they have negative cultures for 1 year. Patients that have had negative cultures for 1 year will not be approved for continued treatment.) 2. The patient is compliant in taking the medication as scheduled. 3. The patient tolerated the medication. 4. The patient has responded to treatment, as determined by the prescribing physician.

Auryxia (ferric citrate)

Products Affected

- **AURYXIA**

PA Criteria	Criteria Details
Covered Uses	1. Hyperphosphatemia in patients with chronic kidney disease (CKD). 2. Iron-deficiency anemia in CKD.
Exclusion Criteria	
Required Medical Information	1. For a diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD), must meet all of the following: a. Require dialysis to control disease. b. Must have failed on calcium acetate or sevelamer. 2. For a diagnosis of iron-deficiency anemia in CKD, must meet all of the following: a. Not be on dialysis. b. Have an estimated GFR of less than 60 ml/min. c. Must have had an inadequate response on therapeutic doses of oral iron supplements. d. Must have hemoglobin (Hgb) between 9 g/dL and 11.5 g/dL. e. Must have serum ferritin no greater than 200 ng/mL and transferrin saturation (TSAT) of less than 25%.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	4 months (initial for CKD anemia), 12 months (continuation)
Other Criteria	For continuation in iron-deficiency anemia after initial 4 month approval, patient must have met the following requirements: 1. Must not require dialysis to control CKD. 2. Must be free of the need for additional therapy with erythropoiesis-stimulating agents (ESA), intravenous iron, or blood transfusions.

Banzel (rufinamide)

Products Affected

- **BANZEL ORAL SUSPENSION**
- **BANZEL ORAL TABLET**
- *rufinamide oral suspension*
- *rufinamide oral tablet*

PA Criteria	Criteria Details
Covered Uses	Adjunctive treatment for seizures associated with Lennox-Gastaut syndrome (documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Benlysta (belimumab)

Products Affected

- **BENLYSTA SUBCUTANEOUS**

PA Criteria	Criteria Details
Covered Uses	Autoantibody-positive systemic lupus erythematosus (SLE). Biopsy-proven lupus nephritis Class III through V.
Exclusion Criteria	Benlysta is not covered in combination with any other biologic drug or intravenous cyclophosphamide. Must not have central nervous system manifestations, or chronic infection.
Required Medical Information	For autoantibody-positive systemic lupus erythematosus (SLE): 1. Must have active disease as demonstrated by a score greater than 6 (as documented by a SELENA-SLEDAI) while on treatment with standard therapy (e.g., corticosteroids, immunosuppressants, and hydroxychloroquine) for at least 12 weeks each. 2. Must be autoantibody-positive with one of the following: i. Anti-nuclear antibody (ANA) titer of at least 1:80, or ii. Anti-doublestranded DNA (anti-dsDNA) level of at least 30 IU/mL. For biopsy-proven lupus nephritis Class III through V: 1. Must have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants). 2. Must be autoantibody-positive with one of the following: i. Anti-nuclear antibody (ANA) titer of at least 1:80, or ii. Anti-doublestranded DNA (anti-dsDNA) level of at least 30 IU/mL. 3. Must not have estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2.
Age Restrictions	Must be at least 5 years of age (SLE) or at least 18 years of age (lupus nephritis).
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)

PA Criteria	Criteria Details
Other Criteria	For continuation, patient must have meet the following requirements: For active, autoantibody-positive systemic lupus erythematosus (SLE), must have met 3 of the 6 following requirements: 1. Must have a SELENA-SLEDAI score point reduction of 4 or more based on a 30-day assessment. 2. Must have a Physician Global Assessment change indicating showing no disease progression (worsening) compared to baseline treatment with Benlysta. 3. Must have a British Lupus Assessment Group (BILAG) score of zero in Category A (very active disease) -and- a score of one or less in Category B (moderately active, in any organ system in the last 4 weeks). 4. A reduction in dose of steroid therapy. 5. A negative seroconversion or a 20% reduction in autoantibody levels from baseline. 6. Free of significant clinical flares that require steroid boost treatment with Benlysta. For biopsy-proven lupus nephritis Class III through V: 1. Must have evidence of efficacy (defined as urinary protein creatinine ratio less than or equal to 0.7, eGFR less than or equal to 20% below the pre-flare or at least 60mL/min/1.73m2), and no use of rescue therapy for treatment failure. Note: The formulation of Benlysta (subcutaneous syringe vs. intravenous vial) that is approved depends on the member's weight. The intravenous formulation will be required for members who weigh less than 80 kg. Member's that weigh 80 kg or more are required to use the subcutaneous syringe. On and after 12/1/2017, infusion of Benlysta is not covered at hospital-affiliated infusion centers. First infusions of a drug may be covered in a hospital outpatient infusion center when physician supervision is desired. Patients age 17 and younger may choose to have this drug administered at a hospital-affiliated infusion center.

Bethkis/Kitabis Pak/TOBI Podhaler (tobramycin inhalation)

Products Affected

- **BETHKIS**
- **KITABIS PAK**

PA Criteria	Criteria Details
Covered Uses	Cystic fibrosis.
Exclusion Criteria	
Required Medical Information	1. Must have suspected or confirmed diagnosis of Pseudomonas aeruginosa lung infection. 2. Must first have a trial and clinical failure on tobramycin inhalation solution (generic TOBI).
Age Restrictions	Must be at least 6 years of age.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	

Buphenyl (sodium phenylbutyrate)

Products Affected

- **BUPHENYL ORAL POWDER 3 GM/TSP**
- **BUPHENYL ORAL TABLET**
- *sodium phenylbutyrate oral powder 3 gm/tsp*
- *sodium phenylbutyrate oral tablet*

PA Criteria	Criteria Details
Covered Uses	Chronic hyperammonemia because of a urea cycle disorder.
Exclusion Criteria	
Required Medical Information	1. Patient's condition cannot be managed by dietary protein restriction, and 2. Patient's condition cannot be managed by amino acid supplementation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Caplyta (lumateperone)

Products Affected

- **CAPLYTA**

PA Criteria	Criteria Details
Covered Uses	Schizophrenia.
Exclusion Criteria	Caplyta is not covered in combination with other atypical antipsychotics.
Required Medical Information	1. Have tried two of the following for 28 days each with clinical failure: olanzapine, quetiapine (either immediate release or extended release), risperidone, ziprasidone, aripiprazole.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Carbaglu (carglumic acid)

Products Affected

- **CARBAGLU**

PA Criteria	Criteria Details
Covered Uses	Deficiency of N-acetylglutamate synthase (NAGS).
Exclusion Criteria	
Required Medical Information	Acute or chronic hyperammonemia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Cayston (aztreonam oral inhalation)

Products Affected

- **CAYSTON**

PA Criteria	Criteria Details
Covered Uses	Cystic Fibrosis confirmed by appropriate diagnostic or genetic testing (documentation of a cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 Codes for Cystic Fibrosis include: E84.0, E84.11, E84.19, E84.8, E84.9.
Exclusion Criteria	
Required Medical Information	Confirmation of Pseudomonas aeruginosa in cultures of the airways confirmed by a copy of positive sputum culture. 1. Susceptibility results showing aztreonam is the only inhaled antibiotic to which the Pseudomonas aeruginosa is sensitive OR 2. At least one of the following: a. Previous use of tobramycin inhalation solution and experienced a clinically significant adverse drug reaction or unsatisfactory therapeutic response. b. Contraindication/intolerance to tobramycin inhalation solution. c. Culture shows resistance to tobramycin.
Age Restrictions	Must be at least 7 years of age.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: 1. Continues to require treatment of Pseudomonas aeruginosa infection. 2. Documentation of stabilization or improvement by pulmonologist or CF specialist. Coverage for Cayston is to be used for 28 days, following 28 days off.

CGRP Preventative Agents

Products Affected

- **AIMOVIG**
- **AJOVY**
- **EMGALITY (300 MG DOSE)**
- **EMGALITY SUBCUTANEOUS SOLUTION AUTO-INJECTOR**
- **EMGALITY SUBCUTANEOUS SOLUTION PREFILLED SYRINGE**

PA Criteria	Criteria Details
Covered Uses	Applies to Aimovig, Ajovy, Emgality, Vyepti, Qulipta. Prevention of migraine headaches, treatment of episodic cluster headaches (Emgality only).
Exclusion Criteria	Not covered in combination with Botox or any other branded prophylactic agent. Qulipta is not covered in combination with Ubrelvy or Nurtec. Qulipta is not covered for use in chronic migraines.
Required Medical Information	For prevention of migraine headaches, the patient: 1. Must experience 4 or more migraines per month. 2. Must have tried and failed at least 1 agent in 2 of the following groups of prophylactic treatment options (minimum of 28 days for each): a. Blood pressure agents: Propranolol, timolol, or metoprolol. b. Antidepressant agents: Amitriptyline or nortriptyline. c. Antiepileptic drugs: Topiramate or valproic acid and its derivatives. 3. For non-preferred drug product: Trial and failure, or intolerance to Aimovig, Emgality, and Ajovy for 3 continuous months and not achieving adequate reduction in migraines. For episodic cluster headaches (Emgality only), the patient must have tried and failed at least 2 of the following treatments: a. Injectable triptan drugs: sumatriptan. b. Intranasal triptan drugs: sumatriptan or zolmitriptan. c. Oxygen therapy.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months (migraine headache), 3 months (cluster headache)

PA Criteria	Criteria Details
Other Criteria	For continuation of treatment of migraine headaches, patient must have met the following requirements: 1. Patient has experienced a significant decrease in the frequency migraine headaches (at least a 50% reduction in monthly migraine days). For continuation of treatment of episodic cluster headaches, patient must have met the following requirements: 1. Patient has experienced a significant decrease in the frequency and/or intensity of cluster headaches. 2. Patient is currently in a cluster period. Coverage of Vyepti is limited to initial dosing of 100mg given every 3 months. For patients not responsive to the 100mg dose, a single authorization can be made for a 300mg dose which will be assessed for efficacy beyond that observed for the 100mg dose.

Cholbam (cholic acid)

Products Affected

- **CHOLBAM**

PA Criteria	Criteria Details
Covered Uses	Bile acid synthesis disorder due to single enzyme defects (SED) or peroxisomal disorder (PD).
Exclusion Criteria	
Required Medical Information	1. Must provide a serum very long chain fatty acid value (VLCFA). 2. Must provide baseline liver function tests.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continued coverage, patient must have met the following requirements: 1. Body weight increased by 10 percent or is stable of at least the 50th percentile. 2. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is less than 50 U/L or baseline levels reduced by 80 percent. 3. Total bilirubin level reduced to less than or equal to 1mg/dL. 4. Must not have evidence of cholestasis on liver biopsy.

Cimzia (certolizumab)

Products Affected

- **CIMZIA PREFILLED**
- **CIMZIA SUBCUTANEOUS KIT 2 X 200 MG**

PA Criteria	Criteria Details
Covered Uses	1. Ankylosing spondylitis. 2. Non-radiographic axial spondyloarthritis (nr-axSpA). 3. Crohn's disease. 4. Psoriatic arthritis. 5. Rheumatoid arthritis. 6. Plaque psoriasis. Cimzia may also be covered under the member's medical benefit. For physician-administered drug coverage, please refer to the Injectable Drug List and search for drug name. You can view criteria and submit using electronic Prior Authorization (ePA) or via the drug specific Prior Authorization form.
Exclusion Criteria	Cimzia will not be covered in combination with another biologic drug.
Required Medical Information	1. Ankylosing Spondylitis: a) Patient has tried at least TWO of the following: Cosentyx, Enbrel, or Humira, each for a period of at least 3 months. 2. Non-radiographic axial spondyloarthritis (nr-axSpA): a) Patient has objective signs of inflammation, defined as C-reactive protein (CRP) elevated beyond the upper limit of normal AND/OR sacroiliitis reported on magnetic resonance imaging (MRI). 3. Crohn's Disease: a) Patient has tried one other agent for Crohn's disease (e.g., corticosteroid, azathioprine, 6-mercaptopurine, methotrexate). b) Patient has tried Humira for a period of at least 3 months. 4. Psoriatic Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months, AND b)Patient has tried at least TWO of the following: Cosentyx, Enbrel, Humira, Xeljanz/XR, Otezla, or Stelara, each for a period of at least 3 months. 5. Rheumatoid Arthritis: a)Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months, AND b) Patient has tried at least TWO of the following: Actemra, Enbrel, Humira, or Xeljanz/XR, or Rinvoq each for a period of at least 3 months. 6. Plaque psoriasis: a) Patient has tried ALL of the following for a period of at least 3 months: a. One topical agent. b. One non-biologic systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin). c. Phototherapy. d. TWO of Cosentyx, Humira, Otezla, Stelara, Tremfya, or Skyrizi.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months
Other Criteria	Before Cimzia is covered, the patient must meet all of the General Criteria for Cimzia and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Cosentyx (secukinumab)

Products Affected

- **COSENTYX SENSOREADY PEN SUBCUTANEOUS SOLUTION AUTO-INJECTOR 150 MG/ML**
- **COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML**

PA Criteria	Criteria Details
Covered Uses	1. Ankylosing Spondylitis. 2. Plaque Psoriasis. 3. Psoriatic Arthritis. 4. Non-radiographic axial spondyloarthritis (nr-axSpA).
Exclusion Criteria	Cosentyx will not be covered in combination with another biologic drug.
Required Medical Information	1. Ankylosing Spondylitis: a) There are no Specific Induction Criteria for this indication. Cosentyx is covered for any patient who meets the above General Initiation Criteria. 2. Plaque Psoriasis: b) Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii. One traditional non-biologic systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin). iii. Phototherapy. 3. Psoriatic Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. 4. Non-radiographic axial spondyloarthritis (nr-axSpA): a) The patient has objective signs of inflammation, defined as C-reactive protein (CRP) elevated beyond the upper limit of normal AND/OR sacroiliitis reported on magnetic resonance imaging (MRI).
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months
Other Criteria	Before Cosentyx is covered, the patient must meet all of the General Criteria for Cosentyx and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Cresemba (isavuconazole)

Products Affected

- **CRESEMBA ORAL**

PA Criteria	Criteria Details
Covered Uses	Treatment of invasive aspergillosis or invasive mucormycosis (i.e., Rhizopus, Rhizomucor, Lichtheimia, Mucormycetes).
Exclusion Criteria	
Required Medical Information	Must have inadequate response, intolerable side effect, or contraindication to voriconazole or itraconazole.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed or recommended by an infectious disease specialist.
Coverage Duration	3 months (initial), 12 months (continuation)
Other Criteria	

Daliresp (roflumilast)

Products Affected

- **DALIRESP ORAL TABLET 250 MCG, 500 MCG**

PA Criteria	Criteria Details
Covered Uses	Stage 3 or 4 Chronic Obstructive Pulmonary Disease (COPD) defined as an FEV1 less than 50%.
Exclusion Criteria	
Required Medical Information	1. Must have chronic bronchitis (a productive, long-term cough that lasts 3 months out of the year for 2 consecutive years). 2. Must have tried and failed on triple therapy with an inhaled corticosteroid (ICS), long-acting beta agonist (LABA) and a long-acting antimuscarinic (LAMA). a. Fail is defined as no improvement or a worsening of the condition (an exacerbation) after trying triple therapy at the maximum dosages for at least 4 weeks consistently. 3. Must have more than 1 COPD exacerbation in the past year. 4. Must be a current non-smoker.
Age Restrictions	Must be at least 40 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements: 1. Must have documentation illustrating a reduction in COPD exacerbations. 2. Must be a current non-smoker.

Depen (penicillamine)

Products Affected

- *penicillamine oral tablet*

PA Criteria	Criteria Details
Covered Uses	1. Wilson's disease (hepatolenticular degeneration). 2. Cystinuria.
Exclusion Criteria	
Required Medical Information	For cystinuria and treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated (supporting documentation must be submitted to Priority Health).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Quantity limit of 120 tablets per 30 days. For approval over the quantity limit, documentation proving conservative measures have continued in combination with Depen Titratabs or penicillamine 250 mg oral tablet, and that member has been compliant with these measures must be faxed to Priority Health.

