Priority Health
Employer Group and
MyPriority Plans

Medical Drug Prior Authorization Criteria

July 2026

This manual is updated frequently. Last revised: July 01, 2026

Priority Health™

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 Medical Drug List (MDL).

How to know when a medication requires prior authorization

The best way to know when a medication requires prior authorization is to use the Medical Drug List (MDL) tool. The MDL 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 Medical Drug List (MDL) for your plan's drug coverage, with the following prior authorization forms:

- Medical Prior Authorization form (general form used to request coverage for medications administered by a healthcare provider under your medical benefit requiring prior authorization)
- Oncology Medical Drug Request form (general form used to request coverage for chemotherapeutic medications requiring prior authorization under the medical benefit)

These forms may also be used when requesting coverage for medications that may not be listed under the MDL (e.g., formulary exception requests), or for quantities that exceed the limits stated on either the MDL (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(s) is required. Failure of a drug for prior authorization purposes may be defined in the prior authorization criteria in a way that is specific to the drug and/or disease (e.g. a laboratory measurement or disease activity score may be assessed). When not defined in the prior authorization criteria, drug failure shall be broadly interpreted as a lack of adequate therapeutic response when the drug was used appropriately in a way that was consistent with the label and drug compendia or guidelines, taken adherently, and for an adequate period of time to assess the outcome. When prior authorization criteria require failure of other drugs before coverage is offered, the plan limits the accepted drug trials to drugs that the plan covers or prefers (i.e. Nonformulary and nonpreferred drugs will not satisfy requirements that preferred and/or cost-effective drugs be used first for the purposes of prior authorization).

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.

Adakveo

Products Affected

- Adakveo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:

- Initial: 6 months
- Continuation: 12 months

Adzynma

Products Affected

- Adzynma

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Adzynma (ADAMTS13, recombinant)

Before this drug is covered, the patient must meet all of the following requirements:

- Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by genetic testing with ADAMTS13 activity is provided and is less than 10% (supporting documentation must be submitted to Priority Health); **AND**
- Provide documentation of current weight; **AND**
- Patient is at least 18 years of age; **AND**
- Must be prescribed by or in consultation with a specialist for the disease state.

For continuation of coverage, patient must have met the following requirements:

- Has demonstrated a beneficial response to therapy (e.g. decrease in acute and subacute TTP events, improvement in platelet count from baseline, decrease in microangiopathic hemolytic anemia episodes).

Duration of Approval:

- Initial: 6 month
- Continuation: 12 months

Note: Initial dosing frequency for prophylactic use is not to exceed every 2 weeks.

Afilibercept

Products Affected

- Eylea
- Eylea HD
- Pavblu

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Afilibercept (ophthalmic)

Preferred Agent(s):

- **Eylea**
- **Eylea HD**
- **Pavblu**

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:
  - Retinopathy of Prematurity (ROP):
    - Diagnosis of ROP must be included in request.
  - 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.
  - 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.
  - Diabetic macular edema (DME) with baseline visual acuity 20/50 or worse:
    - Baseline best-corrected visual acuity (BCVA) score must be included in request.
  - 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.

- 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 afilibercept 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

Aldurazyme

Products Affected

- Aldurazyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Alpha1-proteinase Inhibitors

Products Affected

- Aralast NP
- Glassia
- Prolastin-C
- Zemaira

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: 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:
  - 11 mmol/L is equal to 80 mg/dL if measured by radial immunodiffusion; **OR**
  - 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

Antimigraine Agents, Preventive Treatment

Products Affected

- Vyepti

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Antimigraine Agents, Preventive Treatment

Preferred Agent(s):

- **Aimovig (erenumab) - Pharmacy Benefit Drug**
- **Emgality (galcanezumab) - Pharmacy Benefit Drug**
- **Ajovy (fremanezumab) - Pharmacy Benefit Drug**

Non-Preferred Agent(s):

- **Qulipta (atogepant) - Pharmacy Benefit Drug**
- **Vyepti (eptinezumab) - Medical Benefit Drug**

Before this drug is covered, the patient must meet all of the following requirements:

- For migraine headache requests:
  - Patient has a diagnosis of migraine with or without aura; **AND**
  - Patient has at least four migraine days per month; **AND**
  - Patient has tried 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)
  - 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 continuation of coverage, the patient must have met the following

requirements:

- For migraine headache requests:
  - Demonstrate effectiveness (more than 50% reduction in monthly migraine days).

Duration of Approval:

- For migraine headache requests: 12 months

Note:

- Vyepti, Qulipta are not covered in combination with Botox or any other branded prophylactic agent.
- 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.
- "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to step therapy requirements.

Antiretroviral Agents, Miscellaneous

Products Affected

- Trogarzo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Antiretroviral Agents, Miscellaneous

Preferred Agent(s):

- **Sunlenca (lenacapavir) - Pharmacy Benefit Drug**

Non-Preferred Agent(s):

- **Rukobia (fostemsavir) - Pharmacy Benefit Drug**
- **Trogarzo (ibalizumab) - Medical Benefit Drug**

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:

- Initial: 6 months
- Continuation: 12 months

Benlysta

Products Affected

- Benlysta intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Benlysta (belimumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For active, autoantibody-positive systemic lupus erythematosus (SLE) requests:
  - Patient is at least 5 years of age; **AND**
  - 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**
  - 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.

- For biopsy-proven lupus nephritis Class III through V:
  - Patient is at least 5 years of age; **AND**
  - 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**
  - Have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants); **AND**
  - Not have an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2

For continuation of coverage, patient must have met the following requirements:

- For active, autoantibody-positive systemic lupus erythematosus (SLE) requests, patient must have met 3 of 6 of the following requirements:

- Have a SELENA-SLEDAI score point reduction of 4 or more based on a 30-day assessment
- Have a Physician Global Assessment change indicating showing no disease progression (worsening) compared to baseline treatment with Benlysta
- 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)
- A reduction in dose of steroid therapy
- A negative seroconversion or a 20% reduction in autoantibody levels from baseline
- Free of significant clinical flares that require steroid boost treatment with Benlysta.

- For biopsy-proven lupus nephritis Class III through V:
  - 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:

- Initial: 6 months
- Continuation: 12 months

Note: Benlysta is not covered in combination with other biologic drug therapy (e.g., Gazyva, rituximab), Lupkynis (voclosporin), or in patients with central nervous system manifestations.

Botulinum toxins

Products Affected

- Botox
- Daxxify
- Dysport
- Myobloc
- Xeomin

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: 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®).
- **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:
        - Antidepressants (e.g., amitriptyline, nortriptyline)
        - Beta blockers (e.g., propranolol, metoprolol, timolol)
        - 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.

Brineura

Products Affected

- Brineura intraventricular kit

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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**
- 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

Casgevy

Products Affected

- Casgevy

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Casgevy (exagamglogene autotemcel)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- For Beta Thalassemia requests:
  - 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**
  - Prescribed by a hematologist, transplant specialist, or another board-certified prescriber with qualifications to treat specified condition; **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).

- For Sickle Cell requests:
  - Have a diagnosis of Sickle Cell Disease (SCD) with βS/βS, βS/β0, or βS/β+ genotype; **AND**
  - Documentation submitted supporting member has severe disease (i.e. ≥ 2 severe VOEs per year in the previous 2 years); **AND**
  - Absence of an HLA-matched donor for HSCT; **AND**
  - Patient has tried at least **TWO** of the following:

        - hydroxyurea, Adakveo each for a period of at least 6 months; **AND**
    - Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider.

Note: Casgevy 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.

- Casgevy 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 Casgevy 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 Casgevy is dependent on member's eligibility and benefit plan documents.

Cerezyme

Products Affected

- Cerezyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Cerezyme (imiglucerase)

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of Non-neuropathic Gaucher's disease, chronic, symptomatic.

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: clinically significant reduction in spleen or liver volume, increase in platelet or hemoglobin values.

Duration of Approval: 12 months

Cimzia

Products Affected

- Cimzia Powder for Reconst

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Cimzia (certolizumab)

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:
  - Patient has tried at least **TWO** of the following:
    - adalimumab, Cosentyx, Enbrel, Xeljanz/XR each for a period of at least 3 months.
- For **Non-radiographic axial spondyloarthritis (nr-axSpA)** requests:
  - 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:
  - Patient has a diagnosis of moderate to severe Crohn's disease; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
  - Patient has tried at least **ONE** of the following:
    - adalimumab, infliximab, ustekinumab for a period of at least 3 months.
- For **Juvenile Idiopathic Arthritis** requests:
  - Patient has tried at least **TWO** of the following:
    - adalimumab, Enbrel, tocilizumab, Xeljanz/XR, each for a period of at

least 3 months.

- For **Psoriatic Arthritis** requests:
  - 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**
  - Patient has tried at least **TWO** of the following:
    - Cosentyx, Enbrel, adalimumab, Xeljanz/XR, Otezla/XR, ustekinumab, each for a period of at least 3 months.

- For **Rheumatoid Arthritis** requests:
  - 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**
  - Patient has tried at least **TWO** of the following:
    - tocilizumab, Enbrel, adalimumab, or Xeljanz/XR each for a period of at least 3 months.

- For **Plaque Psoriasis** requests:
  - Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND**
  - Patient has tried at least **TWO** of the following:
    - Cosentyx, Enbrel, adalimumab, Otezla/XR, or ustekinumab, 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Cinqair

Products Affected

- Cinqair

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Cinqair (reslizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **AND**
- Patient has tried the following:
  - One inhaled corticosteroid (ICS) **AND**
  - One additional asthma controller medication (e.g., long-acting beta agonist, long-acting anti-muscarinic agent, leukotriene receptor antagonist); **AND**
- Have had at least one asthma exacerbation in the previous year.

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: Cinqair is not covered in combination with other biologic drug therapy.

Cosela

Products Affected

- Cosela

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical Oncology drug request form or Web Form.

Drug: Cosela (trilaciclib)

Before this drug is covered, the patient must meet all of the following requirements:

- For chemotherapy-induced myelosuppression requests:
  - Have a diagnosis of extensive small cell lung cancer (SCLC); **AND**
  - Is receiving platinum/etoposide +/- immune checkpoint inhibitor OR a topotecan-containing regimen; **AND**
  - Have previously experienced severe neutropenia while using one of the regimens described above, despite use of G-CSF products (i.e. filgrastim, pegfilgrastim).

For continuation of coverage, patient must have met the following requirements:

- 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.

Duration of Approval: 12 months

Cresemba

Products Affected

- Cresemba intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Cresemba (isavuconazole)

Before this drug is covered, the patient must meet all of the following requirements:

- 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.

For continuation of coverage, patient must have met the following requirements:

- Have a positive clinical response to Cresemba as evidenced by experiencing disease stability or improvement.

Duration of Approval:

- Initial: 3 months
- Continuation: 12 months

Crysvita

Products Affected

- Crysvita

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Crysvita (burosumab)

Before this drug is covered, the patient must meet all of the following requirements:

- Treatment of X-linked hypophosphatemia (XLH) in patients 6 months of age and older. Diagnosis must be confirmed by:
  - Genetic testing (PHEX-gene mutation), **OR**
  - 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.).

For continuation of coverage, patient must have met the following requirements:

- 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).

Duration of Approval: 12 months

Note: Dosing of Crysvita should not be adjusted more frequently than every 4 weeks

and must be administered by a healthcare professional.

Dalbavancin

Products Affected

- dalbavancin

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Dalbavancin (generic for Dalvance)

Before this drug is covered, the patient must meet all of the following requirements:

- 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).

Duration of Approval: One to two dose infusion (based on FDA-approved labeling).

Duopa

Products Affected

- Duopa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - Dopamine agonist (e.g. pramipexole, ropinirole); **OR**
  - Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline); **OR**
  - 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

Eculizumab

Products Affected

- Epysqli

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Eculizumab

Preferred Agent(s):

- **Epysqli (eculizumab-aagh)**

Before this drug is covered, the patient must meet all of the following requirements:

- Paroxysmal nocturnal hemoglobinuria (PNH) requests:
  - 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).

- Atypical hemolytic uremic syndrome (aHUS) requests:
  - Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out.

- Refractory generalized myasthenia gravis (MG) requests:
  - 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 6; **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**
- Trial and failure of Vyvgart; **AND**
- Prescribed by or in consultation with a neurologist.

