Priority Health Commercial and Individual Plans

Prior Authorization Criteria

January 2024

Priority Health

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What is a prior authorization?

When a medication requires prior authorization, it means that certain criteria must be met before the medication can be covered. Prior authorization may also be required if a drug is being used in a manner that exceeds established coverage limits as stated on the Approved Drug List (ADL) or the Medical Benefit Drug List (MBDL).

How to know when a medication requires prior authorization

The best way to know when a medication requires prior authorization is to use the Approved Drug List (ADL) or the Medical Benefit Drug List (MBDL) tools. The ADL lists the medications covered under your pharmacy benefit and the MBDL lists the medications covered under your medical benefit (medications administered by a healthcare professional).

How to use this criteria document

Coverage of drugs depends on your prescription drug plan. Not all drugs included in this document are necessarily covered by your plan. This criteria document is meant to be used alongside the Approved Drug List (ADL) and the Medical Benefit Drug List (MBDL) for your plan's drug coverage, with the following prior authorization forms:

- Pharmacy Prior Authorization form (general form used to request coverage for medications dispensed at the retail pharmacy requiring prior authorization)
- Medical Prior Authorization form (general form used to request coverage for medications administered by a healthcare provider under your medical benefit requiring prior authorization)
- Immune Globulin Request form (general form used to request coverage for intravenous or subcutaneous immune globulin)
- Oncology Pharmacy Drug Request form and Oncology Medical Drug Request form (general forms used to request coverage for chemotherapeutic medications requiring prior authorization under the pharmacy or medical benefit)

These forms may also be used when requesting coverage for medications that may not be listed under the ADL or MBDL (e.g., formulary exception requests), or for quantities that exceed the limits stated on either the ADL or MBDL (e.g., quantity limit exception requests) or other posted limitations in coverage (e.g., age limits per FDA-approved labeling).

Most drugs on this criteria document are listed in alphabetical order according to their trade name unless the drug is available generically in which the drug will be listed by its generic name. Occasionally, when two or more medications used to treat the same condition have the same coverage criteria, these may be grouped into one listing. One example would be the Antimigraine Agents, Preventive Treatment [Aimovig (erenumab), Emgality (galcanezumab), Ajovy (fremanezumab), Qulipta (atogepant), Vyepti (eptinezumab)].

Please note that authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. In situations such as this, please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication. For medications with step

therapy requirements, please note that a documented trial and therapeutic failure or an intolerance or contraindication to the preferred medication is required.

Following initial authorization, coverage may be discontinued if the patient is noncompliant with pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy **OR** if patient no longer meets the initial criteria.

DRUG	CRITERIA
Abecma (idecabtagene vicleucel) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of relapsed or refractory multiple myeloma; **AND** • Have received at least 4 prior multiple myeloma treatment regimens (induction with or without hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen); **AND** • Have received a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; **AND** • Patient is at least 18 years of age; **AND** • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; **AND** • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. **Note:** Abecma will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Abecma will not be authorized for use in patients: • that have received a previous treatment course of Abecma or another anti-BCMA02 chimeric antigen-directed receptor (CAR) T-cell therapy. The safety and effectiveness of repeat administration have not been evaluated (**one treatment per lifetime**). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Abecma is dependent on member's eligibility and benefit plan documents.
Accrufer (ferric maltol)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of iron deficiency anemia; **AND** • Documentation of baseline (pre-treatment) hemoglobin and ferritin levels; **AND** • Have an inadequate response to 2 different generic oral iron therapies. For continuation of coverage, the patient must have met the following requirements: • Documentation of improvement in condition from baseline (e.g., improved tolerance and/or increased hemoglobin and ferritin levels). Duration of Approval: 12 months **Note:** 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.).

DRUG	CRITERIA
Actemra (tocilizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Polyarticular Juvenile Idiopathic Arthritis requests: o Patient has tried methotrexate for a period of at least 3 months; **AND** o Patient has tried Adalimumab for a period of at least 3 months. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; **AND** o Patient has tried Adalimumab for a period of at least 3 months. • For Systemic Juvenile Idiopathic Arthritis requests: o Patient has tried a nonsteroidal anti-inflammatory drug (NSAID). • For Giant Cell Arteritis requests: o Patient has tried one systemic corticosteroid. • For Polymyalgia Rheumatica requests: o Patient has tried one systemic corticosteroid; **AND** o Patient has evidence of large vessel vasculitis by angiography or imaging (e.g. MRI, PET/CT). Supporting documentation must be submitted to Priority Health. • For Systemic sclerosis (SSc) related Interstitial Lung Disease (ILD) (SSc-ILD) requests: o Patient has tried one systemic corticosteroid. o Diagnosis is confirmed by high-resolution computed tomography; **AND** o Forced vital capacity (FVC) is greater than 55% of the predicted value; **AND** o Actemra will not be covered in combination with Ofev. • For Cytokine Release Syndrome requests: o Patient is experiencing a severe or life-threatening T-cell induced reaction; **AND** o The IV formulation of Actemra is being used for treatment; **AND** o A maximum of 4 doses is requested. **Note:** Actemra will not be covered in combination with another biologic drug. Before Actemra is covered, the patient must meet all of the General Criteria for Actemra 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.

DRUG	CRITERIA
Acthar (corticotropin)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of infantile spasms • Be less than 2 years of age • For the diagnosis of infantile spasms, 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. Additional Information: 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. • Acute exacerbations of multiple sclerosis. • Rheumatic disorders (psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis). • Collagen diseases (systemic lupus erythematosus, systemic dermatomyositis). • Dermatologic diseases (severe erythema multiforme, Stevens-Johnson syndrome). • Allergic states (serum sickness). • Ophthalmic diseases (keratitis, iritis, iridocyclitis, uveitis, choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation). • Respiratory diseases (symptomatic sarcoidosis). • Edematous state Duration of Approval: 1 month
Adakveo (crizanlizumab)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of sickle cell anemia; AND • Patient is at least 16 years of age; AND • Has had a trial of at least 6 months with hydroxyurea, or intolerance/contraindication; AND • Has had at least 2 vaso-occlusive crises in the last year. For continuation of coverage, patient must have met the following requirements: • Have experienced a reduction in vaso-occlusive crises while on Adakveo therapy. Duration of Approval: 6 months (initial); 12 months (continuation)
Adalimumab	Preferred Agent(s): Adalimumab-adaz (unbranded by Sandoz) Adalimumab-fkjp (unbranded by Mylan/Viatris) Adalimumab-bwwd (Hadlima by Organon) Adalimumab-aqvh (Yusimry by Coherus) *Effective 1/1/2024, Humira and Amjevita were removed from coverage for Traditional and Optimized plans.* Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Crohn's Disease requests: o Patient has tried or is currently taking corticosteroids (such as prednisone or methylprednisolone); OR o Patient has tried at least ONE other agent for this condition (e.g., azathioprine, 6-mercaptopurine, methotrexate, Cimzia, infliximab, or Stelara) for a period of at least 3 months; OR o Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistula; OR o Patient has had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). • For Ulcerative Colitis requests: o 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 o 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. *(Criteria continues on next page)*

DRUG	CRITERIA
Adalimumab *continued*	• For Uveitis (noninfectious intermediate, posterior and panuveitis) requests: o The 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). • For Hidradenitis Suppurativa requests: o 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. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. • For Ankylosing Spondylitis requests: o There are no Specific Induction Criteria for this indication. Adalimumab is covered for any patient who meets the General Initiation Criteria. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months. • For Juvenile Idiopathic Arthritis requests: o Patient has tried at least **ONE** other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug, a biologic [Enbrel, Orencia, Kineret, Actemra]) for a period of at least 3 months; **OR** o Patient will be starting on Adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide; **OR** o Patient has aggressive disease, as determined by the prescribing physician. **Note:** Adalimumab will not be covered in combination with another biologic drug. Before Adalimumab is covered, the patient must meet all of the General Criteria for Adalimumab 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.

DRUG	CRITERIA
Adbry (tralokinumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For atopic dermatitis requests: o Patient is at least 18 years of age; **AND** o Patient has moderate to severe atopic dermatitis; **AND** o Patient has tried **ALL** of the following: ▪ One medium to high potency topical corticosteroid for a period of at least 3 months; **AND** ▪ One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months; **AND** ▪ One traditional non-biologic systemic agent for a period of at least 3 months. <u>For continuation of coverage, the patient must have met the following requirements</u>: • For atopic dermatitis requests: o Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL). <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation) **Note:** Adbry is not covered in combination with other biologic drug therapy. Adbry will initially be approved for the 300 mg every other week maintenance dosing, regardless of the patient's weight. Request to continue this dosing (versus 300 mg every 4 weeks) after 16 weeks of therapy (for patients less than 100 kg only): • Must have tried Adbry 600 mg once followed by 300 mg every other week for at least 16 weeks; **AND** • Documentation must be provided that shows that the patient has not achieved clear or almost clear skin after 16 weeks of therapy.
Adstiladrin (nadofaragene firadenovec) Gene Therapy	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ; **AND** • Have Bacillus Calmette-Guerin (BCG)-unresponsive disease, defined as persistent or recurrent disease following adequate BCG therapy, or T1 disease following a single induction course of BCG.); **AND** • Patient is ineligible or elected not to undergo cystectomy; **AND** • Patient is at least 18 years of age; **AND** • Prescribed by an oncologist, urologist, or another board-certified prescriber with qualifications to treat specified cancer type; **AND** • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Disease response defined as stabilization or decrease in size of tumor or tumor spread. <u>Duration of Approval</u>: 6 months **Note:** Adstiladrin will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Adstiladrin is dependent on member's eligibility and benefit plan documents.

DRUG	CRITERIA
Aldurazyme (laronidase)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of Mucopolysaccharidosis, Type I (Hurler and Hurler-Scheie forms) and Scheie form with moderate to severe symptoms. For continuation of coverage, patient must have met the following requirements: • Has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: stabilization or improvement in FVC and/or 6MWT. Duration of Approval: 12 months
Alosetron (generic Lotronex)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of severe diarrhea-predominant irritable bowel syndrome; AND • Be a female; AND • Have tried and be adherent to dietary changes to improve symptoms; AND • Have tried and failed, or have intolerance/contraindication with at least two of the following: o Loperamide o Antispasmodic (i.e. dicyclomine) o Bile Acid Sequestrant (i.e. cholestyramine, colestipol) Note: Maximum covered dose is 2 mg/day
Alpha1-proteinase Inhibitors	Preferred Agent(s): Aralast NP Glassia Prolastin Zemaira Non-Preferred Agent(s): Not applicable Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of congenital alpha1-antitrypsin deficiency; AND • Be a non-smoker; AND • Have clinically evident emphysema; AND • Have a predicted FEV1 value between 30% and 65%; AND • Have a baseline serum alpha1-antitrypsin (AAT) level less than 11 mmol/L: o 11 mmol/L is equal to 80 mg/dL if measured by radial immunodiffusion; OR o 11 mmol/L is equal to 50 mg/dL if measured by nephelometry For continuation of coverage, patient must have met the following requirements: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: serum alpha1-antitrypsin (AAT) level greater than 11 mmol/L Duration of Approval: 12 months

DRUG	CRITERIA
Amvuttra (vutrisiran)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy; AND • Genetic testing confirms a transthyretin (TTR) mutation (e.g., V30M); AND • Have presence of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.); AND • Have documentation of one of the following: o Baseline polyneuropathy disability (PND) score no greater than IIIb; OR o Baseline FAP Stage 1 or 2 • Be at least 18 years of age; AND • Have not had a liver transplant. For continuation of coverage, the patient must have met the following requirements: • Documentation that the patient has experienced a positive clinical response to Amvuttra compared to baseline (e.g., improved neurologic improvement, motor function, quality of life, slowing of disease progression). Duration of Approval: 12 months Note: Amvuttra is not covered in combination with tafamidis (Vyndaqel, Vyndamax), Onpattro or Tegsedi.
Antimigraine Agents, Acute Treatment	Preferred Agent(s): Ubrelvy (ubrogepant) Non-Preferred Agent(s): Nurtec (rimegepant) Reyvow (lasmiditan) Zavzpret (zavegepant) Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of migraine with or without aura; AND • Patient is at least 18 years of age; AND • Have tried and failed, or have intolerance/contraindication to 2 triptan drugs. • Non-preferred drug product: Trial and failure, or intolerance/contraindication to the preferred product. For continuation of coverage, patient must have met the following requirements: • Must address preventative treatment regimen; AND • Must demonstrate effectiveness (i.e., pain free and/or most bothersome symptom free at 2 hours post dose). Duration of Approval: 6 months (initial), 12 months (continuation) Note: Ubrelvy, Reyvow, Nurtec, Zavzpret are not covered in combination with one another or any other branded acute treatment agent.

DRUG	CRITERIA
Antimigraine Agents, Preventive Treatment	Preferred Agent(s): Aimovig (erenumab) Emgality (galcanezumab) Ajovy (fremanezumab) Non-Preferred Agent(s): Qulipta (atogepant) Vyepti (eptinezumab) Before this drug is covered, the patient must meet all of the following requirements: • For migraine headache requests: o Patient is at least 18 years of age; AND o Patient has a diagnosis of migraine with or without aura; AND o Patient has at least four migraine days per month; AND o Patient has tried and failed at least one-month trial of any two of the following oral medications: ▪ Antidepressants (e.g., amitriptyline, nortriptyline) ▪ Beta blockers (e.g., propranolol, metoprolol, timolol) ▪ Anti-epileptics (e.g., valproate, topiramate) o Non-preferred drug product: Trial and failure, or intolerance/contraindication to Aimovig, Emgality, AND Ajovy for 3 continuous months each and not achieving adequate reduction in migraines. • For cluster headache requests (Emgality only): o Patient is at least 18 years of age; AND o Patient has a diagnosis of episodic cluster headache; AND o Has tried and failed at least 2 of the following treatments: ▪ Injectable triptan drugs: sumatriptan ▪ Intranasal triptan drugs: sumatriptan or zolmitriptan ▪ Oxygen therapy ▪ Verapamil, topiramate, valproate For continuation of coverage, the patient must have met the following requirements: • For migraine headache requests: o Demonstrate effectiveness (more than 50% reduction in monthly migraine days). • For cluster headache requests (Emgality only): o Demonstrate significant decrease in the frequency and/or intensity of cluster headaches; AND o Be in a current cluster period. Duration of Approval: • For migraine headache requests: 12 months • For cluster headache requests (Emgality only): 6 months Note: Vyepti, Qulipta are not covered in combination with Botox or any other branded prophylactic agent Additionally, Qulipta is not covered in combination with Ubrelvy or Nurtec. Coverage of Vyepti is limited to initial dosing of 100mg given every 3 months. For patients not responsive to the 100mg dose, a one-time authorization can be made for a 300mg dose which will be assessed for efficacy beyond that observed for the 100mg dose.

DRUG	CRITERIA
Antiretroviral Agents, Miscellaneous	Preferred Agent(s): Sunlenca (lenacapavir) Non-Preferred Agent(s): Rukobia (fostemsavir) Trogarzo (ibalizumab) Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection; AND • Have confirmed HIV infection with failure of current antiretroviral (ARV) regimen (baseline HIV-1 RNA at least 400 copies/mL), with no viable ARV combination therapy available [defined as documented resistance to two or more agents from three of four main antiretroviral classes (nucleoside reverse transcriptase inhibitor class, non-nucleoside reverse transcriptase inhibitor, protease inhibitor, and integrase strand-transfer inhibitor)]; AND • The requested agent 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 the requested agent) as determined by resistance testing. • Non-preferred drug product: Trial and failure, or intolerance/contraindication to the preferred product. For continuation of coverage, patient must have met the following requirements: • Patient has achieved clinically significant viral response to therapy; AND • Patient has continued to take an optimized background antiretroviral regimen. Duration of Approval: 6 months (initial); 12 months (continuation)
Apretude (cabotegravir)	Before this drug is covered, the patient must meet all of the following requirements: • Be using for pre-exposure prophylaxis (PrEP) of human immunodeficiency virus (HIV); AND • Not have a diagnosis of HIV disease (IDC10 codes: B20); AND • Have tried and failed, or demonstrated intolerance to generic Truvada (emtricitabine/tenofovir DF).
Aptiom (eslicarbazepine)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of partial-onset seizure (documentation confirming diagnosis must be submitted); AND • Patient is at least 4 years of age; AND • Have a trial and failure with or intolerance to all the following: o Oxcarbazepine o One additional generic anti-seizure medication

DRUG	CRITERIA
Arikayce (amikacin oral inhalation)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of mycobacterium avium complex (MAC) lung disease (sputum culture supporting diagnosis must be submitted to Priority Health); AND • Failure to obtain a negative sputum culture after a minimum of 6 consecutive months of a multidrug background regimen for MAC lung disease such as clarithromycin (or azithromycin), rifampin, and ethambutol; AND • Be used as part of a multi-drug regimen and will not be approved for use as a single agent treatment; AND • Prescribed by or in consultation with an infectious disease specialist. For continuation of coverage, the patient must have met the following requirements: • Documentation of a negative sputum culture obtained within the last 30 days; AND • Be compliant in taking the medication as scheduled; AND • Be tolerating the medication; AND • Responded to treatment as determined by the prescribing physician. Duration of Approval: 6 months (initial); 12 months (continuation) Note: 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.
Auryxia (ferric citrate)	Before this drug is covered, the patient must meet all of the following requirements: • For hyperphosphatemia in patients with chronic kidney disease (CKD): o Require dialysis to control disease; AND o Trial and failure on calcium acetate or sevelamer. • For iron-deficiency anemia in CKD: o Not be on dialysis; AND o Have an estimated GFR of less than 60 ml/min; AND o Trial and failure on therapeutic doses of oral iron supplements; AND o Have a hemoglobin (Hgb) between 9 g/dL and 11.5 g/dL; AND o Have a serum ferritin no greater than 200 ng/mL and transferrin saturation (TSAT) less than 25% For continuation of coverage, the patient must have met the following requirements: • For iron-deficiency anemia in CKD: o Not require dialysis to control CKD; AND o Be free of the need for additional therapy with erythropoiesis-stimulating agents (ESA), intravenous iron, or blood transfusions. Duration of Approval: 4 months (initial for CKD anemia); 12 months (continuation)

DRUG	CRITERIA
Benlysta (belimumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For active, autoantibody-positive systemic lupus erythematosus (SLE) requests: o Patient is at least 5 years of age; **AND** o Be autoantibody-positive with one of the following: ▪ Anti-nuclear antibody (ANA) titer at least 1:80, **OR** ▪ Anti-double-stranded DNA (anti-dsDNA) level at least 30 IU/mL; **AND** o SLE is active as demonstrated by a score greater than 6 (as documented by a SELENA-SLEDAI) while on treatment with standard therapy (e.g., corticosteroids, immunosuppressants, hydroxychloroquine) for at least 12 weeks each. • For biopsy-proven lupus nephritis Class III through V: o Patient is at least 5 years of age; **AND** o Be autoantibody-positive with one of the following: ▪ Anti-nuclear antibody (ANA) titer at least 1:80, **OR** ▪ Anti-double-stranded DNA (anti-dsDNA) level at least 30 IU/mL; **AND** o Have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants). ▪ Not have an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2 <u>For continuation of coverage, patient must have met the following requirements</u>: • For active, autoantibody-positive systemic lupus erythematosus (SLE) requests, patient must have met 3 of 6 of the following requirements: o Have a SELENA-SLEDAI score point reduction of 4 or more based on a 30-day assessment o Have a Physician Global Assessment change indicating showing no disease progression (worsening) compared to baseline treatment with Benlysta o 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) o A reduction in dose of steroid therapy o A negative seroconversion or a 20% reduction in autoantibody levels from baseline o Free of significant clinical flares that require steroid boost treatment with Benlysta. • For biopsy-proven lupus nephritis Class III through V: o Have evidence of efficacy (defined as urinary protein creatinine ratio no greater than 0.7, eGFR no greater than 20% below the pre-flare or at least 60mL/min/1.73m2), and no use of rescue therapy for treatment failure. <u>Duration of Approval</u>: • Initial: 6 months • Continuation: 12 months **Note:** Benlysta is not covered in combination with other biologic drug therapy (e.g., rituximab), Lupkynis (voclosporin), or in patients with central nervous system manifestations. 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. Additionally, Benlysta SQ syringes are only covered for patients at least 18 years of age.

DRUG	CRITERIA
Besremi (ropeginterferon alfa- 2b)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of high-risk polycythemia vera (supporting documentation must be submitted to Priority Health); AND • Patient is at least 18 years of age; AND • Prescribed by or in consultation with a hematologist or oncologist; AND • Trial and failure to hydroxyurea AND pegylated interferon-alfa 2a; AND • Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2; AND • Not have an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m^2. For continuation of coverage, the patient must have met the following requirements: • Have a positive clinical response to Besremi as evidenced by experiencing disease stability or improvement. Duration of Approval: 12 months
Bimzelx (bimekizumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Cosentyx, Enbrel, Adalimumab, Enbrel, Otezla, Tremfya, or Stelara, each for a period of at least 3 months. Note: Bimzelx will not be covered in combination with another biologic drug. Before Bimzelx is covered, the patient must meet all of the General Criteria for Bimzelx 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.

DRUG	CRITERIA
Botulinum toxins	Preferred Agent(s): Botox (onabotulinumtoxinA) Dysport (abobotulinumtoxinA) Myobloc (rimabotulinumtoxinA) Xeomin (incobotulinumtoxinA) Daxxify (daxibotulinumtoxinA) Non-Preferred Agent(s): Not applicable Before this drug is covered, the patient must meet all of the following requirements: Before botulinum toxin is covered, the patient must meet all of the requirements for the treatment diagnosis listed in this policy and the prescribe dose is within covered dosing limits. Priority Health only covers the diagnoses listed below in this policy. Priority Health may consider a diagnosis not listed in this policy to be not medically necessary and/or experimental and investigational. If the criteria outlined in this coverage policy are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. The following diagnoses are covered if associated with spasticity or dystonia: • Blepharospasm • Cerebral palsy • Cervical dystonia • Demyelinating diseases of the CNS and copus callosum including Leukodystrophy • Esophageal achalasia • Facial nerve VII disorder (facial myokymia, Melkersson's syndrome, facial/hemifacial spasms) • Focal hand dystonia (i.e. organic writer's cramp) • Hereditary spastic paraplegia • Jaw-closing oromandibular dystonia • Laryngeal spasm, Laryngeal adductor spastic dysphonia or stradulus • Lingual dystonia • Multiple Sclerosis • Neuromyelitis optica • Orofacial dyskinesia • Schilder's disease • Spastic hemiplegia due to stroke or brain injury • Strabismus • Torsion dystonia, idiopathic and symptomatic • Torticollis The following diagnoses are covered only if additional requirements for the diagnosis are satisfied: • Anal fissures: Coverage for anal fissures is reserved for patients who remain symptomatic after 8 weeks of topical therapy with either nitroglycerin ointment or diltiazem and who decline, or are not candidates for, surgical intervention. • Detrusor over activity associated with a neurologic condition: Coverage for detrusor over activity requires documentation of the underlying neurological condition that is the cause of detrusor activity (e.g. spinal cord injury or multiple sclerosis). In addition, the patient must have a therapeutic trial with an anticholinergic drug, which requires specific documentation of the trial(s) with the request for coverage. The recommended and maximum dose is 200 units intramuscularly for each treatment, once every 90 days. • Hyperhidrosis (HH): Coverage is authorized for primary axillary or palmar HH. Plantar HH is not covered. For primary axillary HH, the patient must be unable to achieve satisfactory results using aluminum chloride (generic for Drysol®) or other extra strength (more than 20%) antiperspirants or be intolerant to these therapies because of severe rash. For palmar HH, the patient must be unable to achieve satisfactory results using aluminum chloride (generic for Drysol®). *(Criteria continues on next page)*

DRUG	CRITERIA
Botulinum toxins *continued*	• **Migraine (chronic):** Cluster, tension, and cervicogenic headaches are not a covered benefit. Chronic migraine means the patient's headaches are disabling and occur on 15 days or more each month, lasting four hours each day or longer. Coverage for prophylaxis of chronic migraine requires documentation to show the patient's condition meets Priority Health's definition of chronic migraine. **Note:** Botulinum toxin is not covered in combination with Vyepti or Qulipta. Patient has tried and failed at least one-month trial of any two of the following oral medications: o Antidepressants (e.g., amitriptyline, nortriptyline) o Beta blockers (e.g., propranolol, metoprolol, timolol) o Anti-epileptics (e.g., valproate, topiramate) • **Overactive bladder:** Coverage for overactive bladder requires documentation of therapeutic trials with two or more anticholinergic drugs. The recommended and maximum dose is 100 units intramuscularly for each treatment, once every 90 days. • **Ptyalism/sialorrhea:** The patient's condition must be refractory to pharmacotherapy. Coverage for ptyalism/sialorrhea requires documentation the patient has previously tried anticholinergic therapy. **Duration of Approval:** up to 24 months **Note:** If approved, authorization will be for one dose every 90 days for two years. It is usually not considered medically necessary to give botulinum toxin injection more frequently than every 90 days. An exception is for migraine prophylaxis, which will be authorized for one dose every 84 days. The maximum cumulative dose should generally not exceed 400 units in a 3 month interval when treating one or more indications. Requests exceeding 400 units in a 3-month interval must be explained by the provider and are subject to Priority Health's medical necessity review. The following conditions are **not** covered: • Botulinum toxin for the treatment of anal spasm, irritable colon, biliary dyskinesia, craniofacial wrinkles or any treatment of other spastic conditions not listed as covered on this prior authorization form are considered experimental (including the treatment of smooth muscle spasm). • Botulinum toxin for patients receiving aminoglycosides. • Botulinum toxin for patients with chronic paralytic strabismus, except to reduce antagonistic contractor with surgical repair. • Treatment exceeding accepted dosage parameters unless supported by individual medical record review as well as treatments where the goal is to improve appearance rather than function. • Use of botulinum toxin for all other conditions not listed as a covered benefit.

