Priority Health

Priority Health
Employer Group Optimized Plans

Pharmacy Drug Prior Authorization Criteria

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What is a prior authorization?

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

How to know when a medication requires prior authorization

The best way to know when a medication requires prior authorization is to use the Approved Drug List (ADL) tool. The ADL lists the medications covered under your pharmacy benefit.

How to use this criteria document

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

- Pharmacy Prior Authorization form (general form used to request coverage for medications dispensed at the retail pharmacy requiring prior authorization)
- Oncology Pharmacy Drug Request form (general forms used to request coverage for chemotherapeutic medications requiring prior authorization under the pharmacy or medical benefit)

These forms may also be used when requesting coverage for medications that may not be listed under the ADL (e.g., formulary exception requests), or for quantities that exceed the limits stated on either the ADL (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.

Opioid Quantity/Dose Limit Exception

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Opioid Quantity/Dose Limit Exception

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

- Patients are limited to a total of 120 MEqD (morphine equivalent dose per day). For requests that exceed this amount, the following are required:
  - An opioid treatment agreement is in place; **AND**
  - Member has a diagnosis of chronic pain due to a documented medical condition; **AND**
  - A dose taper or taper attempt is documented or valid clinical rationale as to why taper has not been attempted; **AND**
  - Member's pain management and function are routinely evaluated using validated tools (e.g. Pain, Enjoyment of Life, General Activity (PEG) Assessment Scale) at follow-up visits and show sustained improvement; **AND**
  - Non-drug therapy has been tried in the last 18 months or is contraindicated; **AND**
  - Non-opioid medications are being used concurrently (unless contraindicated) to reduce total opioid use; **AND**
  - Documentation to support clinical appropriateness and safety when concurrently using benzodiazepines, sedative-hypnotics, barbiturates, or other medications that may be harmful when used in combination with opioid medications; **AND**
  - Member has been educated on naloxone.
- Opioid medications subject to the 120 MEqD per day limit may also have individual drug quantity limits, step therapy, and other utilization management that also apply. Non-preferred long-acting opioids are subject to prior authorization.
- When approved, treatment will be authorized for the duration necessary to treat the patient's pain for up to a maximum of one year (12 months).

Duration of Approval: 12 months

Accrufer

Products Affected

- ACCRUFeR

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Accrufer (ferric maltol)

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

- Diagnosis of iron deficiency anemia; **AND**
- Documentation of baseline (pre-treatment) hemoglobin and ferritin levels; **AND**
- Have an inadequate response to 2 different generic oral iron therapies.

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

- Documentation of improvement in condition from baseline (e.g., improved tolerance and/or increased hemoglobin and ferritin levels).

Duration of Approval: 12 months

Note:

- For intolerances to previously tried oral iron, the following strategies must have been attempted to improve tolerability:
    1. Increase interval to every other day dosing and
    2. Lifestyle and dietary changes (e.g., take iron with food, use a stool softener, etc.).

Acthar

Products Affected

- Acthar

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Acthar (corticotropin)

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

- Have a diagnosis of infantile spasms; **AND**
- Be less than 2 years of age.

Additional Information:

Acthar Gel is not considered medically necessary for the following corticosteroid-responsive conditions because it has not been proven to be more effective than corticosteroids for these conditions.

- Acute exacerbations of multiple sclerosis.
- Rheumatic disorders (psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis).
- Collagen diseases (systemic lupus erythematosus, systemic dermatomyositis).
- Dermatologic diseases (severe erythema multiforme, Stevens-Johnson syndrome).
- Allergic states (serum sickness).
- Ophthalmic diseases (keratitis, iritis, iridocyclitis, uveitis, choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation).
- Respiratory diseases (symptomatic sarcoidosis).
- Edematous state

Duration of Approval: 1 month (up to a dose of 75 units/m2 twice daily for two weeks, followed by a tapering schedule for an additional two weeks).

Adalimumab

Products Affected

- Adalimumab-aaty (1 Pen)
- Adalimumab-aaty (2 Pen)
- Adalimumab-aaty (2 Syringe)
- Adalimumab-aaty CD/UC/HS Start
- Adalimumab-adaz
- Adalimumab-adbm (2 Pen)
- Adalimumab-adbm (2 Syringe)
- Hadlima
- Hadlima PushTouch
- Simlandi (1 Pen)
- Simlandi (2 Pen)
- Simlandi (2 Syringe)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Adalimumab

Preferred Agent(s):

- **Adalimumab-adaz (unbranded by Sandoz)**
- **Adalimumab-adbm (unbranded by Boehringer Ingelheim)**
- **Adalimumab-bwwd (Hadlima by Organon)**
- **Adalimumab-ryvk (Simlandi by Teva)**
- **Adalimumab-aaty (unbranded by Celltrion)**

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 **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).

- For **Uveitis (noninfectious intermediate, posterior and panuveitis)** requests:
  - The patient has tried **ONE** other agent for this condition (e.g., periocular, intraocular, or systemic corticosteroids, immunosuppressives [such as methotrexate, mycophenolate mofetil, cyclosporine, azathioprine, or cyclophosphamide]).