- Neuromyelitis optica spectrum disorder (NMOSD) requests:
  - Confirmed diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (documentation must be provided); **AND**
  - Be 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, inebilizumab (Uplizna) **AND** satralizumab (Enspryng); **AND**
  - Expanded Disability Status Scale (EDSS*) score of less than or equal to 7.

For continuation of coverage, patient must have met the following requirements:

- Paroxysmal nocturnal hemoglobinuria (PNH) requests:
  - Have a decrease disabling symptoms; **AND**
  - Hemoglobin levels must be stabilized; **AND**
  - Patient has experienced an improvement in fatigue and quality of life.

- Atypical hemolytic uremic syndrome (aHUS) requests:
  - Have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine).
  - Refractory generalized myasthenia gravis (MG) requests:
  - 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:
  - Have documentation of a decrease in relapse rate.

Duration of Approval:

- Initial: 12 weeks
- Continuation: 12 months

Note: Epysqli will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Imaavy, Rystiggo, Ultomiris, Vyvgart, Zilbrysq.

Elaprase

Products Affected

- Elaprase

Criteria Details

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Elelyso

Products Affected

- Elelyso

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Products Affected

- Elzonris

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical Oncology drug request form or Web Form.

Drug: 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).
- 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

Products Affected

- Empaveli

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Empaveli (pegcetacoplan)

Before this drug is covered, the patient must meet all of the following requirements:

- Paroxysmal nocturnal hemoglobinuria (PNH) requests:
  - Have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): **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).

- Complement 3 glomerulopathy (C3G) requests:
  - Confirmed diagnosis of complement 3 glomerulopathy (C3G) via renal biopsy (supporting documentation must be submitted to Priority Health); **AND**
  - Patient has tried and failed **ALL** of the following:
    - Maximally tolerated dose of ACE inhibitor or ARB (minimum of 3 months); **AND**
    - 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**
  - Patient is not currently receiving dialysis and has not undergone kidney transplant; **AND**
  - Prescribed by or in consultation with a nephrologist.

For continuation of coverage, the patient must have met the following requirements:

- Paroxysmal nocturnal hemoglobinuria (PNH) requests:
  - Have a decrease in disabling symptoms; **AND**
  - Hemoglobin levels have stabilized; **AND**
  - Patient has experienced an improvement in fatigue and quality of life.

- Complement 3 glomerulopathy (C3G) requests:
  - Patient is not currently receiving dialysis and has not undergone kidney transplant; **OR**
  - Have eGFR of at least 15 mL/min/1.73 m2.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Empaveli is not covered in combination with other complement drug therapy (e.g., Soliris/Epysqli, Ultomiris, Fabhalta).

Encelto

Products Affected

- Encelto

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Encelto (revakinagene taroretcel)

Gene/Cellular Therapy

Before this drug is covered, the patient must meet all of the following requirements:

- Have confirmed diagnosis MacTel type 2 (supporting documentation must be submitted to Priority Health); **AND**
- Have documentation of IS/OS PR break (loss) in EZ between 0.16 and 2.00 mm2c; **AND**
- Have a BCVA score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart; **AND**
- Have no evidence of neovascular MacTel type; **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by an ophthalmologist.

Note: Encelto 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.

Encelto will not be authorized for use in patients:

- that have received a previous Encelto implant. The safety and effectiveness of repeat administration have not been evaluated (**one treatment per eye per lifetime**).

Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).

Coverage of Encelto is dependent on member's eligibility and benefit plan documents.

Enjaymo

Products Affected

- Enjaymo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Enjaymo (sutimlimab)

Before this drug is covered, the patient must meet all of the following requirements:

- 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.

For continuation of coverage, patient must have met the following requirements:

- 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.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Entyvio IV

Products Affected

- Entyvio

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Entyvio IV (vedolizumab)

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:
  - Patient has a diagnosis of moderate to severe Crohn's disease; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
  - Patient has tried at least **TWO** of the following:
    - adalimumab, Cimzia, infliximab, ustekinumab, each for a period of at least 3 months.

- For **ulcerative colitis** requests:
  - Patient has a diagnosis of moderate to severe Ulcerative Colitis; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
  - Patient has tried at least **TWO** of the following:
    - adalimumab, infliximab, Omvoh, Simponi, ustekinumab, Xeljanz/XR, each for a period of at least 3 months.

Note: Entyvio will not be covered in combination with another biologic drug. Before Entyvio is covered, the patient must meet all of the General Criteria for Entyvio 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, two IV induction doses given at week 0 and 2 will be covered under the medical benefit. Subsequent maintenance doses can be covered under the medical benefit (continued IV dosing) or the pharmacy benefit (subcutaneous pens).

Enzyme Replacement Inhibitors, Fabry Disease

Products Affected

- Elfabrio
- Fabrazyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: 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:
  - Classically affected assigned male at birth (i.e. assigned at birth male with very low or undetectable levels of alpha-galactosidase A [alphaGal A]); **OR**
  - Assigned female at birth carrier or assigned male at birth 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

Evenity

Products Affected

- Evenity

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Evenity (romosozumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For postmenopausal osteoporosis in patients at a high risk for fracture and no history of an osteoporotic/fragility fracture, the patient must meet the following:
  - 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**
  - Have a documented treatment failure, contraindication* or ineffective response** to a minimum of a 12-month trial with zoledronic acid (generic Reclast) **OR** denosumab (also requires prior authorization).

- For postmenopausal osteoporosis in patients at very high risk for fracture the patient must meet the following:
  - Have a documented T-score of -3.0 or less, a T-score of -2.5 or less with a fragility fracture, or a history of severe or multiple fragility fractures regardless of T-score.

**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.

Duration of Approval: 12 months

Note: Evenity is not covered in combination with other injectable drugs for the treatment of osteoporosis (e.g., denosumab, Tymlos, Forteo). If osteoporosis therapy remains warranted beyond 12 months, continued therapy with an anti- resorptive agent should be considered.

Evkeeza

Products Affected

- Evkeeza

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Evkeeza (evinacumab)

Before this drug is covered, the patient must meet all of the following requirements:

- 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:
  - Presence of two mutant alleles at the LDL receptor, Apolipoprotein B, or PCSK9 gene; **OR**
  - 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:
  - Patient must continue to receive maximally tolerated statin therapy or have a intolerance/contraindication of statin therapy.
  - 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.

For continuation of coverage, the patient must have met the following requirements:

- Have improved and maintained an improved LDL compared to baseline.

Duration of Approval: 12 months

Note: Evkeeza is not covered in combination with Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe), or a PCSK9 inhibitor (Repatha, Praluent).

Fasenra

Products Affected

- Fasenra

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Fasenra (benralizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For **severe eosinophilic asthma** requests:
  - Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **AND**
  - Patient has tried the following:
    - One inhaled corticosteroid (ICS) **AND** one additional asthma controller medication (e.g., long-acting beta agonist, long-acting anti-muscarinic agent, leukotriene receptor antagonist); **AND**
  - Have had at least one asthma exacerbation in the previous year

- For **eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss)** requests:
  - Diagnosis of EGPA confirmed by a peripheral blood eosinophil count greater than 1,000 cells/mcL or at least 10% of leukocytes; **AND**
  - Patient has tried **ONE** of the following:
    - One systemic corticosteroid; **OR**
    - One immunosuppressive therapy

For continuation of coverage, the patient must have met the following requirements:

- For **severe eosinophilic asthma** requests:
  - 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:
    - 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].

Duration of Approval: 12 months

Note: Fasenra is not covered in combination with other biologic drug therapy.

Gamifant

Products Affected

- Gamifant

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Gamifant (emapalumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For **HLH** requests:
  - Have a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) that is refractory/recurrent or progressive disease confirmed by genetic testing (supporting documentation must be submitted to Priority Health); **AND**
  - Have previously tried and failed on conventional therapy (e.g. etoposide, dexamethasone, cyclosporine).

- For **HLH/MAS** requests:
  - Have a diagnosis of HLH/macrophage activation syndrome in known or suspected Still's disease; **AND**
  - Have previously tried and failed on conventional therapy (e.g., systemic glucocorticoids).

For continuation of coverage, patient must have met the following requirements:

- Have objective evidence of response to therapy (i.e. normalization of HLH abnormalities).

Duration of Approval: 3 months

Note: Gamifant is not covered in combination with other biologic drug therapy.

Gazyva

Products Affected

- Gazyva

Criteria Details

Priority Health

Depending on the condition, click and complete the Web Form or:

- Employer Group & MyPriority Plans Medical Oncology drug request form
- Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form

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Drug: Gazyva (obinutuzumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For follicular lymphoma, chronic lymphocytic leukemia, and diffuse large B cell lymphoma, please refer to the Oncology Agents criteria.
- For biopsy-proven lupus nephritis Class III through V:
  - Patient is at least 18 years of age; **AND**
  - 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**
  - Have active renal disease requiring use of standard therapy (e.g., corticosteroids, immunosuppressants); **AND**
  - Not have an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2.

For continuation of coverage, the patient must have met the following requirements:

- For biopsy-proven lupus nephritis Class III through V:
  - Have evidence of efficacy (defined as urinary protein creatinine ratio no greater than 0.5, eGFR no greater than 15% below the pre-flare or at least 60mL/min/1.73m2), **AND**
  - No use of rescue therapy for treatment failure.

Duration of Approval:

- Initial: 6 Months
- Continuation: 12 months

Note: Gazyva is not covered in combination with other biologic drug therapy (e.g. Benlysta, rituximab) or Lupkynis.

Givlaari

Products Affected

- Givlaari

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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
- Continuation: 12 months

Hemophilia Products, Hemophilia A

Products Affected

- Roctavian

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Hemophilia Products, Hemophilia A

- ***Gene/Cellular Therapy***

Preferred Agent(s):

- **Roctavian (valoctocogene roxaparvovec)**

Non-Preferred Agent(s):

- *Not Applicable*

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**
- Patient is at least 18 years of age; **AND**
- Prescribed by or in consultation with a hematologist; **AND**
- Have one of the following:
  - 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**
  - Patient has current or historical life-threatening hemorrhage; **OR**
  - 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.

Hemophilia Products, Hemophilia B

Products Affected

- Hemgenix

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Hemophilia Products, Hemophilia B

- ***Gene/Cellular Therapy***

Preferred Agent(s):

- **Hemgenix (etranacogene dezaparvovec)**

Non-Preferred Agent(s):

- *Not Applicable*

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**
- Patient is at least 18 years of age; **AND**
- Prescribed by or in consultation with a hematologist; **AND**
- Have one of the following:
  - 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**
  - Patient has current or historical life-threatening hemorrhage; **OR**
  - 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, Miscellaneous

Products Affected

- Qfitlia
- Qfitlia Pen

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Hemophilia Products, Miscellaneous

Preferred Agent(s):

- **Alhemo (concizumab) - *Pharmacy Benefit Drug***
- **Hemlibra (emicizumab) - *Pharmacy Benefit Drug***
- **Hympavzi (marstacimab) - *Pharmacy Benefit Drug***

Non-Preferred Agent(s):

- **Qfitlia (fitusiran) - *Medical Benefit Drug***

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 routinely receive extended half-life factor VIII replacement products (e.g., Eloctate, Adynovate, Jivi, Esperoct, Altuviiio) or longer-lasting factor IX replacement products (e.g., Alprolix, Idelvion, Rebinyn) for the treatment of breakthrough bleeding episodes.
- For **hemophilia A** requests (Hemlibra, Hympavzi, Alhemo, Qfitlia):
  - Diagnosis of Hemophilia A with factor VIII inhibitors; **OR**
  - Diagnosis of severe hemophilia A without factor VIII inhibitors (endogenous factor VIII level less than 1% of normal factor VIII) or moderate hemophilia A with at least two documented episodes of spontaneous bleeding into joints (supporting documentation must be submitted to Priority Health); **AND**

- Trial and failure (e.g. repeated, serious spontaneous bleeding episodes, or prolonged bleeding with minor trauma/surgery with documentation of the number of bleeds in the past year), intolerance (including but not limited to dosing frequency issues), or contraindication to factor VIII prophylaxis therapy.

- For **hemophilia B** requests (Hympavzi, Alhemo, Qfitlia):
  - Diagnosis of Hemophilia B with factor IX inhibitors; **OR**
  - Diagnosis of severe hemophilia B without factor IX inhibitors (factor IX level less than less than or equal to 2% of normal) or moderate hemophilia B with at least two documented episodes of spontaneous bleeding into joints (supporting documentation must be submitted to Priority Health) **AND**
  - Trial and failure (e.g. repeated, serious spontaneous bleeding episodes, or prolonged bleeding with minor trauma/surgery with documentation of the number of bleeds in the past year), intolerance (including but not limited to dosing frequency issues), or contraindication to factor IX prophylaxis therapy

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 or factor IX replacement products or bypassing agents). Supporting documentation must by submitted to Priority Health.