DRUG	CRITERIA
Breyanzi (lisocabtagene maraleucel) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma; AND • Have received prior treatment with two or more chemoimmunotherapy regimens which included at least one anthracycline-based regimen and an anti-CD20 antibody, unless contraindicated (Breyanzi is also covered for large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy); AND • Patient is at least 18 years of age; AND • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; AND • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Note: Breyanzi will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Breyanzi will not be authorized for use in patients: • with primary central nervous system lymphoma; OR • that have received a previous treatment course of Breyanzi or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy. The safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Breyanzi is dependent on member's eligibility and benefit plan documents.
Brineura (cerliponase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease which was confirmed by tripeptidyl peptidase 1 (TPP1) deficiency; AND • Be symptomatic; AND • Treatment is being given to slow the loss of ambulation in a patient with a baseline motor-language CLN2 clinical rating scale (CRS) greater than or equal to 3; AND • Patient is at least 3 years of age; AND • Be ordered by a neurologist. For continuation of coverage, the patient must have met the following requirements: • Patient has a score of 1 or higher in the motor domain of the CLN2 clinical rating scale; AND • Clinical documentation, including chart notes, of disease stability or improvement must be provided. Duration of Approval: 12 months

DRUG	CRITERIA
Cablivi (caplacizumab)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP), which includes thrombocytopenia and microscopic evidence of red blood cell fragmentation; AND • Patient is at least 18 years of age; AND • Cablivi will be administered in addition to plasma exchange and immunosuppressive therapy and continued for 30 days after discontinuation of plasma exchange. For continuation of coverage, the patient must have met the following requirements: • Patient has received Cablivi in combination with plasma exchange and immunosuppressive therapy during plasma exchange and for 30 days beyond the last plasma exchange; AND • Patient has sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels; AND • Treatment will be extended for a maximum of 28 days. Duration of Approval: • Initial: approval duration of 30 days with a quantity limit of 31 vials per 30 days. • Continuation: approval duration of 28 days with a quantity limit of 28 vials per 28 days.
Camzyos (mavacamten)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of symptomatic NYHA class II or III obstructive hypertrophic cardiomyopathy; AND • Patient is at least 18 years of age; AND • Have a left ventricular ejection fraction of at least 55%; AND • Prescribed by or in consultation with a cardiologist; AND • Has a history of trial and failure (at least 30 days), intolerance/contraindication, or intolerance to both of the following medications: o Beta blocker (e.g., metoprolol); AND o Calcium channel blocker (e.g., verapamil, diltiazem). For continuation of coverage, patient must have met the following requirements: • Documentation that the patient has experienced a positive clinical response to Camzyos compared to baseline (e.g., improvement in patient reported symptoms, improvement in NT-proBNP, decreased shortness of breath); AND • Improvement of pVO2 by at least 1.5 mL/kg/min PLUS at least one NYHA class reduction or at least a 3 mL/kg/min pVO2 improvement with stable NYHA class. Duration of Approval: 6 months (initial); 12 months (continuation)
Carglumic acid (generic Carbaglu)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of deficiency of N -acetylglutamate synthase (NAGS); AND • Has acute or chronic hyperammonemia. For continuation of coverage, the patient must have met the following requirements: • Clinical documentation, including chart notes, of disease stability or improvement must be provided. Duration of Approval: 12 months

DRUG	CRITERIA
Carvykti (ciltacabtagene autoleucel) Gene Therapy	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of relapsed or refractory multiple myeloma; **AND** • Have received at least 4 prior multiple myeloma treatment regimens (induction with or without hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen); **AND** • Have received a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody; **AND** • Patient is at least 18 years of age; **AND** • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; **AND** • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. **Note:** Carvykti will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Carvykti will not be authorized for use in patients: • that have received a previous treatment course of Carvykti or another anti-BCMA02 chimeric antigen-directed receptor (CAR) T-cell therapy. The safety and effectiveness of repeat administration have not been evaluated (**one treatment per lifetime**). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Carvykti is dependent on member's eligibility and benefit plan documents.
Cayston (aztreonam inhalation)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of cystic fibrosis confirmed by appropriate diagnostic or genetic testing (documentation of cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health); **AND** • Patient is at least 7 years of age; **AND** • Confirmation of Pseudomonas aeruginosa in cultures of the airways confirmed by a copy of positive sputum culture; **AND** • Susceptibility results showing aztreonam is the only inhaled antibiotic to which the Pseudomonas aeruginosa is sensitive **OR** at least one of the following: o Previous use of tobramycin inhalation solution and experienced a clinically significant adverse drug reaction or unsatisfactory therapeutic response. o Contraindication/intolerance to tobramycin inhalation solution. o Culture shows resistance to tobramycin. <u>For continuation of coverage, patient must have met the following requirements</u>: • Continues to require treatment of Pseudomonas aeruginosa infection; **AND** • Documentation of stabilization or improvement by pulmonologist or CF specialist. <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation) **Note:** Coverage for Cayston is to be used for 28 days, following 28 days off.
Cerezyme (imiglucerase)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of Non-neuropathic Gaucher's disease, chronic, symptomatic. <u>For continuation of coverage, patient must have met the following requirements</u>: • Has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: clinically significant reduction in spleen or liver volume, increase in platelet or hemoglobin values. <u>Duration of Approval</u>: 12 months

DRUG	CRITERIA
Cholbam (cholic acid)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of bile acid synthesis disorder due to single enzyme defects (SED) or peroxisomal disorder (PD); **AND** • Provide a serum very long chain fatty acid value (VLCFA); **AND** • Provide baseline liver function tests. <u>For continuation of coverage, patient must have met the following requirements</u>: • Body weight increased by 10 percent or is stable of at least the 50th percentile; **AND** • Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is less than 50 U/L or baseline levels reduced by 80 percent; **AND** • Total bilirubin level reduced to less than or equal to 1mg/Dl; **AND** • Not have evidence of cholestasis on liver biopsy. <u>Duration of Approval</u>: 12 months

Cibinqo
(abrocitinib)
	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	
	• For atopic dermatitis requests:
	  o Patient is at least 12 years of age; **AND**
	  o Patient has moderate to severe atopic dermatitis; **AND**
	  o Patient has tried **ALL** of the following:
	  ▪ One medium to high potency topical corticosteroid for a period of at least 3 months; **AND**
	  ▪ One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months; **AND**
	  ▪ One traditional non-biologic systemic agent for a period of at least 3 months; **AND**
	  o Patient has tried at least **TWO** of the following: Dupixent, Adbry, each for a period of at least 3 months.
	
	<u>For continuation of coverage, the patient must have met the following requirements</u>:
	• Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL).
	
	<u>Duration of Approval</u>: 12 months
	
	Note: Cibinqo is not covered in combination with other biologic drug therapy.

DRUG	CRITERIA
Cimzia (certolizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Ankylosing Spondylitis requests: o Patient has tried at least **TWO** of the following: Cosentyx, Enbrel, or Adalimumab, each for a period of at least 3 months. • For Non-radiographic axial spondyloarthritis (nr-axSpA) requests: o 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). • For Crohn's Disease requests: o Patient has tried one other agent for Crohn's disease (e.g., corticosteroid, azathioprine, 6-mercaptopurine, methotrexate); **AND** o Patient has tried Adalimumab for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; **AND** o Patient has tried at least **TWO** of the following: Cosentyx, Enbrel, Adalimumab, Xeljanz/XR, Otezla, Stelara, or Tremfya, each for a period of at least 3 months. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; **AND** o Patient has tried at least **TWO** of the following: Actemra, Enbrel, Adalimumab, or Xeljanz/XR each for a period of at least 3 months. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND** o Patient has tried at least **TWO** of the following: Cosentyx, Enbrel, Adalimumab, Otezla, Tremfya, or Stelara, each for a period of at least 3 months. **Note:** Cimzia will not be covered in combination with another biologic drug. 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 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.
Cinqair (reslizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient is at least 18 years of age; **AND** • Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **AND** • Not currently be using tobacco products; **AND** • Be compliant on all of the following therapies for at least 3 months: o High-dose inhaled corticosteroid (ICS) o Long-acting beta agonist (LABA) o One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); **AND** • Be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique); **AND** • Have had at least 2 asthma exacerbations in the previous year that required at least one of the following: o Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days o Hospitalization and/or ED visit. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use). <u>Duration of Approval</u>: 12 months **Note:** Cinqair is not covered in combination with other biologic drug therapy..

DRUG	CRITERIA
Cosela (trilaciclib)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For chemotherapy-induced myelosuppression requests: o Has a diagnosis of extensive small cell lung cancer (SCLC); **AND** o Is receiving platinum/etoposide +/- immune checkpoint inhibitor **OR** a topotecan-containing regimen; **AND** o Has previously experienced severe neutropenia while using one of the regimens described above, despite use of G-CSF products (i.e. filgrastim, pegfilgrastim). <u>For continuation of coverage, patient must have met the following requirements</u>: • Have a positive clinical response to Cosela as evidenced by experiencing disease stability or improvement; **AND** • Continues to receive platinum/etoposide +/- immune checkpoint inhibitor **OR** a topotecan-containing regimen. <u>Duration of Approval</u>: 12 months
Cosentyx (secukinumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. • For Ankylosing Spondylitis requests: o There are no Specific Induction Criteria for this indication. Cosentyx is covered for any patient who meets the General Initiation Criteria. • For Non-radiographic axial spondyloarthritis (nr-axSpA) requests: o 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). • For Juvenile Idiopathic Arthritis requests: o Patient has tried at least **ONE** other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug, a biologic [Enbrel, Orencia, Kineret, Actemra]) for a period of at least 3 months; **OR** o Patient will be starting on Cosentyx concurrently with methotrexate, sulfasalazine, or leflunomide; **OR** o Patient has aggressive disease, as determined by the prescribing physician. **Note:** Cosentyx will not be covered in combination with another biologic drug. 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 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.

DRUG	CRITERIA
Cresemba (isavuconazole)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of invasive aspergillosis or invasive mucormycosis (i.e., Rhizopus, Rhizomucor, Lichtheimia, Mucormycetes); **AND** • Have tried and failed, or have intolerance/contraindication to drug voriconazole or itraconazole; **AND** • Prescriber is a specialist or has consulted with a specialist for the condition being treated. <u>For continuation of coverage, patient must have met the following requirements</u>: • Have a positive clinical response to Cresemba as evidenced by experiencing disease stability or improvement. <u>Duration of Approval</u>: 3 months (initial); 12 months (continuation)

Crysvita (burosumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Treatment of X-linked hypophosphatemia (XLH) in patients 6 months of age and older. Diagnosis must be confirmed by:
	  o Genetic testing (PHEX-gene mutation), **OR**
	  o Serum fibroblast growth factor-23 (FGF23) level greater than 30 pg/mL; **AND**
	• Treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in patients 2 years of age and older; **AND**
	• Have baseline serum phosphorus level below lower limit of laboratory reference range with current hypophosphatemia; **AND**
	• Have clinical signs and symptoms of XLH (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures, etc.).
	
	<u>For continuation of coverage, patient must have met the following requirements</u>:
	• Is compliant in taking the medication as scheduled; **AND**
	• Have experienced normalization of serum phosphate while on therapy (documentation of laboratory levels must be submitted to Priority Health); **AND**
	• Have experienced a positive clinical response to therapy (e.g. enhanced height velocity, improvement in skeletal deformities, reduction in bone fractures).
	
	<u>Duration of Approval</u>: 12 months
	
	Note: Dosing of Crysvita should not be adjusted more frequently than every 4 weeks and must be administered by a healthcare professional.

Cystic Fibrosis Agents (CFTR modulators)	<u>Preferred Agent(s)</u>: Kalydeco (ivacaftor) Orkambi (lumacaftor/ivacaftor) Symdeko (tezacaftor/ivacaftor) Trikafta (elexacaftor/tezacaftor/ivacaftor, ivacaftor) <u>Non-Preferred Agent(s)</u>: Not applicable <u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of cystic fibrosis (CF) (documentation of a CF ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 codes for CF include: E84.0, E84.11, E84.19, E84.8, E84.9; **AND** • Have laboratory confirmation for any one of the approved mutations in the CFTR gene (per package labeling for each individual preferred drug); **AND** • Drug formulation (i.e. granules, tablets) requested must match FDA label for age.

DRUG	CRITERIA
Dalfampridine ER (generic Ampyra)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of multiple sclerosis (MS); **AND** • Be receiving immunomodulatory therapy (unless immunomodulatory therapy is not indicated for patients MS type); **AND** • Be between the ages of 18 to 70 years; **AND** • 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; **AND** • Patient does not require the use of a wheelchair (bilateral assistance is acceptable, such as a brace, cane, or crutch, if the patient can walk 20 meters without resting); **AND** • Baseline timed 25-foot walk test (T25FW) is completed within 8 to 45 seconds **OR** patient has an Expanded Disability Status Scale (EDSS) score greater than or equal to 4.5 but less than 7. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Documentation that the patient has met all the following requirements: o Maintain an 85% adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient; **AND** o Patients' functional impairment must resolve because of increased speed of ambulation resulting in the member being able to complete instrumental activities (meal preparation, household chores, etc.); **AND** o Requires at least a 20% improvement in timed walking speed as documented by the T25FW test from pre-treatment baseline. <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation) **Note:** Patient must not have a spinal cord injury, myasthenia gravis, or demyelinating peripheral neuropathies (such as Guillain-Barre syndrome), Alzheimer's disease, or Lambert Eaton myasthenic syndrome.
Dalvance (dalbavancin)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Be started in the hospital or other health care facility and will be continued in outpatient facility; **AND** • Have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives; **AND** • Infection is not susceptible to alternative antibiotic treatments (supporting documentation must be submitted to Priority Health). <u>Duration of Approval</u>: One to three dose infusion (based on FDA-approved labeling).
Daybue (trofinetide)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of classic/typical Rett syndrome with MCEP2 gene mutation (supporting documentation must be submitted to Priority Health); **AND** • Provide documentation of current Rett Syndrome Behavior Questionnaire (RSBQ) score including all 8 subscales; **AND** • Have undergone an in-depth behavioral assessment by a neurologist, geneticist, or developmental pediatrician; **AND** • Patient is at least 2 years of age**; AND** • Prescriber is a specialist or has consulted with a neurologist, geneticist, or developmental pediatrician. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Documentation of positive clinical response as evidenced by: o Improvement in overall RSBQ score including all 8 subscales; **AND** o Improvement in CGI-S score. <u>Duration of Approval</u>: 3 months (initial); 3 months (continuation) **Note:** Daybue will not be covered for patients with atypical or variant Rett syndrome.

DRUG	CRITERIA
Diacomit (stiripentol)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Dravet syndrome and will be using Diacomit as adjunctive treatment for seizures; AND • Patient is at least 2 years of age; AND • Will use in combination with clobazam (there are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome); AND • Have a trial and failure with valproate and clobazam.
Droxidopa (generic Northera)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by one of the following: o Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure); o Dopamine beta-hydroxylase deficiency; OR o Non-diabetic autonomic neuropathy; AND • Diagnosis excludes other causes of orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy); AND • Patient has tried at least two of the following non-pharmacologic interventions: o 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]; o Raising the head of the bed 10 to 20 degrees; o Compression garments to the lower extremities or abdomen; o Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise); o Increased salt and water intake, if appropriate; o Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing); AND • Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist; AND • Has a history of trial and failure (at least 30 days), intolerance/contraindication, or intolerance to both of the following medications: o Midodrine; AND o Fludrocortisone. For continuation of coverage, the patient must have met the following requirements: • Documentation of positive clinical response to droxidopa therapy; AND • Member has experienced a sustained decrease in dizziness since initiation of therapy; AND • Member has maintained an increase in systolic and diastolic blood pressure within 3 minutes of standing since the initiation of therapy. Duration of Approval: 3 months (initial); 6 months (continuation)

DRUG	CRITERIA
Duopa (levodopa and carbidopa enteral suspension)	Before this drug is covered, the patient must meet all of the following requirements: • Be used for treatment of advanced Parkinson's disease; AND • Levodopa-responsive with clearly defined "on" periods; AND • Experiencing acute, intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements); AND • Receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release and multiple daily dosing); AND • Prescribed by, or in consultation with, a neurologist; AND • Has undergone or has planned placement of a procedurally-placed tube; AND • Therapeutic trial and failure of, or intolerance/contraindication to, adjunctive therapy with at least one medication in each of the drug classes listed below: o Dopamine agonist (e.g. pramipexole, ropinirole); OR o Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline); OR o Catechol-O-methyl transferase (COMT) inhibitor (e.g. entacapone). For continuation of coverage, the patient must have met the following requirements: • Documentation of positive clinical response to Duopa therapy. Duration of Approval: 12 months
Dupixent (dupilumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For atopic dermatitis requests: o Patient is at least 6 months of age; AND o Patient has moderate to severe atopic dermatitis; AND o Patient has tried ALL of the following: ▪ One medium to high potency topical corticosteroid for a period of at least 3 months; AND ▪ One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months; AND ▪ One traditional non-biologic systemic agent for a period of at least 3 months. • For moderate-to-severe asthma requests: o Patient is at least 6 years of age; AND o Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; OR required dependence on daily oral corticosteroids; AND o Not currently be using tobacco products; AND o Have been compliant on all of the following therapies for at least 3 months: ▪ High-dose inhaled corticosteroid (ICS) ▪ Long-acting beta agonist (LABA) ▪ One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); AND o Be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique); AND o Have had at least 2 asthma exacerbations in the previous year that required at least one of the following: ▪ Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days ▪ Hospitalization and/or ED visit. • For chronic rhinosinusitis with nasal polyp (CRSwNP) requests: o Patient is at least 18 years of age; AND o Baseline Nasal Polyps Score (NPS) of at least 5, with a unilateral score of at least 2 for each nostril; AND o Symptomatic disease that is persistent for a minimum of 12 weeks, including all of the following: ▪ Nasal obstruction ▪ Rhinorrhea (anterior/posterior) ▪ Diminished or loss of smell; AND o Member has tried and failed ALL of the following: ▪ At least one prior treatment course with a systemic corticosteroid ▪ Minimum 3 months compliant treatment with an intranasal glucocorticoid ▪ Minimum 1-month trial with either a non-sedating antihistamine or antileukotriene agent (e.g., montelukast). *(Criteria continues on next page)*

DRUG	CRITERIA
Dupixent (dupilumab) *continued*	• For prurigo nodularis requests: o Patient is at least 18 years of age; **AND** o Patient has moderate to severe prurigo nodularis (score of at least 7 on the Worst Itching Intensity Numerical Rating Scale (WI-NRS) and at least 20 nodular lesions); **AND** o Patient has tried **ALL** of the following: ▪ One H1 antihistamine for a period of at least 3 months; **AND** ▪ One medium to high potency topical corticosteroid for a period of at least 3 months; **AND** ▪ One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months; **AND** ▪ One traditional non-biologic systemic agent for a period of at least 3 months. • For eosinophilic esophagitis (EoE) requests: o Patient is at least12 years of age; **AND** o Patient weighs at least 40 kg; **AND** o Eosinophilic esophagitis confirmed through biopsy (at least 15 intraepithelial eos/hpf); **AND** o Patient has tried and failed **ALL** of the following: ▪ Dietary modification; **AND** ▪ One proton pump inhibitor for a period of at least 2 months; **AND** ▪ One topical corticosteroid (i.e., fluticasone, budesonide) for a period of at least 2 months. *Failure is defined as the inability to achieve and maintain remission of low or mild disease activity. **For continuation of coverage, the patient must have met the following requirements:** • For atopic dermatitis requests: o Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL). • For moderate-to-severe asthma requests: o Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use). • For chronic rhinosinusitis with nasal polyp (CRSwNP) requests: o Adherence to therapy including Dupixent and intranasal steroid; **AND** o Have a positive clinical response (e.g., 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). • For prurigo nodularis requests: o Adherence to therapy including Dupixent; **AND** o Have positive clinical response (e.g., absolute change in Worst Itching Intensity Numerical Rating Scale (WI-NRS) and reduction in nodular lesions from baseline. • For eosinophilic esophagitis (EoE) requests: o Adherence to therapy including Dupixent; **AND** o Have histological remission (defined as less than or equal to 6 eos/hpf); **AND** o Have positive clinical response (e.g., absolute change in Dysphagia Symptom Questionnaire (DSQ) score from baseline). **Duration of Approval:** 12 months **Note:** Dupixent is not covered in combination with other biologic drug therapy.
Elaprase (idursulfase)	**Before this drug is covered, the patient must meet all of the following requirements:** • Have a diagnosis of Hunter syndrome (Mucopolysaccharidosis II). **For continuation of coverage, the patient must have met the following requirements:** • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: stabilization or improvement in FVC and/or 6MWT. **Duration of Approval:** 12 months

DRUG	CRITERIA
Elelyso (taliglucerase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Gaucher's Disease, Type 1. For continuation of coverage, the patient must have met the following requirements: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: clinically significant reduction in spleen or liver volume, increase in platelet or hemoglobin values. Duration of Approval: 12 months
Elzonris (tagraxofusp)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is at least 2 years of age; AND • Has an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2; AND • Has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) (supporting documentation must be submitted to Priority Health). o Per protocol RX138 (Requiring Second Opinion prior to Drug Approval), Priority Health may require a second opinion confirming the diagnosis with a hematopathologist. For continuation of coverage, the patient must have met the following requirements: • Not have disease progression. • Not have intolerable adverse effects Duration of Approval: 3 months Note: Elzonris uses weight-based dosing. Patients weighing 92 kg or less should be rounded down to the nearest vial size (within 10%).
Empaveli (pegcetacoplan)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of paroxysmal nocturnal hemoglobinuria: AND • Have flow cytometric confirmation at least 10% granulocyte clone cells; OR • Have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage). For continuation of coverage, the patient must have met the following requirements: • Have a decrease in disabling symptoms; AND • Hemoglobin levels have stabilized; AND • Patient has experienced an improvement in fatigue and quality of life. Duration of Approval: 6 months (initial), 12 months (continuation)

DRUG	CRITERIA
Enbrel (etanercept)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. • For Ankylosing Spondylitis requests: o There are no Specific Induction Criteria for this indication. Enbrel is covered for any patient who meets the General Initiation Criteria. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months. • For Juvenile Idiopathic Arthritis requests: o Patient has tried at least ONE other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug, a biologic [Adalimumab, Orencia, Kineret, Actemra]) for a period of at least 3 months; OR o Patient will be starting on Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide; OR o Patient has aggressive disease, as determined by the prescribing physician. Note: Enbrel will not be covered in combination with another biologic drug. 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 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.
Enjaymo (sutimlimab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have confirmed diagnosis of cold agglutinin disease (CAD); AND • Have documentation of at least one blood transfusion within 6 months of starting Enjaymo; AND • Have a hemoglobin value less than or equal to 10 g/dL; AND • Have presence of one or more symptoms associated with CAD: symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event; AND • Have had a documented trial and failure with a rituximab-containing regimen; AND • Prescribed by or in consultation with a hematologist. <u>For continuation of coverage, patient must have met the following requirements</u>: • Have documented clinical benefit from use of Enjaymo as evidenced by an increase in baseline Hgb level and no blood transfusions 5 weeks from initiation of therapy. <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation)

DRUG	CRITERIA
Enspryng (satralizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) (supporting documentation must be submitted to Priority Health); **AND** • Anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided); **AND** • Have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years; **AND** • Prescribed by or in consultation with a neurologist; **AND** • Have progressive disease on a therapeutic trial of rituximab; **AND** • Expanded Disability Status Scale (EDSS) score of less than or equal to 7. <u>For continuation of coverage, patient must have met the following requirements</u>: • Have a positive clinical response to Enspryng as evidenced by a documented decrease in relapse rate <u>Duration of Approval</u>: 12 months
Entyvio (vedolizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient is at least 18 years of age; **AND** • For moderate to severe Crohn's disease requests: o Patient has prior use of corticosteroids; **AND** o First try infliximab **OR** adalimumab. • For mild Crohn's disease requests, requires **ALL** of the following: o First try one of the following: corticosteroids, mesalamine, olsalazine, sulfasalazine, azathioprine, 6-MP, or methotrexate; **AND** o First try infliximab **OR** adalimumab. • For severe ulcerative colitis requests, requires **ALL** of the following: o Patient has frequent loose bloody stools (at least6 per day) with severe cramps and evidence of systemic toxicity; **AND** o Patient has prior use of corticosteroids; **AND** o First try infliximab **OR** adalimumab. • For mild to moderate ulcerative colitis requests, requires **ALL** of the following: o First try two of the following: 6-mercaptopurine (6-MP), azathioprine, balsalazide, corticosteroids, mesalamine, and sulfasalazine; **AND** o First try infliximab **OR** adalimumab. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Have a positive clinical response to Entyvio (e.g., decrease in bowel movements per day, no blood in stool, decrease in oral corticosteroid use; **OR** decrease in inflammatory markers such as fecal calprotectin, C-reactive protein). <u>Duration of Approval</u>: 12 months **Note:** Entyvio is not covered in combination with other biologic drug therapy.

DRUG	CRITERIA
Enzyme Replacement Inhibitors, Fabry Disease	Preferred Agent(s): Fabrazyme Elfabrio Non-Preferred Agent(s): Not applicable Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Fabry disease [(please provide supporting documentation to confirm diagnosis (e.g. alpha- Gal A activity in leukocytes or plasma, mutation analysis of the alpha-Gal A gene)]; AND • Patient is either: o Classically affected male (i.e. male with very low or undetectable levels of alpha-galactosidase A [alphaGal A]); OR o Female carrier or male with atypical presentations (i.e. with marginal levels of alpha-Gal A) with clinical manifestations of Fabry disease (e.g. renal, neurologic, cardiovascular) present; AND • Prescribed by, or in consultation with, a nephrologist, cardiologist, or a specialist in metabolic disorders or genetics. For continuation of coverage, the patient must have met the following requirements: • Continued response to treatment (e.g. reduction in plasma glycosphingolipid GL-3 levels compared to baseline); AND • Compliance with at least 50 percent of treatments; AND • Regularly attends follow-up visits; AND • Has not developed ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV); AND • Does not have end-stage Fabry disease or other comorbidities with a life expectancy of less than 1 year; AND • Has not experienced severe cognitive decline. Duration of Approval: 12 months
Epidiolex (cannabidiol)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex (documentation must be submitted to Priority Health); AND • Be using Epidiolex as an adjunctive treatment for seizures associated with one of the above diagnoses; AND • Patient is at least 1 year of age; AND • Has tried and failed, or have intolerance/contraindication to at least two generic anticonvulsants.
Esbriet (pirfenidone)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Idiopathic pulmonary fibrosis; AND • Prescribed by, or in consultation with, a pulmonologist; AND • Prescriber has ruled out other known causes of interstitial lung disease; AND • Have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy; and possibly surgical lung biopsy; AND • Be a current non-smoker. For continuation of coverage, patient must have met the following requirements: • Be a current non-smoker; AND • 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); AND • Be adherent to Esbriet. Duration of Approval: 12 months Note: Esbriet is not covered in combination with Ofev.