Diacomit (stiripentol)

Products Affected

- **DIACOMIT ORAL CAPSULE 250 MG, 500 MG**
- **DIACOMIT ORAL PACKET**

PA Criteria	Criteria Details
Covered Uses	Adjunctive treatment for seizures associated with Dravet syndrome (documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Must use in combination with clobazam (there are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome). 2. Must try and fail valproate and clobazam.
Age Restrictions	Must be at least 2 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Direct acting antivirals for hepatitis C

Products Affected

- *ledipasvir-sofosbuvir*
- *sofosbuvir-velpatasvir*
- **SOVALDI**
- **VIEKIRA PAK**
- **VOSEVI**
- **ZEPATIER**

PA Criteria	Criteria Details
Covered Uses	Applies to Epclusa, Harvoni, Mavyret, Sovaldi, Technivie, Viekira, Vosevi, Zepatier. Chronic hepatitis C infection (documentation of a hepatitis C ICD10 code from within the last 12 months must be submitted to Priority Health). Approved ICD10 Codes for Hepatitis C include: B17.11, B18.2, B18.8, B18.9, B19.0, B19.21.
Exclusion Criteria	
Required Medical Information	1. Must try Zepatier or Mavyret before any other direct-acting antiviral. 2. Requirements for elbasvir/grazoprevir (Zepatier): a. For genotypes 1 or 4 must use Zepatier. b. Must be tested for NS5A resistance-associated polymorphisms if genotype 1a. c. Zepatier must be taken with ribavirin for genotype 1a patients with baseline polymorphisms, genotype 1a or 1b patients with prior NS3/4A protease inhibitor use, and genotype 4 patients that are treatment experienced. 3. Requirements for glecaprevir/pibrentasvir (Mavyret): a. For genotypes 1 or 4 must use Zepatier. 4. Requirements for velpatasvir/sofosbuvir (Epclusa): a. Must be taken with ribavirin if decompensated cirrhosis is present. 5. Requirements for sofosbuvir (Sovaldi): a. Must have genotype 1, 2, 3, or 4 infection. b. Must be age 12 years or older. 6. Requirements for ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira): a. Must have genotype 1 infection. 7. Requirements for ombitasvir/paritaprevir/ritonavir (Technivie): a. Must have genotype 4 infection. 8. Requirements for ledipasvir/sofosbuvir (Harvoni): a. Must have genotype 1, 4, 5, or 6 infection. b. Must be age 12 years or older. 9. Requirements for sofosbuvir/velpatasvir/voxilaprevir (Vosevi): a. Must use Zepatier or Mavyret.
Age Restrictions	Must be at least 18 years of age unless stated otherwise.
Prescriber Restrictions	Must be a gastroenterologist, hepatologist, or infectious disease specialist.
Coverage Duration	Based on the recommended duration of therapy in the most recent AASLD/IDSA guidelines.
Other Criteria	

DPP-4 Agents

Products Affected

- **JANUMET**
- **JANUMET XR ORAL TABLET EXTENDED RELEASE 24 HOUR 100-1000 MG, 50-1000 MG, 50-500 MG**
- **JANUVIA**
- **JENTADUETO**
- **JENTADUETO XR**
- **TRADJENTA**

PA Criteria	Criteria Details
Covered Uses	Applies to Januvia, Janumet, Janumet XR, Jentadueto, Kombiglyze XR, Onglyza, Tradjenta. Type 2 diabetes mellitus.
Exclusion Criteria	Not covered for Type 1 diabetes mellitus.
Required Medical Information	1. Trial, failure, or intolerance to metformin plus a formulary sulfonylurea, thiazolidinedione (TZD), or dipeptidyl peptidase4 (DPP-4) inhibitor. 2. Hemoglobin A1c less than or equal to 9%. 3. For non-preferred drug product (Januvia, Onglyza, Tradjenta, Janumet, Janumet XR, Jentadueto, Kombiglyze): Trial and failure, or intolerance to one of the preferred products (alogliptin, alogliptin-metformin) after 3 continuous months of receiving maximal daily doses and not achieving adequate glycemic control.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Dupixent (dupilumab)

Products Affected

- **DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR** **200 MG/1.14ML, 300 MG/2ML**
- **DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/0.67ML,**

PA Criteria	Criteria Details
Covered Uses	Moderate to severe atopic dermatitis (AD), moderate to severe asthma, chronic rhinosinusitis with nasal polyp (CRSwNP).
Exclusion Criteria	Dupixent will not be covered in combination with another biologic medication (e.g. Xolair, Fasenra, Cinqair, Nucala, Remicade, Enbrel, Rituxan).
Required Medical Information	1. For AD with all of the following: a. Failure on all of the following topical treatments (applied daily for at least 28 days): i. One medium to high potency corticosteroid. ii. One calcineurin inhibitor. b. Failure on UVB/UVA phototherapy for at least 3 months. c. Failure on one of the following for at least 3 months: cyclosporine, azathioprine, methotrexate, or mycophenolate. 2. For moderate-to-severe asthma with all of the following: a. Must have been compliant on all of the following therapies for at least 3 months: i. High-dose inhaled corticosteroid, ii. Long-acting beta agonist, iii. One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva Respimat). b. Must have had greater than 3 asthma exacerbations in the previous year that required at least one of the following: i. Systemic steroids (or an increase in the current steroid dose) for at least 3 days, ii. Hospitalization and/or ED visit. c. Must not currently use tobacco products. d. Must try and fail Fasenra. AND one of the following (either e or f): e. Eosinophilic asthma confirmed by peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months, or f. Required dependence on daily oral corticosteroids. 3. Chronic rhinosinusitis with nasal polyp with baseline Nasal Polyps Score of at least 5, with a unilateral score of at least 2 for each nostril. a. Symptomatic disease that is persistent for a minimum of 12 weeks, including all of the following: nasal obstruction, rhinorrhea, diminished or loss of smell. b. Must have tried and failed all of the following: at least one prior systemic corticosteroid treatment, at least 3 months of an intranasal steroid, at least 1 month of one additional controller medication (anti-leukotriene agent, non-sedating antihistamine).
Age Restrictions	Must be at least 6 years of age (atopic dermatitis), at least 6 years of age (asthma), at least 18 years of age (chronic rhinosinusitis).

PA Criteria	Criteria Details
Prescriber Restrictions	Must be prescribed by a dermatologist, allergist, or immunologist.
Coverage Duration	6 months (initial for AD, CRSwNP), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: For atopic dermatitis, patient must have a documented positive clinical response including: clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares. For moderate-to-severe asthma, patient must not currently be using tobacco products, must not be using in combination with another biologic, must be compliant on Dupixent therapy, and must have experienced clinical benefit from Dupixent (e.g. decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use). For chronic rhinosinusitis with nasal polyp, patient must have a documented positive clinical response including: improvement in nasal congestion, decrease in nasal polyp size, improvement in ability to smell, decrease in rhinorrhea, decrease in nasal inflammation, decrease in oral corticosteroid use, AND the patient has maintained compliance with Dupixent in combination with an intranasal steroid.

Enbrel (etanercept)

Products Affected

- **ENBREL MINI**
- **ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML**
- **ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 25 MG/0.5ML, 50 MG/ML**
- **ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED**
- **ENBREL SURECLICK SUBCUTANEOUS SOLUTION AUTO-INJECTOR**

PA Criteria	Criteria Details
Covered Uses	1. Ankylosing spondylitis. 2. Juvenile idiopathic arthritis. 3. Plaque psoriasis. 4. Psoriatic arthritis. 5. Rheumatoid arthritis.
Exclusion Criteria	Enbrel will not be covered in combination with another biologic drug.
Required Medical Information	1. Ankylosing Spondylitis: There are no Specific Initiation Criteria for this indication. Enbrel is covered for any patient who meets the above General Initiation Criteria. 2. Juvenile Idiopathic Arthritis: a) Patient has tried at least ONE other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug, a biologic [Humira, Orencia, Enbrel, Kineret, Actemra]) for a period of at least 3 months, OR b) Patient will be starting on Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide, OR c) Patient has aggressive disease, as determined by the prescribing physician. 3. Plaque Psoriasis: a) Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii. One non-biologic systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin). iii. Phototherapy. 4. Psoriatic Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. 5. Rheumatoid Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Before Enbrel is covered, the patient must meet all of the General Criteria for Enbrel and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Endothelin Receptor Antagonists

Products Affected

- *ambrisentan*
- *bosentan*
- **OPSUMIT**

PA Criteria	Criteria Details
Covered Uses	Applies to Letairis (abrisentan), Opsumit (macitentan), Tracleer (bosentan). Treatment of pulmonary arterial hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH), World Health Organization Group 1, the patient: 1. Must have WHO functional Class II or greater symptoms prior to therapy initiation. 2. For Opsumit, must first have a trial and failure on ambrisentan or bosentan.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	If requesting the Tracleer (bosentan) tablet for suspension formulation, you must be 12 years of age or younger.

Enspryng (satralizumab)

Products Affected

- **ENSPRYNG**

PA Criteria	Criteria Details
Covered Uses	Neuromyelitis optica spectrum disorder (NMOSD) (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided). 2. Must have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years. 3. Must have progressive disease on a therapeutic trial of rituximab. 4. Expanded Disability Status Scale (EDSS) score of less than or equal to 7.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	For continuation, patient must meet all of the following requirements every 12 months: 1. Documentation of a decrease in relapse rate.

Epidiolex (cannabidiol)

Products Affected

- **EPIDIOLEX**

PA Criteria	Criteria Details
Covered Uses	Adjunctive treatment for seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex (documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Must try and fail at least two generic anticonvulsants.
Age Restrictions	Must be at least 1 year of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Esbriet (pirfenidone)

Products Affected

- **ESBRIET ORAL CAPSULE**
- **ESBRIET ORAL TABLET 267 MG, 801 MG**

PA Criteria	Criteria Details
Covered Uses	Idiopathic pulmonary fibrosis (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Esbriet is not covered in combination with Ofev.
Required Medical Information	1. Prescriber must rule out: other known causes of interstitial lung disease, AND have presence of a usual interstitial pneumonia (UIP) pattern on HRCT in patients not subjected to surgical lung biopsy and possibly surgical lung biopsy. 2. Must be a current non-smoker.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a pulmonologist.
Coverage Duration	12 months
Other Criteria	For continuation of previously authorized coverage, the patient must meet all the following requirements: 1. Must be a current non-smoker. 2. Documentation of stable FVC (recommended to discontinue if there is a greater than 10 percent decline in FVC over a 12 month period, indicating disease progression). 3. Member must be adherent to Esbriet.

Evrysdi (risdiplam)

Products Affected

- **EVRYSDI**

PA Criteria	Criteria Details
Covered Uses	Spinal muscular atrophy (SMA), confirmed by genetic testing (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Must not be receiving concurrent Spinraza or have previously received or be planning to receive gene therapy for SMA (Zolgensma).
Required Medical Information	1. Must have genetic testing confirming the member has no more than 2 copies of SMN2 or experienced SMA-associated symptoms before 6 months of age (please submit documentation). 2. Must be symptomatic at the time of the request, but must not be receiving invasive ventilation or have a tracheostomy. 3. Must submit a baseline 32-item motor function measure (MFM-32), Hammersmith Infant Neurologic Exam (HINE), or other validated assessment tool for SMA.
Age Restrictions	Must be 2 months of age or older.
Prescriber Restrictions	Must be prescribed by a neurologist or in consultation with a neurologist with experience treating SMA.
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: 1. Member must be adherent to Evrysdi. 2. Must submit documentation to show maintenance or improvement of condition: a.Repeat measurement of the MFM-32, HINE or other validated assessment tool appropriate for patient age. i. Must show improvement or stable results. ii. For HINE results, must show improvement in more categories of motor milestones than worsening. b. For members over 2 years of age, please submit documentation to show clinically significant improvement in spinal muscular atrophy-associated symptoms (for example, progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease.

Fasenra (benralizumab)

Products Affected

- **FASENRA PEN**

PA Criteria	Criteria Details
Covered Uses	Severe eosinophilic asthma.
Exclusion Criteria	Fasenra will not be covered in combination with another biologic medication (e.g. Xolair, Cinqair, Nucala, Dupixent).
Required Medical Information	For severe eosinophilic asthma with all of the following: 1. confirmed by peripheral blood eosinophil count of at least 150 cells/mcL in the past 12 months, 2. must be compliant on all of the following therapies for at least 3 months: a. High-dose inhaled corticosteroid (ICS), b. Long-acting beta agonist (LABA), c. One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva Respimat). 3. Must be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique). 4. Must have had more than 3 asthma exacerbations in the previous year that required at least one of the following: a. Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days, b. Hospitalization and/or ED visit. 5. Must not currently use tobacco products.
Age Restrictions	Must be at least 12 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements: 1. Must have been compliant on therapy with Fasenra. 2. Must not currently use tobacco products. 3. Must not use in combination with other biologics (e.g., Cinqair, Dupixent, Nucala, or Xolair). 4. Must have experienced clinical benefit from therapy with Fasenra confirmed by the following: a. Documented decrease in exacerbation frequency and/or decrease in oral corticosteroid use, b. Documented improvement in asthma symptoms.

Fintepla (fenfluramine)

Products Affected

- **FINTEPLA**

PA Criteria	Criteria Details
Covered Uses	Treatment for seizures associated with Dravet syndrome (documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Must try and fail two of the following generic drugs alone or in combination: clobazam, valproate/divalproex, or topiramate. 2. Must try and fail Diacomit (stiripentol).
Age Restrictions	Must be at least 2 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Forteo (teriparatide)

Products Affected

- *teriparatide (recombinant)*

PA Criteria	Criteria Details
Covered Uses	For osteoporosis, whether postmenopausal, primary or hypogonadal, or due to corticosteroids, in patients with and without a history of an osteoporotic fracture.
Exclusion Criteria	
Required Medical Information	1. For osteoporosis, whether postmenopausal, primary or hypogonadal, or due to corticosteroids, in patients with no history of an osteoporotic fracture, the patient: a. must try one of the following: alendronate, Actonel, or ibandronate and b. must try zoledronic acid (generic Reclast) or Prolia. 2. For osteoporosis, whether postmenopausal, primary or hypogonadal, or due to corticosteroids, in patients who have a history of an osteoporotic fracture, the patient: a. must try one of the following: alendronate, ibandronate, risedronate, zoledronic acid (generic Reclast), or Prolia and b. experience an additional osteoporotic fracture while on one of above therapies. 3. If using for diagnosis of postmenopausal osteoporosis, must first try Tymlos (in addition to the above).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 24 months
Other Criteria	Parathyroid hormone treatment may be authorized for up to two years in a lifetime. For example, Priority Health will not authorize teriparatide if Tymlos has already been used for two years. Additional efficacy beyond two years has not been established.

Galafold (miglastat)

Products Affected

- **GALAFOLD**

PA Criteria	Criteria Details
Covered Uses	Fabry disease and an amenable galactosidase alpha gene variant based on in-vitro assay data (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Galafold is not covered to be used in combination with ERT, thus combination use with Fabrazyme is not covered.
Required Medical Information	
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements: 1. Continued response to treatment (e.g. reduction in plasma glycosphingolipid GL-3 levels compared to baseline, decline in GFR or progression to end stage renal disease) as determined by the prescribing physician. 2. The patient is compliant in taking the medication as scheduled. 3. The patient tolerated the medication.

Gattex (teduglutide)

Products Affected

- **GATTEX**

PA Criteria	Criteria Details
Covered Uses	Short bowel syndrome dependent on parenteral support.
Exclusion Criteria	Patient must not have a history of: 1. Colorectal or gastrointestinal malignancy, 2. Radiation enteritis, 3. Cancer within 5 years before starting Gattex, 4. Use of human growth hormone within 6 months before starting Gattex, 5. Treatment for active Crohn's disease within 12 weeks before start, 6. More than 4 admissions within 12 months before starting Gattex.
Required Medical Information	1. Patient's body mass index is 15 kg/m2 or greater. 2. The following laboratory results must be assessed within 6 months before starting Gattex and at least every 6 months while using the drug: Alkaline phosphatase, Amylase, Bilirubin, Lipase. 3. If the patient has inflammatory bowel disease, he or she must not have taken immunosuppressant drugs within 3 months before starting Gattex and not used a biologic drug within 6 months before starting Gattex. 4. If the patient has his or her large intestine intact, a colonoscopy must be completed within 6 months before starting Gattex. 5. A reasonable expectation the patient will be removed from parenteral support within 6 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For a 24-week continuation, patient must have met the following requirements: 1. The patient is compliant in taking the medication as scheduled. 2. The patient tolerated the medication. 3. The patient did not experience any severe adverse reactions while taking the medication. 4. The patient had a 50% reduction in parenteral support volume. 5. With continued treatment, the patient can be removed from parenteral support within the next 6 months.

GLP-1 Agents

Products Affected

- **ADLYXIN**
- **ADLYXIN STARTER PACK**
- **BYDUREON BCISE**
- **BYDUREON SUBCUTANEOUS PEN-INJECTOR**
- **BYETTA 10 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR**
- **BYETTA 5 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR**
- **OZEMPIC (0.25 OR 0.5 MG/DOSE)**
- **OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/1.5ML, 4 MG/3ML**
- **TRULICITY**
- **VICTOZA SUBCUTANEOUS SOLUTION PEN-INJECTOR**

PA Criteria	Criteria Details
Covered Uses	Applies to Adlyxin, Byetta, Bydureon, Ozempic, Trulicity (preferred), Victoza. Type 2 diabetes mellitus.
Exclusion Criteria	Not covered for Type 1 diabetes mellitus.
Required Medical Information	1. Trial and failure, or intolerance to at least 2 generic oral antidiabetic agents or insulin after 3 continuous months of receiving maximal daily doses and not achieving adequate glycemic control. 2. Hemoglobin A1c less than or equal to 9%, but not less than 7%. 3. For non-preferred drug product: Trial and failure, or intolerance to Trulicity for 3 continuous months of receiving maximal daily doses and not achieving adequate glycemic control.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Hemlibra (emicizumab)

Products Affected

- **HEMLIBRA**

PA Criteria	Criteria Details
Covered Uses	Prevention of bleeding episodes (i.e., routine prophylaxis) associated with Hemophilia A with factor VIII inhibitors, severe Hemophilia A (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Hemlibra is not covered in combination with prophylactic use of other factor VIII replacement products or bypassing agents.
Required Medical Information	1. Must meet one of the following: a. Diagnosis of Hemophilia A with factor VIII inhibitors, b. Diagnosis of severe Hemophilia A (endogenous factor VIII level less than 1 percent of normal factor VIII [less than 0.01 IU/mL]) without factor VIII inhibitors AND patient is not a suitable candidate for treatment with shorter half-life Factor VIII (recombinant) products at a total weekly dose of 100 IU/kg or less (as attested by the prescribing physician with appropriate clinical rationale). 2. Physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate) for the treatment of breakthrough bleeding episodes.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a hematologist or other specialist.
Coverage Duration	12 months
Other Criteria	Coverage of Hemlibra is limited to the FDA approved dosing of 3 mg/kg for the first 4 weeks of therapy, then 1.5 mg/kg weekly thereafter. Additionally, when approved, Hemlibra must be obtained from a participating Hemophilia Specialty Pharmacy as noted in Medical Policy 91569.