Duration of Approval: 12 months

Note: Hemlibra, Hympavzi, Alhemo, Qfitlia are not covered in combination with prophylactic use of other factor VIII or IX replacement products or bypassing agents. Coverage of these agents is limited to the FDA approved dosing.

Ilaris

Products Affected

- Ilaris (PF)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Ilaris (canakinumab)

Before this drug is covered, the patient must meet all of the following requirements:

- 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; **OR**
- Have a diagnosis of acute gout flare; **AND**
  - Has had three or more flares in the last 12 months; **AND**
  - Patient has tried lifestyle modifications such as reduced alcohol consumption, discontinuing or changing other medications known to precipitate gout attacks when possible); **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy including colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), **AND** systemic corticosteroids.

For continuation of coverage, the patient must have met the following requirements:

- For gout flares requiring treatment beyond the initial dose, patient must be established on maintenance therapy with urate-lowering agents such as allopurinol, febuxostat, and/or probenecid.

Duration of Approval:

- **Gout:**
  - Initial: single dose for 12 weeks
  - Continuation: 12 months
- **CAPS, FCAS, MWS, FMF, sJIA/AOSD:** 12 months

Note: Ilaris will not be covered in combination with another biologic drug. Before Ilaris is covered, the patient must meet all of the General Criteria for Ilaris 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Ilumya

Products Affected

- Ilumya

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND**
  - Patient has tried at least **TWO** of the following:
    - Cosentyx, Enbrel, adalimumab, Otezla/XR, or ustekinumab, 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Imaavy

Products Affected

- Imaavy

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Imaavy (nipocalimab)

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of refractory generalized myasthenia gravis (MG) that is 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.

For continuation of coverage, patient must have met the following requirements:

- Have documented response as evidenced by BOTH of the following:
  - improved MG-ADL total score from baseline (at least a 2-point reduction); **AND**
  - improved (QMG) total score from baseline (at least a 3-point improvement).

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Imaavy will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Soliris/Epysqli, Ultomiris, Rystiggo, Vyvgart, Zilbrysq.

Immune Globulin (IVIG, SCIG)

Products Affected

- Cutaquig
- Cuvitru
- Flebogamma DIF
- Gammagard Liquid
- Gammagard Liquid ERC
- Gammagard S-D (IgA < 1 mcg/mL)
- Gammaked
- Gammaplex
- Gammaplex (with sorbitol)
- Gamunex-C
- Hizentra
- HyQvia
- Octagam
- Privigen
- Xembify

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Intravenous Immune Globulin (Preferred)*

- J1572 Flebogamma / Flebogamma DIF
- J1569 Gammagard Liquid / Gammagard ERC
- J1557 Gammaplex
- J1561 Gamunex-C / Gammaked
- J1568 Octagam
- J1459 Privigen

** Asceniv, Alyglo, Bivigam, Gammagard S/D, Panzyga, Yimmugo, Qivigy not covered*

Subcutaneous Immune Globulin (Non-Preferred)

- J1555 Cuvitru
- J1551 Cutaquig
- J1559 Hizentra
- J1557 HyQvia
- J1558 Xembify

IMMUNE GLOBULIN COVERAGE POLICY

Priority Health considers conditions not listed in the Immune Globulin Coverage Policy to be not medically necessary.

Required Prescriber Compliance

Submission of an immune globulin prior authorization request constitutes the prescriber's agreement to comply with the requirements outlined below. Approval and continuation of therapy are contingent upon adherence to these conditions:

- The prescriber will objectively monitor and document patient progress/improvement during immune globulin therapy. Requests to continue therapy will not be considered medically necessary in the absence of documented objective, quantitative assessment(s). All continuation requests must include documentation of the same baseline objective assessment(s) performed prior to initiation of therapy.
- The prescriber will attempt dose reduction for future requests once clinical improvement has occurred and will discontinue immune globulin therapy if improvement is sustained with a reduced dose. This requirement does not apply to authorizations for primary immunodeficiency, provided immunoglobulin levels are maintained within the appropriate range as referenced in *Table 1*.

Dosing requirements

Dosing should be calculated using adjusted body weight if the patient's:

- body mass index (BMI) is 30kg/m2 or more; or
- actual body weight is 20% higher than his or her ideal body weight (IBW)

Use the following dosing formulas to calculate the adjusted body weight (round dose to nearest 5 gram increment in adult patients):

Dosing formulas
BMI = 703 x (weight in pounds/height in inches^2)
IBW(kg) for males = 50 + [2.3 (height in inches – 60)]
IBW(kg) for females = 45.5 + [2.3 x (height in inches – 60)]
Adjusted body weight = IBW + 0.5 (actual body weight – IBW)

Table 1

Refer to the covered dosing section of this policy for additional details about covered dosing.

Precertification Requirements

The patient must meet all of the following criteria:

- Diagnosis of the disorder must be reasonably certain and based on a thorough history, physical examination, and appropriate laboratory testing (e.g., electromyography [EMG], spinal fluid tests, serum tests, and biopsy findings).
- Documentation of previous treatment failures must be provided.
- In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for individuals with rapidly progressive disease in which a clinical response could not be achieved quickly enough using conventional agents. In these situations, IVIG therapy should be administered in conjunction with conventional treatment(s); however, continued administration of IVIG is not considered medically necessary once conventional therapy has taken effect.
- Any metric assessment used for objective monitoring of progress is acceptable, including the Medical Research Council (MRC) scale (most commonly used for muscle strength), the INCAT Disability Scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to support continuation of IVIG or coverage.
- Clinical monitoring takes precedence over laboratory monitoring. If clinical improvement is evident, laboratory monitoring solely to guide IVIG therapy is not considered medically necessary.
- If improvement does not occur with IVIG therapy, continued infusion may not be considered medically necessary.
- The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the diagnosis prior authorization criteria below. Dosing recommendations are listed in Table 1.
- Coverage for subcutaneous immunoglobulin therapy requires trial and failure of at least one preferred intravenous immunoglobulin formulation listed above (e.g., poor venous access or documented adverse reactions).

The Medical Research Council (MRC) scale is the most commonly used grading of muscle strength.

Scale:

0 = no muscle improvement
1 = flicker of muscle movement
2 = trace movement but not able to fully overcome gravity
3 = just able to overcome gravity
4 = moves against resistance, but weak
5 = full strength against resistance

INCAT Disability scale of the arm or leg:

Arm disability:

0 = no upper limb problems
1 = symptoms, in one or both arms, not affecting the ability to perform any of the following functions: doing all zips and buttons; washing or brushing hair; using a knife and fork together; handing small coins
2 = symptoms, in one arm or both arms, affecting but not preventing any of the above mentioned functions
3 = symptoms, in one arm or both arms, preventing one or two of the above mentioned functions
4 = symptoms, in one arm or both arms, preventing three or all of the functions listed, but some purposeful movements still possible
5 = inability to use either arm for any purposeful movement

Leg disability:

0 = walking not affected
1 = walking affected, but walks independently outdoors
2 = usually uses unilateral support (stick, single crutch, one arm) to walk outdoors
3 = usually uses bilateral support (sticks, crutches, frame, two arms) to walk outdoors
4 = usually uses wheelchair to travel outdoors, but able to stand and walk a few steps with help
5 = restricted to wheelchair, unable to stand and walk a few steps with help

General Documentation Requirements

When requesting immune globulin for a patient not previously approved by Priority Health, the request must include the patient's history of previous therapies, including when therapies were tried and the outcomes. A relevant copy of the patient's medical record must be provided.

Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes demonstrating the patient's response to immune globulin therapy.

Specific Documentation Requirements

Specific documentation requirements are listed under the following sections:

1. Primary immunodeficiency

2. Hematologic conditions
3. Neurological conditions
4. Autoimmune disorders
5. Dermatologic conditions

Section 1: Primary Immunodeficiency

Priority Health covers immune globulin for the following primary immunodeficiencies:

- Hypogammaglobulinemia, unspecified
- Selective IgM immunodeficiency
- Other selective immunoglobulin deficiencies
- X-linked agammaglobulinemia
- X-linked immunodeficiency with hyper IgM
- Severe combined immunodeficiency (SCID)
- Common variable immunodeficiency
- Wiskott-Aldrich syndrome

For all primary immunodeficiencies and secondary immunosuppression, the following criteria must be met:

1. Patient's IgG level is less than 200 mg/dL
   - **OR**
2. Patient has a history of *multiple hard-to-treat infections**;
3. Patient has a deficiency in producing antibodies in response to vaccination;
4. Baseline titers were drawn before challenging with vaccination; *and*
5. Post-vaccination titers were obtained 48 weeks after vaccination (with less than 70% of antigens in the protective range).

**Multiple hard-to-treat infections* means:

a. Four or more ear infections within one year;
b. Two or more serious sinus infections within one year;
c. Two or more months of antibiotics with little effect;
d. Two or more pneumonias within one year;
e. Recurrent or deep skin abscesses;
f. Need for intravenous antibiotics to clear infections; *or*
g. Two or more deep-seated infections, including septicemia

In addition, for secondary immunosuppression, immune globulin is covered when

the patient's hypogammaglobulinemia is caused by solid organ transplant, extensive surgery, allograft rejection, hematological malignancy, extensive burns, or collagen-vascular disease.

For chronic lymphoid leukemia (CLL), the following criteria must be met:

1. Patient has a history of *multiple hard to treat infections**;
2. The patient has a deficiency in producing antibodies in response to vaccination;
3. Baseline titers were drawn before challenging with vaccination; *and*
4. Titers were draw between four and eight weeks of vaccination (less than 70% of antigens are in protective range)

**Multiple hard-to-treat infections* means:

a. Four or more ear infections within one year;
b. Two or more serious sinus infections within one year;
c. Two or more months of antibiotics with little effect;
d. Two or more pneumonias within one year;
e. Recurrent or deep skin abscesses;
f. Need for intravenous antibiotics to clear infections; *or*
g. Two or more deep-seated infections, including septicemia

Section 2: specific documentation requirements for hematologic conditions

For primary thrombocytopenia, the following requirements must be met:

1. For treatment of acute ITP, a rapid rise in platelet count must be medically necessary. Medically necessary means:

a. immune globulin is used before surgery and the platelet count is less than 100,000/mm^3;
b. patient has acute bleeding and platelet count is less than 30,000/mm^3; *or*
c. patient is at risk for intracerebral hemorrhage (i.e. platelet is less than 20,000/mm^3)

2. For treatment of chronic ITP, the patient:

a. must be age 10 or older;

b. must have a platelet count less than 30,000/mm^3 for children or less than 20,000/mm^3 for adults;
c. has illness present for more than six months; *and*
d. failed, has a contraindication to, or is intolerant to corticosteroid therapy

For renewals, achievement and maintenance of a platelet count equal to or greater than 50 x 10^9/L and
documented in the patient's medical record indicates a disease response.