DRUG	CRITERIA
Evenity (romosozumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For postmenopausal osteoporosis in women at high risk for fracture and no history of an osteoporotic/fragility fracture, the patient must meet **ALL** of the following: o 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** o Have a documented treatment failure, contraindication* or ineffective response** to a minimum of a 12-month trial with zoledronic acid (generic Reclast) or Prolia (also requires prior authorization). • For postmenopausal osteoporosis in women at high risk for fracture and a history of an osteoporotic fracture, the patient must meet the following: o 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 (also requires prior authorization). **Contraindication examples to oral bisphosphonate therapy include the following:* o Documented inability to sit or stand upright for at least 30 minutes o Documented pre-existing gastrointestinal disorder such as inability to swallow, esophageal stricture, or achalasia ***Ineffective response is defined as one of the following:* o Decrease in T-score in comparison to previous T-score from DEXA scan o New fracture while on therapy. <u>Duration of Approval</u>: 12 months **Note:** Evenity is not covered in combination with other injectable drugs for the treatment of osteoporosis (e.g., Prolia, Tymlos, Forteo). If osteoporosis therapy remains warranted beyond 12 months, continued therapy with an anti- resorptive agent should be considered.
Evkeeza (evinacumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist; **AND** • Have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), confirmed by one or more of the following: o Presence of two mutant alleles at the LDL receptor, Apolipoprotein B, or PCSK9 gene; **OR** o 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); **AND** • 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 AND PCSK9 inhibitor (e.g. Repatha/evolocumab) for at least 8 consecutive weeks with failure to achieve LDL-C goal: o Patient must continue to receive maximally tolerated statin therapy or have a intolerance/contraindication of statin therapy. o If one high-intensity statin is not tolerated, a trial of a second statin is required; **AND** • Requires documentation of failure to reach LDL-C goal using LDL apheresis. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Have improved and maintained an improved LDL compared to baseline. <u>Duration of Approval</u>: 12 months **Note:** Evkeeza is not covered in combination with Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe), or a PCSK9 inhibitor (Repatha, Praluent).

DRUG	CRITERIA
Evrysdi (risdiplam)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescribed by a neurologist or in consultation with a neurologist with experience treating SMA; AND • Have a diagnosis of spinal muscular atrophy (SMA); **AND** • Have genetic testing confirming spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reports as at least one of the following: homozygous gene deletion, homozygous conversion mutation, or compound heterozygous mutation; **AND** • Have genetic testing confirming the member has no more than 2 copies of SMN2 or experienced SMA- associated symptoms before 6 months of age; **AND** • Be symptomatic at the time of the request, but not have advanced SMA (i.e., complete paralysis of limbs, permanent ventilator dependence); **AND** • Submit a baseline 32-item motor function measure (MFM-32), Hammersmith Infant Neurologic Exam (HINE), or other validated assessment tool for SMA. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Submit documentation to show maintenance or improvement of condition: o Repeat measurement of the MFM-32, HINE or other validated assessment tool appropriate for patient age to show improvement or stable results; **AND** for HINE results, must show improvement in more categories of motor milestones than worsening. o 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. <u>Duration of Approval</u>: 6 months **Note:** Evrysdi will only be authorized in accordance with FDA-approved dosing for SMA. Initial authorization for loading doses will be limited to a total of 4 doses. Maintenance therapy will be limited to 12mg every 4 months, starting 4 months after the last loading dose. Evrysdi is considered experimental and investigational for non-5q-spinal muscular atrophy disorders. Evrysdi will not be authorized for use in patients previously treated with Zolgensma and will not be authorized for coverage in combination with Spinraza.
Eylea (afilibercept)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have one of the following diagnoses and meet any required criteria: o Retinopathy of Prematurity (ROP): ▪ Diagnosis of ROP must be included in request. o Neovascular (wet) age-related macular degeneration (AMD): ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. ▪ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. o Macular edema following retinal vein occlusion (RVO): ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. o Diabetic macular edema (DME) with baseline visual acuity 20/50 or worse: ▪ Baseline best-corrected visual acuity (BCVA) score must be included in request. o Diabetic macular edema (DME) with baseline visual acuity better than 20/50: ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. o Diabetic retinopathy: ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. • Patients currently receiving treatment with Eylea and who have demonstrated an adequate response are not required to try Avastin. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Disease response as indicated by stabilization of visual acuity or improvement in BCVA score when compared to baseline. <u>Duration of Approval</u>: 12 months

DRUG	CRITERIA
Fasenra (benralizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient is at least 12 years of age; **AND** • Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **AND** • Not be currently using tobacco products; **AND** • Have been compliant on all of the following therapies for at least 3 months: o High-dose inhaled corticosteroid (ICS) o Long-acting beta agonist (LABA) o One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); **AND** • Be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique); **AND** • Have had at least 2 asthma exacerbations in the previous year that required at least one of the following: o Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days o Hospitalization and/or ED visit. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use). <u>Duration of Approval</u>: 12 months **Note:** Fasenra is not covered in combination with other biologic drug therapy.
Fentanyl citrate lozenge (generic Actiq)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient is at least 16 years of age; **AND** • Be using to manage breakthrough pain in cancer patients; **AND** • Be receiving and tolerant to around-the-clock opioid therapy for persistent cancer pain. **Note:** Limited to 120 lozenges per 30 days.
Fintepla (fenfluramine)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome (documentation must be submitted); **AND** • Patient is at least 2 years of age; **AND** • Have tried and failed two of the following drugs alone or in combination: clobazam, valproate/divalproex, or topiramate; **AND** • Have tried and failed, or have contraindication to Diacomit (stiripentol)—*Dravet Syndrome only*.

DRUG	CRITERIA
Firdapse (amifampridine)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by one of the two electrodiagnostic studies and the antibody test as follows: o 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** o Positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody test • Have clinical symptoms of LEMS (i.e., proximal lower extremity weakness) that interfere with daily activities; **AND** • Be ambulatory; **AND** • Provide a baseline disease severity score using the Quantitative Myasthenia Gravis (QMG) or the Triple-Timed Up-And-Go (3TUG) test; **AND** • For adult patients only, have tried and failed pyridostigmine (fail is defined as taking the medication as prescribed and at an appropriate dose for the condition) ; **AND** • If the patient has a cancer diagnosis associated with LEMS (e.g., small cell lung cancer), the cancer has been appropriately treated prior to starting Firdapse. For continuation of coverage, patient must have met the following requirements: • 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); **AND** • Have disease response indicated by an improvement or stabilization from baseline in objective measures using the 3TUG test. Duration of Approval: 4 weeks (initial); 12 months (continuation) **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
Filspari (sparsentan)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of biopsy-verified primary immunoglobulin A nephropathy (documentation must be submitted to Priority Health); **AND** • Patient has tried and failed **ALL** of the following: o Maximally tolerated dose of ACE inhibitor or ARB (minimum of 3 months); **AND** o SGLT2 inhibitor (minimum of 3 months); **AND** o Systemic oral glucocorticoids (i.e., prednisone, methylprednisolone) unless the patient has documentation of serious adverse effects or contraindication to systemic oral glucocorticoids (minimum of 6 weeks); AND • Prescriber is a specialist or has consulted with a specialist for the condition being treated; **AND** • Patient is at least 18 years of age; **AND** • Patient is not currently receiving dialysis and has not undergone kidney transplant. For continuation of coverage, the patient must have met the following requirements: • Have reduced proteinuria from baseline; **AND** • Have eGFR of at least 15 mL/min/1.73 m2. Duration of Approval: 9 months (initial); 12 months (continuation)

DRUG	CRITERIA
Galafold (miglastat)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Fabry disease, and an amenable galactosidase alpha gene variant based on in-vitro assay data (supporting documentation must be submitted to Priority Health); AND • Patient is at least 18 years of age. For continuation of coverage, patient must have met the following requirements: • Have a 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; AND • The patient is compliant in taking the medication as scheduled. Duration of Approval: 12 months Note: Galafold is not covered when used in combination with enzyme replacement therapy (ERT), thus combination use with Fabrazyme is not covered.
Gamifant (emapalumab)	Before this drug is covered, the patient must meet all of the following requirements: • Be treating primary hemophagocytic lymphohistiocytosis (HLH); AND • Have previously tried and failed on conventional therapy (e.g. etoposide, dexamethasone, cyclosporine). For continuation of coverage, patient must have met the following requirements: • Have objective evidence of response to therapy (i.e. normalization of HLH abnormalities); AND • Provide update and/or plan for hematopoietic stem cell transplant (HSCT). Duration of Approval: 3 months

Gattex (teduglutide)	Before this drug is covered, the patient must meet all of the following requirements:
	• Diagnosis of short bowel syndrome dependent on parenteral support. Please provide the following information:
	  o Patient's current body mass index;
	  o How long the patient has received parenteral support;
	  o Total daily volume of parenteral support; AND
	• Patient's body mass index is 15 kg/m2 or greater; AND
	• 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; AND
	• If the patient has their large intestine intact, a colonoscopy must be completed within 6 months before starting Gattex; AND
	• A reasonable expectation the patient will be removed from parenteral support within 6 months; AND
	• Patient must not have a history of:
	  o Colorectal or gastrointestinal malignancy
	  o Radiation enteritis
	  o Cancer within 5 years before starting Gattex
	  o Use of human growth hormone within 6 months before starting Gattex
	  o Treatment for active Crohn's disease within 12 weeks before starting Gattex
	  o More than 4 admissions within 12 months before starting Gattex
	
	For continuation of coverage, the patient must have met the following requirements:
	• The patient is compliant in taking the medication as scheduled; AND
	• The patient had a 50% reduction in parenteral support volume; AND
	• With continued treatment, the patient can be removed from parenteral support within the next 6 months.
	
	Duration of Approval: Initial: 6 months (initial); 6 months (one time continuation approval only)

DRUG	CRITERIA
Givlaari (givosiran)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of acute hepatic porphyria (including AIP, HCP, variegate porphyria, or ALA dehydratase deficient porphyria); **AND** • Patient is at least 18 years of age; **AND** • Have active disease defined as 2 documented porphyria attacks with in the past 6 months, which can include hospitalization urgent healthcare visits or IV hemin administration at home. For continuation of coverage, the patient must have met the following requirements: • Stabilization of the disease or absence of disease progression (reduction in attacks from baseline). Duration of Approval: Initial: 6 months (initial); 12 months (continuation)
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists	Preferred Agent(s): Trulicity (dulaglutide) Mounjaro (tirzepatide) Non-Preferred Agent(s): *Effective 1/1/2024, Byetta, Bydureon, Ozempic, and Victoza were removed from coverage for Traditional and Optimized plans.* Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Type 2 diabetes mellitus; **AND** • Patient is at least 18 years of age; **AND** • Trial and failure of, or intolerance of at least 2 oral antidiabetic agents (used in combination) **OR** insulin after 3 continuous months of receiving maximal daily doses in conjunction with diet and exercise (as defined in the American Diabetes Standards of Care) and not achieving adequate glycemic control (must be within the last 6 months); **AND** • Hemoglobin A1c less than or equal to 9%, but not less than 7%. **Note:** Medications in this category are only covered for type 2 diabetes mellitus (applies to Priority Health Optimized and Traditional Formularies). For Traditional, prior authorization is required if ICD10 diagnosis code for type 2 diabetes (E11.0-E11.9) is not on file; for Optimized, the above criteria applies.

Gralise (gabapentin extended release)	Before this drug is covered, the patient must meet all of the following requirements:
	• Patient has a diagnosis of postherpetic neuralgia (supporting documentation must be submitted to Priority Health); **AND**
	• Patient is at least 18 years of age; **AND**
	• Have tried and failed, or have intolerance/contraindication to all the following:
	  o One generic tricyclic antidepressant (i.e. amitriptyline) at max tolerated doses for a minimum of 28 days
	  o Gabapentin 1,800 mg daily (immediate release) used for a minimum of 28 days

DRUG	CRITERIA
Hemophilia Products, Factor VIII *Coverage update effective 1/1/2024*	Preferred Agent(s): Advate, Afstyla, Hemofil, Koate, Kogenate, Kovaltry, NovoEight, Nuwiq, Recombinate, Xyntha Non-Preferred Agent(s): Altuviiio, Adynovate, Eloctate, Esperoct, Jivi Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of severe Hemophilia A (factor VIII level of less than 1%) has been confirmed by blood coagulation testing; OR diagnosis of moderate Hemophilia A with at least two documented episodes of spontaneous bleeding into joints (supporting documentation must be submitted to Priority Health); AND • Be used for at least one of the following: o Control and prevention of acute bleeding episodes, OR o Perioperative management, OR o Routine prophylaxis to prevent/reduce the frequency of bleeding episodes. • Prescribed by a hematologist or other specialist; AND • NOT to be used for induction of immune tolerance in patients with hemophilia A; AND • Non-preferred drug product: Trial and failure, or intolerance/contraindication to a preferred product. For continuation of coverage, the patient must have met the following requirements: • Have evidence of efficacy (i.e., less breakthrough bleeds as documented in the treatment log and/or chart notes). Duration of Approval: Perioperative management (1 month); acute bleeding management (see below); routine prophylaxis (12 months). Note: Dosing should be provided through the nearest available vial size and/or dosing interval that will produce the least amount of waste per dose. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label. Additionally, when approved, Hemophilia Products should be obtained from a participating Hemophilia Specialty Pharmacy as noted in Medical Policy 91569. For acute bleeding management: Limited to a total of five on-hand doses. Each additional fill requires documentation of the patient's use of the previous supply of factor product. Information regarding cumulative quantities of on-hand factor must be provided when requesting for acute bleeding management.

DRUG	CRITERIA
Hemophilia Products, Factor IX *Coverage update effective 1/1/2024*	Preferred Agent(s): BeneFIX, Ixinity, Mononine Non-Preferred Agent(s): AlphaNine, Alprolix, Idelvion, Rebinyn, Rixubis Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of severe Hemophilia B (factor IX level of less than 1%) has been confirmed by blood coagulation testing; OR diagnosis of moderate Hemophilia B with at least two documented episodes of spontaneous bleeding into joints (supporting documentation must be submitted to Priority Health); AND • Be used for at least one of the following: o Control and prevention of acute bleeding episodes, OR o Perioperative management, OR o Routine prophylaxis to prevent/reduce the frequency of bleeding episodes. • Prescribed by a hematologist or other specialist; AND • NOT to be used for induction of immune tolerance in patients with hemophilia B; AND • Non-preferred drug product: Trial and failure, or intolerance/contraindication to a preferred product. For continuation of coverage, the patient must have met the following requirements: • Have evidence of efficacy (i.e., less breakthrough bleeds as documented in the treatment log and/or chart notes). Duration of Approval: Perioperative management (1 month); acute bleeding management (see below); routine prophylaxis (12 months). Note: Dosing should be provided through the nearest available vial size and/or dosing interval that will produce the least amount of waste per dose. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label. Additionally, when approved, Hemophilia Products should be obtained from a participating Hemophilia Specialty Pharmacy as noted in Medical Policy 91569. For acute bleeding management: Limited to a total of five on-hand doses. Each additional fill requires documentation of the patient's use of the previous supply of factor product. Information regarding cumulative quantities of on-hand factor must be provided when requesting for acute bleeding management.

DRUG	CRITERIA
Hemophilia Products, Hemgenix (etranacogene dezaparvovec) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of moderate or severe hemophilia B (factor IX level less than 2 IU/dL or less than or equal to 2% of normal); AND • Be male; AND • Patient is at least 18 years of age; AND • Prescribed by or in consultation with a hematologist; AND • Have one of the following: o Current use of factor IX prophylaxis therapy (have received therapy for at least 2 months with at least 150 previous exposure days with the factor IX product); OR o Patient has current or historical life-threatening hemorrhage; OR o Patient has had repeated, serious spontaneous bleeding episodes (Must include documentation of the number of bleeds in the past year). Note: Hemgenix will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling. Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles. Hemgenix will not be authorized for use in patients: • that have received a previous treatment course of Hemgenix or another adeno-associated virus vector-based gene therapy. The safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Hemgenix is dependent on member's eligibility and benefit plan documents.
Hemophilia Products, Roctavian (valoctocogene roxaparvovec) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of moderate or severe hemophilia A (factor VIII level less than 1 IU/dL or less than or equal to 1% of normal); AND • Be male; AND • Patient is at least 18 years of age; AND • Prescribed by or in consultation with a hematologist; AND • Have one of the following: o Current use of factor VIII prophylaxis therapy (have received therapy for at least 2 months with at least 150 previous exposure days with the factor VIII product); OR o Patient has current or historical life-threatening hemorrhage; OR o Patient has had repeated, serious spontaneous bleeding episodes (Must include documentation of the number of bleeds in the past year). Note: Roctavian will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling. Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles. Roctavian will not be authorized for use in patients: • that have received a previous treatment course of Roctavian or another adeno-associated virus vector-based gene therapy. The safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Roctavian is dependent on member's eligibility and benefit plan documents.

DRUG	CRITERIA
Hemophilia Products, Hemlibra (emicizumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescribed by a hematologist or other specialist; AND • Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis); AND • Have physician attestation that the patient is not to receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Jivi, Esperoct, Altuviiio) for the treatment of breakthrough bleeding episodes; AND • Meet one of the following (supporting documentation must be submitted to Priority Health): o Diagnosis of Hemophilia A with factor VIII inhibitors; OR o Diagnosis of severe Hemophilia A without factor VIII inhibitors (endogenous factor VIII level less than 1% of normal factor VIII [less than 0.01 IU/mL]) AND patient is not a suitable candidate for treatment with shorter half-life factor VIII products at a total weekly dose of 100 IU/kg or less (as attested by the prescribing physician with appropriate clinical rationale). For continuation of coverage, the patient must have met the following requirements: • Have evidence of efficacy (i.e., less breakthrough bleeds as documented in the treatment log and/or chart notes; AND reduced overall usage of factor VIII replacement products or bypassing agents). Supporting documentation must by submitted to Priority Health. Duration of Approval: 12 months Note: Hemlibra is not covered in combination with prophylactic use of other factor VIII replacement products or bypassing agents. 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 once every week, or 3 mg/kg once every two weeks, or 6 mg/kg once every four weeks. Hemlibra is available in the following presentations: 30 mg/mL (1 mL); 60 mg/0.4 mL (0.4 mL); 105 mg/0.7 mL (0.7 mL); 150 mg/mL (1 mL). Dosing should be provided through the nearest available vial size and/or dosing interval that will produce the lease amount of waste per dose. If necessary, more than one injection can be provided per dose. Additionally, when approved, Hemlibra must be obtained from a participating Hemophilia Specialty Pharmacy as noted in Medical Policy 91569.
Hepatitis C Antivirals, Direct Acting agents	Preferred Agent(s): *Prior authorization not required if Hep C IDC10 codes are on file.* Mavyret (glecaprevir/pibrentasvir) Zepatier (elbasvir/grazoprevir) Non-Preferred Agent(s): *See criteria below* Sovaldi (sofosbuvir) Viekira (ombitasvir/paritaprevir/ritonavir/dasabuvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir) Ledipasvir/sofosbuvir (generic Harvoni) Sofosbuvir/velpatasvir (generic Epclusa) Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of chronic hepatitis C (IDC10 codes: B18.2, B19.2, and B19.21); AND • Non-preferred drug product: Trial and failure, or intolerance/contraindication to Mavyret or Zepatier.

DRUG	CRITERIA
Hereditary Angioedema Agents, Acute Treatment	Preferred Agent(s): Berinert (C1 esterase inhibitor) Icatibant Non-Preferred Agent(s): Kalbitor (ecallantide) Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of 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); **AND** • Prescribed by an allergist, immunologist, hematologist, or other specialist experienced in treating HAE; **AND** • Follow age-appropriate use as listed in FDA-approved label for each drug; **AND** • Documentation of patient attacks affecting upper airways, **OR** involving the face, neck, or abdomen, OR resulting in debilitation or dysfunction; **AND** • Patient has received training for self-administration; **AND** • Patient is not on an angiotensin-converting enzyme (ACE) inhibitor. For continuation of coverage, the patient must have met the following requirements: • 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. • 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. Duration of Approval: • Icatibant: Limited to a total of three syringes on-hand. Each additional fill requires documentation of the patient's use of the previous supply of icatibant, 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 if icatibant 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 if Kalbitor showed benefit for the patient. **Note:** As noted in the plan documents, Priority Health may require a second opinion confirming the diagnosis. Two or more acute-use agents (Firazyr, Berinert, and Kalibtor) are not covered in combination.

DRUG	CRITERIA
Hereditary Angioedema Agents, Preventative Treatment	<u>Preferred Agent(s):</u> Orladeyo (berotralstat) Takhzyro (lanadelumab) <u>Non-Preferred Agent(s):</u> Haegarda (C1 esterase inhibitor) <u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Diagnosis of 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); **AND** • Prescribed by an allergist, immunologist, hematologist, or other specialist experienced in treating HAE; **AND** • Follow age-appropriate use as listed in FDA-approved label for each drug; **AND** • Documentation of severe (e.g. airway swelling, debilitating attacks of the face, neck, or abdomen) acute attacks occurring at least twice per month; **AND** • Documentation that on-demand/acute therapy (e.g. Firazyr, Berinert, Kalbitor) did not provide adequate symptom control; **AND** • Patient has received training for self-administration (Takhzyro and Haegarda); **AND** • Patient is not on an angiotensin-converting enzyme (ACE) inhibitor. • <u>Non-preferred drug product</u>: Trial and failure, or intolerance/contraindication to a preferred product. <u>For continuation of coverage, the patient must have met the following requirements:</u> • Submission and review of patient's HAE treatment plan; **AND** • Compliance on therapy; **AND** • Documentation of a decrease in the frequency of acute attacks from baseline (prior to treatment); **AND** • 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. <u>Duration of Approval:</u> • Takhzyro: Limited to either 150mg or 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 week for 12 months. • Haegarda: Limited to 60units/kg (in combinations of 3,000- & 2,000-unit vials) every 3 days for 12 months. • Orladeyo: 12-month authorization **Note:** As noted in the plan documents, Priority Health may require a second opinion confirming the diagnosis. Two or more prophylactic agents (i.e. Takhyzro, Haegarda, Orladeyo) are not covered in combination.

DRUG	CRITERIA
Hetlioz (tasimelteon)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of Non-24-hour Sleep-Wake Disorder; **AND** • Patient must be totally blind; **AND** • Patient is at least 18 years of age; **AND** • Prescribed by a sleep specialist; **AND** • Have tried and failed at least a 6-month trial with melatonin or Rozerem (documentation of the medication's inability to improve the patients overall sleep quality must be submitted); **AND** • Have tried and failed eszopiclone or zolpidem. <u>For continuation of coverage, patient must have met the following requirements</u>: • The patient's use of Hetlioz must be continuous without any gaps in treatment. Hetlioz will only continue to be covered for patients with 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); **AND** • Prescriber must provide an objective evaluation of the patient's sleep quality, including documentation of an improvement in overall sleep quality while taking Hetlioz. <u>Duration of Approval</u>: 6 months
Human Growth Hormone for Patients Less than 18 Years of Age	<u>Preferred Agent(s)</u>: Genotropin Omnitrope *Effective 1/1/2024, Norditropin was removed from coverage for Traditional and Optimized plans..* <u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, pediatric nephrologist); **AND** • Meet one of the following diagnoses and the applicable criteria for each diagnosis below. • For Growth Hormone Deficiency (GHD) requests: o Meet one of the following: ▪ Height is at least 2.5 SD below the mean for chronological age and sex; **OR** ▪ Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile; **OR** ▪ Using for neonatal hypoglycemia associated with growth hormone deficiency; **AND** o Growth plates must be open; **AND** o Meet one of the following: ▪ Documented GH deficiency via 2 growth hormone (GH) stimulation tests below 10 ng/mL; **OR** ▪ GH stimulation test level below 15 ng/mL, and IGF-1 and IGF-PB3 levels below normal for bone age and gender; **OR** ▪ One GH stimulation test below 10 ng/mL for children with defined CNS pathology (ex. pituitary surgery, radiation therapy, precocious puberty); **OR** ▪ If using for neonatal hypoglycemia associated with GHD, one random GH level less than 20 ng/mL. • For Turner's syndrome requests: o Growth plates must be open; **AND** o Diagnosis must be confirmed by genetic testing. • For Pre-transplant chronic renal insufficiency requests: o Meet one of the following: ▪ Height is at least 2.5 SD below the mean for chronological age and sex; **OR** ▪ Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile; **AND** o Patient is receiving weekly dialysis or creatinine clearance is less than 75 ml/min; **AND** o No evidence of active malignancy; **AND** o Growth plates must be open. *(Criteria continues on next page)*

DRUG	CRITERIA

Human Growth Hormone for Patients Less than 18 Years of Age *continued*	• For Prader-Willi Syndrome requests:
	  o Diagnosis must be confirmed by genetic testing; **AND**
	  o Growth plates must be open.
	
	• For Noonan Syndrome requests:
	  o Diagnosis must be confirmed by genetic testing; **AND**
	  o Growth plates must be open.
	
	• For Small for Gestational Age (SGA) requests:
	  o Child born small for gestational age, defined as birth weight or length less than 10th percentile of birth weight for gestational age; **AND**
	  o Child fails to manifest catch up growth by age of 2 years, defined as height 2 or more SDs below the mean for age and sex; **AND**
	  o Growth plates must be open.
	