Hereditary Angioedema Agents

Products Affected

- **BERINERT**
- **HAEGARDA**
- *icatibant acetate*
- **KALBITOR**
- **ORLADEYO**
- **SAJAZIR**
- **TAKHZYRO**

PA Criteria	Criteria Details
Covered Uses	Applies to Firazyr (icatibant), Kalbitor (ecallantide), Berinert (C1 esterase inhibitor), Takhzyro (lanadelumab), Haegarda (C1 esterase inhbitor), berotralstat (Orladeyo). Hereditary angioedema (HAE) Type I or Type II with two sets of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis (supporting documentation must be submitted to Priority Health). As noted in the plan documents, Priority Health may require a second opinion confirming the diagnosis.
Exclusion Criteria	Two or more acute-use agents (Firazyr, Berinert, and Kalibtor) are not covered in combination. Two or more prophylactic agents (Takhyzro, Haegarda, Orladeyo) are not covered in combination.
Required Medical Information	For all acute-use agents for hereditary angioedema (HAE), the following criteria must be met: 1. Patient has attacks affecting upper airways, OR involving the face, neck, or abdomen, OR resulting in debilitation or dysfunction. 2. Patient is not on an angiotensin-converting enzyme (ACE) inhibitor. 3. Patient has received training for self-administration. For all prophylactic agents for HAE, the following criteria must be met: 1. Documentation of severe (e.g. airway swelling, debilitating attacks of the face, neck, or abdomen) acute attacks occurring at least twice per month. 2. Documentation that on-demand/acute therapy (e.g. Firazyr, Berinert, Kalbitor) did not provide adequate symptom control. 3. Patient has received training for self-administration (Takhzyro and Haegarda). 4. Patient is not on an angiotensin-converting enzyme (ACE) inhibitor.
Age Restrictions	Age appropriate per drug as listed in FDA-approved label.
Prescriber Restrictions	Must be an allergist, immunologist, hematologist, or other specialist experienced in treating HAE.
Coverage Duration	Up to 12 months based on agent

PA Criteria	Criteria Details
Other Criteria	The WAO/EAACI recommends that a patient's HAE treatment plan and use of prophylactic and acute therapies be reviewed and evaluated at least yearly to gauge efficacy, safety, and dosing. Renewal of previously authorized prophylactic therapy requires (1) submission and review of patient's HAE treatment plan, (2) compliance on therapy, and (3) documentation of a decrease in the frequency of acute attacks from baseline (prior to treatment). For Acute Use Agents, if use of an acute agent is required to treat on average more than 3 attacks per month, Priority Health may require a second opinion of your HAE treatment plan, as noted in the plan documents. Drug-specific limitations for acute-use agents includes: Firazyr: Limited to a total of three syringes on-hand. Each additional fill requires documentation of the patient's use of the previous supply of Firazyr, as well as documentation of symptom relief with use. For example, if the member has two syringes on hand, then Priority Health will authorize a fill of one syringe to total three syringes on hand as long as Firazyr showed benefit for the patient. Berinert: Limited to one fill of 20 units/kg (supplied in 500 unit vials). Each additional fill requires documentation of the patient's use of the previous supply of Berinert, as well as documentation of symptom relief with use. Kalbitor: Limited to a total of six injections (two doses of 30mg given as three 10mg injections) on-hand. Each additional fill requires documentation of the patient's use of the previous supply of Kalbitor, as well as documentation of symptom relief with use. For example, if the patient has one dose of 30 mg (three 10 mg syringes) on hand, then Priority Health will authorize one dose of 30 mg to provide a total on hand supply of two 30 mg doses as long as Kalbitor showed benefit for the patient.Drug-specific limitations for prophylactic use agents includes: Takhzyro: Limited to 300mg (one vial) every 2 weeks. Duration of each authorization is limited to 6 months. Patients who are attack-free after 6 months of treatment with Takhzyro are authorized for 300mg (one vial) every 4 weeks. Haegarda: Limited to 60units/kg (in combinations of 3,000 & 2,000 unit vials) every 3 days. Duration of each authorization is limited to 12 months.

Hetlioz (tasimelteon)

Products Affected

- **HETLIOZ**

PA Criteria	Criteria Details
Covered Uses	Treatment of Non-24-Hour Sleep-Wake Disorder.
Exclusion Criteria	
Required Medical Information	1. Patient must have Non-24-Hour Sleep-Wake disorder. 2. Patient must be totally blind. 3. Must first try melatonin or Rozerem for 6 months and provide documentation of the medication's inability to improve the patient's overall sleep quality. 4. Must first try eszopiclone or zolpidem.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by a sleep specialist.
Coverage Duration	6 months
Other Criteria	For continuation, every 6 months the patient must have met the following requirements: 1. The patient's use of Hetlioz must be continuous without any gaps in treatment. Hetlioz will only continue to be covered for patientswith a proportion of days covered greater than or equal to 95 percent (must fill the prescription to have enough medication at least 28.5days or more for each month). 2. Prescriber must provide an objective evaluation of the patient's sleep quality, including documentation of an improvement in overall sleep quality while taking Hetlioz.

Humira (adalimumab)

Products Affected

- **HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML**
- **HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT**
- **HUMIRA PEN-CD/UC/HS STARTER SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML, 80 MG/0.8ML**
- **HUMIRA PEN-PEDIATRIC UC START**
- **HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML**
- **HUMIRA PEN-PSOR/UVEIT STARTER**
- **HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML**

PA Criteria	Criteria Details
Covered Uses	1. Ankylosing spondylitis. 2. Crohn's disease. 3. Hidradenitis suppurativa. 4. Juvenile idiopathic arthritis. 5. Plaque psoriasis. 6. Psoriatic arthritis. 7. Rheumatoid arthritis. 8. Ulcerative colitis. 9. Uveitis.
Exclusion Criteria	Humira will not be covered in combination with another biologic drug.

PA Criteria	Criteria Details
Required Medical Information	1. Ankylosing Spondylitis: There are no Specific Initiation Criteria for this indication. Humira is covered for any patient who meets the above General Initiation Criteria. 2. Crohn's Disease: a) Patient has tried or is currently taking corticosteroids (such as prednisone or methylprednisolone), OR b) Patient has tried at least ONE other agent for this condition (e.g., azathioprine, 6-mercaptopurine, methotrexate, Cimzia, Remicade, Entyvio, or Stelara) for a period of at least 3 months, OR c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistula, OR d) Patient has had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). 3. Hidradenitis Suppurativa: a) Patient has tried at least ONE other agent for this condition (e.g., intralesional or oral corticosteroids (such as triamcinolone or prednisone), or systemic antibiotics (such as clindamycin, dicloxacillin, or erythromycin), or isotretinoin. 4. Juvenile Idiopathic Arthritis: a) Patient has tried at least ONE other agent for this condition (e.g., a conventional synthetic DMARD (such as methotrexate, sulfasalazine, or leflunomide), or a nonsteroidal anti-inflammatory drug (NSAID), or a biologic DMARD (such as Orencia, Enbrel, Kineret, or Actemra)) for a period of at least 3 months, OR b) Patient will be starting on Humira concurrently with methotrexate, sulfasalazine, or leflunomide, OR c) Patient has aggressive disease, as determined by the prescribing physician. 5. Plaque Psoriasis a) Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii. One non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin). iii. Phototherapy. 6. Psoriatic Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months.Please see 'Other Criteria' section for Rheumatoid Arthritis, Ulcerative Colitis, Uveitis criteria.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	7. Rheumatoid Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months. 8. Ulcerative Colitis: a) Patient has tried ONE systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, Remicade, Simponi, or a corticosteroid [such as prednisone or methylprednisolone]) for a period of at least 2 months, OR b) Patient has pouchitis AND has tried therapy with an antibiotic (such as metronidazole or ciprofloxacin), probiotic, corticosteroid enema (such as hydrocortisone), or mesalamine enema. 9. Uveitis - noninfectious intermediate, posterior and panuveitis: a) Patient has tried ONE other agent for this condition (e.g., periocular, intraocular, or systemic corticosteroids (such as triamcinolone, betamethasone, methylprednisolone, or prednisone), immunosuppressives (such as methotrexate, mycophenolate mofetil, cyclosporine, azathioprine, or cyclophosphamide), Enbrel, or infliximab).Before Humira is covered, the patient must meet all of the General Criteria for Humira and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Idhifa (enasidenib)

Products Affected

- **IDHIFA**

PA Criteria	Criteria Details
Covered Uses	Relapsed or refractory acute myeloid leukemia (AML) with an IDH2 (isocitrate dehydrogenase-2) mutation as detected by an FDA approved companion test (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Must have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	Continuation Criteria after initial 6 month approval that must be met: 1. Absence of unacceptable toxicity from the drug including differentiation syndrome and leukocytosis, AND 2. One of the following: a. Patient has achieved less than 5 percent of blasts in the bone marrow, no evidence of disease, and full recovery of peripheral blood counts (platelets greater than 100,000/microliter and absolute neutrophil counts [ANC] greater than 1,000/microliter), OR b. Patient has achieved less than 5 percent of blasts in the bone marrow, no evidence of disease, and partial recovery of peripheral blood counts (platelets greater than 50,000/microliter and ANC greater than 500/microliter), OR c. If patient was previous dependent on red blood cell and/or platelet transfusions and is now independent of both red blood cell and platelet transfusions, OR d. If patient was previous independent on red blood cell and platelet transfusions and remains independent of both red blood cell and platelet transfusions.

Impavido (miltefosine)

Products Affected

- **IMPAVIDO**

PA Criteria	Criteria Details
Covered Uses	Visceral, mucosal, or cutaneous leishmaniasis caused by one of the following: Leishmania donovani, Leishmania braziliensis, Leishmania guyanensis or Leishmania panamensis (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One month
Other Criteria	

Increlex (mecasermin)

Products Affected

- **INCRELEX**

PA Criteria	Criteria Details
Covered Uses	1. Severe primary insulin-like growth factor-1 (IGF-1) deficiency. 2. Primary growth hormone deficiency caused by growth hormone gene deletions with development of neutralizing antibodies to growth hormone (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Baseline height less than 3rd percentile or greater than 2 standard deviations (SD) below the mean for gender and age. 2. IGF-1 at least 3 SD below the normal range for age and sex. 3. History of lower than normal growth velocity. 4. Epiphyses are open (must be confirmed for patients 10 years of age and older, submit radiograph). 5. Patient's bone age must be less than 16 years for males, less than 14 years for females. For severe primary insulin-like growth factor deficiency requires additional documentation of growth hormone concentration is normal or increased, OR confirmation by molecular genetic testing of growth hormone receptor mutations. For primary growth hormone deficiency caused by growth hormone gene deletion requires additional documentation of prior treatment with growth hormone (typically 3-6 month trial) and subsequent antibody development.
Age Restrictions	Must be between 2 to 65 years of age.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a pediatric endocrinologist.
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements: 1. Epiphyses are open. 2. Rate of growth with Increxlex is greater than pretreatment rate of growth. 3. Patient's bone age must be less than 16 years for males, less than 14 years for females.

Inqovi (decitabine/cedazuridine)

Products Affected

- **INQOVI**

PA Criteria	Criteria Details
Covered Uses	Myelodysplastic syndrome.
Exclusion Criteria	
Required Medical Information	Must first try decitabine injection or have a reason it cannot be used.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Inrebic (fedratinib)

Products Affected

- **INREBIC**

PA Criteria	Criteria Details
Covered Uses	Intermediate-2 or high-risk primary or secondary myelofibrosis.
Exclusion Criteria	
Required Medical Information	1. Must have a complete blood count (CBC) before starting therapy (platelet count greater than 50 x 109/L) with monitoring every 2 to 4 weeks until dosing is stable, then as clinically necessary. 2. Must have previously tried Jakafi with either a non-response or intolerance or have a contraindication to Jakafi.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: 1. The patient has experienced a 35 percent reduction in spleen volume (approximately a 50 percent reduction in spleen size on palpation).

Intrarosa (prasterone)

Products Affected

- **INTRAROSA**

PA Criteria	Criteria Details
Covered Uses	Moderate to severe dyspareunia caused by vulvovaginal atrophy.
Exclusion Criteria	
Required Medical Information	1. Plan documents must have sexual dysfunction rider. 2. Documented trial with an OTC vaginal lubricants for at least 90 days. 3. Documented trial of vaginal estrogen product for at least 90 days.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Jakafi (ruxolitinib)

Products Affected

- **JAKAFI**

PA Criteria	Criteria Details
Covered Uses	Myelofibrosis and at intermediate or high-risk, including primary myelofibrosis, postpolycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis.
Exclusion Criteria	
Required Medical Information	Complete blood count before starting therapy (platelet count more than 100 x 109/L) and monitored every 2 to 4 weeks until dosing is stable, then as clinically necessary. For polycythemia vera, must have had an inadequate response to hydroxyurea.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 weeks (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: Must have experienced a 35 percent reduction in spleen volume (approximately a 50 percent reduction in spleen size on palpation).

Jynarque (tolvaptan)

Products Affected

- **JYNARQUE**

PA Criteria	Criteria Details
Covered Uses	Autosomal dominant polycystic kidney disease (ADPKD) confirmed via ultrasound (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Must have an estimated glomerular filtration rate (eGFR) of 25-90 mL/min/1.73m2. 2. Must have disease that is rapidly progressing or likely to rapidly progress as evidenced by: a. Total kidney volume (TKV) of at least 750mL or b. Rapid loss of eGFR of at least 2.5mL/min/1.73m2 per year. 3. Hypertension, if present, must be adequately controlled (to 130/80mmHg or less).
Age Restrictions	Must be between 18 and 65 years of age.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a nephrologist.
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements every 12 months: 1. Patient must show signs of declining rate of progression in CKD via increase in total kidney volume of less than 5% per year or decline in eGFR by less than 2.5mL/min/1.73m2. 2. Must maintain an 85 percent adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient.

Kalydeco (ivacaftor)

Products Affected

- **KALYDECO ORAL PACKET**
- **KALYDECO ORAL TABLET**

PA Criteria	Criteria Details
Covered Uses	Treatment of cystic fibrosis (documentation of a cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 Codes for cystic fibrosis include: E84.0, E84.11, E84.19, E84.8, E84.9.
Exclusion Criteria	
Required Medical Information	1. Must have laboratory confirmation for any one of the approved mutations in the CFTR gene (per package labeling). 2. Formulation requested must match FDA label for age (4 months to 5 years for the oral granules and at least 6 years for the oral tablet).
Age Restrictions	Must be at least 4 months of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Kerendia (finerenone)

Products Affected

- **KERENDIA**

PA Criteria	Criteria Details
Covered Uses	To reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).
Exclusion Criteria	
Required Medical Information	Must have 1) diagnosis of type 2 diabetes. 2) eGFR of at least 25 mL/min/1.73 m2 or stage 2, 3, or 4 CKD. 3) concurrent therapy with an ACE inhibitor (e.g. lisinopril) or ARB (e.g. losartan). and 4) have tried and failed one preferred SGLT2 inhibitor (e.g. Farxiga (dapagliflozin).
Age Restrictions	At least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Keveyis (dichlorphenamide)

Products Affected

- **KEVEYIS**

PA Criteria	Criteria Details
Covered Uses	Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Must have diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants, confirmed by ONE of the following: Genetic testing, established family history, provocative testing, or electromyography. 2. Baseline and periodic monitoring of serum potassium and bicarbonate levels. 3. Documentation that lifestyle modifications, dietary restrictions and exercise restrictions have been maximally challenged. 4. Inadequate response, intolerance, or contraindication to acetazolamide.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 months (initial), 12 months (continuation)
Other Criteria	Continuation criteria, must meet the following (initial approval will be for 2 months): 1. Must continue to meet all of the initial requirements. 2. Documentation that the patient has had a reduction in the number of paralytic attacks.

Kevzara (sarilumab)

Products Affected

- **KEVZARA**

PA Criteria	Criteria Details
Covered Uses	1. Rheumatoid Arthritis.
Exclusion Criteria	Kevzara will not be covered in combination with another biologic.
Required Medical Information	1. Rheumatoid Arthritis. a) Patient has tried at least ONE conventional synthetic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months, AND b)Patient has tried TWO of the following: Actemra, Enbrel, Humira, Rinvoq, or Xeljanz/XR, each for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Kevzara is covered, the patient must meet all of the General Criteria for Kevzara and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Kineret (anakinra)

Products Affected

- **KINERET SUBCUTANEOUS SOLUTION PREFILLED SYRINGE**

PA Criteria	Criteria Details
Covered Uses	1. Rheumatoid Arthritis.
Exclusion Criteria	Kineret will not be covered in combination with another biologic drug.
Required Medical Information	1. Rheumatoid Arthritis. a) Patient has tried at least ONE synthetic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months, AND b)Patient has tried TWO of the following: Actemra, Enbrel, Humira, Rinvoq, or Xeljanz/XR, each for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months
Other Criteria	Before Kineret is covered, the patient must meet all of the General Criteria for Kineret and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Korlym (mifepristone)

Products Affected

- **KORLYM**

PA Criteria	Criteria Details
Covered Uses	Hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome.
Exclusion Criteria	
Required Medical Information	1. Must have a diagnosis of endogenous Cushing's syndrome AND type II diabetes mellitus (DM) or glucose intolerance secondary to hypercortisolism. 2. Must have failed surgical treatment or are not a candidate for surgery. 3. Must have tried maximally titrated dosages of insulin and other agents used to treat DM for at least 3 months, and have been unable to achieve adequate diabetes control.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by an endocrinologist.
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, must meet the following: 1. Requires documentation of improvement in hyperglycemia control.