For ITP in pregnancy and fetal alloimmune thrombocytopenia, one of the following criteria must be met:

1. The patient is refractory to steroids with a platelet count less than 10,000/mm^3 during her third trimester;
2. The platelet count is less than 30,000/mm^3 and associated with bleeding prior to vaginal delivery or C-section;
3. The patient previously delivered infants with autoimmune thrombocytopenia;
4. At 20 weeks gestation or later, cordocentesis reveals fetal platelets less than 20,000/mm^3; *or*
5. Screening reveals platelet alloantibodies

For neonatal alloimmune thrombocytopenia, immune globulin is not covered for routine use. Both of the following criteria must be met:

1. the patient is severely thrombocytopenic (i.e. a platelet count less than 30,000/mm^3) and/or symptomatic; *and*
2. the neonate failed, has a contraindication to, or is intolerant to platelet transfusions

For post-transfusion purpura, one of the following criteria must be met:

1. platelet count is less than 10,000/mm^3; *or*
2. the patient experienced bleeding complications due to thrombocytopenia

For autoimmune hemolytic anemia, immune globulin is not covered for routine use. All the following criteria must be met:

1. The patient has warm-type AIHA;
2. The patient failed, has a contraindication to, or intolerance to corticosteroid therapy; *and*
3. The patient had a splenectomy or is the patient at high risk for post-

splenectomy sepsis

For immune-mediated neutropenia, which is not covered for routine use, all of the following criteria must be met:

1. The patient has a serious clinical infection related to neutropenia; *and*
2. The patient failed to respond to both (1) corticosteroids and (2) filgrastim or pegfilgrastim therapies

For anemia due to pure red cell aplasia secondary to chronic parvovirus B19 infection, all of the following criteria must be met:

1. The patient has severe, refractory anemia;
2. The patient has documented erythrovirus B19 viremia; *and*
3. The patient was evaluated for underlying conditions that could lead to aplasia

For anemia due to pure red cell aplasia, immunologic subtype, the patient must have:

1. failed, have a contraindication to, or be intolerant to corticosteroid therapy;
2. failed, have a contraindication to, or be intolerant to cyclosporine; *and*
3. failed, have a contraindication to, or be intolerant to cyclophosphamide

For allogeneic bone marrow or stem cell transplant, all of the following criteria must be met:

1. Immune globulin is used for prevention of acute graft-versus-host disease or infection (e.g. cytomegalovirus); and
2. the transplant was between 0 to 99 days before starting immune globulin

Immune globulin is approved for allogeneic bone marrow or stem cell transplant for 3 months. Continuation of immune globulin is approved when:

a. the patient's IgG is less than or equal to 400 mg/dL; *and*
b. treatment duration does not exceed 360 days measured from the date of the transplant

For complications of transplanted solid organ (e.g. heart, kidney, liver, lung, pancreas) or bone marrow transplant, one of the following criteria must be met:

Immune globulin is used to:

1. suppress panel reactive anti-HLA antibodies prior to transplantation;
2. treat antibody mediated rejection of solid organ transplantation; *or*
3. prevent cytomegalovirus-induced pneumonitis

For human immunodeficiency virus infection (HIV):

Immune globulin is covered for patients with HIV to reduce significant bacterial infections in patients age 13 or younger who also have evidence of a *humoral immunologic defect** with presence of bacterial infections.

* *Humoral immunologic defect* means:

a. recurrent serious bacterial infections despite appropriate prophylactic antibiotic therapy;
b. demonstrated antibody deficiency to common antigens (i.e. measles, pneumococcal, and/or H. flue type B vaccine) as demonstrated by poor antibody titers;
c. bronchiectasis suboptimally responsive to antimicrobial and pulmonary therapy; or
d. HIV-associated thrombocytopenia despite antiretroviral therapy

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Section 3: specific documentation requirements for neurological conditions

For Guillain-Barré syndrome, Priority Health considers immune globulin an equivalent alternative to plasma exchange in children and adults. Immune globulin is covered when all the following criteria are met:

1. The patient has severe disease and is requiring aid to stand and/or walk; and
2. Immune globulin is started within 4 weeks of symptom onset; and

The initial approval is limited to one dose. A maximum of two doses are covered. The second dose is covered when the patient has an inadequate response to the first dose of immune globulin and will be given within 3 weeks of the first dose.

For myasthenia gravis (MG), immune globulin is not covered for routine use.

Coverage is limited to patients with severe MG to treat *acute, severe decompensation** when other treatments have been unsuccessful or are contraindicated and given concomitantly with either glucocorticoids or other immunosuppressive therapy (e.g. azathioprine, cyclosporine).

**acute, severe decompensation* means:

1. The patient has myasthenic crisis (i.e. impending respiratory or bulbar compromise);
2. The patient is experiencing disease exacerbation and/or decompensation, such as difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity;

When immune globulin is used to bridge immunosuppressive therapies, immune globulin is only covered until the immunosuppressive therapy takes effect, and the patient is:

1. unable to use or tolerate glucocorticoid therapy; *and*
2. being started on immunosuppressive therapies, such as azathioprine, mycophenolate, or cyclosporine

For Eaton-Lambert syndrome, all the following criteria must be met:

1. The patient failed, has a contraindication to, or has an intolerance to cholinesterase inhibitors used in combination with guanidine or an aminopyridine; *and*
2. The patient failed, has a contraindication to, or has an intolerance to corticosteroid therapy and immunosuppressive therapy (e.g. azathioprine, cyclosporine)

For polyneuropathy (chronic inflammatory demyelinating), all of the following criteria must be met:

1. The patient had a progressive or relapsing course of disease over at least 2 months;
2. The patient has abnormal or absent deep tendon reflexes in upper or lower limbs;
3. Baseline strength and weakness (and current strength and weakness for continuation requests) is documented in the patient's medical record using an objective clinical measuring tool (e.g. INCAT, MRC, 6-minute timed walking test, Rankin, Modified Rankin); *and*
4. Electrodiagnostic testing indicates demyelination, documented by one of the following demyelination criteria:

a. partial motor conduction block in two or more motor nerves or in one nerve plus one other demyelination criterion listed in (b)-(g) in one or more other nerves;
b. distal CMAP duration increase in one or more nerves plus one other demyelination criterion listed in (a) or (c)-(g) in one or more other nerves;
c. abnormal temporal dispersion conduction must be present in two or more motor nerves;
d. reduced conduction velocity in two or more motor nerves;
e. prolonged distal motor latency in two or more motor nerves;
f. absent F wave in two or more motor nerves plus one other demyelination criterion listed in (a)-(e) or (g) in one or more other nerves; or
g. prolonged F wave latency in two or more motor nerves

For multifocal motor neuropathy, all of the following criteria must be met:

1. The patient has progressive, symptomatic multifocal motor neuropathy (characterized limb weakness or motor involvement having a motor nerve distribution in at least two nerves);
2. Electrophysiological findings rule out other possible conditions that may not respond to immune globulin; and
3. Baseline strength and weakness (and current strength and weakness for continuation requests) is documented in the patient's medical record using an objective clinical measuring tool (e.g. INCAT, MRC, 6-minute timed walking test, Rankin, Modified Rankin)

For stiff-man syndrome, immune globulin is covered for patients with *severe active illness** when other treatment interventions have been *unsuccessful or intolerable*** and a baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam).

* *Severe active illness* means the patient is positive for anti-glutamic acid decarboxylase (GAD) antibody.
** *Unsuccessful or intolerable treatment interventions* means the patient failed, has a contraindication to, or intolerance to:

1. two or more benzodiazepine therapies;
2. baclofen; and
3. corticosteroid therapy

Section 4: specific documentation requirements for autoimmune disorders

Immune globulin is not covered for routine use in autoimmune disorders.

Immune globulin is covered for the following conditions for patients with severe active illness and other interventions have been unsuccessful or intolerable (i.e. the patient has treatment resistance to first- and second-line therapies).

For dermatomyositis and polymyositis, all of the below criteria must be met:

1. A baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam and improvement in CPK);
2. The condition is confirmed by biopsy; *and*
3. The patient:

   a. has severe active disease state;
   b. has muscle weakness in all upper and/or lower limbs;
   c. failed, has a contraindication to, or intolerance to corticosteroid therapy; *and*
   d. failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine

For systemic sclerosis dermatomyositis overlap syndrome, all the following criteria must be met:

1. the patient failed, has a contraindication to, or intolerance to corticosteroid therapy;
2. the patient failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine, methotrexate, cyclophosphamide, and cyclosporine; *and*
3. the prescriber must indication in advance what objective clinical endpoints will be used to determine efficacy of immune globulin therapy (Priority Health will use this criteria to evaluate ongoing effectiveness of treatment)

For Kawasaki disease, all of the following criteria must be met:

1. fever is present in patient for at least 5 days;
2. treatment is initiated within 10 days of onset of fever; *and*
3. concomitant aspirin treatment be given with immune globulin

For severe vasculitic syndrome, specify which syndrome the patient has: systemic (polyarteritis nodosa), Churg-Strauss Vasculitis, or livedoid vasculitis (atrophie blanche).

Section 5: specific documentation requirements for dermatologic conditions

Immune globulin is not covered for routine use in dermatologic conditions.

Priority Health considers immune globulin medically necessary for the following conditions:

1. Toxic epiderma necrolysis
2. Stevens-Johnson Syndrome, with or without toxic epidermal necrolysis overlap syndrome
3. Pyoderma gangrenosum, but only when the patient:

    a. failed, has a contraindication to, or intolerance to corticosteroid therapy
    b. failed, has a contraindication to, or intolerance to cyclosporine
    c. first tried two of the following other treatments:

        i. conventional immunosuppressive medications (in addition to cyclosporine)
        ii. Dapsone
        iii. minocycline
        iv. TNF-alpha inhibitors

4. Autoimmune mucocutaneous blistering disease
5. Mucous membrane pemphigold without ocular involvement
6. Mucous membrane pemphigold with ocular involvement
7. Epidermolysis bullosa
8. linear IgA dermatosis

For conditions listed in 4-8 above, all the following criteria must be met:

a. a baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam);
b. the condition:

    I. is rapidly progressing, extensive, or debilitating; *and*

II. has been confirmed by a biopsy

c. and the patient:

I. failed, has a contraindication to, or intolerance to corticosteroid therapy
II. failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine

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Additional information

1. Use of immune globulin in HLA-identical sibling transplants or autologous transplants is not considered medically necessary.
2. Additional conditions may be covered for members covered under an HMO/EPO, POS, PPO, ASO, or Individual policy
3. A diagnosis of high-risk pregnancy with history of previously affected infant with fetal-neonatal thrombocytopenia is not covered for members with an HMO/EPO, POS, PPO, ASO, or Individual policy

References available upon request

Kanuma

Products Affected

- Kanuma

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Korsuva

Products Affected

- Korsuva

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - topical analgesic (e.g. capsaicin, pramoxine)
  - oral antihistamine (e.g. hydroxyzine, diphenhydramine)
  - gabapentin or pregabalin
  - montelukast
  - 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:

- Initial: 3 months
- Continuation: 12 months

Krystexxa

Products Affected

- Krystexxa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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 12 months; **AND**
- Have gout tophus or gouty arthritis; **AND**
- Patient has tried lifestyle modifications such as reduced alcohol consumption, discontinuing or changing other medications known to precipitate gout attacks when possible); **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.

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:

- Initial: 3 months
- Continuation: 12 months

Lamzede

Products Affected

- Lamzede

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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.

Lantidra

Products Affected

- Lantidra

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Lantidra (donislecel-jujn)

Gene/Cellular Therapy

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of type 1 diabetes for a duration of at least 5 years; **AND**
- Have a negative T- and B-cell crossmatch assay; **AND**
- Patient is at least 18 years of age; **AND**
- Use in conjunction with immunosuppressants; **AND**
- Have recurrent, acute, and severe metabolic and potentially life-threatening complications requiring medical attention frequent ER visits and/or hospitalizations related to hypo-, hyper-glycemia, and/or ketoacidosis (supporting documentation must be submitted to Priority Health); **AND**
- Consistent failure of exogenous insulin-based management, defined as inability to achieve sufficient glycemic control (HbA1c greater than 8%) or recurrent hypoglycemia unawareness, despite aggressive conventional therapy.

For continuation of coverage, patient must have met the following requirements:

- Documentation of that patient has not achieved independence from exogenous insulin within one year of infusion or within one year after losing independence from exogenous insulin after previous infusion.

Duration of Approval: 1 infusion (maximum of 3 infusions per lifetime if continuation criteria are met)

Note: Lantidra 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.

Lantidra will not be authorized for use in patients that do not have approval for islet cell transplant on file.

Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).

Coverage of Lantidra is dependent on member's eligibility and benefit plan documents.

Lenmeldy

Products Affected

- Lenmeldy

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Lenmeldy (atidarsagene autotemcel)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of metachromatic leukodystrophy (MLD) confirmed by: presence of two disease-causing arylsulfatase A gene (ARSA) alleles **AND** ARSA activity below normal range **AND** in patients with novel ARSA variant(s), presence of sulfatides in a 24-hour urine collection; **AND**
- Have one of the following MLD subtypes [pre-symptomatic late infantile (PSLI) **OR** -symptomatic early juvenile (PSEJ) **OR** early symptomatic early juvenile (ESEJ) disease with GMFC-MLD score less than 2].
- Prescribed by a board-certified prescriber with qualifications to treat specified condition

Note: Lenmeldy 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.

Lenmeldy will not be authorized for use in patients:

- that have received a previous treatment course of Lenmeldy or another autologous hematopoietic stem cell-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 Lenmeldy is dependent on member's eligibility and benefit plan documents.