	For continuation of coverage, patient must have met the following requirements:
	• During first 12 months of therapy: 7.0 cm/year or more
	• If more than 12 months of therapy: 6 cm/year or more
	• Bone age for females more than 13 years: 2.5 cm/year or more; males more than 15 years: 2.5 cm/year or more
	• If not on maximum recommended dose
	• Duration of therapy is limited to (whichever comes first):
	  o Growth velocity is less than 2.5 cm/year
	  o Bone age in males reaches 16
	  o Bone age in females reaches 14
	
	Duration of Approval: 12 months
	
	Note: The following conditions are not covered for patients less than 18 years of age: constitutional growth delay, idiopathic short stature, familial short stature, and those with acute or chronic catabolic illness.

DRUG	CRITERIA
Human Growth Hormone for Patients 18 Years of Age and Older	<u>Preferred Agent(s)</u>: Genotropin Omnitrope *Effective 1/1/2024, Norditropin was removed from coverage for Traditional and Optimized plans..* <u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, pediatric nephrologist); **AND** • Meet one of the following diagnoses and the applicable criteria for each diagnosis below. • For Growth hormone deficiency (GHD) requests: o GHD documented by one of the following: ▪ suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge (if contraindicated, another acceptable method is allowed); **OR** ▪ at least 2 other pituitary-related hormone deficiencies **AND** an abnormally low IGF; **AND** o Patient has one of the following: ▪ hypothalamic pituitary disease resulting from tumor or infarct ▪ history of cranial irradiation during childhood or adulthood resulting in GH deficiency ▪ Pituitary surgery resulting in GH deficiency ▪ Continuing treatment of childhood onset GH deficiency ▪ History of head trauma or subarachnoid hemorrhage • For Short bowel syndrome requests: o Be receiving total parenteral nutrition (TPN); **AND** o Be participating in a program that manages dietary intake and hydration. <u>For continuation of coverage, patient must have met the following requirements</u>: • Low IGF-1 (within the past 12 months), but dose is being increased; **OR** • IGF-1 (within the past 12 months) within appropriate range for age and sex <u>Duration of Approval</u>: 12 months **Note:** The following conditions are not covered for patients at least 18 years of age: treated during childhood without documented evidence of persistent growth hormone deficiency; physiologic reductions in growth hormone related to aging; and treatment of Turner's syndrome or cystinosis.
Ilaris (canakinumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults **AND** children 4 years or older; **OR** • Have a diagnosis of periodic fever syndromes including familial Mediterranean fever (FMF), hyper immunoglobulinD syndrome (HIDS), mevalonate kinase deficiency (MKD), and tumor necrosis receptor- associated periodic syndrome (TRAPS) in adults and children; **OR** • Have a diagnosis of systemic Juvenile Idiopathic Arthritis (SJIA) or Adult-Onset Still's Disease (AOSD) in patients 2 years or older. **Note:** If approved, authorization for diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) is one injection (150 mg for patients weighing more than 40 kg and 2 mg/kg for patients weighing 15–40 kg), given every 8 weeks by a health care professional, indefinitely. Authorization for diagnosis of periodic fever syndromes is one injection (150 mg for patients weighing more than 40 kg and 2 mg/kg for patients weighing 15–40 kg), given every 4 weeks by a health care professional, indefinitely.

DRUG	CRITERIA
Ilumya (tildrakizumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Cosentyx, Enbrel, Adalimumab, Otezla, Tremfya, or Stelara, each for a period of at least 3 months. Note: Ilumya will not be covered in combination with another biologic drug. Before Ilumya is covered, the patient must meet all of the General Criteria for Ilumya 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.
Impavido (miltefosine)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of 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). Duration of Approval: 1 month
Imvexxy (estradiol)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of moderate to severe dyspareunia caused by vulvovaginal atrophy; AND • Plan documents must have sexual dysfunction rider; AND • Documented trial with an OTC vaginal lubricant for at least 90 days; AND • Documented trial of a vaginal estrogen product for at least 90 days.

DRUG	CRITERIA
Increlex (mecasermin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of severe primary insulin-like growth factor-1 (IGF-1) deficiency or 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); AND • Patient is 2 to 65 years of age; AND • Prescribed by, or after consultation with, a pediatric endocrinologist; AND • Have the following: o Baseline height less than 3rd percentile or greater than 2 standard deviations (SD) below the mean for gender and age o IGF-1 at least 3 SD below the normal range for age and sex o History of lower-than-normal growth velocity o Epiphyses are open (must be confirmed for patients 10 years of age and older, submit radiograph) o 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 additional criteria includes: o 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 additional criteria includes: o Documentation of prior treatment with growth hormone (typically 3-6 month trial) and subsequent antibody development. For continuation of coverage, patient must have met the following requirements: • Epiphyses are open; AND • Rate of growth with Increxlex is greater than pretreatment rate of growth; AND • Patient's bone age must be less than 16 years for males, less than 14 years for females. Duration of Approval: 12 months
Intrarosa (prasterone)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of moderate to severe dyspareunia caused by vulvovaginal atrophy; AND • Plan documents must have sexual dysfunction rider; AND • Documented trial with an OTC vaginal lubricant for at least 90 days; AND • Documented trial of a vaginal estrogen product for at least 90 days.
Isturisa (osilodrostat)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Cushing's disease (documentation must be faxed to Priority Health); AND • Patient is at least 18 years of age; AND • Prescribed by an endocrinologist; AND • Documentation of failed pituitary surgery or contraindication to pituitary surgery; AND • Documentation of treatment failure on two of the following: ketoconazole, Lysodren, cabergoline, and/or Signifor/LAR.

DRUG	CRITERIA
Jelmyto (mitomycin ureteral gel)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of non-metastatic low-grade upper tract urothelial cancer (LG-UTUC) with a residual, low-grade, low volume (5-15mm), solitary tumor with documentation that the patient is not a surgical candidate or not seeking nephroureterectomy as a definitive treatment; OR • Have a diagnosis of non-metastatic LG-UTUC status post complete endoscopic resection. • Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2. For continuation of coverage, patient must have met the following requirements: • Documentation of a complete response at least 6 weeks post last installation (defined as complete absence of tumor lesions). Duration of Approval: 6 doses (initial); 11 doses (continuation). Note: Jelmyto may be approved up to a lifetime maximum of 17 doses as continuation beyond this amount has not been studied).
Joenja (leniolisib)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of activated phosphoinositide 3-kinase delta syndrome which was confirmed with either biochemical or molecular genetic testing (supporting documentation must be submitted to Priority Health); AND • Have nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g. lung, liver); AND • Patient is at least 12 years of age; AND • Prescriber is a specialist or has consulted with a specialist for the condition being treated (APDS). For continuation of coverage, the patient must have met the following requirements: • Documentation of positive clinical response in signs and manifestations of APDS. Duration of Approval: 6 months (initial); 12 months (continuation)
Jynarque (tolvaptan)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is between 18 to 65 years of age; AND • Patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed via ultrasound (supporting documentation must be submitted to Priority Health); AND • Prescribed by, or in consultation with, a nephrologist; AND • Have an estimated glomerular filtration rate (eGFR) of 25-90 mL/min/1.73m2; AND • Have disease that is rapidly progressing or likely to rapidly progress as evidenced by: o Total kidney volume (TKV) of at least 750mL, OR o Rapid loss of eGFR of at least 2.5mL/min/1.73m2 per year; AND • Hypertension, if present, must be adequately controlled (to 130/80mmHg or less). For continuation of coverage, patient must have met the following requirements: • 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; AND • Maintain an 85 percent adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient. Duration of Approval: 12 months
Kanuma (sebelipase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of lysosomal acid lipase (LAL) deficiency, confirmed by genetic testing with evidence of a LIPA mutation (supporting documentation must be submitted to Priority Health). Duration of Approval: 12 months

DRUG	CRITERIA
Kerendia (finerenone)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is using 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); AND • Patient is at least 18 years of age; AND • Have diagnosis of type 2 diabetes; AND • eGFR of at least 25 mL/min/1.73 m2 or stage 2, 3, or 4 CKD; AND • Use concurrently with an ACE inhibitor (i.e. lisinopril) or ARB (i.e. losartan); AND • Have tried and failed, or have intolerance/contraindication to one preferred SGLT2 inhibitor (i.e. Faxiga).
Keveyis (dichlorphenamide)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants (supporting documentation must be submitted to Priority Health); AND • Diagnosis confirmed by ONE of the following: o Genetic testing o Established family history o Provocative testing o Electromyography; AND • Baseline and periodic monitoring of serum potassium and bicarbonate levels; AND • Documentation that lifestyle modifications, dietary restrictions and exercise restrictions have been maximally challenged; AND • Have tried and failed, or have intolerance/contraindication to acetazolamide. For continuation of coverage, patient must have met the following requirements: • Documentation that the patient has had a reduction in the number of paralytic attacks. Duration of Approval: 2 months (initial); 12 months (continuation)
Kevzara (sarilumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried TWO of the following: Actemra, Enbrel, Adalimumab, or Xeljanz/XR, each for a period of at least 3 months. • For Polymyalgia Rheumatica requests: o Patient has tried one systemic corticosteroid; AND o Patient has evidence of large vessel vasculitis by angiography or imaging (e.g. MRI, PET/CT). Supporting documentation must be submitted to Priority Health. Note: Kevzara will not be covered in combination with another biologic drug. 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 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.

DRUG	CRITERIA
Kineret (anakinra)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried TWO of the following: Actemra, Enbrel, Adalimumab, or Xeljanz/XR, each for a period of at least 3 months. Note: Kineret will not be covered in combination with another biologic drug. 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 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.
Korlym (mifepristone)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome; AND • Patient is at least 18 years of age; AND • Prescribed by an endocrinologist; AND • Have a diagnosis of endogenous Cushing's syndrome AND type II diabetes mellitus (DM) or glucose intolerance secondary to hypercortisolism; AND • Have failed surgical treatment or are not a candidate for surgery; AND • 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. For continuation of coverage, patient must have met the following requirements: • Have documentation of an improvement in hyperglycemia control. Duration of Approval: 6 months (initial); 12 months (continuation)
Korsuva (difelikefalin)	Before this drug is covered, the patient must meet all of the following requirements: • Be using for a diagnosis of moderate to severe, treatment-resistant pruritis in patients with chronic kidney disease (CKD) on hemodialysis at least 3 days per week; AND • Documentation has been provided showing any existing hyperparathyroidism, hyperphosphatemia, and/or hypermagnesemia has been treated to optimal target values; AND • First have a therapeutic trial and failure of at least 4 weeks with THREE of the following therapies: o topical analgesic (e.g. capsaicin, pramoxine) o oral antihistamine (e.g. hydroxyzine, diphenhydramine) o gabapentin or pregabalin o montelukast o Phototherapy (UVA or UVB) For continuation of coverage, patient must have met the following requirements: • Korsuva treatment has demonstrated effectiveness in reducing pruritis. Duration of Approval: 3 months (initial); 12 months (continuation)

DRUG	CRITERIA
Krystexxa (pegloticase)	Before this drug is covered, the patient must meet all of the following requirements: • Have chronic, treatment-failure gout (TFG); AND • Has had three or more flares in the last 18 months; AND • Have first tried allopurinol using a daily dose of 900 mg for 6 months (or probenecid or febuxostat if allopurinol is contraindicated) and be unable to maintain a serum uric acid level less than or equal to 6 mg/dL; AND • Have gout tophus or gouty arthritis. For continuation of coverage, patient must have met the following requirements: • Patient's serum uric acid level must remain at or below 6 mg/dL. Duration of Approval: 3 months (initial); 12 months (continuation)
Kymriah (tisagenlecleucel) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • For Pediatric and young adult relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) requests: o Patient is age 25 years or younger; AND o Refractory to treatment or in second or later relapse as defined by not achieving a complete response after 2 cycles of a standard chemotherapy regimen or chemo refractory as defined by not achieving a complete response after 1 cycle of standard chemotherapy for relapsed leukemia; AND o Patient is ineligible for allogeneic stem cell transplant; AND o Have B-cells that are CD19-positive as confirmed by testing or analysis; AND o If Philadelphia chromosome-positive disease and failed at least two tyrosine kinase inhibitors (TKI) (e.g., imatinib, dasatinib, nilotinib, bosutinib, ponatinib), or if TKI therapy is contraindicated. • For adult B-cell Lymphomas including Diffuse Large B-cell Lymphoma (DLBCL) unspecified or from follicular lymphoma, and high-grade B-cell lymphoma requests: o Patient is at least 18 years of age; AND o Have received prior treatment with two or more chemoimmunotherapy regimens which included at least one anthracycline-based regimen and an anti-CD20 antibody, unless contraindicated. • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; AND • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Note: Kymriah will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Kymriah will not be authorized for use in patients: • with primary central nervous system lymphoma; OR • that have received a previous treatment course of Kymriah or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy. The safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Kymriah is dependent on member's eligibility and benefit plan documents.

DRUG	CRITERIA
Kynmobi (apomorphine)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of advanced Parkinson's disease (supporting documentation must be submitted to Priority Health); AND • Prescribed by, or in consultation with, a neurologist; AND • Patient is experiencing acute, intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements); AND • Patient is receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release tablets and multiple daily dosing); AND • Therapeutic trial and failure of, or contraindication to, adjunctive therapy with at least one medication in each of the drug classes listed below: o Dopamine agonist (e.g. pramipexole, ropinirole) o Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline) o Catechol-O-methyl transferase (COMT) inhibitor (e.g. entacapone) For continuation of coverage, patient must have met the following requirements: • Must have a positive clinical response to Kynmobi as evidenced by experiencing disease stability or improvement. Duration of Approval: 6 months (initial); 12 months (continuation)
Lamzede (velmanase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of alpha-mannosidosis in adult and pediatric patients (supporting documentation must be submitted to Priority Health); AND • Clinical manifestations non-central nervous system manifestations must be present; AND • Diagnosis must be confirmed with either biochemical or molecular genetic testing; AND • Prescribed by or in consultation with a physician who specializes in the management of patients with alpha-mannosidosis, or in the administration of other enzyme replacement therapies for lysosomal storage disorders. For continuation of coverage, patient must have met the following requirements: • Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (e.g. motor function, FVC, rate of infections, serum oligosaccharides, etc.) compared to the predicted natural history trajectory of disease. Duration of Approval: 12 months Note: Lamzede is not covered when the patient has CNS disease manifestations or rapidly progressive disease; patient cannot walk without support; AND patient has a history of HSCT or bone marrow transplant.

DRUG	CRITERIA
Leqvio (inclisiran)	Before this drug is covered, the patient must meet all of the following requirements: • Have one of the following diagnoses: o Heterozygous familial hypercholesterolemia (HeFH) confirmed by one or more of the following: ▪ Genetic testing ▪ Score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria ▪ Score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria o Very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol; AND • Prescribed by a cardiologist, endocrinologist, or board-certified lipidologist; AND • Not be using in combination with a PCSK9 inhibitor, Nexletol (bempedoic acid), or Nexlizet (bempedoic acid/ezetimibe); AND • Patient's most recent LDL-C laboratory report must be submitted with authorization request; AND • Patient must continue to receive maximally tolerated statin therapy or have a intolerance/contraindication to or intolerance of statin therapy*; AND • 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. If one high-intensity statin is not tolerated, a trial of a second statin is required ; AND • Try and fail two formulary PCSK9 inhibitors (Repatha AND Praluent). Note: *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 rechallenge, 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.
Livtencity (maribavir)	Before this drug is covered, the patient must meet all of the following requirements: • Has a diagnosis of post-transplant (hematopoietic stem cell or solid organ transplantation) cytomegalovirus (CMV) infection/disease (supporting documentation must be submitted to Priority Health); AND • Have baseline CMV DNA level (e.g., PCR); AND • Have documentation of trial and failure with ganciclovir or valganciclovir; AND • Not be used concomitantly with other CMV antivirals (e.g., ganciclovir, valganciclovir); AND • Patient is at least at least 18 years of age; AND • Patient weight is greater than 35 kilograms. Duration of Approval: 8 weeks Note: Livtencity 200 mg tablet has a quantity limit of 112 tablets per 28 days (400 mg twice daily). For patients requiring higher dosages, such as those taking selected interacting drugs, please provide rationale as to which co- administered drugs are being used.

DRUG	CRITERIA
Lumizyme (alglucosidase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency) that is supported by enzyme assay or DNA testing (supporting documentation must be submitted to Priority Health); AND • Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders; AND • Documented baseline values for one or more of the following: o Infantile-onset disease: muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6 minute walk test (6MWT); OR o Late-onset (non-infantile) disease: FVC and/or 6 MWT For continuation of coverage, the patient must have met the following requirements: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: o Infantile-onset disease: stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, and/or 6 MWT; OR o Late-onset (non-infantile) disease: stabilization or improvement in FVC and/or 6MWT. Duration of Approval: 12 months Note: Lumizyme is not covered in combination with Nexviazme. Priority Health does not cover a dose that exceeds 20mg/kg body weight administered every 2 weeks as an intravenous infusion. For adult patients, doses should be rounded down to the nearest vial size within 10% of the calculated dose. Priority Health may not cover Lumizyme for ventilator-dependent patients requiring ventilation 24 hours per day.
Lupkynis (voclosporin)	Before this drug is covered, the patient must meet all of the following requirements: • For biopsy-proven lupus nephritis Class III through V: o Patient is at least 18 years of age; AND o Be autoantibody-positive with one of the following: ▪ Anti-nuclear antibody (ANA) titer at least 1:80; OR ▪ Anti-double-stranded DNA (anti-dsDNA) level at least 30 IU/mL; AND o Have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants); AND o Not have an estimated glomerular filtration rate (eGFR) less than 45 mL/min/1.73m2; AND o Have tried and failed Benlysta. For continuation of coverage, the patient must have met the following requirements: • For biopsy-proven lupus nephritis Class III through V: o Have evidence of efficacy (defined as urinary protein creatinine ratio no greater than 0.7, eGFR no greater than 20% below the pre-flare or at least 60mL/min/1.73m2), and no use of rescue therapy for treatment failure. Duration of Approval: 6 months (initial); 12 months (continuation) Note: Lupkynis is not covered in combination with other biologic drug therapy (e.g. Benlysta, rituximab).

DRUG	CRITERIA
Luxturna (voretigene neparvovec) Gene Therapy	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Diagnosis of biallelic RPE65 mutation-associated retinal dystrophy (confirmed by genetic testing). Pathogenic and/or likely pathogenic classification of the RPE65 mutations has been affirmed within the last 12 months; **AND** • Sufficient viable retinal cells as determined by optical coherence tomography (OCT) and/or ophthalmoscopy with an area of retina within the posterior pole of greater than 100 µm thickness; **AND** • Patient is at least at least12 months of age; **AND** • Prescribed by an ophthalmologist or retinal surgeon. **Note:** Luxturna will only be authorized in accordance with FDA-approved dosing for retinal dystrophy as the safety and effectiveness of repeat administration has not been evaluated **(one treatment per eye per lifetime)**. Luxturna will not be authorized for use in patients previously treated with Luxturna or another RPE65 gene therapy. Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Luxturna is dependent on member's eligibility and benefit plan documents.
Mavenclad (cladribine)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of relapsing-remitting multiple sclerosis (MS) or active secondary progressive MS; **AND** • Have had an inadequate response to at least **TWO** other disease modifying therapies for MS, one of which must be glatiramer or dimethyl fumarate; **AND** • Not have concurrent use with other MS disease modifying drugs; **AND** • Not have clinically isolated syndrome (CIS); **AND** • Patient is at least 18 years old. <u>Duration of Approval</u>: 2 years **Note:** Mavenclad is limited to a maximum of 20 tablets per year, and 40 tablets total treatment. Treatment duration is limited to two courses (4 cycles) over 2 years. Priority Health will not cover any other MS disease modifying drug therapies for 2 years after the first course of Mavenclad for patients who have completed 4 cycles of therapy.
Miglustat (generic Zavesca)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of mild to moderate type 1 Gaucher disease (must fax documentation of diagnostic testing confirming disease (i.e. genotyping) to Priority Health); **AND** • Patient is at least 18 years of age; **AND** • Patient must not be a candidate for enzyme replacement therapy (i.e. because of allergy, hypersensitivity). <u>For continuation of coverage, patient must have met the following requirements</u>: • Has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: clinically significant reduction in spleen or liver volume, increase in platelet or hemoglobin values. <u>Duration of Approval</u>: 12 months

DRUG	CRITERIA
Multiple Sclerosis Agents, Anti-CD20 Antibodies	Preferred Agent(s): Ocrevus (ocrelizumab) Briumvi (ublituximab) Non-Preferred Agent(s): Not applicable Before this drug is covered, the patient must meet all of the following requirements: • Have a definitive diagnosis of Primary Progressive Multiple Sclerosis (PPMS) has been established by a neurologist or specialist in MS; AND • Have a diagnosis of multiple sclerosis (relapsing-remitting [RRMS] or secondary progressive MS) that has been established by a neurologist or specialist in MS. Duration of Approval: 24 months Note: Documentation of a multiple sclerosis ICD10 code (G35, G36.0, G37.0, G37.5) within the last 12 months must be submitted to Priority Health for commercial individual members.
Myalept (metreleptin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of acquired or congenital generalized lipodystrophy resulting in leptin deficiency complications (supporting documentation must be submitted to Priority Health); AND • Provide laboratory leptin assay results confirming leptin deficiency: o 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/mL in males); AND • Patient has ONE of the following metabolic abnormalities: o Type 2 diabetes mellitus o Triglyceride level more than 200 mg/dL o Hyperinsulinemia (defined by fasting serum insulin greater than 30 microunits/mL Note: Myalept is not covered in the following conditions: HIV, infectious liver disease, acquired lipodystrophy with hematologic abnormalities. Limited to maximum weight based daily dosing per FDA label.
Myfembree (relugolix/estradiol/ norethindrone)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of either: o heavy menstrual bleeding associated with uterine fibroids; OR o moderate to severe pain associated with endometriosis; AND • Have a trial and failure of Oriahnn (elagolix/estradiol/norethindrone) or Orilissa (elagolix) used for at least 3 months. Duration of Approval: 24 months total
Naglazyme (galsulfase)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Maroteaux-Lamy syndrome (supporting documentation must be submitted to Priority Health). For continuation of coverage, patient must have met the following requirements: • Has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: stabilization or improvement in 12MWT. Duration of Approval: 12 months

DRUG	CRITERIA

Nexletol (bempedoic acid)
 	
Nexlizet (bempedoic acid/ezetimibe)
	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Have one of the following diagnoses:
	  o Heterozygous familial hypercholesterolemia (HeFH) confirmed by one or more of the following:
	  ▪ Genetic testing
	  ▪ Score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria
	  ▪ Score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria
	  o Very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol; **AND**
	• Prescribed by a cardiologist, endocrinologist, or board-certified lipidologist; **AND**
	• Not be using in combination with Repatha (evolocumab) or Praluent (alirocumab); **AND**
	• Patient's most recent LDL-C laboratory report must be submitted with authorization request; **AND**
	• Patient must continue to receive maximally tolerated statin therapy or have a intolerance/contraindication to or intolerance of statin therapy*; **AND**
	• 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. If one high-intensity statin is not tolerated, a trial of a second statin is required.
	
	Note: *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 rechallenge, 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.

Nexviazyme (avalglucosidase alfa)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of late-onset Pompe disease (acid alpha-glucosidase [GAA] deficiency) that is supported by enzyme assay or DNA testing (supporting documentation must be submitted to Priority Health); **AND** • Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders; **AND** • Documented baseline values for FVC and/or 6 MWT. <u>For continuation of coverage, patient must have met the following requirements</u>: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in stabilization or improvement in FVC and/or 6 MWT. <u>Duration of Approval</u>: 12 months **Note:** Nexviazyme is not covered in combination with Lumizyme. Priority Health does not cover a dose that exceeds 20 mg/kg for body weight at least 30 kg or 40 mg/kg for body weight less than 30 kg administered every 2 weeks as an intravenous infusion. For adult patients, doses should be rounded down to the nearest vial size within 10% of the calculated dose. Priority Health <u>may not</u> cover Nexviazyme for ventilator-dependent patients requiring ventilation 24 hours per day.