Kuvan (sapropterin)

Products Affected

- **KUVAN**
- *sapropterin dihydrochloride*

PA Criteria	Criteria Details
Covered Uses	Phenylketonuria (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Kuvan is not covered in combination with Palynziq.
Required Medical Information	For phenylkeotonuria, the following criteria must be met: 1. Current adherence to dietary restriction of phenylalanine defined as an average of 65 grams of protein per day [from combination of medical foods that supply approximately 75 percent of protein requirements (except phenylalanine) and natural foods]. 2. Must continue phenylalanine-restricted diet if approved for Kuvan. 3. Tetrahydrobiopterin (BH4) deficiency has been ruled out. 4. Baseline blood phenylalanine levels must be provided.
Age Restrictions	Must be at least 1 month of age.
Prescriber Restrictions	Must be prescribed by a metabolic disease specialist.
Coverage Duration	2 months (initial), 12 months (continuation)
Other Criteria	For continuation, the patient must meet the following requirements: 1. Documented compliant maintenance therapy on Kuvan. 2. Continued adherence to a phenylalanine-restricted diet. 3. Achieved a 30 percent or greater reduction in phenylalanine (Phe) blood levels from baseline.

Kynmobi (apomorphine)

Products Affected

- **KYNMOBI**

PA Criteria	Criteria Details
Covered Uses	Treatment of advanced Parkinson's disease (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Patient is experiencing acute, intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). 2. Patient is receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release tablets and multiple daily dosing). 3. Therapeutic trial and failure of, or contraindication to, adjunctive therapy with at least one medication in each of the drug classes listed below: a. Dopamine agonist (e.g. pramipexole, ropinirole). b. Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline). c. Catechol-O-methyl transferase (COMT) inhibitor (e.g. entacapone).
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, documentation that the patient has met all of the following requirements must be provided every 12 months: positive response to Kynmobi therapy.

Lotronex (alosetron)

Products Affected

- *alosetron hcl*
- **LOTRONEX**

PA Criteria	Criteria Details
Covered Uses	Severe diarrhea-predominant irritable bowel syndrome.
Exclusion Criteria	
Required Medical Information	1. Patient is female. 2. Must have failed conventional treatment with at least two of the following: dietary changes, loperamide, an antispasmodic (ex. dicyclomine) or a bile acid sequestrant (cholestyramine, colestipol or colesevelem).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Maximum covered dose is 2mg/day.

Lupkynis (voclosporin)

Products Affected

- **LUPKYNIS**

PA Criteria	Criteria Details
Covered Uses	Biopsy-proven lupus nephritis Class III through V.
Exclusion Criteria	Lupkynis is not covered in combination with other biologic drug therapy (e.g., Benlysta, rituximab).
Required Medical Information	For biopsy-proven lupus nephritis Class III through V: 1. Must have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants). 2. Must be autoantibody-positive with one of the following: i. Anti-nuclear antibody (ANA) titer of at least 1:80, or ii. Anti-doublestranded DNA (anti-dsDNA) level of at least 30 IU/mL. 3. Must not have estimated glomerular filtration rate (eGFR) less than 45 mL/min/1.73m2. 4. Must have tried and failed Benlysta.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must have meet the following requirements: For biopsy-proven lupus nephritis Class III through V: 1. Must have evidence of efficacy (defined as urinary protein creatinine ratio less than or equal to 0.7, eGFR less than or equal to 20% below the pre-flare or at least 60mL/min/1.73m2), and no use of rescue therapy for treatment failure.

Myalept (metreleptin)

Products Affected

- **MYALEPT**

PA Criteria	Criteria Details
Covered Uses	Acquired or congenital generalized lipodystrophy resulting in leptin deficiency complications (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Myalept is not covered in the following conditions: HIV, Infectious liver disease, Acquired lipodystrophy with hematologic abnormalities.
Required Medical Information	For acquired or congenital generalized lipodystrophy resulting in leptin deficiency complications, laboratory leptin assay results (i.e. serum leptin levels less than the 7th percentile of normal values reported by the 3rd National Health and Nutrition Examination survey (less than 7.0 ng/mL in females and less than 3.0 ng/mLin males) confirming leptin deficiency must be provided. Patient must have one of the following metabolic abnormalities: Type 2 Diabetes mellitus, Triglyceride level more than 200 mg/dL, or Hyperinsulinemia (defined by fasting serum insulin greater than 30 microunits/mL).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Must not exceed maximum weight based daily dosing per FDA approved label.

Myfembree (relugolix/estradiol/norethindrone)

Products Affected

- **MYFEMBREE**

PA Criteria	Criteria Details
Covered Uses	Heavy menstrual bleeding associated with uterine fibroids.
Exclusion Criteria	
Required Medical Information	Trial of an oral contraceptive (estrogen/progestin or progestin only) for at least 3 months. Trial of Oriahnn for at least 3 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months (24 months total coverage)
Other Criteria	For continuation, patient must have met the following requirements: 1. The patient has experienced a clinically significant reduction in menstrual blood loss. 2. The patient is compliant in taking the medication as scheduled.

Natpara (parathyroid hormone)

Products Affected

- **NATPARA**

PA Criteria	Criteria Details
Covered Uses	Hypocalcemia in patients with hypoparathyroidism (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For hypocalcemia associated with hypoparathyroidism, the patient: 1. Must provide documentation of serum parathyroid hormone, calcium, magnesium, and phosphate levels (all drawn together). 2. Must be concurrently taking a calcium supplement and a Vitamin D supplement.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Nexletol (bempedoic acid)

Products Affected

- **NEXLETOL**

PA Criteria	Criteria Details
Covered Uses	1. Heterozygous familial hypercholesterolemia (HeFH), 2. very high risk clinical atherosclerotic cardiovascular disease (ASCVD).
Exclusion Criteria	Nexletol is not covered in combination with Praluent (evolocumab) or Repatha (evolocumab).
Required Medical Information	1. Must meet one of the following requirements: a. for a diagnosis of heterozygous familial hypercholesterolemia (HeFH), must be confirmed by one or more of the following: i. Genetic testing, ii. score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria, iii. score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria. b. for a diagnosis of very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. Additional requirements include: 2. Patient's most recent LDL-C laboratory report must be submitted with authorization request. 3. Patient must continue to receive maximally tolerated statin therapy or have a contraindication or intolerance to statin therapy*. 4. Requires documentation of compliant use with at least one high-intensity statin (rosuvastatin at least 20 mg daily or atorvastatin at least 40 mg daily) in combination with ezetimibe for at least 8 consecutive weeks with failure to achieve LDL-C less than 70 mg/dL in patients with history of CVD, or LDL-C less than 100 mg/dL in patients without history of CVD.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a cardiologist, endocrinologist, or board-certified lipidologist.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	*Statin intolerance defined as: 1. Trial of at least 3 different statins, one of which must be a non-daily, long-acting statin dosing regimen (i.e. rosuvastatin every-other-day), as well as a low-moderate intensity statin trial if high-intensity is not tolerated 2. Medical records documenting that intolerable skeletal-muscle related symptoms to each statin trialed resolve upon statin discontinuation, and are reproducible by statin re-challenge, and 3. Statin intolerance/symptoms are not attributable to drug interactions, concurrent illness, underlying muscle disease, or significant changes in physical activity. Note: If patient experiences statin-associated rhabdomyolysis, no further statin trials are required.

Nexlizet (bempedoic acid/ezetimibe)

Products Affected

- **NEXLIZET**

PA Criteria	Criteria Details
Covered Uses	1. Heterozygous familial hypercholesterolemia (HeFH), 2. very high risk clinical atherosclerotic cardiovascular disease (ASCVD).
Exclusion Criteria	Nexlizet is not covered in combination with Praluent (evolocumab) or Repatha (evolocumab).
Required Medical Information	1. Must meet one of the following requirements: a. for a diagnosis of heterozygous familial hypercholesterolemia (HeFH), must be confirmed by one or more of the following: i. Genetic testing, ii. score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria, iii. score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria. b. for a diagnosis of very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. Additional requirements include: 2. Patient's most recent LDL-C laboratory report must be submitted with authorization request. 3. Patient must continue to receive maximally tolerated statin therapy or have a contraindication or intolerance to statin therapy*. 4. Requires documentation of compliant use with at least one high-intensity statin (rosuvastatin at least 20 mg daily or atorvastatin at least 40 mg daily) in combination with ezetimibe for at least 8 consecutive weeks with failure to achieve LDL-C less than 70 mg/dL in patients with history of CVD, or LDL-C less than 100 mg/dL in patients without history of CVD.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a cardiologist, endocrinologist, or board-certified lipidologist.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	*Statin intolerance defined as: 1. Trial of at least 3 different statins, one of which must be a non-daily, long-acting statin dosing regimen (i.e. rosuvastatin every-other-day), as well as a low-moderate intensity statin trial if high-intensity is not tolerated 2. Medical records documenting that intolerable skeletal-muscle related symptoms to each statin trialed resolve upon statin discontinuation, and are reproducible by statin re-challenge, and 3. Statin intolerance/symptoms are not attributable to drug interactions, concurrent illness, underlying muscle disease, or significant changes in physical activity. Note: If patient experiences statin-associated rhabdomyolysis, no further statin trials are required.

Northera (droxidopa)

Products Affected

- *droxidopa*

PA Criteria	Criteria Details
Covered Uses	Symptomatic neurogenic orthostatic hypotension (nOH).
Exclusion Criteria	Other causes of orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy).
Required Medical Information	1. For a diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by one of the following: a. Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure), b. Dopamine beta-hydroxylase deficiency, c. Non-diabetic autonomic neuropathy. 2. Patient has tried at least two of the following non-pharmacologic interventions: a. Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants]. b. Raising the head of the bed 10 to 20 degrees. c. Compression garments to the lower extremities or abdomen. d. Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise). e. Increased salt and water intake, if appropriate. f. Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing). 3. Has a history of trial and failure (at least 30 days), contraindication, or intolerance to both of the following medications: a. Midodrine. b. Fludrocortisone.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist.
Coverage Duration	3 months (initial), 6 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: 1. Documentation of positive clinical response to droxidopa therapy 2. Member has experienced a sustained decrease in dizziness since initiation of therapy, AND 3. Member has maintained an increase in systolic and diastolic blood pressure within 3 minutes of standing since the initiation of therapy.

Noxafil (posaconazole)

Products Affected

- **NOXAFIL ORAL SUSPENSION**
- **NOXAFIL ORAL TABLET DELAYED RELEASE**
- *posaconazole*

PA Criteria	Criteria Details
Covered Uses	Prophylaxis of invasive Aspergillosis and Candida infections, treatment of invasive fungal disease (i.e., Aspergillus spp., Fusarium spp., Zygomycetes), treatment of oropharyngeal and esophageal candidiasis.
Exclusion Criteria	
Required Medical Information	1. Patient has one of the following conditions: a. Prophylaxis of invasive Aspergillosis and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with graft versus host disease or those with hematologic malignancies with prolonged neutropenia from chemotherapy. b. Treatment of invasive fungal disease (i.e., Aspergillus spp., Fusarium spp., Zygomycetes). c. Treatment of oropharyngeal and esophageal candidiasis. 2. Must have had an inadequate response, intolerable side effect, or contraindication to clotrimazole troches, nystatin suspension, fluconazole and itraconazole (oropharyngeal/esophageal candidiasis), or voriconazole or itraconazole (all other approved indications).
Age Restrictions	
Prescriber Restrictions	Must be prescribed or recommended by an infectious disease specialist.
Coverage Duration	Dependent upon indication
Other Criteria	If approved, initial authorization is for a maximum of 3 months (invasive fungal disease, prophylaxis of invasiveAspergillosis/Candida), oropharyngeal candidiasis (4 weeks), esophageal candidiasis (6 weeks).

Nucala (mepolizumab)

Products Affected

- **NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR**
- **NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE**

PA Criteria	Criteria Details
Covered Uses	1. Severe eosinophilic asthma (SEA). 2. Eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss). 3. Hypereosinophilic Syndrome (HES).
Exclusion Criteria	Nucala will not be covered in combination with another biologic medication (e.g. Xolair, Cinqair, Fasenra, Dupixent).
Required Medical Information	For SEA with all of the following: 1. confirmed by peripheral blood eosinophil count of at least 150 cells/mcL in the past 12 months, 2. must be compliant on all of the following therapies for at least 3 months: a. High-dose inhaled corticosteroid (ICS), b. Long-acting beta agonist (LABA), c. One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva Respimat). 3. Must be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique). 4. Must have had more than 3 asthma exacerbations in the previous year that required at least one of the following: a. Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days, b. Hospitalization and/or ED visit. 5. Must not currently use tobacco products. 6. Must try and fail Fasenra (for patients 12 years of age and older only). For EGPA with all of the following: 1. Diagnosis of EGPA for at least 6 months and confirmed by the following: a. A history or presence of asthma, AND b. A blood eosinophil level of greater than or equal to 10% of leukocytes or an absolute eosinophil count of greater than 1,000 cells/mm3 (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection), AND c. The presence of: i. Two or more features of eosinophilic granulomatosis with polyangiitis, OR ii. Antineutrophil cytoplasmic antibody [ANCA] positive status. 2. Must have EGPA that either has/is: a. Failed induction therapy with the following: i. Systemic glucocorticoids, AND ii. Cyclophosphamide or methotrexate, b. Refractory to or relapsed on (defined by a Birmingham Vasculitis Activity Score [BVAS] of greater than 3) at least two of the following: i. Azathioprine ii. Methotrexate iii. Leflunomide. For HES see 'Other Criteria' below.
Age Restrictions	Must be at least 6 years of age.

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For Hypereosinophilic Syndrome (HES) with all of the following: 1. Diagnosis of HES for at least 6 months. 2. Must have had at least two HES flares in the last 12 months (defined as signs or symptoms of HES requiring an increase in steroid dosing or addition of another therapy). 3. Must have a blood eosinophil count of at least 1,000 cells/mcL. 4. Must be stable on chronic steroid therapy (e.g. prednisone). 5. Must have tried and failed one generic, steroid-sparing therapy (e.g., methotrexate, hydroxyurea).For continuation, patient must have met the following requirements: For severe eosinophilic asthma: 1. Must have been compliant on therapy with Fasenra. 2. Must not currently use tobacco products. 3. Must not use in combination with other biologics (e.g., Cinqair, Dupixent, Nucala, or Xolair). 4. Must have experienced clinical benefit from therapy with Fasenra confirmed by the following: a. Documented decrease in exacerbation frequency and/or decrease in oral corticosteroid use, b. Documented improvement in asthma symptoms. For Eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss): 1. Birmingham Vasculitis Activity Score (BVAS) of 0 (no active vasculitis), 2. Prednisolone or prednisone dose less than or equal to 4 mg/day. For Hypereosinophilic Syndrome (HES): 1. Must have experienced clinical benefit from therapy with Nucala confirmed by the following: a. Documented decrease in exacerbation frequency and/or decrease in oral corticosteroid use, b. Documented improvement in HES symptoms.

Nuedexta (dextromethorphan/quinidine)

Products Affected

- **NUEDEXTA**

PA Criteria	Criteria Details
Covered Uses	Pseudobulbar affect caused by a structural neurologic condition (e.g. amyotrophic lateral sclerosis [ALS], multiple sclerosis [MS], or stroke).
Exclusion Criteria	
Required Medical Information	1. Patient has not had an exacerbation of the underlying neurologic condition in the two months before starting Nuedexta. 2. Patient does not have a history of: a. Alzheimer's or other dementia, b. Major psychiatric disturbance (e.g. bipolar disorder, major depression, schizophrenia), c. Substance abuse or drug-seeking behavior, d. Recent falls, or be at risk for falls. 3. Baseline ECG with no significant abnormalities and no history of QT prolongation syndrome. 4. Patient has at least 10 episodes of inappropriate laughing or crying per day before therapy. 5. Documented trial with one tricyclic antidepressant and one selective serotonin reuptake inhibitor (SSRI) for a total of 6 months.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
Coverage Duration	3 months (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: 1. Documentation of a 50 percent decrease in number of episodes of laughing or crying compared to baseline (before Nuedexta was started).