Leqvio

Products Affected

- Leqvio

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Leqvio (inclisiran)

Before this drug is covered, the patient must meet all of the following requirements:

- 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; **AND**
- Prescribed by a cardiologist, endocrinologist, or board-certified lipidologist; **AND**
- Not be using in combination with a PCSK9 inhibitor (Repatha, Praluent), 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 an 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.

Lumizyme

Products Affected

- Lumizyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - 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**
  - 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:
  - Infantile-onset disease: stabilization or improvement in muscle weakness, motor function, respiratory function, cardiac involvement, FVC, and/or 6 MWT; **OR**
  - 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.

Luxturna

Products Affected

- Luxturna

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Luxturna (voretigene neparvovec)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- 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.

Multiple Sclerosis Agents, Anti-CD20 Antibodies

Products Affected

- Briumvi
- Ocrevus
- Ocrevus Zunovo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Multiple Sclerosis Agents, Anti-CD20 Antibodies

Preferred Agent(s):

- **Ocrevus (ocrelizumab)**
- **Ocrevus Zunovo (ocrelizumab/hyaluronidase)**
- **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; **OR**
- 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.

Naglazyme

Products Affected

- Naglazyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Nexviazyme

Products Affected

- Nexviazyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Nexviazyme (avalglucosidase alfa)

Before this drug is covered, the patient must meet all of the following requirements:

- 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.

For continuation of coverage, patient must have met the following requirements:

- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in stabilization or improvement in FVC and/or 6 MWT.

Duration of Approval: 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 may not cover Nexviazyme for ventilator-dependent patients requiring ventilation 24 hours per day.

Nplate

Products Affected

- Nplate

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Nplate (romiplostim)

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) with:
  - platelet count less than 30,000/microL; **AND**
  - significant bleeding symptoms.
- Have a diagnosis of severe, persistent or recurrent ITP with:
  - platelet count less than 20,000/microL; **AND**
  - an insufficient response to corticosteroids, immunoglobulin, or splenectomy; **OR**
  - patient is not a candidate for splenectomy or immunoglobulin therapy.

For continuation of coverage, patient must have met the following requirements:

- Meet one of the following:
  - Platelet count has increased to at least 50 x 109/L; **OR**
  - If platelet count is less than 50 x 109/L must have documented response to therapy (i.e. reduction in clinically significant bleeding events)

Duration of Approval:

- Initial: 3 months
- Continuation: 12 months

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

Products Affected

- Nucala subcutaneous recon soln

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Nucala (mepolizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For **severe eosinophilic asthma** requests:
  - Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **AND**
  - Patient has tried the following:
    - One inhaled corticosteroid (ICS) **AND** one additional asthma controller medication (e.g., long-acting beta agonist, long-acting anti-muscarinic agent, leukotriene receptor antagonist); **AND**
  - Have had at least one asthma exacerbation in the previous year

- For **moderate-to-severe eosinophilic COPD** requests:
  - Have a diagnosis of moderate-to-severe COPD (FEV1/FVC less than 0.7 **AND** FEV1 between 30-70%); **AND**
  - Eosinophilic phenotype confirmed by a peripheral blood eosinophil count greater than 300 cells/mcL in the past 12 months; **AND**
  - Have symptomatic COPD (a mMRC dyspnea grade of at least 2 or CAT score of at least 10); **AND**
  - Try and fail LABA/LAMA or triple therapy (LABA/LAMA/ICS) following at least 3 months of consistent use; **AND**
  - Continue LABA/LAMA or triple therapy in conjunction with Nucala; **AND**
  - Have experienced one of the following within the past year:
    - 2 COPD exacerbations requiring oral steroids and/or antibiotics; **OR**
    - 1 COPD exacerbation requiring hospitalization/ED visit; **AND**
  - Patient is a current non-smoker.

- For **eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss)** requests:
  - Diagnosis of EGPA confirmed by a peripheral blood eosinophil count greater than 1,000 cells/mcL or at least 10% of leukocytes; **AND**
  - Patient has tried **ONE** of the following:
    - One systemic corticosteroid; **OR**
    - One immunosuppressive therapy
  - Trial and failure, or intolerance/contraindication to Fasenra.

- For **Hypereosinophilic Syndrome (HES)** requests:
  - Diagnosis of HES for at least 6 months; **AND**
  - 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**
  - Have a blood eosinophil count of at least 1,000 cells/mcL; **AND**
  - Be stable on chronic steroid therapy (e.g. prednisone); **AND**
  - Have tried and failed one generic, steroid-sparing therapy (e.g., methotrexate, hydroxyurea).

- For **chronic rhinosinusitis with nasal polyp (CRSwNP)** requests:
  - Patient will use as add-on maintenance treatment (e.g., nasal corticosteroid) for inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

For continuation of coverage, the patient must have met the following requirements:

- For **severe eosinophilic asthma** requests:
  - Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use).

- For **moderate-to-severe eosinophilic COPD** requests:
  - Must demonstrate a decrease in symptoms and/or COPD exacerbations compared to baseline; **AND**
  - Continue use of dual or triple therapy that includes (LABA/LAMA) in conjunction with Nucala.

- For **eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss)** requests:
  - 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:
  - 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:
    - 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

Nulibry

Products Affected

- Nulibry

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - neurological function
  - gross motor function
  - developmental milestones

Duration of Approval: 12 months

Omvoh IV

Products Affected

- Omvoh intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Omvoh IV (mirikizumab)

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:
  - Patient has a diagnosis of moderate to severe Crohn's disease; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
  - Patient has tried at least **TWO** of the following:
    - adalimumab, infliximab, ustekinumab each for a period of at least 3 months.

- For **Ulcerative Colitis** requests:
  - Patient has a diagnosis of moderate to severe Ulcerative Colitis; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
  - Patient has tried at least **TWO** of the following:
    - adalimumab, infliximab, ustekinumab, each for a period of at least 3 months.

Note: Omvoh will not be covered in combination with another biologic drug. Before Omvoh is covered, the patient must meet all of the General Criteria for Omvoh 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

When used for Crohn's disease or ulcerative colitis, 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.

Onapgo

Products Affected

- Onapgo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Onapgo (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**
- 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:
  - Dopamine agonist (e.g. pramipexole, ropinirole)
  - Monoamine oxidase (MAO) type-B inhibitor (e.g. rasagiline, selegiline)
  - Catechol-O-methyl transferase (COMT) inhibitor (e.g. entacapone)

For continuation of coverage, patient must meet one of the following requirements:

- Documentation that the patient has had a positive response to Onapgo therapy.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Oncology Agents

Products Affected

- Abecma
- Adcetris
- Adstiladrin
- ALIQOPA 60 MG VIAL
- Amtagvi
- Anktiva
- Arzerra
- Aucatzyl
- Bavencio
- Beleodaq
- Besponsa
- Blenrep
- Breyanzi
- Breyanzi CD4 Component (2of 2)
- Breyanzi CD8 Component (1of 2)
- Carvykti
- Columvi
- Cyramza
- Danyelza
- Datroway
- Elahere
- Enhertu
- Epkinly
- Evomela
- Fyarro
- Hepzato
- Hepzato (50 mm catheter)
- Hepzato (62 mm catheter)
- Imdelltra
- Imfinzi
- Imjudo
- Imlygic
- Inlexzo
- Istodax
- Jemperli
- Jevtana
- Kadcyla
- Keytruda
- Keytruda Qlex
- Kimmtrak
- Kymriah
- Libtayo
- Loqtorzi
- Lunsumio
- Lunsumio Velo
- Lutathera
- Lymphir
- Margenza
- Monjuvi
- Mylotarg
- Niktimvo
- Omisirge
- Onivyde
- Opdivo
- Opdivo Qvantig
- Opdualag
- Padcev
- Polivy
- Poteligeo
- pralatrexate
- Provenge
- romidepsin
- Rybrevant
- Rylaze
- Rytelo
- Sarclisa
- Tecartus
- Tecelra
- Tecentriq
- Tecentriq Hybreza
- Tecvayli
- Tevimbra
- Tivdak
- Trodelvy
- Unituxin
- Unloxcyt
- Vectibix
- Vyloy
- Vyxeos
- Xofigo
- Yervoy
- Yescarta

- Yondelis
- Zepzelca
- Zevalin (Y-90)
- Ziihera
- Zynlonta
- Zynyz

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical Oncology drug request form or Web Form.

Group Description: Oncology Agents

Before this drug is covered, the patient must meet all of the following requirements:

- 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 (must be submitted within past 30 days).
- Additional criteria as stated on Priority Health's website.

For continuation of coverage, the patient must have met the following requirements:

- 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.

Duration of Approval: 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.

Orencia IV

Products Affected

- Orencia (with maltose)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Orencia IV (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:
  - 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**
  - Patient has tried at least **TWO** of the following:
    - Cosentyx, Enbrel, adalimumab, Xeljanz/XR, Otezla/XR, ustekinumab, or each for a period of at least 3 months.
- For **Juvenile Idiopathic Arthritis** requests:
  - Patient has tried at least **TWO** of the following: tocilizumab, adalimumab, Enbrel, Xeljanz/XR each for a period of at least 3 months.
- For **Rheumatoid Arthritis** requests:
  - 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**
  - Patient has tried at least **TWO** of the following:
    - tocilizumab, 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Oritavancin

Products Affected

- Kimyrsa
- Orbactiv

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug(s): Oritavancin (Orbactiv, Kimyrsa)

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).

Oxlumo

Products Affected

- Oxlumo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Oxlumo (lumasiran)

Before this drug is covered, the patient must meet all of the following requirements:

- 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).

For continuation of coverage, the patient must have met the following requirements:

- Submit documentation that the patient is tolerating therapy and there was an improvement in urinary oxalate excretion from baseline.

Duration of Approval: 12 months

Note: The dose of Oxlumo approved will be limited to the weight-based dosing found in the FDA label.

Palforzia

Products Affected

- Palforzia Initial (1-3 yrs)
- Palforzia Initial (4-17 yrs)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - Peanut-specific immunoglobulin E (psIgE) level greater than 0.35 kUA/L; **OR**
  - Skin prick test with mean wheal diameter greater than 3 mm larger than control; **AND**
- Have a clinical history of a significant allergic reaction to peanuts or peanut-containing food; **AND**
- Patient is 1 to 17 years of age for initiation of therapy; **AND**
- Prescriber is an allergist, immunologist or has consulted with a specialist for the condition being treated.

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.

Papzimeos

Products Affected

- Papzimeos

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Papzimeos (zopapogene imadenovec)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of recurrent respiratory papillomatosis (RRP) and documented HPV serotype 6 or 11 (supporting documentation must be submitted to Priority Health); **AND**
- Patient is at least 18 years of age; **AND**
- Patient has had a trial of bevacizumab; **AND**
- Patient has had HPV vaccination (if 9 to 45 years of age); **AND**
- Patient has had at least 3 surgeries in previous 12 months (surgical debulking of laryngotracheal papillomas).

Note: Papzimeos 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.

Papzimeos will not be authorized for use in patients:

- that have received a previous treatment course of Papzimeos. The safety and effectiveness of repeat administration have not been evaluated (**one treatment consisting of 4 injections given over 12 weeks per lifetime**).

Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).

Coverage of Papzimeos is dependent on member's eligibility and benefit plan

documents.

Parsabiv

Products Affected

- Parsabiv

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

PiaSky

Products Affected

- Piasky

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: PiaSky (crovalimab)

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): **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:

- Initial: 6 months
- Continuation: 12 months

Note: PiaSky is not covered in combination with other complement drug therapy (e.g., Soliris/Epysqli, Ultomiris, Fabhalta).

Pluvicto

Products Affected

- Pluvicto

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical Oncology drug request form or Web Form.

Drug: Pluvicto (Lutetium Lu-177 vipivotide tetraxetan)

Before this drug is covered, the patient must meet all of the following requirements:

- 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 (must be submitted within past 30 days).

For continuation of coverage, patient must have met the following requirements:

- 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.

Duration of Approval:

- Initial: 4 doses
- Continuation: 2 doses
- The total number of doses (200 mCi/dose) authorized cannot exceed 6 doses.

Pombiliti + Opfolda

Products Affected

- Opfolda
- Pombiliti

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug(s):

- **Pombiliti (cipaglucosidase alfa) - Medical Benefit Drug**
- **Opfolda (miglustat) - Pharmacy OR Medical Benefit Drug**

Before this drug is covered, the patient must meet all of the following requirements:

- 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.