DRUG	CRITERIA
Nourianz (istradefylline)	<u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Have a diagnosis of advanced Parkinson's disease (supporting documentation must be submitted to Priority Health); **AND** • Patient is at least 18 years of age; **AND** • Prescribed by, or in consultation with, a neurologist; **AND** • Patient is experiencing acute, intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements); **AND** • Patient is receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release tablets and multiple daily dosing); **AND** • Therapeutic trial and failure of, or contraindication to, adjunctive therapy with at least one medication in each of the drug classes listed below: o Dopamine agonist (e.g. pramipexole, ropinirole) o Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline) o Catechol-O-methyl transferase (COMT) inhibitor (e.g. entacapone) <u>For continuation of coverage, patient must have met the following requirements:</u> • Have a positive clinical response to Nourianz <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation)
Nplate (romiplostim)	<u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Have a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) with: o platelet count less than 30,000/microL; **AND** o significant bleeding symptoms. • Have a diagnosis of severe, persistent or recurrent ITP with: o platelet count less than 20,000/microL; **AND** o an insufficient response to corticosteroids, immunoglobulin, or splenectomy; **OR** o patient is not a candidate for splenectomy or immunoglobulin therapy. <u>For continuation of coverage, patient must have met the following requirements:</u> • Meet one of the following: o Platelet count has increased to at least 50 x 109/L; **OR** o If platelet count is less than 50 x 109/L must have documented response to therapy (i.e. reduction in clinically significant bleeding events) <u>Duration of Approval</u>: 3 months (initial); 12 months (continuation) **Note:** Nplate (romiplostim) is not covered in combination with another thrombopoietin receptor agonist [e.g., Promacta (eltrombopag)] **AND** is not being used as an attempt to normalize platelet count.
Nucala (mepolizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For severe eosinophilic asthma requests: o Patient is at least 6 years of age; **AND** o Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **AND** o Not currently using tobacco products; **AND** o Have been compliant on all of the following therapies for at least 3 months: ▪ High-dose inhaled corticosteroid (ICS) ▪ Long-acting beta agonist (LABA) ▪ One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); **AND** o Be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique); **AND** o Have had at least 2 asthma exacerbations in the previous year that required at least one of the following: ▪ Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days ▪ Hospitalization and/or ED visit. *(Criteria continues on next page)*

DRUG	CRITERIA
Nucala (mepolizumab) *continued*	• For eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss) requests: o Diagnosis of EGPA for at least 6 months and confirmed by the following: ▪ A history or presence of asthma; **AND** ▪ 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** ▪ The presence of: ❖ Two or more features of eosinophilic granulomatosis with polyangiitis (examples below), **OR** ❖ Antineutrophil cytoplasmic antibody [ANCA] positive status. o Have EGPA that either has/is: ▪ Failed induction therapy with the following: Systemic glucocorticoids, **AND** cyclophosphamide or methotrexate; **AND** ▪ Refractory to or relapsed on (defined by a Birmingham Vasculitis Activity Score [BVAS] of more than 3) at least two of the following: Azathioprine, Methotrexate, Leflunomide. • For Hypereosinophilic Syndrome (HES) requests: o Diagnosis of HES for at least 6 months; **AND** o 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); **AND** o Have a blood eosinophil count of at least 1,000 cells/mcL; **AND** o Be stable on chronic steroid therapy (e.g. prednisone); **AND** o Have tried and failed one generic, steroid-sparing therapy (e.g., methotrexate, hydroxyurea). • For chronic rhinosinusitis with nasal polyp (CRSwNP) requests: o Patient is at least 18 years of age; **AND** o Baseline Nasal Polyps Score (NPS) of at least 5, with a unilateral score of at least 2 for each nostril; **AND** o Symptomatic disease that is persistent for a minimum of 12 weeks, including all of the following: ▪ Nasal obstruction ▪ Rhinorrhea (anterior/posterior) ▪ Diminished or loss of smell; **AND** o Member has tried and failed all of the following: ▪ At least one prior treatment course with a systemic corticosteroid ▪ Minimum 3 months compliant treatment with an intranasal glucocorticoid ▪ Minimum 1-month trial with either a non-sedating antihistamine or antileukotriene agent (e.g., montelukast) For continuation of coverage, the patient must have met the following requirements: • For severe eosinophilic asthma requests: o Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use). • For eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss) requests: o Have a positive clinical response [Birmingham Vasculitis Activity Score (BVAS) equals 0 (no active vasculitis); **AND** prednisolone or prednisone dose less than or equal to 4 mg/day]. • For Hypereosinophilic Syndrome (HES) requests: o Have a positive clinical response (documented decrease in exacerbation frequency and/or decrease in oral corticosteroid use, documented improvement in HES symptoms). • For chronic rhinosinusitis with nasal polyp (CRSwNP) requests: o Adherence to therapy including Nucala and intranasal steroid; **AND** o Have a positive clinical response (e.g., 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). Duration of Approval: 12 months **Note:** Nucala is not covered in combination with other biologic drug therapy

DRUG	CRITERIA
Nuedexta (dextromethorphan/ quinidine)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of pseudobulbar affect caused by a structural neurologic condition (e.g. amyotrophic lateral sclerosis [ALS], multiple sclerosis [MS], or stroke); AND • Prescribed by, or in consultation with, a neurologist; AND • Patient has not had an exacerbation of the underlying neurologic condition in the two months before starting Nuedexta; AND • Patient does not have a history of Alzheimer's or other dementia, major psychiatric disturbance (e.g. bipolar disorder, major depression, schizophrenia), substance abuse or drug-seeking behavior, or recent falls/be at risk for falls; AND • Patient has at least 10 episodes of inappropriate laughing or crying per day before therapy; AND • Documented trial with one tricyclic antidepressant and one selective serotonin reuptake inhibitor (SSRI) for a total of 6 months. For continuation of coverage, the patient must have met the following requirements: • Documentation of a 50 percent decrease in number of episodes of laughing or crying compared to baseline (before Nuedexta was started) Duration of Approval: 3 months (initial); 12 months (continuation)
Nulibry (fosdenopterin)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis Molybdenum cofactor deficiency Type A that is supported by genetic testing (supporting documentation must be submitted to Priority Health); AND • Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders. For continuation of coverage, the patient must have met the following requirements: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: o neurological function o gross motor function o developmental milestones Duration of Approval: 12 months
Ocaliva (obeticholic acid)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of primary biliary cholangitis; AND • Have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol; AND • Have one of the following: alkaline phosphatase level at least 1.67 times the upper limit of normal (ULN) or total bilirubin at least 1 time the ULN but less than 2 times the ULN; AND • Patient must not have any of the following: o Clinically significant hepatic decompensation (e.g. known esophageal varices, poorly controlled or diuretic resistant ascites, history of variceal bleeds or related interventions); o Severe pruritus; o Inadequate response to ursodiol due to patient adherence; OR o Superimposed liver disease (e.g. hepatitis C, alcoholic liver disease).

DRUG	CRITERIA
Ofev (nintedanib)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is a current non-smoker; AND • Patient is at least 18 years of age; AND • Prescribed by, or in consultation with, a specialist for the condition being treated; AND • Have one of the following diagnoses: o Idiopathic Pulmonary Fibrosis (IPF) ▪ Prescriber must rule out: other known causes of interstitial lung disease; AND ▪ Have presence of a UIP pattern on High Resolution Computer Tomography (HRCT) in patients not subjected to surgical lung biopsy; and possibly surgical lung biopsy o Chronic, progressive fibrosing interstitial lung disease (PF-ILD) ▪ Be confirmed by HRCT; AND ▪ Extent of fibrotic disease in the lung must be at least 10%; AND ▪ Forced Vital Capacity (FVC) decline of greater than 10%. ▪ If FVC decline is at least 5% but less than 10%, must have: ❖ Experiencing worsening respiratory symptoms; OR ❖ Exhibiting increasing extent of fibrotic changes on chest imaging. o Systemic sclerosis (SSc) related Interstitial Lung Disease (ILD) (SSc-ILD) ▪ Be confirmed by HRCT; AND ▪ Extent of fibrotic disease in the lung must be at least 10%; AND ▪ Forced Vital Capacity (FVC) must be at least 40% of predicted normal; AND ▪ SSc disease onset (defined by first non-Raynaud symptom) within 7 past years; AND ▪ Carbon Monoxide Diffusion Capacity (DLCO) 30% to 89% of predicted normal; AND ▪ Disease progression (e.g., at least10 percent decline in FVC or DLCO) on trials of mycophenolate mofetil and or cyclophosphamide at maximally tolerated doses, or medical contraindication; AND ▪ 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 continuation of coverage, the patient must have met the following requirements: • Documentation of stable FVC (recommended to discontinue if there is more than a 10% decline in FVC over a 12 month period, indicating disease progression) for IPF. Duration of Approval: 12 months Note: Ofev will not be covered in combination with Actemra or Esbriet.
Olumiant (baricitinib)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried at least TWO of the following, one of which must be a TNF inhibitor: Actemra, Enbrel, Adalimumab, or Xeljanz/XR each for a period of at least 3 months. Note: Olumiant will not be covered in combination with another biologic drug OR for alopecia areata. 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 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.

DRUG	CRITERIA
Oncology Agents	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • 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. • 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. • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type. • Appropriate genetic testing results to support use based on FDA approved package labeling and NCCN guidelines. • Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2. • Additional criteria as stated on Priority Health's website. <u>For continuation of coverage, the patient must have met the following requirements</u>: • Current chart notes must be provided detailing response and compliance to therapy. • Coverage may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** disease progression has occurred after initiation of drug therapy. <u>Duration of Approval</u>: 12 months **Note:** Select oncology mediations are limited to a 14-day supply at any network pharmacy. Patients are responsible for applicable deductible and copayments. The select oncology medications are limited to a 14-day supply for the first four fills (2 months). Following this initial period, patients will be able to fill up to a 30-day supply.

Onpattro
(patisiran)
	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy; **AND**
	• Genetic testing confirms a transthyretin (TTR) mutation (e.g., V30M); **AND**
	• Have presence of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.); **AND**
	• Have documentation of one of the following:
	  o Baseline polyneuropathy disability (PND) score no greater than IIIb; **OR**
	  o Baseline FAP Stage 1 or 2
	• Patient is at least 18 years of age; **AND**
	• Patient has not had a liver transplant.
	
	<u>For continuation of coverage, the patient must have met the following requirements</u>:
	• Documentation that the patient has experienced a positive clinical response to Onpattro compared to baseline (e.g., improved neurologic improvement, motor function, quality of life, slowing of disease progression).
	
	<u>Duration of Approval</u>: 12 months
	
	Note: Onpattro is not covered in combination with tafamidis (Vyndaqel, Vyndamax) or Tegsedi

DRUG	CRITERIA
Opioid Quantity/ Dose Limit Exception	Before this drug is covered, the patient must meet all of the following requirements: • Patients are limited to a total of 120 MEqD (morphine equivalent dose per day). For requests that exceed this amount, the following are required: o An opioid treatment agreement is in place; AND o Member has a diagnosis of chronic pain due to a documented medical condition; AND o A dose taper or taper attempt is documented or valid clinical rationale as to why taper has not been attempted; AND o Member's pain management and function are routinely evaluated using validated tools (e.g. Pain, Enjoyment of Life, General Activity (PEG) Assessment Scale) at follow-up visits and show sustained improvement; AND o Non-drug therapy has been tried in the last 18 months or is contraindicated; AND o Non-opioid medications are being used concurrently (unless contraindicated) to reduce total opioid use; AND o Documentation to support clinical appropriateness and safety when concurrently using benzodiazepines, sedative-hypnotics, barbiturates, or other medications that may be harmful when used in combination with opioid medications; AND o Member has been educated on naloxone. • Opioid medications subject to the 120 MEqD per day limit may also have individual drug quantity limits, step therapy, and other utilization management that also apply. Non-preferred long-acting opioids are subject to prior authorization. • When approved, treatment will be authorized for the duration necessary to treat the patient's pain for up to a maximum of one year (12 months). Duration of Approval: 12 months
Orbactiv, Kimyrsa (oritavancin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is at least 18 years of age; AND • Have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives; AND • Infection is not susceptible to alternative antibiotic treatments (supporting documentation must be submitted to Priority Health). Duration of Approval: Single infusion (based on FDA-approved labeling).

DRUG	CRITERIA
Orencia (abatacept)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Cosentyx, Enbrel, Adalimumab, Xeljanz/XR, Otezla, Stelara, or Tremfya, each for a period of at least 3 months. • For Juvenile Idiopathic Arthritis requests: o Patient has tried at least TWO of the following: Enbrel, Adalimumab, or Actemra for a period of at least 3 months each. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Actemra, Enbrel, Adalimumab. or Xeljanz/XR each for a period of at least 3 months. Note: Orencia will not be covered in combination with another biologic drug. 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 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.
Oriahnn (elagolix/estradiol/ norethindrone)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of heavy menstrual bleeding associated with uterine fibroids; AND • Have a trial and failure of an oral contraceptive (estrogen/progestin or progestin only) used for at least 3 months Duration of Approval: 24 months total
Orillissa (elagolix)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of moderate to severe pain associated with endometriosis; AND • Have a trial and failure of a non-steroidal anti-inflammatory drug (NSAID) and an oral contraceptive used for at least 3 months each. Duration of Approval: Orilissa 150 mg once daily dose is limited to a maximum duration of treatment of 24 months; Orilissa 200 mg twice daily dose is limited to a maximum duration of treatment of 6 months.
Osphena (ospemifene)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of moderate to severe dyspareunia caused by vulvovaginal atrophy; AND • Plan documents must have sexual dysfunction rider; AND • Documented trial with an OTC vaginal lubricant for at least 90 days; AND • Documented trial of a vaginal estrogen product for at least 90 days.

DRUG	CRITERIA
Otezla (apremilast)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. • For Behcet's Disease requests: o The patient has oral ulcers or other mucocutaneous involvement (provide chart note documentation); **AND** o The patient has tried at least **ONE** other systemic therapy (e.g., colchicine, systemic corticosteroids, azathioprine, thalidomide, interferon alpha, tumor necrosis factor inhibitors such as adalimumab, etanercept [Enbrel], certolizumab pegol [Cimzia], golimumab [Simponi/Aria], or infliximab products [Inflectra, infliximab, Renflexis]). **Note:** Otezla will not be covered in combination with another biologic drug. 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 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.
Oxervate (cenegermin)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of neurotrophic keratitis (supporting documentation must be submitted); **AND** • Covered only for stage 2 or stage 3 neurotrophic keratitis <u>Duration of Approval</u>: 8 weeks total treatment
Oxlumo (lumasiran)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of PH1 (primary hyperoxaluria type 1) with AGXT (alanine:glyoxylate aminotransferase gene) mutation (supporting documentation must be submitted to Priority Health); **AND** • Not have a history of kidney or liver transplant; **AND** • Have made efforts to increase fluid intake to at least 3L/m2 BSA per day; **AND** • Have had a trial of at least 3 months of pyridoxine with no significant improvement observed (e.g. less than 30% reduction in urine oxalate concentration after at least 3 months of therapy). <u>For continuation of coverage, the patient must have met the following requirements</u>: • Submit documentation that the patient is tolerating therapy and there was an improvement in urinary oxalate excretion from baseline. <u>Duration of Approval</u>: 12 months **Note:** The dose of Oxlumo approved will be limited to the weight-based dosing found in the FDA label.
Oxtellar XR (oxcarbazepine)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of partial-onset seizure (documentation must be submitted to Priority Health); **AND** • Patient is at least 6 years of age; **AND** • Have a trial and failure with or intolerance to both of the following: o Oxcarbazepine o One additional generic anti-seizure medication

DRUG	CRITERIA

Palforzia (peanut allergen powder)	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of peanut allergy confirmed by one of the following:
	  o Peanut-specific immunoglobulin E (psIgE) level greater than 0.35 kUA/L; OR
	  o Skin prick test with mean wheal diameter greater than 3 mm larger than control; AND
	• Have clinical history of allergy to peanuts or peanut-containing food; AND
	• Use and dosing must follow the FDA approved label; AND
	• Currently, patients must be 4 - 17 years old or have started Palforzia between 4 - 17 years old; AND
	• Prescribed by an allergist.
	
	For continuation of coverage, the patient must have met the following requirements:
	• 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; AND
	• Palforzia treatment has demonstrated effectiveness with manageable side effects; AND
	• Patient has been and is still able to comply with the daily dosing requirements.
	
	Duration of Approval: 12 months
	
	Note: 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.

Palynziq (pegvaliase)	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of phenylketonuria (supporting documentation must be submitted); AND
	• Patient is at least 18 years of age; AND
	• Prescribed by a metabolic disease specialist; AND
	• 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] ; AND
	• Continue phenylalanine restricted diet if approved for Palynziq; AND
	• Baseline/current phenylalanine levels provided showing current levels are greater than 600 micromol/L; AND
	• Clinical trial and failure of sapropterin in combination with phenylalanine restricted diet
	  o Clinical trial defined as 4 weeks treatment with Kuvan 20mg/kg/day
	  o Failure is defined as blood phenylalanine levels greater than 600mcmol/L with combination therapy
	  o 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; AND
	• Palynziq is not covered in combination with Sapropterin (Kuvan). Sapropterin must be stopped within 14 days of beginning therapy on Palynziq.
	
	For continuation of coverage, the patient must have met the following requirements:
	• Documented compliant maintenance therapy on Palynziq; AND
	• Continued adherence to a phenylalanine-restricted diet; AND
	• Achieved at least a 20 percent reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration no greater than 600 micromol/L.
	
	Duration of Approval: up to 12 months (coverage duration may depend on dose requested)
	
	Note: Palynziq is not covered in combination with sapropterin (Kuvan). 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 blood phenylalanine 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.

DRUG	CRITERIA
Parathyroid Hormone Analogs	Preferred Agent(s): Tymlos (abaloparatide) Non-Preferred Agent(s): Teriparatide (generic Forteo) Before this drug is covered, the patient must meet all of the following requirements: • For osteoporosis in patients (e.g., postmenopausal, primary or hypogonadal, or due to corticosteroids) at a high risk for fracture and no history of an osteoporotic/fragility fracture, the patient must meet all of the following: o 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 o Have a documented treatment failure, contraindication* or ineffective response** to a minimum of a 12-month trial with zoledronic acid (generic Reclast) or Prolia (also requires prior authorization): AND o Non-preferred drug product: Trial and failure, or intolerance/contraindication to the preferred product. • For osteoporosis in patients (e.g., postmenopausal, primary or hypogonadal, or due to corticosteroids) at high risk for fracture and a history of an osteoporotic fracture, the patient must meet the following: o 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 (also requires prior authorization); AND o Non-preferred drug product: Trial and failure, or intolerance/contraindication to the preferred product. *Contraindication examples to oral bisphosphonate therapy include the following:* • Documented inability to sit or stand upright for at least 30 minutes • Documented pre-existing gastrointestinal disorder such as inability to swallow, esophageal stricture, or achalasia **Ineffective response is defined as one of the following:* • Decrease in T-score in comparison to previous T-score from DEXA scan • New fracture while on therapy. For continuation of coverage, patient must have met the following requirements: • Have a positive clinical response (i.e., T-score stable or improved, OR no new fractures have occurred while using PTH analog). Duration of Approval: 12 months Note: PTH analogs are not covered in combination with other injectable drugs for the treatment of osteoporosis (e.g., Prolia, Evenity). When criteria are met, parathyroid hormone treatment may be authorized for up to a total of two years in a lifetime as additional efficacy beyond two years has not been established. For example, Priority Health will not authorize Forteo/Tymlos if another parathyroid hormone has already been used for two years.
Parsabiv (etelcalcetide)	Before this drug is covered, the patient must meet all of the following requirements: • Be using for a diagnosis of secondary hyperparathyroidism in patients with chronic kidney disease (CKD) on hemodialysis; AND • Have a therapeutic trial and failure on cinacalcet. Duration of Approval: 12 months

DRUG	CRITERIA
Penicillamine (generic Depen)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of Wilson's disease (hepatolenticular degeneration) or cystinuria; **AND** • For cystinuria, a trial with conservative measures (i.e. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated (supporting documentation of conservative measures failure must be submitted to Priority Health). <u>For continuation of coverage, the patient must have met the following requirements</u>: • Documented compliant maintenance therapy on penicillamine; **AND** • Continued adherence to conservative measures listed above for cystinuria. <u>Duration of Approval</u>: 12 months **Note:** 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.
Pluvicto (Lutetium Lu-177 vipivotide tetraxetan)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has metastatic castration-resistant prostate cancer (mCRPC); **AND** • Patient is at least 18 years of age; **AND** • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; **AND** • Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND** • Patient has at least one prostate-specific membrane antigen (PSMA)-positive lesion and/or predominately PSMA-positive disease; **AND** • Patient has no dominant PSMA-negative metastatic lesions; **AND** • Patient has been previously treated with an androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, etc.) **AND** taxane-based chemotherapy. • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. <u>For continuation of coverage, patient must have met the following requirements</u>: • Patient has shown evidence of response (e.g., radiological, PSA, clinical benefit); **AND** • Patient has signs of residual disease on Computed tomography (CT) with contrast/Magnetic resonance imaging (MRI) or bone scan; AND • Patient has shown good tolerance to 177Lu-PSMA-617 treatment. <u>Duration of Approval</u>: 4 doses (initial); 2 doses (continuation). The total number of doses (200 mCi/dose) authorized cannot exceed 6 doses.

DRUG	CRITERIA
Pombiliti (cipaglucosidase alfa) + **Opfolda** (miglustat)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of late-onset Pompe disease (acid alpha-glucosidase [GAA] deficiency) that is supported by enzyme assay or DNA testing (supporting documentation must be submitted to Priority Health); **AND** • Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders; **AND** • Documented baseline values for FVC and/or 6 MWT. <u>For continuation of coverage, patient must have met the following requirements</u>: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in stabilization or improvement in FVC and/or 6 MWT. <u>Duration of Approval</u>: 12 months **Note:** Pombiliti is covered in combination with Opfolda, neither is covered in combination with Lumizyme or Nexviazyme. Priority Health does not cover a dose that exceeds 20 mg/kg administered every 2 weeks as an intravenous infusion. For adult patients, doses should be rounded down to the nearest vial size within 10% of the calculated dose. Priority Health <u>may not</u> cover Pombiliti + Opfolda for ventilator-dependent patients requiring ventilation 24 hours per day.

Praluent (alirocumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Have one of the following diagnoses:
	  ○ Heterozygous familial hypercholesterolemia (HeFH) confirmed by one or more of the following:
	  ▪ Genetic testing
	  ▪ Score of "Definite Familial Hypercholesterolemia" on the Simon-Broome criteria
	  ▪ Score greater than 8 based on the WHO Dutch Lipid Clinic Network diagnostic criteria
	  ○ Very high risk clinical atherosclerotic cardiovascular disease (ASCVD) defined by the 2018 AHA/ACC Guideline on the Management of Blood Cholesterol which includes a history of multiple major ASCVD events or one major ASCVD event and multiple high-risk conditions
	  ○ Homozygous familial hypercholesterolemia (HoFH) confirmed by one or more of the following:
	  ▪ Presence of two mutant alleles at the LDL receptor, Apolipoprotein B, or PCSK9 gene
	  ▪ 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
	  ▪ Untreated LDL-C levels consistent with heterozygous familiar hypercholesterolemia in both parents (greater than 190 mg/dL); **AND**
	• Prescribed by a cardiologist, endocrinologist, or board-certified lipidologist; **AND**
	• Not be using in combination with another PCSK9 inhibitor, Nexletol (bempedoic acid), or Nexlizet (bempedoic acid/ezetimibe); **AND**
	• Patient's most recent LDL-C laboratory report must be submitted with authorization request; **AND**
	• Patient must continue to receive maximally tolerated statin therapy or have a contraindication to or intolerance of statin therapy*; **AND**
	• 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; **AND**
	• If one high-intensity statin is not tolerated, a trial of a second statin is required; **AND**
	• Try and fail Repatha (evolocumab).
	
	Note: *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 rechallenge, 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.

DRUG	CRITERIA
Prevymis (letermovir)	Before this drug is covered, the patient must meet all of the following requirements: • Be using for prophylaxis of cytomegalovirus (CMV) infection and disease in CMV seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) ; OR high-risk (donor CMV-seropositive/recipient CMV-seronegative; D+/R-) kidney transplant recipients; AND • Patient is at least 18 years of age; AND • Prevymis is not covered in combination with another antiviral agent for CMV treatment. Duration of Approval: 200 days post-transplant Note: Prevymis is not indicated for the treatment of CMV infection or prevention of CMV disease in other types of transplants.
Prolia (denosumab)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of osteoporosis (males or postmenopausal females with T-score of at least -2.5 or T-score greater than -2.5 with fragility fracture); AND o 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) OR zoledronic acid (generic Reclast) • Have prostate cancer and used to increase bone mass in a male taking androgen deprivation therapy or have breast cancer and used to increase bone mass in a female taking adjuvant aromatase inhibitor therapy; AND o 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) OR zoledronic acid (generic Reclast) *Contraindication examples to oral bisphosphonate therapy include the following:* o Documented inability to sit or stand upright for at least 30 minutes o Documented pre-existing gastrointestinal disorder such as inability to swallow, esophageal stricture, or achalasia **Ineffective response is defined as one of the following:* o Decrease in T-score in comparison to previous T-score from DEXA scan o New fracture while on therapy. For continuation of coverage, the patient must have met the following requirements: • Have a positive clinical response to Prolia (i.e., T-score stable or improved while using Prolia, OR no new fractures have occurred while using Prolia). Duration of Approval: 12 months Note: Prolia is not covered in combination with other injectable drugs for the treatment of osteoporosis (e.g., Evenity, Tymlos, Forteo). Prolia may be approved for up to 24 months of therapy.

DRUG	CRITERIA
Promacta (eltrombopag)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For chronic immune (idiopathic) thrombocytopenic purpura (ITP): o Have had an insufficient response to corticosteroids, immunoglobulin, or splenectomy o Have documentation of a treatment-limiting adverse drug reaction to corticosteroids or immunoglobulin o Current platelet count less than 50 x 109/L with a clinical risk of bleeding • For aplastic anemia: o Have had an insufficient response to one immunosuppressive agent o Baseline platelet count must be less than 30 x 109/L <u>For continuation of coverage, the patient must have met the following requirements</u>: • For immune (idiopathic) thrombocytopenia must meet one of the following: o Platelet count has increased to at least 50 x 109/L, or o If platelet count is less than 50 x 109/L must have documented response to therapy (i.e. reduction in clinically significant bleeding events) • For aplastic anemia must have a hematologic response defined as one of the following: o Platelet count increase to 20 x 109/L above baseline or stable platelet counts with transfusion independence for a minimum of 8 weeks o Hemoglobin increase of greater than 1.5 g/dL or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks o ANC increase of 100% or an ANC increase greater than 500/µL. <u>Duration of Approval</u>: All diagnoses 6 months (initial); 12 months (continuation) **Note:** 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
Pulmonary Arterial Hypertension (PAH) Endothelin Receptor Antagonists	<u>Preferred Agent(s)</u>: Ambrisentan (Letairis) Bosentan (Tracleer) <u>Non-Preferred Agent(s)</u>: Opsumit (macitentan) <u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted); **AND** • <u>Non-preferred drug product:</u> Trial and failure, or intolerance to ambrisentan or bosentan. **Note**: If requesting Tracleer (bosentan) tablet for suspension formulation, you must be 12 years of age or younger.
Pulmonary Arterial Hypertension (PAH) Nitric oxide-cyclic guanosine monophosphate enhancers	<u>Preferred Agent(s)</u>: Sildenafil (Revatio) Tadalafil <u>Non-Preferred Agent(s)</u>: Adempas (riociguat) <u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted to Priority Health); **AND** • <u>Non-preferred drug product:</u> Trial and failure, or intolerance to sildenafil or tadalafil. • For diagnosis of 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 (supporting documentation must be submitted). (Adempas only).