Ocaliva (obeticholic acid)

Products Affected

- **OCALIVA ORAL TABLET 10 MG, 5 MG**

PA Criteria	Criteria Details
Covered Uses	Treatment of primary biliary cholangitis.
Exclusion Criteria	Ocaliva is not covered in patients with clinically significant hepatic decompensation (e.g. known esophageal varices, poorly controlled or diuretic resistant ascites, history of variceal bleeds or related interventions), severe pruritus, inadequate response to ursodiol due to patient adherence, or superimposed liver disease (e.g. hepatitis C, alcoholic liver disease).
Required Medical Information	For the treatment of primary biliary cholangitis, the patient must: 1. Have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol. 2. Have one of the following: a. Alkaline phosphatase level at least 1.67 times the upper limit of normal, or b. Total bilirubin at least 1 times the upper limit of normal but less than 2 times the upper limit of normal.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Ofev (nintedanib)

Products Affected

- **OFEV**

PA Criteria	Criteria Details
Covered Uses	Idiopathic pulmonary fibrosis. Systemic sclerosis-associated interstitial lung disease (SSc-ILD). Chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Ofev is not covered in combination with Esbriet or Actemra.
Required Medical Information	For all covered indications, patient must be a current non-smoker. For Idiopathic Pulmonary Fibrosis (IPF): 1. Prescriber must rule out: other known causes of interstitial lung disease, AND have presence of a usual interstitial pneumonia (UIP) pattern on HRCT in patients not subjected to surgical lung biopsy and possibly surgical lung biopsy. For systemic sclerosis (SSc) related Interstitial Lung Disease (ILD) (SSc-ILD): 1. Must be confirmed by HRCT. 2. Extent of fibrotic disease in the lung must be at least 10 percent. 3. Forced Vital Capacity (FVC) must be at least 40 percent of predicted normal. 4. SSc disease onset (defined by first non-Raynaud symptom) within 7 past years. 5. Carbon Monoxide Diffusion Capacity (DLCO) must be 30 percent to 89 percent of predicted normal. 6. Disease progression (e.g., at least 10 percent decline in FVC or DLCO) on trials of mycophenolate mofetil or cyclophosphamide at maximally tolerated doses, or medical contraindication. 7. Patient is being adequately treated for any complications of SSc (e.g.,pulmonary hypertension) and comorbid disease (e.g., chronic obstructive pulmonary disease [COPD]). For chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype: 1. Must be confirmed by HRCT. 2. Extent of fibrotic disease in the lung must be at least 10 percent. 3. Forced Vital Capacity (FVC) decline of greater than 10 percent. 4. If FVC decline is at least 5 percent but less than 10 percent, must have: a. Experiencing worsening respiratory symptoms, OR b. Exhibiting increasing extent of fibrotic changes on chest imaging.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist for the condition being treated.

PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	For continuation of previously authorized coverage, the patient must meet all the following requirements: 1. Must be a current non-smoker. 2. Documentation of stable FVC (recommended to discontinue if there is a greater than 10 percent decline in FVC over a 12 month period, indicating disease progression). 3. Member must be adherent to Ofev.

Olumiant (baricitinib)

Products Affected

- **OLUMIANT**

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis.
Exclusion Criteria	Olumiant will not be covered in combination with a biologic drug.
Required Medical Information	1. Rheumatoid Arthritis. a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months. AND b) Patient has tried at least TWO of the following: Actemra, Enbrel, Humira, Rinvoq, or Xeljanz/XR, each for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Olumiant is covered, the patient must meet all of the General Criteria for Olumiant and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Oncology Drug Request

Products Affected

- *abiraterone acetate oral tablet 250 mg*
- **AFINITOR**
- **AFINITOR DISPERZ**
- **ALECENSA**
- **ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG**
- **ALUNBRIG ORAL TABLET THERAPY PACK**
- **AYVAKIT ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 50 MG**
- **BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG**
- *bexarotene*
- **BOSULIF**
- **BRAFTOVI**
- **BRUKINSA**
- **CABOMETYX**
- **CALQUENCE**
- **CAPRELSA**
- **COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG**
- **COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG**
- **COMETRIQ (60 MG DAILY DOSE)**
- **COPIKTRA**
- **COTELLIC**
- **DAURISMO**
- **ERIVEDGE**
- **ERLEADA**
- *erlotinib hcl*
- *everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg*
- *everolimus oral tablet soluble*
- **FARYDAK**
- **FOTIVDA**
- **GAVRETO**
- **GILOTRIF**
- **IBRANCE ORAL CAPSULE**
- **IBRANCE ORAL TABLET 100 MG, 125 MG, 75 MG**
- **ICLUSIG**
- *imatinib mesylate*
- **IMBRUVICA ORAL CAPSULE 140 MG, 70 MG**
- **IMBRUVICA ORAL TABLET**
- **INLYTA**
- **IRESSA**
- **KISQALI (200 MG DOSE)**
- **KISQALI (400 MG DOSE)**
- **KISQALI FEMARA (400 MG DOSE)**
- **KISQALI FEMARA (600 MG DOSE)**
- **KISQALI FEMARA(200 MG DOSE)**
- **KOSELUGO**
- *lapatinib ditosylate*
- **LENVIMA (10 MG DAILY DOSE)**
- **LENVIMA (12 MG DAILY DOSE)**
- **LENVIMA (14 MG DAILY DOSE)**
- **LENVIMA (18 MG DAILY DOSE)**
- **LENVIMA (20 MG DAILY DOSE)**
- **LENVIMA (24 MG DAILY DOSE)**
- **LENVIMA (4 MG DAILY DOSE)**
- **LENVIMA (8 MG DAILY DOSE)**
- **LONSURF**
- **LORBRENA**
- **LUMAKRAS**
- **LYNPARZA ORAL TABLET**
- **LYSODREN**
- **MATULANE**
- **MEKINIST**
- **MEKTOVI**
- *methyltestosterone oral*
- **NERLYNX**
- **NEXAVAR**
- **NINLARO**
- **ODOMZO**
- **ORGOVYX**
- **PIQRAY (200 MG DAILY DOSE)**
- **PIQRAY (250 MG DAILY DOSE)**
- **PIQRAY (300 MG DAILY DOSE)**
- **POMALYST**
- **RETEVMO**
- **ROZLYTREK**
- **RUBRACA**
- **SPRYCEL**
- **STIVARGA**
- *sunitinib malate*
- **SUTENT**
- **TABRECTA**
- **TAFINLAR**
- **TAGRISSO**

- **TALZENNA**
- **TARGRETIN ORAL**
- **TASIGNA**
- **TAZVERIK**
- **TEMODAR ORAL**
- *temozolomide*
- **TEPMETKO**
- **TIBSOVO**
- *tretinoin oral*
- **TRUSELTIQ (100MG DAILY DOSE)**
- **TRUSELTIQ (125MG DAILY DOSE)**
- **TRUSELTIQ (50MG DAILY DOSE)**
- **TRUSELTIQ (75MG DAILY DOSE)**
- **TUKYSA**
- **TYKERB**
- **UKONIQ**
- **VENCLEXTA**
- **VENCLEXTA STARTING PACK**
- **VERZENIO**
- **VITRAKVI ORAL CAPSULE**
- **VITRAKVI ORAL SOLUTION**
- **VIZIMPRO**
- **VOTRIENT**
- **XALKORI**
- **XOSPATA**
- **XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG**
- **XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG**
- **XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 20 MG**
- **XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG**
- **XPOVIO (60 MG TWICE WEEKLY)**
- **XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG**
- **XPOVIO (80 MG TWICE WEEKLY)**
- **ZEJULA**
- **ZELBORAF**
- **ZOLINZA**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded.
Exclusion Criteria	
Required Medical Information	1. Must have a Food and Drug Administration (FDA) approved indication for use or use must be consistent with National Comprehensive Cancer Network guidelines category 1 or 2A recommendations for cancer type, cancer stage, line of therapy and performance status. Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles. 2. Coverage for National Comprehensive Cancer Network guidelines category 2B recommendations will be considered after failure of category 1 or 2A recommendations or when higher recommendations are not indicated. 3. Appropriate genetic testing results to support use based on FDA approved package labeling and NCCN guidelines. 4. Must have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2.
Age Restrictions	
Prescriber Restrictions	Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	

Onureg (azacitidine)

Products Affected

- **ONUREG**

PA Criteria	Criteria Details
Covered Uses	Acute Myeloid Leukemia (AML).
Exclusion Criteria	
Required Medical Information	1. Must be in first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy plus consolidation therapy within 4 months. 2. Must be ineligible for hematopoietic stem cell transplantation (HSCT). 3. Must have a trial of azacitidine injection or clinical rationale why it cannot be used.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Orencia (abatacept)

Products Affected

- **ORENCIA CLICKJECT**
- **ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 125 MG/ML, 50 MG/0.4ML, 87.5 MG/0.7ML**

PA Criteria	Criteria Details
Covered Uses	1. Rheumatoid arthritis. 2. Juvenile idiopathic arthritis. 3. Psoriatic Arthritis. Orencia may also be covered under the member's medical benefit. For physician-administered drug coverage, please refer to the Injectable Drug List and search for drug name. You can view criteria and submit using electronic Prior Authorization (ePA) or via the drug specific Prior Authorization form.
Exclusion Criteria	Orencia will not be covered in combination with another biologic.
Required Medical Information	1. Rheumatoid Arthritis: a) Patient has tried at least ONE conventional synthetic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months, AND b)Patient has tried TWO of the following: Actemra, Enbrel, Humira, Rinvoq, or Xeljanz/XR, each for a period of at least 3 months. 2. Juvenile Idiopathic Arthritis: a) Patient has tried TWO of the following: Enbrel, Humira, or Actemra for a period of at least 3 months. 3. Psoriatic Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine or azathioprine) for a period of at least 3 months, AND b)Patient has tried TWO of the following: Cosentyx, Enbrel, Humira, Xeljanz/XR, Otezla, or Stelara SC, each for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Before Orencia is covered, the patient must meet all of the General Criteria for Orencia and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Orenitram ER (treprostinil extended-release)

Products Affected

- **ORENITRAM ORAL TABLET EXTENDED RELEASE 0.125 MG, 0.25 MG, 1 MG, 2.5 MG, 5 MG**

PA Criteria	Criteria Details
Covered Uses	Treatment of pulmonary arterial hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH), World Health Organization Group 1, the patient: 1. Must have WHO functional Class II or greater symptoms prior to therapy initiation. 2. Must first have a trial and failure on sildenafil (generic Revatio).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Oriahnn (elagolix/estradiol/norethindrone)

Products Affected

- **ORIAHNN**

PA Criteria	Criteria Details
Covered Uses	Heavy menstrual bleeding associated with uterine fibroids.
Exclusion Criteria	
Required Medical Information	Trial of an oral contraceptive (estrogen/progestin or progestin only) for at least 3 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 months total
Other Criteria	For continuation, patient must have met the following requirements: 1. The patient has experienced a clinically significant reduction in menstrual blood loss. 2. The patient is compliant in taking the medication as scheduled.

Orilissa (elagolix)

Products Affected

- **ORILISSA ORAL TABLET 150 MG, 200 MG**

PA Criteria	Criteria Details
Covered Uses	Moderate to severe pain associated with endometriosis.
Exclusion Criteria	
Required Medical Information	Trial of an NSAID (nonsteroidal anti-inflammatory drug) and an oral contraceptive for at least 3 months each.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: 1. The patient has experienced a clinically significant reduction in pain. 2. The patient is compliant in taking the medication as scheduled. 3. Patient is being monitored as clinically appropriate for condition.

Orkambi (lumacaftor/ivacaftor)

Products Affected

- **ORKAMBI ORAL PACKET**
- **ORKAMBI ORAL TABLET**

PA Criteria	Criteria Details
Covered Uses	1. Must have laboratory confirmation for any one of the approved mutations in the CFTR gene (per package labeling). 2. Formulation requested must match FDA label for age (2 to 5 years for the oral packet and at least 6 years for the oral tablet).
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Must be at least 2 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Osphena (ospemifene)

Products Affected

- **OSPHENA**

PA Criteria	Criteria Details
Covered Uses	Moderate to severe dyspareunia caused by vulvovaginal atrophy.
Exclusion Criteria	
Required Medical Information	1. Plan documents must have sexual dysfunction rider. 2. Documented trial with an OTC vaginal lubricants for at least 90 days. 3. Documented trial of vaginal estrogen product for at least 90 days.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Otezla (apremilast)

Products Affected

- **OTEZLA ORAL TABLET**
- **OTEZLA ORAL TABLET THERAPY PACK**

PA Criteria	Criteria Details
Covered Uses	1. Plaque psoriasis. 2. Psoriatic arthritis. 3. Behcet's Disease.
Exclusion Criteria	Otezla will not be covered in combination with a biologic.
Required Medical Information	1. Plaque Psoriasis. a) Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii. One non-biologic systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin). iii. Phototherapy. 2. Psoriatic Arthritis. a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. 3. Behcet's Disease. a) The patient has oral ulcers or other mucocutaneous involvement (provide chart note documentation), AND b) The patient has tried at least ONE other systemic therapy. Note: Examples of systemic therapies include colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors (e.g., adalimumab [Humira], etanercept [Enbrel], certolizumab pegol [Cimzia], golimumab [Simponi/Aria], or infliximab products [Inflectra, Remicade, Renflexis]).
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months
Other Criteria	Before Otezla is covered, the patient must meet all of the General Criteria for Otezla and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Oxervate (cenegermin)

Products Affected

- **OXERVATE**

PA Criteria	Criteria Details
Covered Uses	Neurotrophic keratitis (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Covered only for stage 2 or stage 3 neurotrophic keratitis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8 weeks (total)
Other Criteria	

Oxtellar XR (oxcarbazepine)

Products Affected

- **OXTELLAR XR ORAL TABLET EXTENDED RELEASE 24 HOUR 150 MG, 300 MG, 600 MG**

PA Criteria	Criteria Details
Covered Uses	Partial-onset seizure (documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Trial and failure with or intolerance to all of the following: 1. Oxcarbazepine. 2. One additional generic anti-seizure medication.
Age Restrictions	Must be at least 6 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Palforzia [Peanut (Arachis hypogaea) Allergen Powder]

Products Affected

- **PALFORZIA (12 MG DAILY DOSE)**
- **PALFORZIA (120 MG DAILY DOSE)**
- **PALFORZIA (160 MG DAILY DOSE)**
- **PALFORZIA (20 MG DAILY DOSE)**
- **PALFORZIA (200 MG DAILY DOSE)**
- **PALFORZIA (240 MG DAILY DOSE)**
- **PALFORZIA (3 MG DAILY DOSE)**
- **PALFORZIA (300 MG MAINTENANCE)**
- **PALFORZIA (300 MG TITRATION)**
- **PALFORZIA (40 MG DAILY DOSE)**
- **PALFORZIA (6 MG DAILY DOSE)**
- **PALFORZIA (80 MG DAILY DOSE)**
- **PALFORZIA INITIAL ESCALATION**

PA Criteria	Criteria Details
Covered Uses	(supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Must have diagnosis of peanut allergy confirmed by one of the following: a. Peanut-specific immunoglobulin E (psIgE) level greater than 0.35 kUA/L. b. Skin prick test with mean wheal diameter greater than 3 mm larger than control. 2. Must have clinical history of allergy to peanuts or peanut-containing food. 3. Use and dosing must follow the FDA-approved label. Currently, patients must be 4 - 17 years old or have started Palforzia between 4 - 17 years old.
Age Restrictions	Must be 4 to 17 years of age.
Prescriber Restrictions	Must be prescribed by an allergist.
Coverage Duration	12 months
Other Criteria	When criteria are met, initial and continuation approvals are for 12 months. Only the first kit (Initial Dose Escalation kit containing the first 5 doses) may be covered under the medical benefit. All other doses are covered under pharmacy benefit. For continuation, patient must have met the following requirements: 1. Use and dosing must continue to follow the FDA-approved label. Currently, patients who started on therapy between 4 - 17 years of age may continue past 17 years old. 2. Palforzia treatment has demonstrated effectiveness with manageable side effects. 3. Patient has been and is still able to comply with the daily dosing requirements.

Palynziq (pegvaliase)

Products Affected

- **PALYNZIQ**

PA Criteria	Criteria Details
Covered Uses	Phenylketonuria (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Palynziq is not covered in combination with Kuvan. Kuvan treatment must be stopped within 14 days of beginning therapy on Palynziq.
Required Medical Information	For phenylkeotonuria, the following criteria must be met: 1. Current adherence to dietary restriction of phenylalanine defined as an average of 65 grams of protein per day [from combination of medical foods that supply approximately 75 percent of protein requirements (except phenylalanine) and natural foods]. 2. Must continue phenylalanine-restricted diet if approved for Palynziq. 3. Baseline/current phenylalanine levels provided showing current levels are greater than 600 mcmol/L. 4. Clinical trial and failure of Kuvan in combination with phenylalanine restricted diet. a. Clinical trial defined as 4 weeks treatment with Kuvan 20mg/kg/day. b. Failure is defined as blood phenylalanine levels greater than 600mcmol/L with combination therapy. c. Patients with mutation analysis documenting two null mutations in trans (i.e. mutations resulting in complete absence of phenylalanine hydroxylase enzyme activity) are not required to trial Kuvan).
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by a metabolic disease specialist.
Coverage Duration	12 months (coverage duration may depend on dose requested)

PA Criteria	Criteria Details
Other Criteria	Initial approval is limited to a maximum of one year (includes minimum 9-week titration and maximum of 24-weeks maintenance therapy) at a maximum dose of 20mg daily. For requests to exceed 20mg Palynziq daily, the patient must meet the following requirements: 1. Must have compliant maintenance therapy on Palynziq 20mg daily for a minimum of 24 weeks. 2. Have failed to achieve a 20 percent reduction in blood phenylalanine concentration from baseline or a bloodphenylalanine concentration no greater than 600 micromol/L by week 24 of 20mg daily Palynziq maintenance therapy. Coverage for Palynziq 40mg daily is limited to an initial duration of 16 weeks. For continuation of coverage after 12-months therapy on an approved dose of Palynziq or after 16-weeks Palynziq 40mg daily, the patient must meet the following requirements: 1. Documented compliant maintenance therapy on Palynziq. 2. Continued adherence to a phenylalanine-restricted diet. 3. Achieved at least a 20 percent reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration no greater than 600 micromol/L.