For continuation of coverage, patient must have met the following requirements:

- Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in stabilization or improvement in FVC and/or 6 MWT.

Duration of Approval: 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 may not cover Pombiliti + Opfolda for ventilator-dependent patients requiring ventilation 24 hours per day.

Prevymis

Products Affected

- Prevymis intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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**
- For non-HSCT transplants, patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy such as valganciclovir.

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.

Pulmonary Arterial Hypertension (PAH), Activin Signaling Inhibitor

Products Affected

- Winrevair

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Pulmonary Arterial Hypertension (PAH), Activin Signaling Inhibitor

Preferred Agent(s):

- **Winrevair (sotatercept)**

Non-Preferred Agent(s):

- *Not Applicable*

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. Supporting documentation must be submitted to Priority Health; **AND**
- Have WHO functional class II or III symptoms; **AND**
- Patient is at least 18 years of age; **AND**
- Patient has tried and failed, or have intolerance/contraindication to one drug from both of the following classes:
  - Phosphodiesterase inhibitor (i.e. sildenafil or tadalafil); **AND**
  - Endothelin receptor antagonist (i.e. ambrisentan or bosentan);
- Prescriber is a specialist or has consulted with a specialist for the condition being treated; **AND**
- Winrevair will be initiated as add on therapy to at least 2 other PAH agents (e.g., ERA, PDE5i, prostaglandins).

For continuation of coverage, the patient must have met the following requirements:

- Have documented benefit to therapy compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, exercise capacity (6MWD).

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Pulmonary Arterial Hypertension (PAH), Other

Products Affected

- Tyvaso
- Tyvaso Institutional Start Kit
- Tyvaso Refill Kit
- Tyvaso Starter Kit

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Pulmonary Arterial Hypertension (PAH), Other

Preferred Agent(s):

- **Orenitram ER (treprostinil tablet) - Pharmacy Benefit Drug**
- **Tyvaso (treprostinil nebulizer) - Pharmacy and Medical Benefit Drug**
- **Uptravi (selexipag) - Pharmacy Benefit Drug**
- **Ventavis (iloprost) - Pharmacy Benefit Drug**

Non-Preferred Agent(s):

- **Tyvaso DPI - Pharmacy Benefit Drug**

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:
  - Phosphodiesterase inhibitor (i.e. sildenafil or tadalafil); **AND**
  - Endothelin receptor antagonist (i.e. ambrisentan or bosentan);
- Patient has tried and failed, or have intolerance/contraindication to Tyvaso nebulizer (Tyvaso DPI only).

Pulmonary Arterial Hypertension (PAH), Prostaglandins

Products Affected

- epoprostenol
- Flolan
- REMODULIN 100 MG/20 ML VIAL
- REMODULIN 20 MG/20 ML VIAL
- REMODULIN 200 MG/20 ML VIAL
- REMODULIN 50 MG/20 ML VIAL
- treprostinil sodium
- Veletri

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: 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).

Qutenza

Products Affected

- Qutenza

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - Neuropathic pain associated with postherpetic neuropathy
  - Pain associated with diabetic peripheral neuropathy; **AND**
- Patient has tried **ALL** of the following for a period of at least 3 months:
  - Gabapentin
  - Pregabalin
  - One generic tricyclic antidepressant (amitriptyline, amoxapine, doxepin, imipramine, nortriptyline, protriptyline, or trimipramine)

Duration of Approval: 12 months

Radicava

Products Affected

- Radicava

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Radicava (edaravone)

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**
- Be 20 to 75 years of age; **AND**
- Baseline ALS functional rating scale (ALSFRS-R); **AND**
- Living independently; **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:

- Documentation that the patient has experienced a positive clinical response compared to baseline (e.g., slowing of disease progression); **AND**
- 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.

Ranibizumab

Products Affected

- Byooviz
- Cimerli
- Lucentis intravitreal syringe

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: 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:
  - 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.
  - 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.
  - 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.
  - Diabetic retinopathy:
    - First try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid.
  - 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

Reblozyl

Products Affected

- Reblozyl

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:

- Initial: 12 weeks
- Continuation: 12 months

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.

Respiratory Syncytial Virus (RSV) Monoclonal Antibodies

Products Affected

- Beyfortus
- Enflonsia
- SYNAGIS 100 MG/ML VIAL
- SYNAGIS 50 MG/0.5 ML VIAL

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Respiratory Syncytial Virus (RSV) Monoclonal Antibodies

Preferred Agent(s):

- **Beyfortus (nirsevimab)**
- **Enflonsia (clesrovimab)**

No PA required if using within first 8 months of life and born during or entering the first RSV season.

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 and Enflonsia only).
- For patients less than 12 months of age, must also have one of the following (Synagis only):
  - Prematurity (born at 28 weeks, 6 days gestation or earlier during their first RSV season); **OR**
  - 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**
  - Congenital heart disease and have hemodynamically significant (cyanotic CHD or acyanotic CHD and receiving medication for CHF); NICU discharge summary must be included; **OR**

    - Pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airways.
    - Non-preferred drug product:
        - Trial and failure, or intolerance/contraindication to the preferred product.

- For patients age 8 through 19 months (Beyfortus), must also have one of the following:
    - 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**
    - Severely immunocompromised during the RSV season.

Duration of Approval:

- Beyfortus and Enflonsia: up to a single dose per RSV season which 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.

Rethymic

Products Affected

- Rethymic

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Rethymic (allogeneic processed thymus tissue)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of congenital athymia with confirmation from specialist (pediatric immunologist) and surgery conducted by surgeon with experience with Rethymic (supporting documentation must be submitted to Priority Health); **AND**
- Patient has been screened for anti-human leukocyte antibodies (HLA); **AND**
- Patient is less than 36 months of age.

Note: Rethymic 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.

Rethymic will not be authorized for use in patients:

- with pre-existing cytomegalovirus infection; **OR**
- that have a severe combined immunodeficiency (SCID); **OR**
- that have received a previous treatment course of Rethymic. 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 Rethymic is dependent on member's eligibility and benefit plan documents.

Revcovi

Products Affected

- Revcovi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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.

Ryoncil

Products Affected

- Ryoncil

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Ryoncil (remestemcel-L)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of Diagnosis of grade BD aGVHD with symptoms involving skin, liver, and/or GI tract (excluding skin-only grade B aGVHD); **AND** SR (progression within 3 days or no improvement within 7 days of consecutive treatment with 2 mg/kg/day MP or equivalent; **AND**
- Documented failure to Jakafi if at least 12 years of age (not applicable to those 2 months to less than 12 years of age); **AND**
- Prescribed by or in consultation with a hematologist.

For continuation of coverage, patient must meet one of the following requirements:

- Partial Response (organ improvement of ≥1 stage without worsening of any other organ); **OR**
- Mixed Response (improvement in ≥1 evaluable organ stage with worsening in another); **OR**
- Complete Response with acute GVHD flare (grade BD progression after achieving CR).

Duration of Approval:

- Initial: 8 doses
- Continuation: 8 doses

- The total number of doses authorized cannot exceed 16 doses.

Note: Ryoncil 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.

Ryoncil will not be authorized for use in patients:

- that have received a previous treatment course of Ryoncil or another allogenic cellular therapy.

Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).

Coverage of Ryoncil is dependent on member's eligibility and benefit plan documents.

Ryplazim

Products Affected

- Ryplazim

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:

- Initial: 12 weeks
- Continuation: 12 months

Rystiggo

Products Affected

- Rystiggo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Rystiggo (rozanolixizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of refractory generalized myasthenia gravis (MG) that is 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.

For continuation of coverage, patient must have met the following requirements:

- Have documented response as evidenced by BOTH of the following:
  - improved MG-ADL total score from baseline (at least a 2-point reduction); **AND**
  - improved (QMG) total score from baseline (at least a 3-point improvement).

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Rystiggo will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Imaavy, Soliris/Epysqli, Ultomiris, Vyvgart, Zilbrysq. 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.

Scenesse

Products Affected

- Scenesse

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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.

Signifor LAR

Products Affected

- Signifor LAR

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Simponi ARIA

Products Affected

- Simponi ARIA

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - Patient has tried at least **TWO** of the following:
    - adalimumab, Cosentyx, Enbrel, Xeljanz/XR each for a period of at least 3 months.
- For **Psoriatic Arthritis** requests:
  - 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**
  - Patient has tried at least **TWO** of the following
    - adalimumab, Cosentyx, Enbrel, Otezla/XR, ustekinumab, Xeljanz/XR, each for a period of at least 3 months.
- For **Rheumatoid Arthritis** requests:
  - Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) for a period of at least 3 months; **AND**
  - Patient has tried at least **TWO** of the following:
    - tocilizumab, adalimumab, Enbrel, Xeljanz/XR, each for a period of at least 3 months.
- For **Ulcerative Colitis** requests:

- Patient has a diagnosis of moderate to severe Ulcerative Colitis; **AND**
- Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
- Patient has tried **ONE** of the following:
    - adalimumab, infliximab, ustekinumab 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Sivextro

Products Affected

- Sivextro intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Skyrizi IV

Products Affected

- Skyrizi intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Skyrizi IV (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:
  - Patient has a diagnosis of moderate to severe Crohn's disease; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); AND
  - Patient has tried at least **TWO** of the following:
    - adalimumab, infliximab, Cimzia, ustekinumab, each for a period of at least 3 months; **AND**
  - Patient has tried Entyvio for a period of at least 3 months.

- For **Plaque Psoriasis** requests:
  - Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND**
  - Patient has tried at least **THREE** of the following:
    - adalimumab, Cosentyx, Enbrel, Otezla/XR, ustekinumab, each for a period of at least 3 months.

- For **Psoriatic Arthritis** requests:
  - 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**

    - Patient has tried at least **THREE** of the following:
        - adalimumab, Cosentyx, Enbrel, Otezla/XR, ustekinumab, Xeljanz/XR, each for a period of at least 3 months.

- For **Ulcerative Colitis** requests:
    - Patient has a diagnosis of moderate to severe Ulcerative Colitis; **AND**
    - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
    - Patient has tried at least **TWO** of the following:
        - adalimumab, infliximab, Omvoh, Simponi, ustekinumab, Xeljanz/XR, each for a period of at least 3 months; **AND**
    - Patient has tried at least **ONE** of the following:
        - Entyvio, Zeposia, for a period of at least 3 months.

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 coverage for use (e.g., indication, dose) not listed in the FDA label.

When used for Crohn's disease and Ulcerative Colitis, 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.

Skysona

Products Affected

- Skysona

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Skysona (elivaldogene autotemcel)

- ***Gene/Cellular 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:
  - Elevated very long chain fatty acids (VLCFA) values; **AND**
  - 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 assigned male at birth and 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.

Spinraza

Products Affected

- Spinraza (PF)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Spinraza (nusinersen)

Before this drug is covered, the patient must meet all of the following requirements:

- 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).

For continuation of coverage, the patient must have met the following requirements:

- Submit documentation to show maintenance or improvement of condition:
  - 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.
  - 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.

Duration of Approval: 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.

Spravato

Products Affected

- Spravato

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Spravato (esketamine)

Before this drug is covered, the patient must meet all of the following requirements:

- Diagnosis of Major Depressive Disorder without psychotic features, with baseline score, prior to starting Spravato, from one of the following:
  - Baseline score on the 17-item Hamilton Rating Scale for Depression (HAMD17); **OR**
  - Baseline score on the 16-item Quick Inventory of Depressive Symptomatology (QIDS-C16); **OR**
  - 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:
  - 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**
  - 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.

For continuation of coverage, patient must have met the following requirements:

- 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:
    - Hamilton Rating Scale for Depression (HAMD17; remission defined as a score of no greater than 7); **OR**
    - Quick Inventory of Depressive Symptomatology (QIDS-C16; remission defined as a score of no greater than 5); **OR**
    - Montgomery-Asberg Depression Rating Scale (MADRS; remission defined as a score of no greater than 12).

Duration of Approval:

- Initial: 12 weeks
- Continuation: 6 months

Note: Intolerance to antidepressant and augmentative therapy is not considered therapeutic failure.

Supprelin LA

Products Affected

- Supprelin LA

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Products Affected

- Syfovre (PF)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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.