DRUG	CRITERIA
Pulmonary Arterial Hypertension (PAH) Prostaglandins	Preferred Agent(s): Epoprostenol (Flolan, Veletri) Treprostinil (Remodulin) Non-Preferred Agent(s): Not Applicable Before this drug is covered, the patient must meet all of the following requirements: • For diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 (supporting documentation must be submitted).
Pulmonary Arterial Hypertension (PAH) Other	Preferred Agent(s): Iloprost (Ventavis) Orenitram ER (treprostinil tablet) Tyvaso (treprostinil nebulizer) Uptravi (selexipag) Ventavis (iloprost) Non-Preferred Agent(s): Tyvaso DPI Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 or Group 3 (Tyvaso only). Supporting documentation must be submitted to Priority Health; AND • Patient has tried and failed, or have intolerance/contraindication to one drug from both of the following classes: o Phosphodiesterase inhibitor (i.e. sildenafil or tadalafil); AND o Endothelin receptor antagonist (i.e. ambrisentan or bosentan); • Patient has tried and failed, or have intolerance/contraindication to Tyvaso nebulizer (Tyvaso DPI only).
Pulmozyme (dornase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of cystic fibrosis (ICD10 codes: E84.0, E84.11, E84.19, E84.8, E84.9).
Pyrimethamine	Before this drug is covered, the patient must meet all of the following requirements: • Have diagnosis of toxoplasmosis, used for either primary prophylaxis or treatment of active disease; AND • Have diagnosis of HIV infection and CD4 count less than 100 cells/mm^3 (if using for prophylaxis): AND • Be used in combination with a sulfonamide (e.g., sulfadiazine) and leucovorin; AND • Prescriber is a specialist or has consulted with a specialist for the condition being treated. Duration of Approval: 8 weeks (treatment); 6 months (prophylaxis). For continuation of coverage, patient must have met the following requirements: • For chronic maintenance following initial therapy for active disease: must have a CD4 count less than or equal to 200 cells/mm3 at any time in the previous 6 months; • For primary prophylaxis: must have a CD4 count less than or equal to 200 cells/mm3 at any time in the previous 3 months; • Adherent to antiretroviral therapy as evidenced by claims data. Note: Pyrimethamine tablets are not covered for malaria, chemoprophylaxis or treatment.

DRUG	CRITERIA

Pyrukynd
(mitapivat)
	Before this drug is covered, the patient must meet all of the following requirements:
	• Treatment of hemolytic anemia in adults with pyruvate kinase deficiency; **WITH**
	  o Genetic testing confirming diagnosis; **AND**
	  o Current hemoglobin less than or equal to 10g/dL; **AND**
	  o At least six red blood cell (RBC) transfusion episodes within the previous year
	• Patient is at least 18 years of age; **AND**
	• Prescribed by or in consultation with a hematologist.
	
	For continuation of coverage, the patient must have met the following requirements:
	• Have documented benefit defined as hemoglobin response of at least 1.5mg/dL over baseline and/or reduction in transfusion burden.
	
	Duration of Approval: 3 months (initial); 12 months (continuation)
	
	Note: Not covered for the following patients: Homozygous for R479H mutation, 2 non-missense variants in PKLR gene, Not regularly transfused.

Qutenza
(capsaicin 8% patch)
	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of one of the following:
	  o Neuropathic pain associated with postherpetic neuropathy
	  o Pain associated with diabetic peripheral neuropathy**; AND**
	• Patient has tried **ALL** of the following for a period of at least 3 months:
	  o Gabapentin
	  o Pregabalin
	  o One generic tricyclic antidepressant (amitriptyline, amoxapine, doxepin, imipramine, nortriptyline, protriptyline, or trimipramine)
	
	Duration of Approval: 12 months

Radicava (endaravone)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial World Federation of Neurology /Arlie House criteria (supporting documentation must be submitted to Priority Health); **AND** • Disease duration of no more than 2 years (please provide date of diagnosis); **AND** • Be 20 to 75 years of age; **AND** • Living independently; **AND** • Score of at least 2 on each individual item of the revised ALS functional rating scale (ALSFRS-R) (supporting documentation must be submitted to Priority Health); **AND** • Forced vital capacity (FVC) of at least 80%; **AND** • Be used in combination with riluzole unless there is documentation of intolerance or contraindication to riluzole; **AND** • Prescribed by or in consultation with a neurologist. For continuation of coverage, the patient must have met the following requirements: • FCV of greater than or equal to 30%, does not require tracheostomy/artificial ventilation, and is not on continuous Bilevel Positive Airway Pressure (BiPAP); **AND** • Ambulatory (able to walk with or without assistance); **AND** • Able to self-feed. Duration of Approval: 6 months **Note:** If approved, initial cycle approved is 60mg IV infusion daily (or 105mg/5mL oral) for 14 days, followed by a 14-day drug-free period. Subsequent cycles approved are 60mg IV infusion daily (or 105mg/5mL oral) 10 days out of 14-day periods, followed by 14-day drug-free periods.

DRUG	CRITERIA
Ranibizumab	Preferred Agent(s): Lucentis Byooviz Cimerli Before this drug is covered, the patient must meet all of the following requirements: • Have one of the following diagnoses and meet any required criteria: o Neovascular (wet) age-related macular degeneration (AMD): ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively ▪ improve baseline visual acuity and/or reduce fluid. ▪ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. o Macular edema following retinal vein occlusion (RVO): ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. o Diabetic macular edema (DME): ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. o Diabetic retinopathy: ▪ First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid. o Myopic Choroidal Neovascularization (mCNV) ▪ Lucentis for mCNV may be authorized for a maximum of 1 injection per month up to a maximum of 3 months. • Patients currently receiving treatment with Lucentis and who have demonstrated an adequate response are not required to try Avastin. For continuation of coverage, the patient must have met the following requirements: • Disease response as indicated by stabilization of visual acuity or improvement in BCVA score when compared to baseline. Duration of Approval: 12 months
Ravicti (glycerol phenylbutyrate)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of chronic hyperammonemia because of a urea cycle disorder; AND • Patient is at least 2 months of age; AND • Patient's condition cannot by managed by dietary protein restriction; AND • Patient's condition cannot be managed by amino acid supplementation; AND • Patient has tried and failed sodium phenylbutyrate. For continuation of coverage, the patient must have met the following requirements: • Clinical documentation, including chart notes, of disease stability or improvement must be provided. Duration of Approval: 12 months

DRUG	CRITERIA
Reblozyl (luspatercept)	Before this drug is covered, the patient must meet all of the following requirements: • Use for the treatment of transfusion-dependent adult patients with anemia due to beta-thalassemia **OR** myelodysplastic syndromes (MDS) who require blood cell transfusions; **AND** • Prescriber is an oncologist/hematologist **OR** another board-certified prescriber with qualifications to treat the specified disease. For continuation of coverage, the patient must have met the following requirements: • Patient has experienced a reduction in transfusion requirements from pretreatment baseline of at least 2 units PRBC while receiving Reblozyl. Duration of Approval: 12 weeks (initial); 12 months (continuation) **Note:** Transfusion-dependence is defined as 6 to 20 RBC units in the 24 weeks prior to Reblozyl treatment and no transfusion-free period for at least 35 days during that period. Initial authorization for 12 weeks. Hemoglobin should be assessed prior to each dose. Based on response, the dose may be increased to a maximum dose of 1.25mg/kg every 3 weeks (beta-thalassemia) or 1.75mg/kg every 3 weeks (MDS). If there is no decrease in transfusion burden after 9 weeks (three doses) at the maximum dose level, it is recommended to discontinue Reblozyl.

Relistor (methylnaltrexone)	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of opioid-induced constipation; **AND**
	• Not have a mechanical gastrointestinal obstruction, indwelling peritoneal catheter, clinically active diverticular disease, fecal impaction, acute surgical abdomen, or fecal ostomy; **AND**
	• Have a trial and failure, or be unable to tolerate, of all the following:
	  o Two other laxative drugs (one of which includes lactulose), **AND**
	  o Movantik or Symproic
	  o For injection only: therapeutic trial and failure of Relistor tablets.

Relyvrio (sodium phenylbutyrate and taurursodiol)	Before this drug is covered, the patient must meet all of the following requirements: • Diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial World Federation of Neurology /Arlie House criteria (supporting documentation must be submitted to Priority Health); **AND** • Disease duration of no more than 2 years (please provide date of diagnosis); **AND** • Be 18 to 80 years of age; **AND** • Living independently; **AND** • Score of at least 2 on each individual item of the revised ALS functional rating scale (ALSFRS-R) (supporting documentation must be submitted to Priority Health); **AND** • Forced vital capacity (FVC) of at least 80%; **AND** • Be used in combination with riluzole unless there is documentation of intolerance or contraindication to riluzole; **AND** • Prescribed by or in consultation with a neurologist. For continuation of coverage, the patient must have met the following requirements: • FCV of greater than or equal to 30%, does not require tracheostomy/artificial ventilation, and is not on continuous Bilevel Positive Airway Pressure (BiPAP); **AND** • Ambulatory (able to walk with or without assistance); **AND** • Able to self-feed. Duration of Approval: 6 months

DRUG	CRITERIA
Repatha (evolocumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Repatha was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders; AND • Not be using in combination with another PCSK9 inhibitor, Nexletol (bempedoic acid), or Nexlizet (bempedoic acid/ezetimibe); AND • For clinical atherosclerotic cardiovascular disease (ASCVD) OR heterozygous familial hypercholesterolemia (HeFH) requests, patient is at least 18 years of age and meets one of the following: o An adult with clinical atherosclerotic cardiovascular disease (ASCVD) and while being treated with a previous lipid lowering therapy the patient cannot achieve either an LDL-C of less than 70 mg/dL, OR o An adult with a LDL-C level suggestive of a diagnosis of heterozygous familial hypercholesterolemia (HeFH) o For ASCVD and HeFH requests, the patient must also meets one of the following ▪ Patient has tried one high-intensity statin (i.e., atorvastatin at least 40 mg daily; rosuvastatin at least 20 mg) for a minimum of 8 weeks continuously and LDL-C remains at least 70mg/dL; OR ▪ Patient is statin intolerant as demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation. • For homozygous familial hypercholesterolemia (HoFH) requests, patient is at least 13 years of age and meets one of the following: o Patient has tried at least one high-intensity statin (i.e., atorvastatin at least 40 mg daily; rosuvastatin at least 20 mg daily) for a minimum of 8 weeks continuously and LDL-C level remains above goal, OR o Patient is statin intolerant as demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation.

DRUG	CRITERIA
Respiratory Syncytial Virus (RSV) Monoclonal Antibodies	Preferred Agent(s): Beyfortus (nirsevimab)—no PA required if using within first 8 months of life and born during or entering the first RSV season Non-Preferred Agent(s): Synagis (palivizumab) Before this drug is covered, the patient must meet all of the following requirements: • Documentation of the patient's chronological age at the start of RSV season (November 1) and gestational age must be submitted to Priority Health. • For routine use in patients less than 8 months of age born during or entering their first RSV season (Beyfortus only). • For patients less than 12 months of age, must also have one of the following (Synagis only): o Prematurity (born at 28 weeks, 6 days gestation or earlier during their first RSV season); OR o Chronic lung disease of prematurity and born before 32 weeks gestational age who required more than 21% oxygen for at least 28 days after birth; NICU discharge summary must be included; OR o Congenital heart disease and have hemodynamically significant (cyanotic CHD or acyanotic CHD and receiving medication for CHF); NICU discharge summary must be included; OR o Pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airways. o Non-preferred drug product: Trial and failure, or intolerance/contraindication to the preferred product. • For patients age 12 months to less than 24 months (Synagis) or 8 through 19 months (Beyfortus), must also have one of the following: o Chronic lung disease of prematurity that required more 28 days of supplemental oxygen after birth that continues to require medical support (i.e. supplemental oxygen, chronic systemic corticosteroid therapy or diuretic therapy within 6 months of the start of the second RSV season); documentation of medical intervention must be included; OR o Severely immunocompromised during the RSV season. o Non-preferred drug product: Trial and failure, or intolerance/contraindication to the preferred product. Duration of Approval: Beyfortus: up to a single dose per RSV season (see below) Synagis: up to 5 doses per RSV season (see below) Note: The routine use of palivizumab (Synagis) for respiratory syncytial virus (RSV) prophylaxis is not a covered benefit. The number of doses approved will be determined based on the patient's age when prophylaxis is initiated and the month in which it is started. Patients who enter their second year of life during RSV season and meet criteriafor patients less than 12 months of age, will be authorized to receive monthly dosing until they are 12 months of age.RSV season is determined by geographic location. Southeast Florida is July 1; North central and southwest Florida is September 15; Most other areas of the United States is November 1. Considerations for the 2023–2024 RSV season with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season: • If nirsevimab is administered, palivizumab should not be administered later that season. • If palivizumab was administered initially for the season and less than 5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered. • If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

DRUG	CRITERIA
Revcovi (elapegademase)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of adenosine deaminase deficiency severe combined immune deficiency (ADA-SCID) (supporting documentation must be submitted to Priority Health); AND • Baseline trough plasma ADA activity must be provided; AND • Patient can adhere to therapy (e.g., weekly or twice weekly dosing); AND • Treatment will be monitored and adjusted based on FDA-labeled recommendations, including target trough plasma ADA activity of at least 30 mmol/hr/L For continuation of coverage, the patient must have met the following requirements: • Patient has been compliant and is able to continue to adhere to therapy; AND • Trough plasma ADA activity is greater than 30 mmol/hr/L (or doses are being adjusted to reach this target); AND • Trough erythrocyte dAXP is less than 0.02 mmol/L (or doses are being adjusted to reach this target); AND • Total and subset lymphocyte counts have increased (or doses are being adjusted to reach this target); AND • Most recent total and subset lymphocyte counts, trough plasma ADA activity, and trough dAXP levels have been provided to support the above levels Duration of Approval: 12 months Note: If self-administered, Revcovi will be covered under the pharmacy benefit.
Rinvoq (upadacitinib)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Ankylosing Spondylitis requests: o Be 18 years of age or older; AND o Patient has tried at least ONE of the following: a tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. o Patient has tried Xeljanz for a period of at least 3 months. • For Non-radiographic axial spondyloarthritis (nr-axSpA) requests: o 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); AND o Patient has tried a tumor necrosis factor inhibitor (TNFI) for at least 3 months. o Patient has tried Cosentyx for a period of at least 3 months. • For Atopic Dermatitis requests: o Patient has moderate to severe atopic dermatitis; AND o Patient has tried ALL of the following: ▪ One medium to high potency topical corticosteroid for a period of at least 3 months; AND ▪ One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months; AND ▪ One traditional non-biologic systemic agent (e.g., cyclosporine, azathioprine, methotrexate, or mycophenolate) for a period of at least 3 months. ▪ Patient has tried at least ONE other agent for this condition (e.g., Dupixent, Adbry) for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months; AND o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. o Patient has tried Xeljanz for a period of at least 3 months. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. o Patient has tried Xeljanz for a period of at least 3 months. *(Criteria continues on next page)*

DRUG	CRITERIA
Rinvoq (upadacitinib) *continued*	• For Crohn's Disease requests: o Be 18 years of age or older; **AND** o Patient has tried at least **ONE** systemic agent such as 6-mercaptopuine, azathioprine, cyclosporine, tacrolimus, or corticosteroids for at least 2 months; **AND** o Patient has tried a tumor necrosis factor inhibitor (TNFI) for at least 3 months. o Patient has tried Stelara for a period of at least 3 months. • For Ulcerative Colitis requests: o Be 18 years of age or older; **AND** o Patient has tried at least **ONE** systemic agent such as 6-mercaptopuine, azathioprine, cyclosporine, tacrolimus, or corticosteroids for at least 2 months; **AND** o Patient has tried a tumor necrosis factor inhibitor (TNFI) for at least 3 months. o Patient has tried Xeljanz for a period of at least 3 months. **Note:** Rinvoq will not be covered in combination with another biologic drug. 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 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.
Rufinamide (generic Banzel)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Lennox-Gastaut syndrome and using as adjunctive treatment (documentation confirming diagnosis must be submitted to Priority Health).
Ryplazim (plasminogen, human)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of plasminogen deficiency type 1 (PLGD type 1). Supporting documentation including plasminogen activity level less than or equal to 45% along with lesions and symptoms present must be submitted to Priority Health; **AND** • Prescribed by or in consultation with a hematologist. For continuation of coverage, patient must meet one of the following requirements: • Documentation of improvement in the number and/or size of lesions. Duration of Approval: 12 weeks (initial); 12 months (continuation)

DRUG	CRITERIA
Rystiggo (rozanolixizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Anti-acetylcholine receptor antibody (AChR-Ab) positive OR anti-muscle-specific tyrosine kinase (MuSK) antibody positive disease; **AND** • Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV; **AND** • Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 3; **AND** • Provide baseline quantitative myasthenia gravis (QMG) total score; **AND** • Progressive disease on a therapeutic trial of at least **TWO** of the following over the course of at least 12 months: azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide; **AND** • Patient has required 2 or more courses of plasamapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control; **AND** • Prescribed by or in consultation with a neurologist. <u>For continuation of coverage, patient must have met the following requirements</u>: • Have documented response as evidenced by BOTH of the following: o improved MG-ADL total score from baseline (at least a 2-point reduction); **AND** o improved (QMG) total score from baseline (at least a 3-point improvement). <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation). **Note:** Rystiggo will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Soliris, Ultomiris, or Vyvgart. Rystiggo is administered as a weight-based injection given once weekly for 6 weeks. Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established.
Rytary (levodopa/ carbidopa)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of advanced Parkinson's disease (supporting documentation must be submitted to Priority Health); **AND** • Patient is at least 18 years of age; **AND** • Prescribed by, or in consultation with, a neurologist; **AND** • Patient is experiencing acute, intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements); **AND** • Patient is receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release tablets and multiple daily dosing); **AND** • Therapeutic trial and failure of, or intolerance/contraindication to, adjunctive therapy with at least one medication in each of the drug classes listed below: o Dopamine agonist (e.g. pramipexole, ropinirole) o Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline) o Catechol-O-methyl transferase (COMT) inhibitor (e.g. entacapone) <u>For continuation of coverage, patient must meet one of the following requirements</u>: • Documentation that the patient has had a positive response to Rytary therapy. <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation)
Samsca (tolvaptan)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of hyponatremia (serum sodium less than 130 mEq/L); **AND** • Hyponatremia must be unresponsive to other therapy including, but not limited to, fluid restriction, loop diuretics, and hypertonic saline (or salt tablets); **AND** • Initiated or re-initiated in an inpatient setting; **AND** • Be screened for drug-induced causes of hyponatremia. <u>Duration of Approval</u>: 1 month **Note:** When criteria are met, the maximum dose authorized is 60 mg per day. Coverage duration is limited to 30 days.

DRUG	CRITERIA
Sapropterin (generic Kuvan)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of phenylketonuria (supporting documentation must be submitted to Priority Health); AND • Patient is at least 1 month of age; AND • Prescribed by a metabolic disease specialist; AND • Be adherent to current 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]; AND • Continue phenylalanine restricted diet if approved for Kuvan; AND • Tetrahydrobiopterin (BH4) deficiency has been ruled out; AND • Baseline blood phenylalanine levels must be provided. For continuation of coverage, patient must have met the following requirements: • Documented compliant maintenance therapy on Kuvan; AND • Continued adherence to a phenylalanine-restricted diet; AND • Achieved a 30 percent or greater reduction in phenylalanine (Phe) blood levels from baseline. Duration of Approval: 2 months (initial); 12 months (continuation) Note: Sapropterin (Kuvan) is not covered in combination with Palynziq.

Scemblix (asciminib)	Before this drug is covered, the patient must meet all of the following requirements:
	• Have one of the following diagnoses:
	  o Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs).
	  o Ph+ CML in CP with the T315I mutation, previously treated with Iclusig (ponatinib); AND
	• Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; AND
	• Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2.
	
	For continuation of coverage, the patient must have met the following requirements:
	• Have a positive clinical response to Scemblix as evidenced by experiencing disease stability or improvement.
	
	Duration of Approval: 12 months
	• For Ph+ CML CP without the T315I mutation: 6 months (initial); 12 months (continuation)
	• For Ph+ CML CP with the T315I mutation: 3 months (initial); 6 months (continuation)

Scenesse (afamelanotide)	Before this drug is covered, the patient must meet all of the following requirements: • Be using for a diagnosis of erythropoietic protoporphyria (EPP); AND • Have genetic testing confirming diagnosis of EPP (supporting documentation must be submitted to Priority Health); AND • Have characteristic symptoms of EPP phototoxicity; AND • Will not be covered in patients with the following: current basal cell carcinoma, squamous cell carcinoma, or other malignant or premalignant skin lesions; personal history of melanoma; or in any other photodermatosis (i.e. solar uticaria, polymorphic light eruption, discoid lupus erythematosus). Duration of Approval: 12 months (4 implants) Note: Covered for a maximum of 4 implants per year.
Serostim (somatropin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of HIV-associated wasting or cachexia.

DRUG	CRITERIA
Signifor & Signifor LAR (pasireotide)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Cushing's disease (supporting documentation must be provided to Priority Health); AND • Documentation of failed pituitary surgery or contraindication to surgery; AND • Have trial and failure with ketoconazole to reduce cortisol secretion. Signifor LAR only: • Be used for treatment of acromegaly; AND • Have inadequate response to surgery, unless surgery is not an option; AND • First try Sandostatin LAR. Duration of Approval: 12 months
Siliq (brodalumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Cosentyx, Enbrel, Adalimumab, Otezla, Tremfya, or Stelara, each for a period of at least 3 months. Note: Siliq will not be covered in combination with another biologic drug. 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 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.
Simponi Simponi Aria (golimumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Ankylosing Spondylitis requests: o Patient has tried at least TWO of the following: Cosentyx, Enbrel, or Adalimumab, each for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Cosentyx, Enbrel, Adalimumab, Xeljanz/XR, Otezla, or Stelara, each for a period of at least 3 months. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, o hydroxychloroquine, or sulfasalazine) for a period of at least 3 months; AND o Patient has tried at least TWO of the following: Actemra, Enbrel, Adalimumab, or Xeljanz/XR, each for a period of at least 3 months. • For Ulcerative Colitis requests: o Patient has tried Adalimumab for a period of at least 3 months. Note: Simponi/Simponi Aria will not be covered in combination with another biologic drug. Before Simponi/Simponi Aria is covered, the patient must meet all of the General Criteria for Simponi/Simponi Aria 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.

DRUG	CRITERIA
Sivextro (tedizolid)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible bacteria; AND • Have documented methicillin-resistant Staphylococcus aureus (MRSA) ABSSSI infection that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives. Fax a copy of culture and sensitivity results to Priority Health showing the patient's infection is not susceptible to alternative antibiotic treatments; AND • Sivextro be started in the hospital or other health care facility and will be continued in outpatient facility (or self-administered if taken orally); AND • Patient is at least 18 years of age. Duration of Approval: 1 month
Skyclarys (omaveloxolone)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Friedreich's ataxia (FA) with genetic confirmation (supporting documentation must be submitted to Priority Health); AND • Provide documentation of modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 to 80; AND • Be ambulatory; AND • Patient is between 16 to 40 years of age; AND • Prescriber is a neurologist or has consulted with a neurologist. For continuation of coverage, the patient must have met the following requirements: • Documentation of positive clinical response as evidenced by improvement of modified Friedreich's Ataxia Rating Scale (mFARS). Duration of Approval: 6 months (initial); 12 months (continuation)
Skyrizi (risankizumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Crohn's Disease requests: o Patient has tried or is currently taking corticosteroids (such as prednisone or methylprednisolone); AND o Patient has tried at least ONE other agent for this condition (e.g., azathioprine, 6-mercaptopurine, methotrexate) for a period of at least 3 months; AND o Patient has tried at least ONE other agent for this condition (e.g., infliximab, adalimumab) for a period of at least 3 months. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; AND o One tumor necrosis factor inhibitor (TNFI). • For Psoriatic Arthritis requests: o Patient has tried ALL of the following for a period of at least 3 months ▪ One traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine); AND ▪ One tumor necrosis factor inhibitor (TNFI). Note: Skyrizi will not be covered in combination with another biologic drug. 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 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. When used for Crohn's disease, three IV induction doses given at weeks 0, 4, and 8 will be covered under the medical benefit. Subsequent maintenance doses will be covered under the pharmacy benefit.

DRUG	CRITERIA

Skysona (elivaldogene autotemcel)
 	
Gene Therapy
	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) confirmed by:
	  o Elevated very long chain fatty acids (VLCFA) values; AND
	  o Active central nervous system disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating a Loes score equal to or between 0.5 and 9 on the 34-point scale; AND gadolinium enhancement of demyelinating lesions on MRI; AND
	• Member has genetic testing confirming ABCD1 mutation; AND
	• Has a Neurologic Function Score (NFS) less than or equal to 1; AND
	• Has documentation confirming the member does NOT have availability of a willing 10/10 human leukocyte antigen (HLA) matched (i.e., full HLA-matching of all evaluated alleles) donor; AND
	• Transplant specialist has attested that member is clinically stable and eligible to undergo myeloablative conditioning and HSCT; AND
	• Patient is a biological male that is 4 to 17 years of age; AND
	• Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat CALD; AND
	• Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.
	
	Note: Skysona will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling and performance status. Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles.
	
	Skysona will not be authorized for use in patients:
	• with hepatitis B, human immunodeficiency virus, hepatitis C. or any other active infection; OR
	• that have a previous history of hematopoietic stem cell transplant (HSCT); OR
	• that have received a previous treatment course of Skysona or another gene therapy for any diagnosis. The safety and effectiveness of repeat administration have not been evaluated **(one treatment per lifetime).**
	
	Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).
	
	Coverage of Skysona is dependent on member's eligibility and benefit plan documents.