Praluent (alirocumab)

Products Affected

- **PRALUENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR**

PA Criteria	Criteria Details
Covered Uses	1. Heterozygous familial hypercholesterolemia (HeFH). 2. Very high risk clinical atherosclerotic cardiovascular disease (ASCVD).
Exclusion Criteria	Praluent is not covered in combination with Repatha (evolocumab), Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe).
Required Medical Information	1. Must meet one of the following requirements: a. for a diagnosis of heterozygous familial hypercholesterolemia (HeFH), must be confirmed by one or more of the following: i. Genetic testing, ii. score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria, iii. score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria. b. for a diagnosis of very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. Additional requirements include: 2. Patient's most recent LDL-C laboratory report must be submitted with authorization request. 3. Patient must continue to receive maximally tolerated statin therapy or have a contraindication or intolerance to statin therapy*. 4. Requires documentation of compliant use with at least one high-intensity statin (rosuvastatin at least 20 mg daily or atorvastatin at least 40 mg daily) in combination with ezetimibe for at least 8 consecutive weeks with failure to achieve LDL-C less than 70 mg/dL in patients with history of CVD, or LDL-C less than 100 mg/dL in patients without history of CVD.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a cardiologist, endocrinologist, or board-certified lipidologist.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	*Statin intolerance defined as: 1. Trial of at least 3 different statins, one of which must be a non-daily, long-acting statin dosing regimen (i.e. rosuvastatin every-other-day), as well as a low-moderate intensity statin trial if high-intensity is not tolerated 2. Medical records documenting that intolerable skeletal-muscle related symptoms to each statin trialed resolve upon statin discontinuation, and are reproducible by statin re-challenge, and 3. Statin intolerance/symptoms are not attributable to drug interactions, concurrent illness, underlying muscle disease, or significant changes in physical activity. Note: If patient experiences statin-associated rhabdomyolysis, no further statin trials are required.

Prevymis (letermovir)

Products Affected

- **PREVYMIS ORAL**

PA Criteria	Criteria Details
Covered Uses	Prophylaxis of cytomegalovirus (CMV) infection and disease in CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). Note: Prevymis is not indicated for the treatment of CMV infection or prevention of CMV disease in other types of transplants.
Exclusion Criteria	Prevymis is not covered in combination with another antiviral agent for CMV treatment.
Required Medical Information	
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	100 days
Other Criteria	

Promacta (eltrombopag)

Products Affected

- **PROMACTA**

PA Criteria	Criteria Details
Covered Uses	Chronic immune (idiopathic) thrombocytopenic purpura (ITP). Aplastic Anemia.
Exclusion Criteria	
Required Medical Information	Must have one of the following conditions and complete applicable step therapy requirements:1. Chronic immune (idiopathic) thrombocytopenic purpura (ITP). i. Have an insufficient response to corticosteroids, immunoglobulin, or splenectomy. ii. Documentation of a treatment-limiting adverse drug reaction to corticosteroids or immunoglobulin. iii. Current platelet count less than 50 x 109/L with a clinical risk of bleeding. 2. Aplastic Anemia. i. Have an insufficient response to one immunosuppressive agent. ii. Baseline platelet count must be less than 30 x 10^9 cells/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	16 weeks (initial-aplastic anemia), 12 months (continuation)
Other Criteria	The maximum daily dose of Promacta for treatment of ITP is 75 mg per day, and the maximum daily dose for treatment of aplastic anemia is 150 mg per day.For continuation for aplastic anemia after the initial 16 weeks, patient must meet the following requirements: Must have a hematologic response defined as either: 1. Platelet count increase to 20 x 10^9 cells/L above baseline or stable platelet counts with transfusion independence for a minimum of 8 weeks. ii. Hemoglobin increase by greater than 1.5 g/dL or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks. iii. ANC increase of 100% or an ANC increase greater than 500/µL.

Pulmozyme (dornase alfa)

Products Affected

- **PULMOZYME**

PA Criteria	Criteria Details
Covered Uses	Treatment of cystic fibrosis (documentation of a cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 Codes for cystic fibrosis include: E84.0, E84.11, E84.19, E84.8, E84.9.
Exclusion Criteria	
Required Medical Information	Must have diagnosis of cystic fibrosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Ravicti (glycerol phenylbutyrate)

Products Affected

- **RAVICTI**

PA Criteria	Criteria Details
Covered Uses	Chronic hyperammonemia because of a urea cycle disorder.
Exclusion Criteria	
Required Medical Information	1. Patient's condition cannot be managed by dietary protein restriction. 2. Patient's condition cannot be managed by amino acid supplementation. 3. Patient has tried sodium phenylbutyrate.
Age Restrictions	Must be at least 2 months of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Relistor (methylnaltrexone oral)

Products Affected

- **RELISTOR ORAL**
- **RELISTOR SUBCUTANEOUS SOLUTION 12 MG/0.6ML, 8 MG/0.4ML**

PA Criteria	Criteria Details
Covered Uses	Opioid-induced constipation.
Exclusion Criteria	Patient must not have a mechanical gastrointestinal obstruction, indwelling peritoneal catheter, clinically active diverticular disease, fecal impaction, acute surgical abdomen, or fecal ostomy.
Required Medical Information	Patient must first try: 1. two other laxative drugs (one of which includes lactulose) or be unable to tolerate oral laxatives. AND 2. A therapeutic trial of Movantik or Symproic. 3. For injection only: therapeutic trial of Relistor tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Repatha (evolocumab)

Products Affected

- **REPATHA**
- **REPATHA PUSHTRONEX SYSTEM**
- **REPATHA SURECLICK**

PA Criteria	Criteria Details
Covered Uses	1. Homozygous Familial Hypercholesterolemia (HoFH). 2. Heterozygous familial hypercholesterolemia (HeFH). 3. Very high risk clinical atherosclerotic cardiovascular disease (ASCVD).
Exclusion Criteria	Repatha is not covered in combination with Praluent (alirocumab), Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe).
Required Medical Information	1. Must meet one of the following requirements: a. for a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), must be confirmed by one or more of the following: i. Presence of two mutant alleles at the LDL receptor, Apolipoprotein B, or PCSK9 gene, or ii. An untreated LDL-C greater than 500 mg/dL (13 mml/L) before treatment or greater than 300 mg/dL (7.76 mmol/L) despite treatment, and either have cutaneous or tendinous xanthoma before age 10 years or untreated LDL-C levels consistent with heterozygous familiar hypercholesterolemia in both parents (greater than 190 mg/dL). b. for a diagnosis of heterozygous familial hypercholesterolemia (HeFH), must be confirmed by one or more of the following: i. Genetic testing, ii. score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria, iii. score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria. c. for a diagnosis of very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol. Additional requirements include: 2. Patient's most recent LDL-C laboratory report must be submitted with authorization request. 3. Patient must continue to receive maximally tolerated statin therapy or have a contraindication or intolerance to statin therapy*. 4. Requires documentation of compliant use with at least one high-intensity statin (rosuvastatin at least 20 mg daily or atorvastatin at least 40 mg daily) in combination with ezetimibe for at least 8 consecutive weeks with failure to achieve LDL-C less than 70 mg/dL in patients with history of CVD, or LDL-C less than 100 mg/dL in patients without history of CVD.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by a cardiologist, endocrinologist, or board-certified lipidologist.

PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	*Statin intolerance defined as: 1. Trial of at least 3 different statins, one of which must be a non-daily, long-acting statin dosing regimen (i.e. rosuvastatin every-other-day), as well as a low-moderate intensity statin trial if high-intensity is not tolerated 2. Medical records documenting that intolerable skeletal-muscle related symptoms to each statin trialed resolve upon statin discontinuation, and are reproducible by statin re-challenge, and 3. Statin intolerance/symptoms are not attributable to drug interactions, concurrent illness, underlying muscle disease, or significant changes in physical activity. Note: If patient experiences statin-associated rhabdomyolysis, no further statin trials are required.

Revatio (sildenafil)

Products Affected

- **REVATIO ORAL SUSPENSION RECONSTITUTED**
- **REVATIO ORAL TABLET**
- *sildenafil citrate oral suspension reconstituted*
- *sildenafil citrate oral tablet 20 mg*

PA Criteria	Criteria Details
Covered Uses	Treatment of pulmonary arterial hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH), World Health Organization Group 1, the patient must have WHO functional Class II or greater symptoms prior to therapy initiation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Revcovi (elapegademase)

Products Affected

- **REVCOVI**

PA Criteria	Criteria Details
Covered Uses	Adenosine deaminase deficiency severe combined immune deficiency (ADA-SCID) (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Baseline trough plasma ADA activity has been provided. 2. Patient can adhere to therapy (e.g., weekly or twice weekly dosing). 3. Treatment will be monitored and adjusted based on FDA-labeled recommendations, including target trough plasma ADA activity of at least 30 mmol/hr/L.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must meet the following requirements: 1. Patient has been compliant and is able to continue to adhere to therapy. 2. Trough plasma ADA activity is greater than 30 mmol/hr/L (or doses are being adjusted to reach this target). 3. Trough erythrocyte dAXP is less than 0.02 mmol/L (or doses are being adjusted to reach this target). 4. Total and subset lymphocyte counts have increased (or doses are being adjusted to reach this target). 5. Most recent total and subset lymphocyte counts, trough plasma ADA activity, and trough dAXP levels have been provided to support the above levels. If self-administered, Revcovi will be covered under the pharmacy benefit.

Rinvoq (upadacitinib)

Products Affected

- **RINVOQ**

PA Criteria	Criteria Details
Covered Uses	Rheumatoid Arthritis.
Exclusion Criteria	Rinvoq will not be covered in combination with a biologic drug.
Required Medical Information	1. Rheumatoid Arthritis. a) Patient has tried at least ONE conventional synthetic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Rinvoq is covered, the patient must meet all of the General Criteria for Rinvoq and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Rukobia (fostemsavir)

Products Affected

- **RUKOBIA**

PA Criteria	Criteria Details
Covered Uses	HIV-1 infection in heavily treatment-experienced (HTE) adults with multidrug-resistant HIV-1 infection failing their current ARV regimen.
Exclusion Criteria	
Required Medical Information	1. Must have confirmed HIV infection with failure of their current ARV regimen (baseline HIV-1 RNA at least 400 copies/mL), with no viable ARV combination therapy available because of exhaustion of a least four of six ARV classes. Exhaustion was defined as the elimination of all ARVs within a given class as a fully active option to pair with Rukobia because of resistance or previous adverse events (AEs). 2. Rukobia is to be used in combination with other antiretroviral agents (optimized background antiretroviral regimen) and have documentation of full viral sensitivity/susceptibility to at least one antiretroviral agent (other than Rukobia) as determined by resistance testing, as Rukobia is to be used in combination with other antiretroviral agents.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, documentation that the patient has met all of the following requirements must be provided every 12 months: 1. Patient has achieved clinically significant viral response to Rukobia therapy, 2. Patient has continued to take an optimized background antiretroviral regimen.

Ruzurgi (amifampridine)

Products Affected

- **RUZURGI**

PA Criteria	Criteria Details
Covered Uses	Lambert-Eaton myasthenic syndrome (LEMS) (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	1. Must have a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by one of the two electrodiagnostic studies and the antibody test as listed below: a. The patient has a normal sensory study with a reproducible post-exercise (i.e., 10 seconds of maximal isometric muscle activation) increase in compound motor action potential (CMAP) amplitude (post-exercise facilitation) of at least 60% compared to pre-exercise baseline OR a similar increment using high-frequency repetitive nerve stimulation (RNS) AND b. Positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody test. 2. Must have clinical symptoms of LEMS (i.e., proximal lower extremity weakness) that interfere with daily activities. 3. Member must be ambulatory. 4. Must provide a baseline disease severity score using the Quantitative Myasthenia Gravis (QMG) or the Triple-Timed Up-And-Go (3TUG) test. 5. For adult patients only, must have tried and failed pyridostigmine (fail is defined as taking the medication as prescribed and at an appropriate dose for the condition). 6. If the patient has a cancer diagnosis associated with LEMS (e.g., small cell lung cancer), the cancer must have been appropriately treated prior to starting Ruzurgi.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	4 weeks (initial), 12 months (continuation)

PA Criteria	Criteria Details
Other Criteria	For continuation, patient must have met the following requirements: 1. Must have disease response indicated by an improvement or stabilization from baseline in subjective measures (e.g., symptoms such as muscle weakness, improvement in daily activities, walking). 2. Must have disease response indicated by an improvement or stabilization from baseline in objectivemeasures using the 3TUG test. Note: The covered quantity of amifampridine is limited to the FDA-approved dose for the drug and depends upon the age and weight of the member.

Rydapt (midostaurin)

Products Affected

- **RYDAPT**

PA Criteria	Criteria Details
Covered Uses	Acute myeloid leukemia (AML). Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SMAHN), or mast cell leukemia (MCL).
Exclusion Criteria	Rydapt is not covered for acute promyelocytic leukemia (APL).
Required Medical Information	For AML, the patient meets all of the following: 1. Newly diagnosed AML. 2. Documentation of FLT3 mutation-positive as detected by an FDA-approved test. 3. Use with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. For ASM, SM-AHN, and MCL, the patient must be at least 18 years of age.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	The patient meets one of the following requirements: 1. Complete resolution or greater than a 20% improvement in one or more C-findings without progression in other C-findings (based on Valent Study 2-D2201) AND a sustained response to therapy for at least 8 weeks. OR 2. Complete remission as observed on bone marrow biopsy. For ASM, SM-AHN, and MCL: Rydapt will be limited to #60 tablets every 30 days. Initial requests are approved for 6 months. Continuation requests are approved in 12 months intervals. For AML: Rydapt will be limited to #56 tablets every 21 days for a total of 6 cycles (e.g., total tablet count of #336).

Sabril (vigabatrin)

Products Affected

- *vigabatrin oral packet*
- *vigabatrin oral tablet*
- **VIGADRONE**

PA Criteria	Criteria Details
Covered Uses	Treatment of infantile spasms (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For infantile spasms, must be 2 years of age or younger. For refractory complex partial seizure, must have treatment failure with two generic anticonvulsants.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	

Samsca (tolvaptan)

Products Affected

- **SAMSCA**
- *tolvaptan*

PA Criteria	Criteria Details
Covered Uses	Treatment of hyponatremia (serum sodium less than 130 mEq/L).
Exclusion Criteria	
Required Medical Information	For treatment of symptomatic hyponatremia (serum sodium less than 130 mEq/L), must be: 1. unresponsive to other therapy including, but not limited to, fluid restriction, loop diuretics, hypertonic saline [or salt tablets]). 2. Must be initiated or re-initiated in an inpatient setting. 3. Patient must be screened for drug-induced causes of hyponatremia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One month
Other Criteria	When criteria are met, the maximum dose authorized is 60 mg per day. Coverage duration is limited to 30 days.