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

Products Affected

- Sylvant

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Tepezza

Products Affected

- Tepezza

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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 an adequate trial of a systemic corticosteroid (a cumulative dose of at least 4.5 gm of methylprednisolone IV **OR** prednisone daily doses of at least 60 mg), 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

Products Affected

- Aveed
- Testopel

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Testosterone Replacement Products

Preferred Agent(s):

- **Testosterone topical 1% and 1.62% gel (generic for AndroGel) - Pharmacy Benefit Drug**
- **Kyzatrex (testosterone undecanoate capsule) - Pharmacy Benefit Drug**

Non-Preferred Agent(s):

- **Aveed (testosterone undecanoate injection) - Medical Benefit Drug**
- **Testopel (testosterone pellet) - Medical Benefit Drug**

Before this drug is covered, the patient must meet all of the following requirements:

- For hypogonadal hypotestosteronism:
  - 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**
  - 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*
  - 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**
  - 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:
    - Documentation of diagnosis must be submitted to Priority Health; **AND**
    - Trial and failure of injectable testosterone; **AND**
    - 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.

Tocilizumab

Products Affected

- Tyenne intravenous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Tocilizumab

Preferred Agent(s):

- **Tyenne IV (tocilizumab-aazg)**

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 **Polyarticular Juvenile Idiopathic Arthritis** requests:
  - Patient has tried methotrexate for a period of at least 3 months; **AND**
  - Patient has tried at least **ONE** of the following:
    - adalimumab, Enbrel, for a period of at least 3 months.
- For **Rheumatoid Arthritis** requests:
  - 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**
  - Patient has tried at least **ONE** of the following:
    - adalimumab, Enbrel, for a period of at least 3 months.
- For **Systemic Juvenile Idiopathic Arthritis** requests:
  - Patient has tried a nonsteroidal anti-inflammatory drug (NSAID).
- For **Giant Cell Arteritis** requests:
  - Patient has tried one systemic corticosteroid.

- For **Systemic sclerosis (SSc) related Interstitial Lung Disease (ILD) (SSc-ILD)** :
  - Patient has tried one systemic corticosteroid.
  - Diagnosis is confirmed by high-resolution computed tomography; **AND**
  - Forced vital capacity (FVC) is greater than 55% of the predicted value; **AND**
  - Tocilizumab will not be covered in combination with Ofev.

- For **Cytokine Release Syndrome** requests:
  - Patient is experiencing a severe or life-threatening T-cell induced reaction; **AND**
  - The IV formulation of tocilizumab is being used for treatment; **AND**
  - A maximum of 4 doses is requested.

Note: Tocilizumab will not be covered in combination with another biologic drug. Before tocilizumab is covered, the patient must meet all of the General Criteria for Tocilizumab 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Transthyretin Silencers (ATTR-PN) & Stabilizers/Silencer (ATTR-CM)

Products Affected

- Amvuttra
- Onpattro

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Transthyretin Silencers (ATTR-PN)

Preferred Agent(s):

- **Amvuttra (vutrisiran) - Medical Benefit Drug**
- **Onpattro (patisiran) - Medical Benefit Drug**
- **Wainua (eplontersen) - Pharmacy Benefit Drug**

Non-Preferred Agent(s):

- *Not applicable*

Before this drug is covered, the patient must meet all of the following requirements:

- Patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy (supporting documentation must be submitted to Priority Health); **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:
  - Baseline polyneuropathy disability (PND) score no greater than IIIb; **OR**
  - Baseline FAP Stage 1 or 2.

For continuation of coverage, patient must have met the following requirements:

- 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 compared to baseline (e.g., improved neurologic improvement, motor function, quality of life, slowing of disease progression).

Duration of Approval: 12 months

Note: Amvuttra, Onpattro, Wainua are not covered with one another or in combinations with one another or in combinations with Vyndaqel/Vyndamax/Attruby.

Group Description: Transthyretin Stabilizers/Silencer (ATTR-CM)

Preferred Agent(s):

- **Attruby (acoramidis) - Pharmacy Benefit Drug**
- **Vyndaqel (tafamidis meglumine) - Pharmacy Benefit Drug**
- **Vyndamax (tafamidis) - Pharmacy Benefit Drug**

Non-Preferred Agent(s):

- **Amvuttra (vutrisiran) - Medical Benefit Drug**

Before this drug is covered, the patient must meet all of the following requirements:

- Patient has a diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) (supporting documentation must be submitted to Priority Health); **AND**
- ATTR-CM confirmed by genetic testing, tissue biopsy, or radionuclide imaging; **AND**
- Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure; **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to a preferred product.

For continuation of coverage, patient must have met the following requirements:

- Documentation that the patient has experienced a positive clinical response to treatment compared to baseline (i.e. reduced cardiovascular-related hospitalizations, improved function, improved quality of life).

Duration of Approval: 12 months

Note: Vyndaqel/Vyndamax/Attruby are not covered with one another or in combinations with Amvuttra, Onpattro, Wainua.

Tyruko

Products Affected

- Tyruko

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Tyruko (natalizumab-sztn)

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** requests:
  - 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:
  - Patient has a diagnosis of moderate to severe Crohn's disease; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months); **AND**
  - Patient has tried 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: Natalizumab will not be covered in combination with another biologic drug or in combination with other drugs for the treatment of Multiple Sclerosis (e.g., Ocrevus, Gilenya, Betaseron). Before natalizumab is covered, the patient must meet all of the

General Criteria for natalizumab 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 coverage for use (e.g., indication, dose) not listed in the FDA label.

Tzield

Products Affected

- Tzield

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Tzield (teplizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of stage 2 (as defined by the American Diabetes Association) type 1 diabetes; **AND**
- Patient is at least 1 year of age; **AND**
- Have at least 2 of the following autoantibodies:
  - Glutamic acid decarboxylase 65 (GAD) autoantibody;
  - Insulin autoantibody (IAA);
  - Insulinoma-associated antigen 2 autoantibody (IA-2A);
  - Zinc transporter 8 autoantibody (ZnT8A);
  - Islet cell autoantibody (ICA); **AND**
- Be prescribed 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 (maximum coverage amount is 14 vials over 14 days).

Ultomiris

Products Affected

- Ultomiris

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Ultomiris (ravulizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For **Paroxysmal nocturnal hemoglobinuria (PNH)** requests:
  - 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 **Atypical hemolytic uremic syndrome (aHUS)** requests:
  - Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out.

- For **Refractory generalized myasthenia gravis (MG)** requests:
  - 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 6; **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**
  - Trial and failure of Vyvgart; **AND**

    - Prescribed by or in consultation with a neurologist.

- For **Neuromyelitis optica spectrum disorder (NMOSD)** requests:
    - Confirmed diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (documentation must be provided); **AND**
    - Be 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, inebilizumab (Uplizna) AND satralizumab (Enspryng); **AND**
    - Expanded Disability Status Scale (EDSS*) score of less than or equal to 7.

For continuation of coverage, patient must have met the following requirements:

- For **Paroxysmal nocturnal hemoglobinuria (PNH)** requests:
    - Have a decrease disabling symptoms; **AND**
    - Hemoglobin levels must be stabilized; **AND**
    - Patient has experienced an improvement in fatigue and quality of life.

- For **Atypical hemolytic uremic syndrome (aHUS)** requests:
    - Have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine).

- For **Refractory generalized myasthenia gravis (MG)** requests:
    - Have documented response as evidenced by BOTH of the following: improved MG-ADL total score from baseline, improved (QMG) total score from baseline.

- For **Neuromyelitis optica spectrum disorder (NMOSD)** requests:
    - Have documentation of a decrease in relapse rate.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Ultomiris will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Imaavy, Rystiggo, Soliris/Epysqli, Vyvgart, Zilbrysq.

Uplizna

Products Affected

- Uplizna

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Uplizna (inebilizumab)

Before this drug is covered, the patient must meet all of the following requirements:

- For **Neuromyelitis optica spectrum disorder (NMOSD)** requests:
  - Confirmed 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.
- For **Ig-G4 Related Disease** requests:
  - Confirmed diagnosis of IgG4-RD (supporting documentation must be submitted to Priority Health); **AND**
  - Score of at least 20 on the 2019 ACR/EULAR classification criteria; **AND**
  - Patient is experiencing (or recently experienced) an IgG4-RD flare that requires initiation or continuation of glucocorticoid (GC) treatment; **AND**
  - IgG4-RD affecting at least 2 organs/sites; **AND**
  - Have progressive disease on a therapeutic trial of glucocorticoids **AND** rituximab; **AND**
  - Prescriber is a specialist or has consulted with a specialist for the condition being treated.

- For **Generalized myasthenia gravis** requests:
  - Confirmed diagnosis of refractory generalized myasthenia gravis (MG) that is 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.

For continuation of coverage, patient must have met the following requirements:

- For **Neuromyelitis optica spectrum disorder (NMOSD)** requests:
  - Have documentation of a decrease in relapse rate.

- For **Ig-G4 Related Disease** requests:
  - Have documentation of a decrease in the number of disease flares.

- For **Generalized myasthenia gravis** requests:
  - Have documented response as evidenced by **BOTH** of the following:
    - improved MG-ADL total score from baseline (at least a 2-point reduction) **AND** improved (QMG) total score from baseline (at least a 3-point improvement).

Duration of Approval: 12 months

Note: Uplizna will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Soliris/Epysqli, Ultomiris, Rystiggo, Vyvgart, Zilbrysq.

Ustekinumab

Products Affected

- Selarsdi intravenous
- Selarsdi subcutaneous solution
- Starjemza intravenous
- Starjemza subcutaneous solution
- Steqeyma intravenous
- Steqeyma subcutaneous solution
- Yesintek intravenous
- Yesintek subcutaneous solution

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Group Description: Ustekinumab

Preferred Agent(s):

- **Selarsdi Prefilled Syringe (ustekinumab-aekn) - Pharmacy Benefit Drug**
- **Selarsdi Solution (ustekinumab-aekn) - Medical Benefit Drug**

- **Starjemza Prefilled Syringe (ustekinumab-hmny) - Pharmacy Benefit Drug**
- **Starjemza Solution (ustekinumab-hmny) - Medical Benefit Drug**

- **SteQeyma Prefilled Syringe (ustekinumab-stba) - Pharmacy Benefit Drug**
- **SteQeyma Solution (ustekinumab-stba) - Medical Benefit Drug**

- **Yesintek Prefilled Syringe (ustekinumab-kfce) - Pharmacy Benefit Drug**
- **Yesintek Solution (ustekinumab-kfce) - Medical Benefit Drug**

Non-Preferred Agent(s):

- *Not applicable*

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:
  - Patient has a diagnosis of moderate to severe Crohn's disease; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days,

immunomodulators such as azathioprine for at least 2 months).

- For **Plaque Psoriasis** requests:
  - Patient has tried one traditional non-biologic systemic agent (e.g., methotrexate, cyclosporine, acitretin) for a period of at least 3 months; **AND**
  - If 90 mg dose is requested, patient weighs more than 100 kg.

- For **Psoriatic Arthritis** requests:
  - 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**
  - If 90 mg dose is requested, patient weighs more than 100 kg.

- For **Ulcerative Colitis** requests:
  - Patient has a diagnosis of moderate to severe Ulcerative Colitis; **AND**
  - Patient has tried and failed, or has had an intolerance/contraindication with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months).

Note: Ustekinumab will not be covered in combination with another biologic drug. Before ustekinumab is covered, the patient must meet all of the General Criteria for ustekinumab 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 coverage for use (e.g., indication, dose) 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.

Vabysmo

Products Affected

- Vabysmo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Vabysmo (faricimab)

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:
  - 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.
  - 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.
  - 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.
  - 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.

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

Veopoz

Products Affected

- Veopoz

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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/Epysqli 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:

- Initial: 6 months
- Continuation: 12 months

Note: Veopoz is not covered in combination with Soliris/ Epysqli or Ultomiris.

Vibativ

Products Affected

- Vibativ

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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: 2 weeks.

Vimizim

Products Affected

- Vimizim

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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)

Vpriv

Products Affected

- VPRIV

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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

Products Affected

- Vyjuvek

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Vyjuvek (beremagene geperpavec)

- ***Gene/Cellular 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**
- 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 is not covered when used in combination with Filsuvez or Zevaskyn.

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.

Vyvgart & Vyvgart Hytrulo

Products Affected

- Vyvgart
- Vyvgart Hytrulo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug(s):

- **Vyvgart (efgartigimod alfa) - Medical Benefit Drug**
- **Vyvgart Hytrulo Solution (efgartigimod alfa-hyaluronidase) - Medical Benefit Drug**
- **Vyvgart Hytrulo Syringe (efgartigimod alfa-hyaluronidase) - Pharmacy Benefit Drug**

Before this drug is covered, the patient must meet all of the following requirements:

- For **refractory generalized myasthenia gravis (MG)** requests:
  - 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 plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control; **AND**
  - Prescribed by or in consultation with a neurologist.