Sodium phenylbutyrate (generic Buphenyl)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of chronic hyperammonemia because of a urea cycle disorder; AND • Patient's condition cannot be managed by dietary protein restriction; AND • Patient's condition cannot be managed by amino acid supplementation. For continuation of coverage, the patient must have met the following requirements: • Clinical documentation, including chart notes, of disease stability or improvement must be provided. Duration of Approval: 12 months
Sohonos (palovarotene)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of fibrodysplasia ossificans progressive (FOP) with a ACVR1 R206H mutation (supporting documentation must be submitted to Priority Health); AND • Patient is between at least 8 years of age (female) OR at least 10 years of age (male); AND • Patients of reproductive potential: attestation that the patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose; AND • Prescribed by or in consultation with a specialist in rare connective tissue diseases. For continuation of coverage, the patient must have met the following requirements: • Documentation of positive clinical response (e.g., no new or minimal new heterotropic ossification). Duration of Approval: 6 months

DRUG	CRITERIA
Soliris (eculizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Paroxysmal nocturnal hemoglobinuria (PNH) requests: o Have flow cytometric confirmation at least 10% granulocyte clone cells; **OR** o Have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage). • Atypical hemolytic uremic syndrome (aHUS) requests: o Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out. • Refractory generalized myasthenia gravis (MG) requests: o Anti-acetylcholine receptor antibody (AChR-Ab) positive disease; **AND** o Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV; **AND** o Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 6; **AND** o Provide baseline quantitative myasthenia gravis (QMG) total score; **AND** o Progressive disease on a therapeutic trial of at least **TWO** of the following over the course of at least 12 months: azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide; **AND** o Patient has required 2 or more courses of plasamapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control; **AND** o Trial and failure of Vyvgart; **AND** o Prescribed by or in consultation with a neurologist. • Neuromyelitis optica spectrum disorder (NMOSD) requests: o Confirmed diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (documentation must be provided); **AND** o Be anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided); **AND** o Have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years; **AND** o Prescribed by or in consultation with a neurologist; **AND** o Have progressive disease on a therapeutic trial of rituximab, inebilizumab (Uplizna) **AND** satralizumab (Enspryng); **AND** o Expanded Disability Status Scale (EDSS*) score of less than or equal to 7. <u>For continuation of coverage, patient must have met the following requirements</u>: • Paroxysmal nocturnal hemoglobinuria (PNH) requests: o Have a decrease disabling symptoms; **AND** o Hemoglobin levels must be stabilized; **AND** o Patient has experienced an improvement in fatigue and quality of life. • Atypical hemolytic uremic syndrome (aHUS) requests: o Have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine). • Refractory generalized myasthenia gravis (MG) requests: o Have documented response as evidenced by BOTH of the following: improved MG-ADL total score from baseline, improved (QMG) total score from baseline. • Neuromyelitis optica spectrum disorder (NMOSD) requests: o Have documentation of a decrease in relapse rate. <u>Duration of Approval</u>: 12 weeks (initial); 12 months (continuation) **Note:** Soliris will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Rystiggo, Ultomiris or Vyvgart.
Somavert (pegvisomant)	<u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Patient has a diagnosis of acromegaly; **AND** • Have an inadequate response to surgery or radiation therapy, unless those therapies are not an option; **AND** • Have had a trial and failure to a somatostatin analog (e.g. Signifor).

DRUG	CRITERIA

Sotyktu (deucravacitinib)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	• For Plaque Psoriasis requests:
	  o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND**
	  o Patient has tried at least **ONE** of the following: Cosentyx, Enbrel, Adalimumab, Otezla, Tremfya, or Stelara, each for a period of at least 3 months.
	
	Note: Sotyktu will not be covered in combination with another biologic drug. Before Sotyktu is covered, the patient must meet all of the General Criteria for Sotyktu 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.

Spinraza (nusinersen)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Prescribed by a neurologist or in consultation with a neurologist with experience treating SMA; **AND**
	• Have a diagnosis of spinal muscular atrophy (SMA); **AND**
	• Have genetic testing confirming spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reports as at least one of the following: homozygous gene deletion, homozygous conversion mutation, or compound heterozygous mutation; **AND**
	• Have genetic testing confirming the member has no more than 2 copies of SMN2 or experienced SMA- associated symptoms before 6 months of age; **AND**
	• Be symptomatic at the time of the request, but not have advanced SMA (i.e., complete paralysis of limbs, permanent ventilator dependence); **AND**
	• Submit a baseline 32-item motor function measure (MFM-32), Hammersmith Infant Neurologic Exam (HINE), or other validated assessment tool for SMA; **AND**
	• First try and fail Evrysdi (risdiplam).
	
	<u>For continuation of coverage, the patient must have met the following requirements</u>:
	• Submit documentation to show maintenance or improvement of condition:
	  o Repeat measurement of the MFM-32, HINE or other validated assessment tool appropriate for patient age to show improvement or stable results; **AND** for HINE results, must show improvement in more categories of motor milestones than worsening.
	  o 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.
	
	<u>Duration of Approval</u>: 6 months
	
	Note: Spinraza will only be authorized in accordance with FDA-approved dosing for SMA. Initial authorization for loading doses will be limited to a total of 4 doses. Maintenance therapy will be limited to 12mg every 4 months, starting 4 months after the last loading dose.
	
	Spinraza is considered experimental and investigational for non-5q-spinal muscular atrophy disorders.
	
	Spinraza will not be authorized for use in patients previously treated with Zolgensma and will not be authorized for coverage in combination with Evrysdi.

DRUG	CRITERIA

Sporanox oral suspension (itraconazole)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• For the treatment of invasive fungal disease (i.e. Aspergillus spp., Blastomycosis, Histoplasmosis)
	  o Prescribed or recommended by an infectious disease specialist; **AND**
	  o Have a trial and failure of itraconazole capsules.
	
	• For the treatment of oropharyngeal and esophageal candidiasis
	  o Prescribed or recommended by an infectious disease specialist; **AND**
	  o Have had a trial and failure, or intolerable side effect to clotrimazole troches, nystatin suspension, fluconazole and itraconazole capsule.
	
	<u>Duration of Approval</u>:
	• For invasive fungal disease or prophylaxis of invasive Aspergillosis/Candida) initial authorization for a maximum of 3 months.
	• For oropharyngeal candidiasis limited to 4 weeks.
	• For esophageal candidiasis limited to 6 weeks.

Spravato (esketamine)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Diagnosis of Major Depressive Disorder without psychotic features, with baseline score, prior to starting Spravato, from one of the following:
	  o Baseline score on the 17-item Hamilton Rating Scale for Depression (HAMD17); **OR**
	  o Baseline score on the 16-item Quick Inventory of Depressive Symptomatology (QIDS-C16); **OR**
	  o Baseline score on the 10-item Montgomery-Asberg Depression Rating Scale (MADRS); **AND**
	• Evidence of Treatment Resistant Depression defined as failure (no greater than 25% improvement in depression symptoms or scores) of at least:
	  o Three different antidepressants, each from a different pharmacologic class (for example, selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants [TCAs], monoamine oxidase inhibitors [MAOIs], bupropion, mirtazapine, serotonin modulators) and each used at therapeutic dosages for at least 12 weeks in the current episode of depression, according to the prescribing physician; **AND**
	  o One augmentation therapy for at least 6 weeks (includes but not limited to lithium, antipsychotics, or anticonvulsants).
	• Patient is at least 18 years of age; **AND**
	• Prescribed by or in consultation with a psychiatrist; **AND**
	• Spravato will be used in combination with at least one oral antidepressant that has not previously been tried; **AND**
	• Spravato will be used with cognitive behavioral therapy or interpersonal psychotherapy weekly for at least 8 weeks of treatment.
	
	<u>For continuation of coverage, patient must have met the following requirements</u>:
	• Maintain an 85% adherence rate to therapy consisting of Spravato and at least one oral antidepressant, which will be verified based on Priority Health's medication fill history for the patient; **AND**
	• Documentation of remission or a positive clinical response to Spravato; **AND**
	• Submission of baseline and recent (within the last month) scoring on at least one of the following assessments demonstrating remission or clinical response (i.e., score reduction from baseline) as defined by the:
	  o Hamilton Rating Scale for Depression (HAMD17; remission defined as a score of no greater than 7); **OR**
	  o Quick Inventory of Depressive Symptomatology (QIDS-C16; remission defined as a score of no greater than 5); **OR**
	  o Montgomery-Asberg Depression Rating Scale (MADRS; remission defined as a score of no greater than 12).
	
	<u>Duration of Approval</u>: 12 weeks (initial); 6 months (continuation)
	
	Note: Intolerance to antidepressant and augmentative therapy is not considered therapeutic failure.

DRUG	CRITERIA
Stelara (ustekinumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Crohn's Disease requests: o Patient has tried or is currently taking corticosteroids (such as prednisone or methylprednisolone); OR o Patient has tried at least **ONE** other agent for this condition (e.g., azathioprine, 6-mercaptopurine, methotrexate, Cimzia, infliximab, Entyvio, or Adalimumab) for a period of at least 3 months • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND** o If 90 mg dose is requested, patient weighs more than 100 kg. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months; **AND** o If 90 mg dose is requested, patient weighs more than 100 kg. • For Ulcerative Colitis requests: o Patient has tried one traditional non-biologic 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** o 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. **Note:** Stelara will not be covered in combination with another biologic drug. 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 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. When used for Crohn's disease or ulcerative colitis, a single IV induction dose will be covered under the medical benefit. Subsequent maintenance doses will be covered under the pharmacy benefit. 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): • Have tried Stelara 45 mg for at least 12 weeks; **AND** • 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)	<u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Patient has a diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia including radiographic evidence (supporting documentation must be submitted to Priority Health); **AND** • Clinical manifestations consistent with hypophosphatasia must be present; **AND** • Diagnosis confirmed with both biochemical and molecular genetic testing; **AND** • A second opinion may be required by Priority Health from a Specialist Provider we choose to help us determine whether Strensiq is medically necessary. <u>For continuation of coverage, patient must have met the following requirements</u>: • Documentation that the patient has had a positive clinical response (e.g., clinical symptoms, Radiographic Global Impression of Change). <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation) **Note:** 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.

DRUG	CRITERIA
Subsys (fentanyl citrate spray)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is at least 18 years of age; AND • Be using to manage breakthrough pain in cancer patients; AND • Be receiving and tolerant to around-the-clock opioid therapy for persistent cancer pain; AND • Have trial and failure, or intolerance, to generic fentanyl buccal lozenge. Note: Limited to 120 units per 30 days
Supprelin LA (histrelin acetate implant)	Before this drug is covered, the patient must meet all of the following requirements: • Documentation of a diagnosis of Central Precocious Puberty in a patient aged 2 years or older; AND • Documented inadequate response to or intolerance to an adequate trial of Lupron injections. Duration of Approval: 12 months
Syfovre (pegcetacoplan)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of geographic atrophy (GA) of the macula secondary to age-related macular degeneration (supporting documentation must be submitted to Priority Health); AND • Prescribed by or in consultation with an ophthalmologist; AND • Visual acuity in the affected eye(s) of 20/320 or better; AND • GA lesion area size of at least 2.5 mm2 and less than or equal to 17.5 mm2; AND • If the GA lesions were multifocal, at least one focal lesion must be at least 1.25 mm. For continuation of coverage, patient must have met the following requirements: • Documentation showing disease response as indicated by reduction in GA lesion growth. Duration of Approval: 12 months Note: The FDA-approved labeling allows for Syfovre to be injected every 25 to 60 days. Initial dosing frequency that will be covered is every 60 days, requests for increased frequency will need to demonstrate failure on every other month dosing.
Sylvant (siltuximab)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of multicentric Castleman disease (MCD); AND • Be HIV negative; AND • Be human herpesvirus (HHV) negative. Duration of Approval: 12 months

DRUG	CRITERIA
Taltz (ixekizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Ankylosing Spondylitis requests: o Patient has tried at least **TWO** of the following: Cosentyx, Enbrel, or Adalimumab, each for a period of at least 3 months. • For Non-radiographic axial spondyloarthritis (nr-axSpA) requests: o 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). o Patient has tried at least **TWO** of the following: Cosentyx, Enbrel, or Adalimumab each for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months; **AND** o Patient has tried at least **TWO** of the following: Cosentyx, Enbrel, Adalimumab, Xeljanz/XR, Otezla, Stelara, or Tremfya each for a period of at least 3 months. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND** o Patient has tried at least **THREE** of the following: Cosentyx, Enbrel, Adalimumab, Enbrel, Otezla, Tremfya, or Stelara, each for a period of at least 3 months. **Note:** Taltz will not be covered in combination with another biologic drug. Before Taltz is covered, the patient must meet all of the General Criteria for Taltz 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.
Tavneos (avacopan)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) (supporting documentation must be submitted to Priority Health); **AND** • Patient is at least 18 years of age; **AND** • Patient does not currently require dialysis or have a kidney transplant, and has not received plasma exchange in the past 12 weeks; **AND** • Prescribed by or in consultation with a specialist; **AND** • Have documentation of the following: o Active, organ or life-threatening disease; **AND** o eGFR at least 15 mL/min/1.72 m2; **AND** o Positive test for either anti-PR3 or anti-MPO. <u>For continuation of coverage, patient must have met the following requirements</u>: • Have a positive clinical response to Tavneos as evidenced by experiencing disease stability or improvement from baseline as assessed by one objective measure (e.g., improvement in the Birmingham Vasculitis Activity Score (BVAS), estimated GFR, decrease in urinary albumin creatinine ratio); **AND** • Have a reduction in steroid dose. <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation) **Note:** Tavneos must be used as adjunctive (add-on) therapy in combination with standard therapy including cyclophosphamide, rituximab, and glucocorticoids (such as methylprednisolone or prednisone) – **AND** – patient must have a medical need to reduce steroid use if not previously relapsed (i.e. infection, osteoporosis).

DRUG	CRITERIA
Tecartus (brexucabtagene autoleucel) Gene Therapy	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Have a diagnosis of relapsed or refractory mantle cell lymphoma; **AND** • Have received prior treatment with chemoimmunotherapy a BTK inhibitor (e.g., Calquence, Imbruvica, Brukinsa), unless contraindicated; **AND** • Patient is at least at least 18 years of age; **AND** • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; **AND** • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. **Note:** Tecartus will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Tecartus will not be authorized for use in patients: • with primary central nervous system lymphoma; **OR** • that have received a previous treatment course of Tecartus or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy. The safety and effectiveness of repeat administration have not been evaluated **(one treatment per lifetime).** Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Tecartus is dependent on member's eligibility and benefit plan documents.

Tegsedi (inotersen)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (supporting documentation must be submitted to Priority Health); **AND**
	• Patient is at least 18 years of age; **AND**
	• Genetic testing confirming a transthyretin (TTR) mutation (e.g., V30M); **AND**
	• Presence of clinical signs and symptoms (e.g., motor disability, peripheral/autonomic neuropathy, etc.); **AND**
	• Have documentation of one of the following:
	  o Baseline polyneuropathy disability (PND) score no greater than IIIb; **OR**
	  o Baseline FAP Stage 1 or 2; **AND**
	• Patient is not receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro.
	
	<u>For continuation of coverage, patient must have met the following requirements:</u>
	• Documentation that the patient continues to have one of the following: Polyneuropathy disability (PND) score no greater than IIIb, or FAP Stage 1 or 2; **AND**
	• 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); **AND**
	• Patient is not receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro.
	
	<u>Duration of Approval</u>: 12 months
	
	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.

DRUG	CRITERIA
Tepezza (teprotumumab)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is at least 18 years of age; AND • Prescriber must be (or working in consultation with) an ophthalmologist; AND • Have a confirmed diagnosis of Grave's disease and documentation that the patient has active moderate to severe TED (not sight-threatening but has an appreciable impact on daily life) with documentation of one or more of the following: lid retraction of more than 2 mm, moderate or severe soft-tissue involvement, proptosis at least 3 mm above normal values for race and sex; and periodic or constant diplopia; AND • Submission of laboratory results indicating that the patient is euthyroid prior to starting Tepezza therapy; AND • Submission of Clinical Activity Score (CAS) Report (score must be at least 4) in the most severely affected eye; AND • Not have had previous orbital surgery (i.e. orbital decompression, extraocular muscle surgery, eyelid repositioning/eyelid retraction, and cosmetic soft tissue redraping) or irradiation for TED prior to the start of therapy; AND • Failure of a 4-week trial of a systemic corticosteroid (at up to maximally indicated doses), unless contraindicated or clinically significant adverse effects are experienced (e.g. poorly-controlled diabetes). Duration of Approval: 8 doses per lifetime Note: The recommended dose is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for 7 additional infusions. Tepezza is limited to a total of 8 doses per lifetime.
Testosterone Replacement Products	Preferred Agent(s): Testosterol topical 1% and 1.62% gel (generic for AndroGel) Kyzatrex (testosterone undecanoate capsule) Non-Preferred Agent(s): Aveed (testosterone undecanoate injection) Testopel (testosterone pellet) Before this drug is covered, the patient must meet all of the following requirements: • For hypogonadal hypotestosteronism: o Have 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); AND o 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; AND o Trial and failure of 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); AND o Non-preferred drug product: Trial and failure, or intolerance to generic topical testosterone for a minimum of two months with failure to improve symptoms and failure to increase total serum testosterone above 300ng/dL. • For gender dysphoria: o Documentation of diagnosis must be submitted to Priority Health; AND o Trial and failure of injectable testosterone; AND o Non-preferred drug product: Trial and failure, or intolerance to generic topical testosterone. Note: Injectable testosterone enanthate (generic Delatestryl) and testosterone cypionate (generic Depo-Testosterone) do not require prior authorization. "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to injectable testosterone therapy.

DRUG	CRITERIA

Tezspire
(tezepelumab)
	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of severe asthma requiring a biologic; **AND**
	• Patient is at least 12 years of age; AND
	• Not currently be using tobacco products; AND
	• Have been compliant on all of the following therapies for at least 3 months:
	  o High-dose inhaled corticosteroid (ICS)
	  o Long-acting beta agonist (LABA)
	  o One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); AND
	• Be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique); **AND**
	• Have had at least 2 asthma exacerbations in the previous year that required at least one of the following:
	  o Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days
	  o Hospitalization and/or ED visit.
	
	For continuation of coverage, the patient must have met the following requirements:
	• Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use).
	
	Duration of Approval: 12 months
	
	Note: Tezspire is not covered in combination with other biologic drug therapy.

Thiola Thiola EC (tiopronin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of severe homozygous cystinuria using tiopronin to prevent cystine stone formation (supporting documentation must be submitted to Priority Health); **AND** • Documentation of a trial with conservative measures (i.e. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated. For continuation of coverage, patient must have met the following requirements: • Documented compliant maintenance therapy on tiopronin; **AND** • Continued adherence to conservative measures listed above. Duration of Approval: 12 months **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.

DRUG	CRITERIA
Tobramycin Inhalation	Preferred Agent(s): Tobramycin inhalation nebulization 300mg/4mL (generic Bethkis) Tobramycin inhalation nebulization 300mg/5mL (generic Kitabis) Kitabis inhalation nebulization 300mg/5mL Non-Preferred Agent(s): Bethkis inhalation nebulization 300mg/4mL Tobi inhalation nebulization 300mg/5mL Tobi Podhaler Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of cystic fibrosis confirmed by appropriate diagnostic or genetic testing (documentation of cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health); AND • Confirmation of Pseudomonas aeruginosa in cultures of the airways confirmed by a copy of positive sputum culture; AND • Patient is at least 6 years of age; AND • Non-preferred drug product: Trial and failure, or intolerance to ONE preferred formulation. For continuation of coverage, patient must have met the following requirements: • Continues to require treatment of Pseudomonas aeruginosa infection; AND • Documentation of stabilization or improvement by pulmonologist or CF specialist. Duration of Approval: 6 months (initial); 12 months (continuation) Note: Coverage for tobramycin inhalation nebulization products is to be used for 28 days, following 28 days off.
Tremfya (guselkumab)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Plaque Psoriasis requests: o Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months. Note: Tremfya will not be covered in combination with another biologic drug. 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 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.
Trientine (generic Syprine)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of Wilson's disease (supporting documentation must be submitted to Priority Health); AND • Prescribed by, or in consultation with, a gastroenterologist; AND • Have had a trial and failure, or intolerance, to penicillamine.

DRUG	CRITERIA

Tysabri
(natalizumab)
	Before this drug is covered, the patient must meet all of the following requirements:
	• For relapsing-remitting multiple sclerosis (MS) or active secondary progressive MS:
	  o Have had an inadequate response to at least TWO other disease modifying therapies for MS, one of which must be glatiramer, dimethyl fumarate, fingolimod, or teriflunomide.
	• For moderate to severe Crohn's disease requests:
	  o Patient has prior use of corticosteroids; AND
	  o First try infliximab OR adalimumab.
	
	For continuation of coverage, the patient must have met the following requirements:
	• Have a positive clinical response to Tysabri as evidenced by experiencing disease stability or improvement.
	
	Duration of Approval: 12 months
	
	Note: Tysabri is not covered in combination with other drugs for the treatment of Multiple Sclerosis (e.g., Ocrevus, Gilenya, Betaseron).

Tzield
(teplizumab)
	Before this drug is covered, the patient must meet all of the following requirements:
	• Have a diagnosis of stage 2 type 1 diabetes; AND
	• Patient is at least 8 years of age; AND
	• Have at least 2 of the following autoantibodies:
	  o Glutamic acid decarboxylase 65 (GAD) autoantibody
	  o Insulin autoantibody (IAA)
	  o Insulinoma-associated antigen 2 autoantibody (IA-2A)
	  o Zinc transporter 8 autoantibody (ZnT8A)
	  o Islet cell autoantibody (ICA); AND
	• Have evidence of dysglycemia defined as a fasting glucose level of 110 to 125 mg/dL (6.1 to 6.9 mmol/L) OR a 2-hour postprandial plasma glucose level of at least 140 mg/dL (7.8 mmol/L) and less than 200 mg/dL (11.1 mmol/L) OR an intervening postprandial glucose level at 30, 60, or 90 minutes of greater than 200 mg/dL on two occasions; AND
	• BPrescribed by an endocrinologist (or in consultation with an endocrinologist).
	
	Duration of Approval: 14 doses per lifetime
	
	Note: Tzield is not covered in patients with a history of type 2 diabetes. The recommended dose is a daily intravenous infusion for 14 days.

DRUG	CRITERIA
Ultomiris (ravulizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements:</u> • Paroxysmal nocturnal hemoglobinuria (PNH) requests: o Have flow cytometric confirmation at least 10% granulocyte clone cells; **OR** o Have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage). • Atypical hemolytic uremic syndrome (aHUS) requests: o Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out. • Refractory generalized myasthenia gravis (MG) requests: o Anti-acetylcholine receptor antibody (AChR-Ab) positive disease; **AND** o Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV; **AND** o Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 6; **AND** o Provide baseline quantitative myasthenia gravis (QMG) total score; **AND** o Progressive disease on a therapeutic trial of at least **TWO** of the following over the course of at least 12 months: azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide; **AND** o Patient has required 2 or more courses of plasamapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control; **AND** o Trial and failure of Vyvgart; **AND** o Prescribed by or in consultation with a neurologist. <u>For continuation of coverage, patient must have met the following requirements</u>: • Paroxysmal nocturnal hemoglobinuria (PNH) requests: o Have a decrease disabling symptoms; **AND** o Hemoglobin levels must be stabilized; **AND** o Patient has experienced an improvement in fatigue and quality of life. • Atypical hemolytic uremic syndrome (aHUS) requests: o Have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine). • Refractory generalized myasthenia gravis (MG) requests: o Have documented response as evidenced by BOTH of the following: improved MG-ADL total score from baseline, improved (QMG) total score from baseline. <u>Duration of Approval</u>: 6 months (initial); 12 months (continuation) **Note:** Ultomiris will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Rystiggo, Soliris or Vyvgart.
Uplizna (inebilizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Patient has a diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) (supporting documentation must be submitted to Priority Health); **AND** • Anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided); **AND** • Have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years; **AND** • Prescribed by or in consultation with a neurologist; **AND** • Have progressive disease on a therapeutic trial of rituximab AND satralizumab (Enspryng); **AND** • Expanded Disability Status Scale (EDSS) score of less than or equal to 7. <u>For continuation of coverage, patient must have met the following requirements</u>: • Have a positive clinical response to Uplizna as evidenced by a documented decrease in relapse rate. <u>Duration of Approval</u>: 12 months

DRUG	CRITERIA

Vabysmo (faricimab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Have one of the following diagnoses and meet any required criteria:
	  o Neovascular (wet) age-related macular degeneration (AMD):
	  ▪ First try bevacizumab for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	  ▪ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome.
	  ▪ First try ranibizumab or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	  o Diabetic macular edema (DME) with baseline visual acuity 20/50 or worse:
	  ▪ Baseline best-corrected visual acuity (BCVA) score must be included in request.
	  ▪ First try ranibizumab or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	  o Diabetic macular edema (DME) with baseline visual acuity better than 20/50:
	  ▪ First try bevacizumab for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	  ▪ First try ranibizumab or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	  o Macular edema following retinal vein occlusion (RVO):
	  ▪ First try bevacizumab for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	  ▪ First try ranibizumab or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
	• Patients currently receiving treatment with Vabysmo and who have demonstrated an adequate response are not required to try Avastin.
	
	<u>For continuation of coverage, the patient must have met the following requirements</u>:
	• Disease response as indicated by stabilization of visual acuity or improvement in BCVA score when compared to baseline.
	
	<u>Duration of Approval</u>: 12 months

Valchlor (mechlorethamine gel)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Patient has a diagnosis of stage 1A or 1B mycosis fungoides (MF) type cutaneous T-cell lymphoma (CTCL); **AND**
	• Have a trial of at least two of the following:
	  o Topical corticosteroid
	  o Topical chemotherapy
	  o Topical retinoid
	  o Imiquimod
	  o Local radiation therapy
	  o Phototherapy
	
	<u>For continuation of coverage, the patient must have met the following requirements</u>:
	• 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.
	