Serostim (somatropin)

Products Affected

- **SEROSTIM SUBCUTANEOUS SOLUTION RECONSTITUTED 4 MG, 5 MG, 6 MG**

PA Criteria	Criteria Details
Covered Uses	HIV-associated wasting or cachexia.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Signifor (pasireotide)

Products Affected

- **SIGNIFOR**

PA Criteria	Criteria Details
Covered Uses	Cushing's disease.
Exclusion Criteria	
Required Medical Information	For treatment of Cushing's disease, must: 1. Provide documentation of failed pituitary surgery or contraindication to surgery. 2. Documented trial and failure with ketoconazole to reduce cortisol secretion.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Siliq (brodalumab)

Products Affected

- **SILIQ**

PA Criteria	Criteria Details
Covered Uses	1. Plaque Psoriasis.
Exclusion Criteria	Siliq will not be covered in combination with another biologic drug.
Required Medical Information	1. Plaque Psoriasis. a)Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii.One traditional, systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin). iii. Phototherapy. iv. At least TWO of the following: Cosentyx, Humira, Otezla, Skyrizi, Tremfya, or Stelara.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Siliq is covered, the patient must meet all of the General Criteria for Siliq and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Simponi (golimumab)

Products Affected

- **SIMPONI SUBCUTANEOUS SOLUTION AUTO-INJECTOR 100 MG/ML, 50 MG/0.5ML**
- **SIMPONI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 50 MG/0.5ML**

PA Criteria	Criteria Details
Covered Uses	1. Ankylosing spondylitis. 2. Psoriatic arthritis. 3. Rheumatoid arthritis. 4. Ulcerative colitis
Exclusion Criteria	Simponi will not be covered in combination with another biologic drug.
Required Medical Information	1. Ankylosing Spondylitis. a) Patient has tried at least TWO of the following: Cosentyx, Enbrel, or Humira, each for a period of at least 3 months. 2. Psoriatic Arthritis. a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months, AND b) Patient has tried at least TWO of the following: Cosentyx, Enbrel, Humira, Xeljanz/XR, Otezla, or Stelara, each for a period of at least 3 months. 3. Rheumatoid Arthritis. a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months. AND b) Patient has tried at least TWO of the following: Actemra, Enbrel, Humira, Rinvoq, or Xeljanz/XR, each for a period of at least 3 months. 4. Ulcerative Colitis. a) Patient has tried Humira for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Simponi is covered, the patient must meet all of the General Criteria and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Skyrizi (risankizumab)

Products Affected

- **SKYRIZI**
- **SKYRIZI (150 MG DOSE)**
- **SKYRIZI PEN**

PA Criteria	Criteria Details
Covered Uses	1. Plaque Psoriasis.
Exclusion Criteria	Skyrizi will not be covered in combination with another biologic drug.
Required Medical Information	1. Plaque Psoriasis. a) Patient has tried ALL of the following for a period of at least 3 months: a. One topical agent. b. One non-biologic traditional DMARD (e.g., methotrexate [MTX], cyclosporine, acitretin). c. Phototherapy.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Skyrizi is covered, the patient must meet all of the General Criteria for Skyrizi and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Soliqua (insulin glargine/lixisenatide)

Products Affected

- **SOLIQUA**

PA Criteria	Criteria Details
Covered Uses	Type 2 diabetes mellitus.
Exclusion Criteria	Not covered for Type 1 diabetes mellitus. Soliqua is not covered in combination with another GLP-1 receptor agonist or basal insulin.
Required Medical Information	Patient meets the current prior authorization criteria for a formulary GLP-1 agonist (Trulicity) which includes all of the following: 1. Trial and failure, or intolerance to at least 2 generic oral antidiabetic agents or insulin after 3 continuous months of receiving maximal daily doses and not achieving adequate glycemic control. 2. Hemoglobin A1c less than or equal to 9%, but not less than 7%.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Somavert (pegvisomant)

Products Affected

- **SOMAVERT**

PA Criteria	Criteria Details
Covered Uses	Treatment of acromegaly.
Exclusion Criteria	
Required Medical Information	For the treatment of acromegaly, must have: 1. An inadequate response to surgery or radiation therapy, unless those therapies are not an option. 2.Must have inadequate response to a somatostatin analog (e.g. Signifor).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Sporanox (itraconazole oral suspension)

Products Affected

- *itraconazole oral solution*
- **SPORANOX ORAL SOLUTION**

PA Criteria	Criteria Details
Covered Uses	Treatment of invasive fungal disease (i.e., Aspergillus spp., Blastomycosis, Histoplasmosis), treatment of oropharyngeal and esophageal candidiasis.
Exclusion Criteria	
Required Medical Information	For the treatment of invasive fungal disease (i.e., Aspergillus spp., Blastomycosis, Histoplasmosis) OR for the treatment of oropharyngeal and esophageal candidiasis. 1. Must have had an inadequate response, intolerable side effect, or contraindication to clotrimazole troches, nystatin suspension, fluconazole and itraconazole capsule (oropharyngeal/esophageal candidiasis), or itraconazole capsule (all other approved indications).
Age Restrictions	
Prescriber Restrictions	Must be prescribed or recommended by an infectious disease specialist.
Coverage Duration	Dependent upon indication
Other Criteria	If approved, initial authorization is for a maximum of 3 months (invasive fungal disease, prophylaxis of invasiveAspergillosis/Candida), oropharyngeal candidiasis (4 weeks), esophageal candidiasis (6 weeks).

Stelara (ustekinumab)

Products Affected

- **STELARA SUBCUTANEOUS SOLUTION MG/ML 45 MG/0.5ML**
- **STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90**

PA Criteria	Criteria Details
Covered Uses	1. Crohn's Disease. 2. Plaque Psoriasis. 3. Psoriatic Arthritis. 4. Ulcerative Colitis. Stelara may also be covered under your medical benefit. For physician-administered drug coverage, please refer to the Injectable Drug List and search for drug name. You can view criteria and submit using electronic Prior Authorization (ePA) or via the separate Prior Authorization form.
Exclusion Criteria	Stelara will not be covered in combination with a biologic drug.
Required Medical Information	1. Crohn's Disease: a) Patient has tried or is currently taking corticosteroids (such as prednisone or methylprednisolone), OR b) Patient has tried at least ONE other agent for this condition (e.g., azathioprine, 6-mercaptopurine, methotrexate, Cimzia, Remicade, Entyvio, or Humira) for a period of at least 3 months. 2. Plaque Psoriasis: a) Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii. One traditional non-biologic systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin). iii. Phototherapy. b) If 90 mg dose is requested, patient must weigh more than 100 kg. 3. Psoriatic Arthritis: a) Patient has tried at least ONE conventional systemic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. b) If 90 mg dose is requested, patient must weigh more than 100 kg. 4. Ulcerative Colitis: a) Patient has tried ONE systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, infliximab, Simponi, or a corticosteroid [such as prednisone or methylprednisolone]) for a period of at least 2 months, OR b) The patient has pouchitis AND has tried therapy with an antibiotic (such as metronidazole or ciprofloxacin), probiotic, corticosteroid enema (such as hydrocortisone), or mesalamine enema.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Before Stelara is covered, the patient must meet all of the General Criteria for Stelara and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. When used for plaque psoriasis and psoriatic arthritis, Stelara will initially be approved for the 45 mg dose only, regardless of the patient's weight. Request to increase dosing to the 90 mg (for patients greater than 100 kg only): 1.Must have tried Stelara 45 mg for at least 12 weeks. 2.Documentation must be provided that shows that the patient's condition has not improved after 12 weeks with the 45 mg dose.

Strensiq (asfotase alfa injection)

Products Affected

- **STRENSIQ**

PA Criteria	Criteria Details
Covered Uses	Perinatal/infantile or juvenile-onset hypophosphatasia (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For perinatal/infantile or juvenile-onset hypophosphatasia: 1. Clinical manifestations consistent with hypophosphatasia must be present. 2. Diagnosis must be confirmed with both biochemical and molecular genetic testing. 3. A second opinion may be required by Priority Health from a Specialist Provider we choose to help us determine whether Strensiq is medically necessary.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	The FDA-approved labeling allows for Strensiq to be injected three times per week or six times per week. Strensiq is only covered as a three times per week injection.

Subsys (fentanyl citrate spray)

Products Affected

- **SUBSYS SUBLINGUAL LIQUID 100 MCG, 1200 (600 X 2) MCG, 1600 (800 X 2) MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG**

PA Criteria	Criteria Details
Covered Uses	To manage breakthrough pain in cancer patients.
Exclusion Criteria	
Required Medical Information	1. Must be receiving and tolerant to around-the-clock opioid therapy for persistent cancer pain. 2.Trial and failure, or intolerance to generic fentanyl buccal lozenge.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Symdeko (Tezacaftor/ivacaftor)

Products Affected

- **SYMDEKO**

PA Criteria	Criteria Details
Covered Uses	Treatment of cystic fibrosis (documentation of a cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 Codes for cystic fibrosis include: E84.0, E84.11, E84.19, E84.8, E84.9.
Exclusion Criteria	
Required Medical Information	1. Must have laboratory confirmation for any one of the approved mutations in the CFTR gene (per package labeling).
Age Restrictions	Must be at least 6 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Syprine (trientine)

Products Affected

- *trientine hcl*

PA Criteria	Criteria Details
Covered Uses	Wilson's disease (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For treatment of Wilson's disease, must have been previously treated with penicillamine (not tolerated) or is contraindicated.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, a gastroenterologist.
Coverage Duration	12 months
Other Criteria	

Tegsedi (inotersen)

Products Affected

- **TEGSEDI**

PA Criteria	Criteria Details
Covered Uses	Hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy, must have: 1. Genetic testing confirming a transthyretin (TTR) mutation (e.g., V30M). 2. Presence of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). 3. Must have documentation of one of the following (see Additional Information below): a. Baseline polyneuropathy disability (PND) score no greater than IIIb. b. Baseline FAP Stage 1 or 2. 4. Patient is not receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements: 1. Documentation that the patient continues to have one of the following: a. Polyneuropathy disability (PND) score no greater than IIIb. b. FAP Stage 1 or 2. Documentation that the patient has experienced a positive clinical response to Tegsedi compared to baseline (e.g., improved neurologic improvement, motor function, quality of life, slowing of disease progression). 3. Patient is not receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro. Note: When criteria are met, coverage duration is 12 months for initial and continuation requests with a quantity limit of 4 syringes per month. Only the first injection is covered under the medical benefit for administration by a healthcare professional. All subsequent injections are intended for self-administration and covered under the pharmacy benefit.

Testosterone topical

Products Affected

- *testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 50 mg/5gm (1%)*

PA Criteria	Criteria Details
Covered Uses	Hypogonadal hypotestosteronism, gender dysphoria (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For the management of hypogonadal hypotestosteronism, member must have: a. Clinical signs and symptoms consistent with androgen deficiency (requests for coverage to treat fatigue or decreased libido with no other symptoms is not a covered benefit). b. A serum total testosterone test result of 300 ng/dL or less on two different dates in the previous 12 months (lab results must be included or faxed with request) prior to treatment. 3. Must first try injectable testosterone (e.g. testosterone enanthate 150 to 200 mg every two weeks) for a minimum of two months with failure to improve symptoms. If patient experiences fluctuations in symptoms, after two months or more, the dosage can be changed (e.g. testosterone enanthate 100 mg once a week). For the management of gender dysphoria: 1. Documentation of diagnosis must be submitted to Priority Health. 2. Must first try injectable testosterone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Injectable testosterone enanthate (Delatestryl) and testosterone cypionate (Depo-Testosterone) do not require prior authorization. "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to injectable testosterone therapy.

Thiola (tiopronin)

Products Affected

- *tiopronin oral*

PA Criteria	Criteria Details
Covered Uses	Prevention of cystine stone formation in patients with severe homozygous cystinuria (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Before this drug is covered, the patient must meet all the following requirements: 1. Have a diagnosis of cystinuria. 2. Provide documentation showing patient's trial and compliance with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalization) was ineffective, not tolerated, or contraindicated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Note: For approval over quantity limit restriction, documentation proving conservative measures have continued in combination with Thiola and that member has been compliant with these measures must be faxed to Priority Health.

Tremfya (guselkumab)

Products Affected

- **TREMFYA SUBCUTANEOUS SOLUTION PEN-INJECTOR**
- **TREMFYA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE**

PA Criteria	Criteria Details
Covered Uses	1. Plaque Psoriasis. 2. Psoriatic arthritis.
Exclusion Criteria	Tremfya will not be covered in combination with another biologic drug.
Required Medical Information	1. Plaque Psoriasis. a) Patient has tried ALL of the following for a period of at least 3 months: i. One topical agent. ii. One non-biologic traditional DMARD (e.g., methotrexate [MTX], cyclosporine, acitretin). iii. Phototherapy. 2. Psoriatic arthritis. a) Patient has tried at least ONE conventional synthetic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Tremfya is covered, the patient must meet all of the General Criteria for Tremfya and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Trikafta (elexacaftor/tezacaftor/ivacaftor, ivacaftor)

Products Affected

- **TRIKAFTA ORAL TABLET THERAPY PACK 100-50-75 & 150 MG, 50-25-37.5 & 75 MG**

PA Criteria	Criteria Details
Covered Uses	Treatment of cystic fibrosis (documentation of a cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 Codes for cystic fibrosis include: E84.0, E84.11, E84.19, E84.8, E84.9.
Exclusion Criteria	
Required Medical Information	Must have laboratory confirmation of at least one F508del mutation in the CFTR (cystic fibrosis transmembrane regulator) gene.
Age Restrictions	Must be at least 6 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Tymlos (abaloparatide)

Products Affected

- **TYMLOS**

PA Criteria	Criteria Details
Covered Uses	Treatment of postmenopausal osteoporosis in a woman at high risk for fracture.
Exclusion Criteria	
Required Medical Information	Must meet the following requirements based on fracture history: 1. If the patient has no history of an osteoporotic fracture, all of the following must be met: a. Must have a documented treatment failure, contraindication* or ineffective response** to a minimum of a 12-month trial with an oral bisphosphonate (e.g., alendronate, risedronate or ibandronate), AND b. Must have a documented treatment failure, contraindication or ineffective response** to a minimum of a 12-month trial with zoledronic acid (generic Reclast) or Prolia. 2. If the patient has a history of an osteoporotic fracture, the following must be met: a. Must have a documented treatment failure, contraindication*, or ineffective response** to a minimum of a 12-month trial with one of the following: alendronate, ibandronate, risedronate, zoledronic acid, or Prolia. 3. Must try Evenity or have a documented contraindication to its use. *Contraindication examples to oral bisphosphonate therapy include the following: a. Documented inability to sit or stand upright for at least 30 minutes. b. Documented pre-existing gastrointestinal disorder such as inability to swallow, esophageal stricture, or achalasia. **Ineffective response is defined as one of the following: a. Decrease in T-score in comparison to previous T-score from DEXA scan. b. New fracture while on therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 24 months
Other Criteria	Parathyroid hormone treatment may be authorized for up to two years in a lifetime. For example, Priority Health will not authorize Tymlos if Forteo has already been used for two years. Additional efficacy beyond two years has not been established.

Tyvaso (treprostinil)

Products Affected

- **TYVASO**
- **TYVASO REFILL**
- **TYVASO STARTER**

PA Criteria	Criteria Details
Covered Uses	Treatment of pulmonary arterial hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For pulmonary arterial hypertension (PAH), World Health Organization Group 1, the patient must have WHO functional Class III or greater symptoms prior to therapy initiation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Ubrelvy (ubrogepant)

Products Affected

- **UBRELVY ORAL TABLET 100 MG, 50 MG**

PA Criteria	Criteria Details
Covered Uses	Acute treatment of migraine with or without aura.
Exclusion Criteria	
Required Medical Information	1. Trial and failure of one non-steroidal anti-inflammatory drug (NSAID). 2. Trial and failure of two preferred triptan medications unless contraindicated.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	Quantity limit: 10 tablets per 30 days, limited to 4 fills per year.

Uptravi (selexipag)

Products Affected

- **UPTRAVI ORAL TABLET**
- **UPTRAVI ORAL TABLET THERAPY PACK**

PA Criteria	Criteria Details
Covered Uses	Treatment of pulmonary arterial hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	PAH meets World Health Organization (WHO) Group 1 criteria.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Valchlor (mechlorethamine gel)

Products Affected

- **VALCHLOR**

PA Criteria	Criteria Details
Covered Uses	Treatment of stage 1A or 1B mycosis fungoides (MF) type cutaneous T-cell lymphoma (CTCL).
Exclusion Criteria	
Required Medical Information	Must first try two of the following therapies: topical corticosteroid, topical chemotherapy, topical retinoid, imiquimod, local radiation therapy, orphototherapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, documentation that the patient has met all of the following requirements must be provided: 1. Positive clinical responses to Valchlor including clinical reduction in body surface area (BSA) affected from baseline, 50 percent reduction in Composite Assessment of Index Lesion Severity (CAILS) from baseline, or 50 percent improvement in Severity Weighted Assessment Tool (SWAT) from baseline.

Vascepa (icosapent ethyl)

Products Affected

- *icosapent ethyl*
- **VASCEPA**

PA Criteria	Criteria Details
Covered Uses	Treatment of severe hypertriglyceridemia. Risk reduction of myocardial infarction (MI), stroke, coronary revascularization, and unstable anginarequiring hospitalization. Supporting documentation must be submitted to Priority Health.
Exclusion Criteria	
Required Medical Information	For severe hypertriglyceridemia, must meet the following requirements: 1. Laboratory confirmation of triglyceride level at or above 500 mg/dL. 2. First try one of the following: fenofibrate, fenofibric acid, or gemfibrozil. 3. Also try omega-3-acid ethyl esters (generic Lovaza). For reducing the risk of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization, must meet the following requirements: 1. Have one of the following diagnoses (provide documentation): a. Established cardiovascular disease (CVD) defined as a documented history of coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease. b. Diabetes mellitus with 2 or more additional risk factors for CVD (e.g., current or recent cigarette smoker, hypertension, elevated CRP, etc.). 2. Be used with maximally tolerated statin therapy. 3. Have elevated triglyceride levels (150 mg/dL or greater).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Ventavis (iloprost)

Products Affected

- **VENTAVIS**

PA Criteria	Criteria Details
Covered Uses	Treatment of pulmonary arterial hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	PAH meets World Health Organization (WHO) Group 1 criteria.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Verquvo (vericiguat)

Products Affected

- **VERQUVO**

PA Criteria	Criteria Details
Covered Uses	Symptomatic worsening chronic heart failure (NYHA Class II-IV).
Exclusion Criteria	
Required Medical Information	1. Must have confirmed diagnosis of symptomatic worsening chronic heart failure (NYHA Class II-IV), defined as one of the following: a. History of previous HF hospitalization within the last 6 months. b. Outpatient intravenous diuretic for HF within the previous 3 months. 2. Patient has been using at least 3 of the following HF medications at goal doses for HF treatment or maximally tolerated dosing: a. ACEI, ARB, or Entresto. b. Bisoprolol, carvedilol or sustained release metoprolol. c. Spironolactone. d. Diuretic (i.e. furosemide). 3. Ejection Fraction less than 45% assessed within the previous 12 months. 4. Documentation of an elevated brain natriuretic peptide (BNP) or NT-proBNP level within the previous 30 days.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Must be prescribed by or in consultation with a cardiologist.
Coverage Duration	12 months
Other Criteria	

Viberzi (eluxadoline)

Products Affected

- **VIBERZI**

PA Criteria	Criteria Details
Covered Uses	Irritable bowel Syndrome (IBS) with diarrhea.
Exclusion Criteria	
Required Medical Information	For Irritable bowel Syndrome (IBS) with diarrhea: 1. Must have failed conventional treatment with lifestyle and dietary modification which may include exclusion of gas-producing foods, diet low in fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs), and in select cases avoidance of lactose and gluten (detailed documentation of lifestyle changes tried for at least 1 month must be faxed to Priority Health). 2. Trial of at least three of the following (tried for at least 1 month each): a. Loperamide. b. Antispasmodic (ex. Dicyclomine). c. Bile acid sequestrant (cholestyramine, colestipol or colesevelem). d. Tricyclic antidepressant (ex. nortriptyline).
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Maximum covered dose is 200 mg/day.