- For **chronic inflammatory demyelinating polyneuropathy** (Vyvgart Hytrulo only) requests:
  - The patient had a progressive or relapsing course of disease over at least 2

months; **AND**

- The patient has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
- Baseline strength and weakness (and current strength and weakness for continuation requests) is documented in the patient's medical record using an objective clinical measuring tool (e.g. INCAT, MRC, 6- minute timed walking test, Rankin, Modified Rankin); **AND**
- Electrodiagnostic testing indicates demyelination, documented by **ONE** of the following demyelination criteria:
  - partial motor conduction block in two or more motor nerves or in one nerve plus one other demyelination criterion listed in (b)-(g) in one or more other nerves;
  - distal CMAP duration increase in one or more nerves plus one other demyelination criterion listed in (a) or (c)-(g) in one or more other nerves;
  - abnormal temporal dispersion conduction must be present in two or more motor nerves;
  - reduced conduction velocity in two or more motor nerves;
  - prolonged distal motor latency in two or more motor nerves;
  - absent F wave in two or more motor nerves plus one other demyelination criterion listed in (a)-(e) or in one or more other nerves; or g. prolonged F wave latency in two or more motor nerves **AND**
- Trial and failure, or intolerance/contraindication to Intravenous Immunoglobulin.

For continuation of coverage, patient must have met the following requirements:

- For MG, have documented response as evidenced by **BOTH** of the following:
  - improved MG-ADL total score from baseline (at least a 2-point reduction); **AND**
  - improved (QMG) total score from baseline (at least a 3-point improvement).
- For CIDP, have documented response as evidenced by clinically significant improvement in neurologic symptoms (e.g., improvement in disability; nerve conduction study results improved or stabilized; physical examination shows improvement in neurological symptoms, strength, and sensation).

Duration of Approval:

- Initial: 3 cycles of 4 doses
- Continuation: 12 months

Note: Vyvgart will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Imaavy, Rystiggo, Soliris/Epysqli, Ultomiris, Zilbrysq.

Xenpozyme

Products Affected

- Xenpozyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
    - For adults: diffusion capacity of the lungs for carbon monoxide (DLco) no greater than 70% of predicted normal
    - 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:

- Initial: 6 months
- Continuation: 12 months

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.

Xiaflex

Products Affected

- Xiaflex

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: 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:
  - 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**
  - Be free of chronic muscular, neurological, or neuromuscular disorders affecting the hands; **AND**
  - 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:
  - Penile curvature of 30 degrees or more for 12 months or longer; **AND**
  - 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.

Xolair

Products Affected

- Xolair subcutaneous recon soln
- Xolair subcutaneous syringe

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug:

- **Xolair Solution (omalizumab) - Medical Benefit Drug**
- **Xolair Syringe (omalizumab) - Pharmacy and Medical Benefit Drug**
- **Xolair Auto-Injector (omalizumab) - Pharmacy Benefit Drug**

Before this drug is covered, the patient must meet all of the following requirements:

- For **moderate to severe persistent asthma** requests:
  - Have a positive skin test or in-vitro reactivity to a perennial aeroallergen (lab results must be submitted); **AND**
  - Be within the recommended dosing range based on current weight and baseline IgE level; **AND**
  - Patient has tried the following:
    - One inhaled corticosteroid (ICS) **AND** one additional asthma controller medication (e.g., long-acting beta agonist, long-acting anti-muscarinic agent, leukotriene receptor antagonist); **AND**
  - Have had at least one asthma exacerbation in the previous year.

- For **chronic urticaria** requests:
  - Patient is at least12 years of age; **AND**
  - First try two or more H1 antihistamines; **OR**
  - 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:

- Patient will use as add-on maintenance treatment (e.g., nasal corticosteroid) for inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

- For **Ig-E mediated food allergy** requests:
  - Prescriber is an allergist, immunologist or has consulted with a specialist for the condition being treated; **AND**
  - Patient is at least 1 year of age; **AND**
  - Patient meets both of the following for specified food allergies (peanut, cashew, milk, egg, walnut, wheat, hazelnut):
    - Positive skin prick test response to the specified foods; **AND**
    - Positive in vitro test for IgE to the specified foods
  - Baseline IgE level of at least 30 IU/mL; **AND**
  - Clinical history of a significant allergic reaction to the specified foods.

For continuation of coverage, patient must have met the following requirements:

- For **moderate to severe persistent asthma** requests:
  - Have a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use).

- For **chronic urticaria** requests:
  - Have a positive clinical response (reduction in the symptoms of urticaria).

- For **chronic rhinosinusitis with nasal polyp (CRSwNP)** requests:
  - 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 **Ig-E mediated food allergy** requests:
  - Continue food allergen-avoidant diet; **AND**
  - Continue to be prescribed by or in consultation with an allergist or immunologist.

Duration of Approval: 12 months

Note: Xolair is not covered in combination with other biologic drug therapy (e.g. Nucala, Cinqair, Fasenra, Dupixent) or Rhapsido.

Yartemlea

Products Affected

- Yartemlea

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Yartemlea (narsoplimab)

Before this drug is covered, the patient must meet all of the following requirements:

- Have received Hematopoietic Stem Cell Transplantation (HSCT); **AND**
- Have a diagnosis of transplant-associated thrombotic microangiopathy (TA-TMA); **AND**
- Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out; **AND**
- Prescribed by or in consultation with a specialist for the condition (hematologist, oncologist, nephrologist); **AND**
- Patient is at least 2 years of age; **AND**
- Must first try eculizumab.

For continuation of coverage, patient must have met the following requirements:

- Have documented benefit from use of Yartemlea that includes an decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine, decreased need for platelet transfusions); AND
- Complete TA-TMA response is not achieve (e.g., platelet count <75 x10^9, LDH > 1.5 ULN, unable to reach freedom from platelet transfusions).

Duration of Approval:

- Initial: 12 weeks
- Continuation: 12 weeks

Note: Yartemlea is not covered in combination with other complement inhibitors (e.g.,

eculizumab, Ultomiris).

Zevaskyn

Products Affected

- Zevaskyn

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Zevaskyn (prademagene zamikeracel)

- ***Gene/Cellular Therapy***

Before this drug is covered, the patient must meet all of the following requirements:

- Have a diagnosis of recessive dystrophic epidermolysis bullosa (RDEB); **AND**
- Documentation of genetic testing confirming mutation(s) in the COL7A1 gene; **AND**
- Have presence of partial-thickness RDEB wounds open chronically for at least 6 months; **AND**
- Will only be applied to partial-thickness RDEB wounds open chronically for at least 6 months; **AND**
- Prescribed by a dermatologist or another board-certified prescriber with qualifications to treat recessive dystrophic epidermolysis bullosa.

Note: Zevaskyn will only be authorized in accordance with Food and Drug Administration (FDA) approved labeling as the safety and effectiveness of repeat administration have not been evaluated (**one treatment per lifetime; any previously untreated areas will require a new prior authorization reqest**). Consideration for coverage which do not meet the above criteria require submission from two peer-reviewed medical journal articles. Zevaskyn is not covered when used in combination with Filsuvez or Vyjuvek.

Requesting physician acknowledges that Priority Health may request documentation, not more frequently than biannually, of follow-up patient assessment(s).

Coverage of Zevaskyn is dependent on member's eligibility and benefit plan

documents.

Zolgensma

Products Affected

- Zolgensma

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Medical (Non-Oncology) drug request form or Web Form.

Drug: Zolgensma (onasemnogene abeparvovec)

- ***Gene/Cellular 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:
  - 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**
  - Baseline anti-AAV9 antibody titers (must be less than or equal to 1:50); **AND**
  - Platelet count; **AND**
  - 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*
  - 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**
    - 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.

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Notice of Nondiscrimination and Language Assistance Services

Priority Health complies with applicable federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. Priority Health does not exclude people or treat them differently because of race, color, national origin, age, disability or sex. Federal law requires that we provide you with this Notice of Nondiscrimination and Language assistance services.

Free aids and services

Priority Health provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Priority Health provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact Priority Health customer service by calling the number at the back of your membership ID card (TTY users call 711).

To file a civil rights grievance

If you believe that Priority Health has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with:

Priority Health Compliance Department
Attention: Civil Rights Coordinator
1231 East Beltline Ave NE
Grand Rapids, MI 49525-4501
Toll free: 866.807.1931 (TTY users call 711) Fax: 616.975.8850
PH-compliance@priorityhealth.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Priority Health Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *ocrportal.hhs.gov* or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW

Room 509F, HHH Building Washington, D.C. 20201

800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at *hhs.gov/ocr/office/file/index.html.*

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia en su idioma. Consulte al número de Servicio al Cliente que está en la parte de atrás de su tarjeta de identificación de miembro. (TTY: 711).

ملاحظة: إذا كنت تتحدث العربية، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. يرجى الاتصال برقم خدمة العملاء على الجانب الخلفي من بطاقة عضويتك الشخصية. (رقم هاتف الصم والبكم:711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請撥打會員卡背面的客服電話 (TTY: 711）。

ܙܘܗܪ̈ܐ: ܐܢ ܐܢܬܘܢ ܟܐ ܗܡܙܡܝܬܘܢ ܠܫܢܐ ܣܘܪ̈ܝܝܐ (ܐܬܘܪ̈ܝܝܐ) ، ܡ̈ܨܝ ܒܬܘܢ ܦܠܚܬܘܢ ܝܠܦܢܐ ܕܗܝܪ̈ܢܘܬܐ ܠܠܫ̈ܢܐ ܡܓ̰ܢܐܝܬ. ܐܢ ܒܥܠܡܠܡܘܢ ܡܢܘ ܠܡܢܝ ܡܢ ܩܪ̈ܝܬܐ ܡܫܡܫܢܝܬܐ ܕܝܠܦܢܐ ܥܠ ܡ̈ܢܝܢܐ ܕܐܝܠܗ ܒܚܕܟܐ ܠܣܛܪܐ ܕܟܪܛܐ ܕܗܕܡܘܬܐ. (TTY: 711).

CHÚ Ý: Nếu quý vị nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho quý vị. Xin hãy gọi tới số điện thoại của bộ phận dịch vụ khách hàng có ở mặt sau thẻ ID thành viên của quý vị. (TTY: 711).

KUJDES: Nëse flisni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Ju lutem kontaktoni qendrën e shërbimit për klient në pjesën e pasme të ID kartës tuaj të anëtaresimit (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 멤버쉽 ID카드의 뒷면에 있는 고객 서비스 번호로 전화해 주십시오. (TTY: 711)

লক্ষ্য করুনঃ আপনি বাংলায় কথা বলতে পারলে আপনার জন্য নিঃখরচায় ভাষা সহায়তা সেবা সুলভ রয়েছে। অনুগ্রহ করে আপনার সদস্যপদ আইডি কার্ডের পেছনে থাকা গ্রাহক সেবা নম্বরে কল করুন। (TTY: 711)

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer telefonicznej obsługi klienta wskazany na odwrocie Twojej legitymacji członkowskiej (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienste zur Verfügung. Bitte rufen Sie die Kundendienstnummer auf der Rückseite Ihrer Mitgliedskarte an. (TTY: 711).

ATTENZIONE: se parla italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero sul retro della tessera identificativa di membro. (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。メンバーシップIDカードの裏面にあるお客様サービスセンターの番号までお電話にてご連絡ください。(TTY: 711).

ВНИМАНИЕ! Если Вы говорите на русском языке, то Вам доступны услуги бесплатной языковой поддержки. Пожалуйста, позвоните в службу поддержки клиентов по номеру, указанному на обратной стороне Вашей идентификационной карточки участника (телетайп (TTY: 711).

OBAVJEŠTENJE: Ako govorite srpsko-hrvatski, usluge jezičke pomoći dostupne su vam besplatno. Molimo nazovite broj službe za korisnike na pozadini vaše članske iskaznice (TTY: 711).

Kung nagsasalita ka ng Tagalog,mga serbisyo ng tulong sa wika, ng libre, ay available para sa iyo. Pakitawan ang numero ng customer service sa likod ng iyong ID card ng pagiging miyembro. (TTY: 711).