	<u>Duration of Approval</u>: 6 months (initial); 12 months (continuation)

DRUG	CRITERIA
Veopoz (pozelimab)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of CHAPLE disease that includes symptoms of the condition (such as diarrhea, vomiting, abdominal pain, etc.) and a low serum albumin with a CD55 loss-of-function mutation (supporting documentation must be submitted to Priority Health); AND • Patient is at least 1 year of age; AND • Prescribed by or in consultation with hematologists, gastroenterologists, or those who specialize in rare genetic hematologic diseases; AND • First try Soliris or Ultomiris. For continuation of coverage, the patient must have met the following requirements: • Documentation of a positive clinical response (e.g. improvement or no worsening in clinical symptoms, increase in or stabilization of albumin and IgG concentrations, increase in growth percentiles. Duration of Approval: 6 months (initial); 12 months (continuation) Note: Veopoz is not covered in combination with Soliris/Ultomiris.
Verquvo (vericiguat)	Before this drug is covered, the patient must meet all of the following requirements: • Have confirmed diagnosis of symptomatic worsening chronic heart failure (NYHA Class II-IV), defined as one of the following: o History of previous heart failure (HF) hospitalization within the last 6 months o Outpatient intravenous diuretic for HF within the previous 3 months; AND • Patient is at least 18 years of age; AND • Prescribed by, or in consultation with, a cardiologist; AND • Patient has been using at least 3 of the following HF medications at goal doses for HF treatment or maximally tolerated dosing: o ACEI, ARB, or Entresto o Bisoprolol, carvedilol or sustained release metoprolol o Spironolactone o Diuretic (i.e. furosemide); AND • Ejection Fraction less than 45% assessed within the previous 12 months; AND • Documentation of an elevated brain natriuretic peptide (BNP) or NT-proBNP level within the previous 30 days.

DRUG	CRITERIA
Vesicular monoamine transporter type 2 (VMAT2)	Preferred Agent(s): Tetrabenazine Ingrezza Non-Preferred Agent(s): Austedo Before this drug is covered, the patient must meet all of the following requirements: • For chorea associated with Huntington's disease; o Documentation confirming diagnosis must be submitted to Priority Health; AND o Patient is at least 18 years of age; AND o Non-preferred drug product: Trial and failure, or intolerance to tetrabenazine used at maximally tolerated doses. • For moderate to severe tardive dyskinesia o Provide documentation of current Abnormal Involuntary Movement Scale (AIMS) score with a minimum score of 3 on item 8 (severity of abnormal movements overall); AND o Have tried and failed a dose reduction, tapering, and/or discontinuation of the offending agent(s); AND o Be 18 years of age; AND o Non-preferred drug product: Trial and failure, or intolerance to Ingrezza. For continuation of coverage, the patient must have met the following requirements: • Medical documentation submitted confirming a positive response to therapy: o Chorea symptoms have improved or stabilized; OR o Decreased AIMS score (items 1 to 7) from baseline. Duration of Approval: 6 months (initial); 12 months (continuation) Note(s): • For tetrabenazine doses greater than 50mg/day, must have CYP2D6 genotype provided. • Austedo, Ingrezza, and tetrabenazine will not be covered in combination with one another.
Vibativ (televancin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient is at least 18 years of age; AND • Have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives; AND • Infection is not susceptible to alternative antibiotic treatments (supporting documentation must be submitted to Priority Health). Duration of Approval: Two weeks.
Viberzi (eluxadoline)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of irritable bowel syndrome (IBS) with diarrhea; AND • Patient is at least 18 years of age; AND • 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); AND • Trial of at least three of the following (tried for at least 1 month each): o Loperamide o Antispasmodic (ex. Dicyclomine) o Bile acid sequestrant (cholestyramine, colestipol or colesevelem) o Tricyclic antidepressant (ex. nortriptyline) Note: Maximum covered dose is 200 mg/day.

DRUG	CRITERIA
Vigabatrin (generic Sabril, Vigadrone)	Before this drug is covered, the patient must meet all of the following requirements: • For Infantile spams: patient is 2 years of age or younger; **OR** • For refractory complex partial seizure: must have treatment failure with two generic anticonvulsants.
Vijoice (alpelisib)	Before this drug is covered, the patient must meet all of the following requirements: • Physician confirmed/documented diagnosis of PROS; **AND** • Patient has at least one target lesion identified on imaging and target lesion volume is documented; **AND** • Documented evidence of a mutation in the PIK3CA; **AND** • Patient is at least 2 years of age; **AND** • Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2; **AND** • Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician. For continuation of coverage, the patient must have met the following requirements: • Documentation of positive response to therapy, as evidenced by at least a 20% reduction in the sum of measurable target lesion volume (one to three lesions, via central review of imaging scans), confirmed by at least one subsequent imaging assessment provided that none of the individual target lesions had at least 20% increase from baseline, nontarget lesions had not progressed, and there were no new lesions; **AND** • Documentation that the member is tolerating therapy. Duration of Approval: Initial: 6 months. Continuation: 12 months. **Note:** For adult patients requiring a 250mg daily dose of alpelisib for PROS, the covered formulation is Piqray.
Vimizim (elosulfase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Morquio A syndrome (supporting documentation must be submitted to Priority Health); **AND** • Be able to walk at least 30 meters in 6 minutes. For continuation of coverage, patient must have met the following requirements: • After 24 weeks of therapy, patient must be able to walk further than he or she did before starting Vimizim in 6 minutes. Duration of Approval: 6 months (initial and maintenance)
Voxzogo (vosoritide)	Before this drug is covered, the patient must meet all of the following requirements: • Patients has a diagnosis of achondroplasia confirmed by genetic testing for variants in the fibroblast growth factor receptor 3 (FGFR3) gene (supporting documentation must be submitted to Priority Health); **AND** • Have documentation of member's current annualized growth velocity (AGV) and the patient has open epiphyses; **AND** • Prescriber attests that there are no plans for the member to have limb-lengthening surgery and the member has not had limb-lengthening surgery in the past 18 months; **AND** • Member has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the 6 months prior to request; **AND** • Prescribed by or in consultation with a board-certified geneticist, endocrinologist, neurologist, orthopedic surgeon, or specialist with experience in treating achondroplasia. For continuation of coverage, patient must have met the following requirements: • Adherence to therapy at least 85% of the time as verified by the prescriber or patient medication fill history; **AND** • Documentation confirming current open epiphyses; **AND** • Documentation of positive clinical response as demonstrated by improvement or stabilization in annualized growth velocity and increase in AGV is at least 1.5 centimeters/year from baseline. Duration of Approval: 12 months (initial and maintenance)

DRUG	CRITERIA
Vpriv (velaglucerase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Have non-neuropathic Gaucher's disease, chronic (supporting documentation must be submitted to Priority Health). For continuation of coverage, patient must have met the following requirements: • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: clinically significant reduction in spleen or liver volume, increase in platelet or hemoglobin values. Duration of Approval: 12 months
Vyjuvek (beremagene geperpavec) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of dystrophic epidermolysis bullosa (DEB); AND • Have presence of open DEB skin wounds; AND • Application is limited to open DEB skin wounds only; AND • Documentation of genetic testing confirming mutation(s) in the COL7A1 gene; AND • Patient is at least 6 months of age; AND • Prescribed by a dermatologist or another board-certified prescriber with qualifications to treat dystrophic epidermolysis bullosa. For continuation of coverage, the patient must have met the following requirements: • Clinical documentation must be provided to confirm that initial criteria are met and that Vyjuvek is providing clinical benefit (e.g. complete wound closure, decrease in wound size, increase in granulation tissue). Duration of Approval: 6 months Note: Vyjuvek will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling. Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles. Vyjuvek will not be authorized for use in patients: • that have current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; OR • active infection in the area to be treated; OR • have had a skin graft in the past 3 months. Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Vyjuvek is dependent on member's eligibility and benefit plan documents.

DRUG	CRITERIA

Vyndaqel (tafamidis meglumine)
 	
Vyndamax (tafamidis)
	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Patient has a diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) (supporting documentation must be submitted to Priority Health); **AND**
	• Patient is at least 18 years of age; **AND**
	• Not have any of the following:
	  o Primary (light-chain) amyloidosis
	  o Prior liver or heart transplant or an implanted cardiac device
	  o NYHA Class 4 heart failure; **AND**
	• ATTR-CM confirmed by genetic testing, tissue biopsy, or radionuclide imaging (99mTc-PYP, 99mTc- DPD, or 99mTc-HMDP scan); **AND**
	• Diagnosis by radionuclide imaging requires all the following to be met:
	  o Grade 2 or 3 cardiac uptake on radionuclide imaging
	  o Echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness)
	  o Absence of monoclonal protein identified in serum and urine immunofixation (IFE) and serum free light chain (sFLC) assay; **AND**
	• Presence of clinical signs and symptoms of cardiomyopathy and HF (i.e. dyspnea, edema, angina); **AND**
	• Patient is not receiving tafamidis (Vyndaqel, Vyndamax) in combination with or Onpattro or Tegsedi.
	
	<u>For continuation of coverage, patient must have met the following requirements</u>:
	• Documentation that the patient has experienced a positive clinical response to Vyndaqel/Vyndamax compared to baseline (i.e. reduced cardiovascular-related hospitalizations, improved function, improved quality of life); **AND**
	• Patient is not receiving tafamidis (Vyndaqel, Vyndamax) in combination with Tegsedi or Onpattro.
	
	<u>Duration of Approval</u>: 12 months
	
	Note: When criteria are met, coverage duration is 12 months for initial and continuation requests. 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).

Vyvgart (efgartigimod alfa)
 	
Vyvgart Hytrulo (efgartigimod alfa-hyaluronidase)
	<u>Before this drug is covered, the patient must meet all of the following requirements</u>:
	• Anti-acetylcholine receptor antibody (AChR-Ab) positive disease; **AND**
	• Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV; **AND**
	• Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 5; **AND**
	• Provide baseline quantitative myasthenia gravis (QMG) total score; **AND**
	• Progressive disease on a therapeutic trial of at least **TWO** of the following over the course of at least 12 months: azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide; **AND**
	• Patient has required 2 or more courses of plasamapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control; **AND**
	• Prescribed by or in consultation with a neurologist.
	
	<u>For continuation of coverage, patient must have met the following requirements</u>:
	• Have documented response as evidenced by BOTH of the following:
	  o improved MG-ADL total score from baseline (at least a 2-point reduction); **AND**
	  o improved (QMG) total score from baseline (at least a 3-point improvement).
	
	<u>Duration of Approval</u>: 2 cycles of 4 doses (initial); 12 months (continuation).
	
	Note: Vyvgart will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Rystiggo, Soliris or Ultomiris. Vyvgart is administered as a 10 mg/kg intravenous infusion once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose of VYVGART is 1200 mg (3 vials) per infusion.
	
	Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

DRUG	CRITERIA
Wakix (pitolisant)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Prescribed by, or in consultation with, a board-certified sleep specialist or neurologist; **AND** • 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; **AND** • Wakix will not be covered in patients who use other sedative hypnotics, drink alcohol when using Wakix; **AND** • Patient is at least 18 years of age; **AND** • Meet diagnosis specific criteria below: • For treatment of excessive daytime sleepiness in patients with narcolepsy: o Have a documented therapeutic trial with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others, with all of the following: ▪ Amphetamine salts, dextroamphetamine or methylphenidate ▪ Modafinil ▪ Armodafinil ▪ Sunosi • For treatment of cataplexy substantial enough to warrant treatment: o Have a documented 6-week trial with continued cataplexy on one of the following: fluoxetine, venlafaxine ER, or Strattera <u>For continuation of coverage, patient must have met the following requirements</u>: • 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 <u>Duration of Approval</u>: 12 months **Note:** Wakix will not be covered in combination with Xyrem.
Xcopri (cenobamate)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • Diagnosis of partial-onset seizure (documentation confirming diagnosis must be submitted); **AND** • Have a trial and failure with one generic anticonvulsant.

DRUG	CRITERIA
Xeljanz/XR (tofacitinib)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For Ankylosing Spondylitis requests: o Be 18 years of age or older; AND o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. • For Ulcerative Colitis requests: o Be 18 years of age or older; AND o Patient has tried at least ONE systemic agent such as 6-mercaptopuine, azathioprine, cyclosporine, tacrolimus, or corticosteroids for at least 2 months; AND o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. • For Juvenile Idiopathic Arthritis requests: o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. • For Psoriatic Arthritis requests: o Patient will use Xeljanz/Xeljanz XR along with methotrexate or another conventional synthetic DMARD; AND o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, sulfasalazine, or azathioprine) for a period of at least 3 months; AND o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. • For Rheumatoid Arthritis requests: o Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months; AND o Patient has tried at least ONE tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months. Note: Xeljanz/XR will not be covered in combination with another biologic drug. Before Xeljanz/XR is covered, the patient must meet all of the General Criteria for Xeljanz/XR 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.
Xenpozyme (olipudase alfa)	Before this drug is covered, the patient must meet all of the following requirements: • Prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders; AND • Patient has a diagnosis of acid sphingomyelinase deficiency (ASMD) type A/B or type B [supporting documentation confirming diagnosis which includes ASM biochemical enzyme assay demonstrating low ASM enzyme activity (less than 10% of controls) must be submitted to Priority Health] and meets age-specific criteria below: o For adults: diffusion capacity of the lungs for carbon monoxide (DLco) no greater than 70% of predicted normal o For pediatrics: spleen volume at least 6 MN for adults or at least 5 MN For continuation of coverage, patient must have met the following requirements: • Documentation of a clinical response to therapy compared to pretreatment baseline in one or more of the following: reduction in spleen or liver volume, increase in platelet count, improvement in lung function (e.g., DLco) or improvement in symptoms (shortness of breath, fatigue, etc.). Duration of Approval: 6 months (initial); 12 months (continuation) Note: Coverage will not be provided in the following circumstances: a. Patient has acute or rapidly progressive neurologic abnormalities; b. Patient requires use of invasive ventilatory support or requires noninvasive ventilatory support while awake and for greater than 12 hours a day; c. Platelet count less than 60,000/mcL; d. International normalized ratio (INR) greater than 1.5; OR e. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) greater than 250 IU/L or total bilirubin greater than 1.5 mg/dL.

DRUG	CRITERIA
Xermelo (telotristat)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of carcinoid syndrome diarrhea; **AND** • Patient is at least 18 years of age; **AND** • Have been receiving stable dose SSA therapy (either long-acting release [LAR], depot, or infusion pump) for at least 3 months; **AND** • Xermelo will be used in combination with a somatostatin analog (SSA); **AND** • Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2; **AND** • Be experiencing 4 or more bowel movements per day; **AND** • Not have any of the following: o 12 or more watery bowel movements per day o History of short bowel syndrome o Clinically significant elevations in liver function tests o Recently undergone tumor directed therapy. Duration of Approval: 12 months
Xdemvy (lotilaner)	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of Demodex blepharitis as evidenced by: o Presence of at least mild erythema of the upper eyelid margin; **AND** o Presence of mite on examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination; **AND** • Patient is at least 18 years of age; **AND** • Prescribed by or in consultation with an optometrist or ophthalmologist; **AND** • First try ivermectin for the current blepharitis condition. Duration of Approval: 1 fill (10 mL bottle) per 12 months
Xgeva (denosumab)	Before this drug is covered, the patient must meet all of the following requirements: • Have one of the following diagnoses: o Giant cell tumor of bone (unresectable or resection may cause severe morbidity). o Bone metastases from solid tumors previously treated with zoledronic acid (generic Zometa) unless the patient has bone metastases with advanced breast cancer, prostate cancer, or lung cancer. o Multiple myeloma for the prevention of skeletal-related events previously treated with zoledronic acid. Duration of Approval: 12 months

DRUG	CRITERIA
Xiaflex (collagenase)	Before this drug is covered, the patient must meet all of the following requirements: • For Dupuytren's contracture requests, must meet the following: o Flexion contracture of at least one finger, other than the thumb, of greater than or equal to 20 degrees at the MP or PIP joints; **AND** o Be free of chronic muscular, neurological, or neuromuscular disorders affecting the hands; **AND** o Xiaflex is an alternative to surgical intervention. For coverage consideration, please provide the medical reason that surgery would not be an option for the patient. **Note:** For Dupuytren's contracture, the maximum amount covered is up to 3 injections per cord every 4 weeks, with a maximum of 2 injections per hand per visit (which may be administered as either 1 injection per cord on 2 cords affecting 2 different joints **OR** 2 injections on 1 cord affecting 2 joints). • For Peyronie's disease requests, must meet the following: o Penile curvature of 30 degrees or more for 12 months or longer; **AND** o Erections are painful. **Note:** For Peyronie's disease, the maximum amount covered is up to 4 treatment cycles. Each treatment cycle consists of two Xiaflex injections given one to three days apart. Each subsequent treatment cycle must be six-weeks apart and is only authorized if the patient's penile curvature is 15 degrees or more. Duration of Approval: as noted above per condition **Note:** Priority Health considers Peyronie's disease cosmetic in the absence of painful erections.
Xifaxan 550 mg tablet (rifaximin)	Before this drug is covered, the patient must meet all of the following requirements: • Patient has a diagnosis of irritable bowel syndrome (IBS) with diarrhea or hepatic encephalopathy; **AND** • Patient is at least 18 years of age. • For irritable bowel syndrome, must meet the additional criteria: o 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); **AND** o Have a trial of at least three of the following (tried for at least 1 month each): ▪ Loperamide ▪ Antispasmodic (ex. Dicyclomine) ▪ Bile acid sequestrant (cholestyramine, colestipol or colesevelem) ▪ Tricyclic antidepressant (ex. nortriptyline) Duration of Approval: Dependent upon indication **Note:** 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.

DRUG	CRITERIA
Xolair (omalizumab)	<u>Before this drug is covered, the patient must meet all of the following requirements</u>: • For moderate to severe persistent asthma requests: o Patient is at least6 years of age; **AND** o Have a positive skin test or in-vitro reactivity to a perennial aeroallergen (lab results must be submitted); **AND** o Be within the recommended dosing range based on current weight and baseline IgE level; **AND** o Not currently using tobacco products; **AND** o Have been compliant on all of the following therapies for at least 3 months: ▪ High-dose inhaled corticosteroid (ICS) ▪ Long-acting beta agonist (LABA) ▪ One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); **AND** o Be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique); **AND** o Have had at least one of the following: ▪ Oral or systemic steroid treatment or an increase in the current oral steroid maintenance dose ▪ Hospitalization and/or ED visit. ▪ Increasing need for short-acting beta2-agonist. • For chronic urticaria requests: o Patient is at least12 years of age; **AND** o First try two or more H1 antihistamines; **OR** o First try one H1 antihistamine and one or more of the following: ▪ H2 antihistamine, ▪ Oral corticosteroid, ▪ Leukotriene modifier. • For chronic rhinosinusitis with nasal polyp (CRSwNP) requests: o Patient is at least 18 years of age; **AND** o Baseline Nasal Polyps Score (NPS) of at least 5, with a unilateral score of at least 2 for each nostril; **AND** o Symptomatic disease that is persistent for a minimum of 12 weeks, including all of the following: ▪ Nasal obstruction ▪ Rhinorrhea (anterior/posterior) ▪ Diminished or loss of smell; **AND** o Member must have tried and failed all of the following: ▪ At least one prior treatment course with a systemic corticosteroid ▪ Minimum 3 months compliant treatment with an intranasal glucocorticoid ▪ Minimum 1-month trial with either a non-sedating antihistamine or antileukotriene agent (e.g., montelukast). <u>For continuation of coverage, patient must have met the following requirements</u>: • For moderate to severe persistent asthma requests: o Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use). • For chronic urticaria requests: o Have a positive clinical response (reduction in the symptom of urticaria). • For chronic rhinosinusitis with nasal polyp (CRSwNP) requests: o Adherence to therapy including Xolair and intranasal steroid; **AND** o Have a positive clinical response (e.g., 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). <u>Duration of Approval</u>: 12 months **Note:** Xolair is not covered in combination with other biologic drug therapy (e.g. Nucala, Cinqair, Fasenra, Dupixent).

DRUG	CRITERIA
Xyrem (sodium oxybate)	Before this drug is covered, the patient must meet all of the following requirements: • Prescribed by, or in consultation with, a board-certified sleep specialist or neurologist; AND • 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; AND • Xyrem will not be covered in patients who use other sedative hypnotics, drink alcohol when using Xyrem; AND • Meet diagnosis specific criteria below: • For treatment of excessive daytime sleepiness in patients with narcolepsy o Have a documented therapeutic trial with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others, with all of the following: ▪ Amphetamine salts, dextroamphetamine or methylphenidate ▪ Modafinil ▪ Armodafinil ▪ Sunosi; AND o Patient is at least 18 years of age. • For treatment of cataplexy substantial enough to warrant treatment o Have a documented 6-week trial with continued cataplexy on one of the following: fluoxetine, venlafaxine ER, or Strattera; AND o Patient is at least 7 of years of age. For continuation of coverage, patient must have met the following requirements: • 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 Duration of Approval: 12 months Note: Xyrem is limited to a maximum dose of 9 grams per night (558 ml every 31 days). Xyrem will not be covered in combination with Wakix.
Yescarta (axicabtagene cileucel) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Patient is at least at least 18 years of age; AND • Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; AND • Have a diagnosis of relapsed or refractory large B-cell lymphoma including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma; AND • Have received prior treatment with two or more chemoimmunotherapy regimens which included at least one anthracycline-based regimen and an anti-CD20 antibody, unless contraindicated (Yescarta is also covered for large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy); AND • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Note: Yescarta will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling 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. Yescarta will not be authorized for use in patients: • with primary central nervous system lymphoma; or • that have received a previous treatment course of Yescarta or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy. The safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Yescarta is dependent on member's eligibility and benefit plan documents.

DRUG	CRITERIA
Zeposia (ozanimod)	Before this drug is covered, the patient must meet all of the following requirements: • Prescriber is a specialist or has consulted with a specialist for the condition being treated. • For ulcerative colitis requests: o Patient is at least 18 years of age; AND o Patient has tried at least one traditional non-biologic systemic agent (e.g., 6-mercaptopuine, azathioprine, cyclosporine, tacrolimus), or corticosteroids for at least 2 months; AND o Patient has tried Adalimumab AND Stelara for a period of at least 3 months. • For multiple sclerosis requests: o Prior authorization required if ICD-10 diagnosis code for Multiple Sclerosis (MS) is not on file. o First try Glatopa, glatiramer, OR dimethyl fumarate. o Not covered in combination with other disease modifying drugs for MS. Note: Zeposia will not be covered in combination with another biologic drug. 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.
Zolgensma (onasemnogene abeparvovec) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Have a diagnosis of spinal muscular atrophy (SMA); AND • Have genetic testing confirming spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene reports as at least one of the following: homozygous gene deletion, homozygous conversion mutation, or compound heterozygous mutation; AND • Have genetic testing confirming the member has no more than 2 copies of SMN2 or experienced SMA- associated symptoms before 6 months of age; AND • Not have advanced SMA (i.e., complete paralysis of limbs, permanent ventilator dependence); AND • Receive systemic corticosteroid, starting 1 day prior to Zolgensma infusion, equivalent to oral prednisolone 1 mg/kg of body weight for a total of 30 days; AND • Have the following laboratory testing evaluated: o Liver function assessment (including aspartate aminotransferase, alanine aminotransferase, total bilirubin, prothrombin time) at baseline (before Zolgensma infusion) and at least 3 months after infusion; AND o Baseline anti-AAV9 antibody titers (must be less than or equal to 1:50); AND o Platelet count; AND o Troponin-I levels. • Physician attests that the patient, while under the care of the physician, will be assessed by one of the following exam scales during subsequent office visits for a period not to exceed 3 years* o Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) scale during subsequent office visits while the patient is 2 to 3 years of age or younger; OR o Hammersmith Functional Motor Scale Expanded (HFMSE) during subsequent office visits while the patient is 2 to 3 years of age or older; AND • Patient is less than 2 years of age; AND • Prescribed by a neurologist or in consultation with a neurologist with experience treating SMA. *For quality purposes only, this information will not be considered as part of the individual coverage decision. Note: Zolgensma will only be authorized in accordance with FDA-approved dosing for SMA as the safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Zolgensma will not be authorized for use in patients currently treated with Spinraza or Evrysdi. Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Zolgensma is dependent on member's eligibility and benefit plan documents.

DRUG	CRITERIA
Ztalmy (ganaxolone)	Before this drug is covered, the patient must meet the following requirements: • Patient has a diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder and will be using Ztalmy as adjunctive treatment for seizures (documentation must be submitted to PH); AND • Patient is at least 2 years of age; AND • Prescribed by a neurologist; AND • Documented therapeutic failure of at least 2 previous antiepileptic drugs; AND • Member's current weight provided; AND • Documentation of baseline monthly seizure frequency. For continuation of coverage, patient must have met the following requirements: • Confirmation of a sustained reduction in monthly seizure frequency. Duration of Approval: 6 months (initial); 12 months (continuation)
Zulresso (brexanolone)	Before this drug is covered, the patient must meet all of the following requirements: No PA required if ICD10 code for post-partum depression (F53.0) is submitted. Duration of Approval: one treatment per postpartum period
Zynteglo (betibeglogene autotemcel) Gene Therapy	Before this drug is covered, the patient must meet all of the following requirements: • Patient is less than or equal to 50 years of age; AND • Prescribed by a hematologist, transplant specialist, or another board-certified prescriber with qualifications to treat specified condition; AND • Have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 ml/kg/year of pRBCs in the 2 preceding years or for patients at least 12 years of age, at least 8 transfusions of pRBCs per year in the prior 2 years); AND • No known and available HLA-fully matched family donor; AND • If NO donor is known and available, provider attestation that the patient would otherwise be clinically stable and eligible to undergo HSCT; AND • Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 OR Karnofsky performance status of at least 80 for adults (at least 16 years of age) or a Lansky performance status of at least 80 for adolescents or children (less than 16 years of age). Note: Zynteglo will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling. Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles. Zynteglo will not be authorized for use in patients: • that have a previous history of hematopoietic stem cell transplant (HSCT); OR • that have received a previous treatment course of Zynteglo or another gene therapy. The safety and effectiveness of repeat administration have not been evaluated (one treatment per lifetime). Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s). Coverage of Zynteglo is dependent on member's eligibility and benefit plan documents.