VMAT2 Agents

Products Affected

- **AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG**
- **INGREZZA ORAL CAPSULE**
- **INGREZZA ORAL CAPSULE THERAPY PACK**
- *tetrabenazine oral tablet 12.5 mg, 25 mg*

PA Criteria	Criteria Details
Covered Uses	Applies to Austedo, Ingrezza, tetrabenazine. 1. Chorea associated with Huntington's disease (Austedo and tetrabenazine only), 2. Moderate to severe tardive dyskinesia (TD).
Exclusion Criteria	Austedo, Ingrezza, tetrabenazine will not be covered in combination with one another.
Required Medical Information	For a diagnosis of chorea associated with Huntington's disease, must have the following: prior to Austedo, must have tried and failed a maximally tolerated dose of tetrabenazine. For tetrabenazine doses greater than 50mg/day, must have CYP2D6 genotype provided. For a diagnosis of moderate to severe tardive dyskinesia (TD), must: 1. provide documentation of the member's current Abnormal Involuntary Movement Scale (AIMS) score with a minimum score of 3 on item 8 (severity of abnormal movements overall). 2. For tetrabenazine doses greater than 50mg/day, must have CYP2D6 genotype provided. 3. have tried and failed the following: a. Dose reduction, tapering, and/or discontinuation of offending agent(s). b. prior to Austedo, must have tried and failed Ingrezza (up to 80mg daily).
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	6 months (initial), 12 months (continuation)
Other Criteria	For continuation, patient must have met the following requirements: Medical documentation submitted confirming a positive response to therapy: 1. Chorea symptoms have improved or stabilized, OR 2. Decreased AIMS score (items 1 to 7) from baseline.

Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)

Products Affected

- **VYNDAMAX**
- **VYNDAQEL**

PA Criteria	Criteria Details
Covered Uses	Transthyretin amyloid cardiomyopathy (ATTR-CM) (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	Vyndaqel and Vyndamax will not be covered in combination with Onpattro or Tegsedi. Must not have any of the following: 1. Primary (light-chain) amyloidosis. 2. Prior liver or heart transplant or an implanted cardiac device. 3. NYHA Class 4 heart failure.
Required Medical Information	Before this drug is covered, the patient must meet all the following requirements: 1. Diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) confirmed by tissue biopsy, genetic testing or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan). a. Diagnosis by radionuclide imaging requires all the following to be met: i. Grade 2 or 3 cardiac uptake on radionuclide imaging. ii. Echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). iii. Absence of monoclonal protein identified in serum and urine immunofixation (IFE) and serum free light chain (sFLC) assay. 2. Must have clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, edema, angina).
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient meet all the following requirements: 1. Must have a positive response to Vyndaqel/Vyndamax compared to baseline (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life). Vyndaqel has a quantity limit of 120 capsules every 30 days (4 capsules daily). Vyndamax has a quantity limit of 30 capsules every 30 days (1 capsule daily).

Xcopri (cenobamate)

Products Affected

- **XCOPRI (250 MG DAILY DOSE) ORAL TABLET THERAPY PACK 100 & 150 MG, 50 & 200 MG**
- **XCOPRI (350 MG DAILY DOSE)**
- **XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 50 MG**
- **XCOPRI ORAL TABLET THERAPY PACK 14 X 12.5 MG & 14 X 25 MG, 14 X 150 MG**

& 14 X200 MG, 14 X 50 MG & 14 X100 MG

PA Criteria	Criteria Details
Covered Uses	Treatment of partial-onset seizures (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	Must have trial and failure of one generic anticonvulsant.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Xeljanz/Xeljanz XR (tofacitinib)

Products Affected

- **XELJANZ ORAL SOLUTION**
- **XELJANZ ORAL TABLET**
- **XELJANZ XR**

PA Criteria	Criteria Details
Covered Uses	1. Rheumatoid arthritis. 2. Psoriatic arthritis. 3. Ulcerative Colitis. 4. Juvenile idiopathic arthritis.
Exclusion Criteria	Xeljanz/XR will not be covered in combination with a biologic drug.
Required Medical Information	1. Rheumatoid Arthritis. a) Patient has tried at least ONE conventional synthetic DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months. 2. Psoriatic Arthritis. a) Patient will use Xeljanz/Xeljanz XR along with methotrexate or another conventional synthetic DMARD. AND b. Patient has tried at least ONE conventional synthetic DMARD (such as methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. 3. Ulcerative Colitis. a) Patient must be 18 years of age or older. b) Patient has tried at least ONE systemic agent such as 6-mercaptopuine, azathioprine, cyclosporine, tacrolimus, or corticosteroids for at least 2 months. c) Patient has tried Humira for at least 3 months. 4. Juvenile Idiopathic Arthritis. a) Patient has tried at least ONE other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug, a biologic [Humira, Orencia, Enbrel, Kineret, Actemra]) for a period of at least 3 months, OR b) Patient will be starting on Xeljanz concurrently with methotrexate, sulfasalazine, or leflunomide, OR c) Patient has aggressive disease, as determined by the prescribing physician.
Age Restrictions	
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	Before Xeljanz is covered, the patient must meet all of the General Criteria for Xeljanz and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed below will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Xermelo (telotristat)

Products Affected

- **XERMELO**

PA Criteria	Criteria Details
Covered Uses	Carcinoid syndrome diarrhea.
Exclusion Criteria	Must not have any of the following: a. 12 or more watery bowel movements per day. b. History of short bowel syndrome. c. Clinically significant elevations in liver function tests. d. Recently undergone tumor-directed therapy.
Required Medical Information	Before this drug is covered, the patient must meet all of the following requirements: 1. Diagnosis of carcinoid syndrome diarrhea in combination with a somatostatin analog (SSA). 2. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. 3. Experiencing 4 or more bowel movements per day. 4. Have been receiving stable dose SSA therapy (either long-acting release [LAR], depot, or infusion pump) for at least 3 months.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Xifaxan 550mg (rifaximin)

Products Affected

- **XIFAXAN ORAL TABLET 550 MG**

PA Criteria	Criteria Details
Covered Uses	Irritable bowel Syndrome (IBS) with diarrhea. Hepatic encephalopathy.
Exclusion Criteria	
Required Medical Information	For Irritable bowel Syndrome (IBS) with diarrhea: 1. Must have failed conventional treatment with lifestyle and dietary modification which may include exclusion of gas-producing foods, diet low in fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs), and in select cases avoidance of lactose and gluten (detailed documentation of lifestyle changes tried for at least 1 month must be faxed to Priority Health). 2. Trial of at least three of the following (tried for at least 1 month each): a. Loperamide. b. Antispasmodic (ex. Dicyclomine). c. Bile acid sequestrant (cholestyramine, colestipol or colesevelem). d. Tricyclic antidepressant (ex. nortriptyline).
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	Dependent upon indication
Other Criteria	For the diagnosis of Irritable bowel syndrome with diarrhea (IBS-D), the quantity is limited to one 550 mg tablet given 3 times daily for 14 days, may be retreated up to 2 times with the same dosing regimen if symptoms recur within a 6 month period. For the diagnosis of hepatic encephalopathy recurrence, the quantity is limited to one 550 mg tablet given 2 times daily.

Xolair (omalizumab)

Products Affected

- **XOLAIR SUBCUTANEOUS SOLUTION PREFILLED SYRINGE**

PA Criteria	Criteria Details
Covered Uses	1. Moderate to severe persistent asthma. 2. Chronic urticaria. 3. Chronic rhinosinusitis with nasal polyp (CRSwNP).
Exclusion Criteria	Xolair will not be covered in combination with another biologic medication (e.g. Fasenra, Cinqair, Nucala, Dupixent).
Required Medical Information	For moderate to severe persistent asthma: 1. Must have been compliant on all of the following therapies for at least 3 months: a. High-dose inhaled corticosteroid (ICS). b. Long-acting beta agonist (LABA). c. One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva Respimat). 2. Compliant use of the above medications must not be effective as demonstrated by at least one of the following: a. Oral or systemic steroid treatment or an increase in the current oral steroid maintenance dose. b. Hospitalization and/or ED visit. c. Increasing need for short-acting beta2-agonist. 3. Must have a positive skin test or in-vitro reactivity to a perennial aeroallergen (lab results must be submitted). 4. Must be within the recommended dosing range based on current weight and baseline IgE level. 5. Must be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique). 6. Must not currently use tobacco products. For chronic urticaria: 1. Must first try two or more H1 antihistamines, or 2. Must first try one H1 antihistamine and one or more of the following: a. H2 antihistamine, b. Oral corticosteroid, c. Leukotriene modifier. For Chronic rhinosinusitis with nasal polyp (CRSwNP): 1. Must have a baseline Nasal Polyps Score (NPS) of at least 5, with a unilateral score of at least 2 for each nostril. 2. Must be within the recommended dosing range based on current weight and baseline IgE level. 3. Must have symptomatic disease that is persistent for a minimum of 12 weeks, including all of the following: a. Nasal obstruction, b. Rhinorrhea (anterior/posterior), c.Diminished or loss of smell. 4. Must have tried and failed all of the following: a. At least one prior treatment course with a systemic corticosteroid. b. Minimum 3 months compliant treatment with an intranasal glucocorticoid. c. Minimum 1-month trial with either a non-sedating antihistamine or antileukotriene agent (e.g., montelukast).
Age Restrictions	Must be at least 6 years of age (asthma). Must be at least 12 years of age (urticaria). Must be at least 18 years of age (nasal polyps).

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	For continuation, patient must have met the following requirements: For asthma: 1. Peak flow improvement by greater than 20%, or FEV1 improved by greater than or equal to 12%, or patient has experienced a reduction in symptoms (i.e. wheezing, shortness of breath, cough, chest tightness). 2. Decrease in the use of quick relief medications or corticosteroids (oral or inhaled). 3. Decrease in ER visits, hospitalizations, physician visits, or school/work absences due to acute asthma attacks. 4.Must not currently use tobacco products. 5. Must not use in combination with other biologics (e.g., Cinqair, Fasenra, or Nucala). For chronic urticaria: 1. Adherence to therapy. 2. Reduction in the symptom of urticaria documented by the prescriber (chart notes supporting symptom reduction must be submitted to Priority Health). For nasal polyps: 1. Adherence to therapy including Xolair and intranasal steroid. 2. Reduction in the symptom of rhinosinusitis with nasal polyp documented by the prescriber (chart notes supporting symptom reduction must be submitted to Priority Health) including, but not limited to: a. Improvement in nasal congestion, b. Decrease in nasal polyp size, c. Improvement in ability to smell, d. Decrease in rhinorrhea, e. Decrease in nasal inflammation, f. Decrease in oral corticosteroid use.

Xtandi (enzalutamide)

Products Affected

- **XTANDI ORAL CAPSULE**
- **XTANDI ORAL TABLET 40 MG, 80 MG**

PA Criteria	Criteria Details
Covered Uses	Treatment of castration-resistant prostate cancer.
Exclusion Criteria	Xtandi is not covered in combination with Zytiga, Nubeqa, or Erleada.
Required Medical Information	For the treatment of castration-resistant prostate cancer, the patient must: 1. First try abiraterone. 2. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. 3. Currently receiving gonadotropin-releasing hormone (GnRH) analog therapy or has had a bilateral orchiectomy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Xultophy (insulin degludec/liraglutide)

Products Affected

- **XULTOPHY**

PA Criteria	Criteria Details
Covered Uses	Type 2 diabetes mellitus.
Exclusion Criteria	Not covered for Type 1 diabetes mellitus. Xultophy is not covered in combination with another GLP-1 receptor agonist or basal insulin.
Required Medical Information	Patient meets the current prior authorization criteria for a formulary GLP-1 agonist (Trulicity) which includes all of the following: 1. Trial and failure, or intolerance to at least 2 generic oral antidiabetic agents or insulin after 3 continuous months of receiving maximal daily doses and not achieving adequate glycemic control. 2. Hemoglobin A1c less than or equal to 9%, but not less than 7%.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Xyrem (sodium oxybate)

Products Affected

- **XYREM**

PA Criteria	Criteria Details
Covered Uses	Treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy (supporting documentation must be submitted to Priority Health). Note: for the pediatric population, Xyrem is only indicated to treat pediatric patients at least 7 years of age with Narcolepsy Type 1 (narcolepsy with cataplexy) and will not be approved for other forms of narcolepsy in this population.
Exclusion Criteria	Xyrem will not be covered in patients who: 1. Take Xyrem with sedative hypnotics. 2. Drink alcohol when using Xyrem. 3. Have succinic semialdehyde dehydrogenase deficiency. 4. Exceed a daily Xyrem dose of 9 grams (558 mL every 31 days).
Required Medical Information	1. Patient must have one of the following conditions and meet requirements specific to that condition: a. Cataplexy substantial enough to warrant treatment. i. Must first try fluoxetine, venlafaxine ER, or Strattera for 6 weeks with continued cataplexy. b. Excessive daytime sleepiness in patients with narcolepsy. i. Must have a documented therapeutic trial with one of the following: amphetamine salts, dextroamphetamine or methylphenidate with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others, AND ii. Must have documented therapeutic trial of modafinil and armodafinil with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others. 2. MSLT plus polysomnogram must meet requirements according to International Classification of Sleep Disorders - Third Edition (ICSD-3*) for the diagnosis of narcolepsy. Must fax MSLT plus polysomnogram results to Priority Health.
Age Restrictions	Must be at least 7 years of age.
Prescriber Restrictions	Must be prescribed by, or in consultation with, a board certified sleep specialist or neurologist.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	For continuation, patient must meet the following requirements: 1. Patient continues to meet precertification requirements, AND 2. Absence of unacceptable toxicities, AND 3. Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline OR reduced frequency of cataplexy attacks from pre-treatment baseline if patient has cataplexy. *ICSD3 Diagnostic Criteria: Narcolepsy type 1 (criteria A and B must be met): A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. B. The presence of one or both of the following: 1. Cataplexy and a mean sleep latency of at least 8 minutes and two or more SOREMPs on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. 2. CSF hypocretin-1 concentration, measured by immunoreactivity, is either no greater than 110 pg/mL or less than 1/3 of mean values obtained in normal subjects with the same standardized assay. Narcolepsy type 2 (criteria A through E must be met): A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months. B. A mean sleep latency of no greater than 8 minutes and two or more SOREMPs are found on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT. C. Cataplexy is absent. D. Either CSF hypocretin concentration has not been measured or CSF hypocretin concentration measured by immunoreactivity is either greater than 110 pg/mL or greater than 1/3 of mean values obtained in normal subjects with the same standardized assay. E. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.

Zavesca (miglustat)

Products Affected

- *miglustat*

PA Criteria	Criteria Details
Covered Uses	Mild to moderate type 1 Gaucher disease (supporting documentation must be submitted to Priority Health).
Exclusion Criteria	
Required Medical Information	For the treatment of mild to moderate type 1 Gaucher disease in patients for whom enzyme replacement therapy is not anoption (i.e. because of allergy, hypersensitivity). Must fax documentation of diagnostic testing confirming disease (i.e. Genotypetesting) to Priority Health.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Zeposia (ozanimod)

Products Affected

- **ZEPOSIA**
- **ZEPOSIA 7-DAY STARTER PACK**
- **ZEPOSIA STARTER KIT**

PA Criteria	Criteria Details
Covered Uses	1. Multiple Sclerosis. 2. Ulcerative Colitis.
Exclusion Criteria	Zeposia will not be covered in combination with a biologic drug.
Required Medical Information	1. For Multiple Sclerosis: a. Prior authorization required if ICD-10 diagnosis code for Multiple Sclerosis (MS) is not on file. b. Must first try Glatopa, glatiramer, or dimethyl fumarate. c. Not covered in combination with other disease modifying drugs for MS. 2. For Ulcerative Colitis: a. Patient has tried at least ONE systemic agent such as 6-mercaptopuine, azathioprine, cyclosporine, tacrolimus, or corticosteroids for at least 2 months. b. Patient has tried Humira AND Stelara SC for at least 3 months.
Age Restrictions	Must be at least 18 years of age.
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the disease being treated.
Coverage Duration	12 months
Other Criteria	Before Zeposia is covered, the patient must meet all of the General Criteria for Zeposia and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label.

Zorbtive (somatropin)

Products Affected

- **ZORBTIVE**

PA Criteria	Criteria Details
Covered Uses	Treatment of short-bowel syndrome in patients receiving specialized nutritional support.
Exclusion Criteria	
Required Medical Information	1. Must have short bowel syndrome. 2. Must be receiving total parenteral nutrition (TPN). 3. Must be participating in a program that manages dietary intake and hydration.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

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