- For **Hidradenitis Suppurativa** requests:
  - Patient has tried at least **ONE** other agent for this condition (e.g., intralesional or oral corticosteroids], or systemic antibiotics, or isotretinoin).

- 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.

- 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.

- For **Ankylosing Spondylitis** requests:
  - There are no Specific Induction Criteria for this indication. Adalimumab is covered for any patient who meets the General Initiation Criteria.

- For **Rheumatoid Arthritis** requests:
  - Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months.

- For **Juvenile Idiopathic Arthritis** requests:
  - Patient has tried at least **ONE** other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory drug; **OR**
  - Patient will be starting on adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide; **OR**
  - Patient has aggressive disease, as determined by the prescribing physician.

Note: Adalimumab will not be covered in combination with another biologic drug. Before adalimumab is covered, the patient must meet all of the General Criteria for adalimumab and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Adbry

Products Affected

- Adbry

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Adbry (tralokinumab)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **atopic dermatitis** requests:
  - Patient has moderate to severe atopic dermatitis; **AND**
  - Patient has tried **ONE** of the following:
    - One medium to high potency topical corticosteroid for a period of at least 3 months; **OR**
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months.

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

- Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL).

Duration of Approval: 12 months

Note: Adbry is not covered in combination with other biologic drug therapy. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Antilipidemic Agents, PCSK9 Inhibitors

Products Affected

- Lerochol
- Praluent

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Antilipidemic Agents, PCSK9 Inhibitors

Preferred Agent(s):

- **Repatha (evolocumab)**

Non-Preferred Agent(s):

- **Praluent (alirocumab)**
- **Lerochol (lerodalcibep)**

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

- For hypercholesterolemia with or without clinical atherosclerotic cardiovascular disease (ASCVD) OR homozygous familial hypercholesterolemia (HoFH) OR heterozygous familial hypercholesterolemia (HeFH):
  - Patient has tried one high-intensity statin (i.e., atorvastatin at least 40 mg daily; rosuvastatin at least 20 mg) for a minimum of 8 weeks continuously and LDL-C level remains above goal, **AND**
  - Not be using in combination with another PCSK9 inhibitor, Leqvio, Nexletol/Nexlizet
- Non-preferred drug product:
  - Prescribed by a cardiologist, endocrinologist, or board-certified lipidologist; **AND**
  - Trial and failure, or intolerance/contraindication to the preferred product **AND** additional statin drug.

Antimigraine Agents, Acute Treatment

Products Affected

- Dihydroergotamine Mesylate Nasal
- Nurtec
- Reyvow Oral Tablet 100 MG, 50 MG
- Zavzpret

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Antimigraine Agents, Acute Treatment

Preferred Agent(s):

- **Ubrelvy (ubrogepant)**

Non-Preferred Agent(s):

- **Dihydroergotamine nasal spray (generic Migranal/Trudhesa)**
- **Nurtec (rimegepant)**
- **Reyvow (lasmiditan)**
- **Zavzpret (zavegepant)**

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

- Patient has a diagnosis of migraine with or without aura; **AND**
- Patient is at least 18 years of age; **AND**
- Have tried one triptan drug (e.g., sumatriptan, rizatriptan, naratriptan, zolmitriptan); **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to the preferred product **AND** additional triptan drug.

Duration of Approval: 12 months

Note: Ubrelvy, Nurtec, Zavzpret, dihydroergotamine are not covered in combination with one another or any other branded acute treatment agent.

Antimigraine Agents, Preventive Treatment

Products Affected

- Aimovig
- Ajovy
- Emgality
- Emgality (300 MG Dose)
- Qulipta

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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 cluster headache requests (Emgality only):

- Patient is at least 18 years of age; **AND**
- Patient has a diagnosis of episodic cluster headache; **AND**
- Has tried and failed at least 2 of the following treatments:
  - Injectable triptan drugs: sumatriptan
  - Intranasal triptan drugs: sumatriptan or zolmitriptan
  - Oxygen therapy
  - Verapamil, topiramate, valproate

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

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

- For cluster headache requests (Emgality only):
  - Demonstrate significant decrease in the frequency and/or intensity of cluster headaches; **AND**
  - Be in a current cluster period.

Duration of Approval:

- For migraine headache requests: 12 months
- For cluster headache requests (Emgality only): 6 months

Note:

- Vyepti, Qulipta are not covered in combination with Botox or any other branded prophylactic agent.
- Qulipta is not covered in combination with Ubrelvy or Nurtec.
- Coverage of Vyepti is limited to initial dosing of 100mg given every 3 months. For patients not responsive to the 100mg dose, a one-time authorization can be made for a 300mg dose which will be assessed for efficacy beyond that observed for the 100mg dose.
- "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to step therapy requirements.

Antiretroviral Agents, Miscellaneous

Products Affected

- Rukobia
- Sunlenca Oral Tablet Therapy Pack

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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

Arcalyst

Products Affected

- Arcalyst

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Arcalyst (rilonacept)

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 12 years or older; **OR**
- Have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults **AND** children weighing at least 10 kg; **OR**
- Have a diagnosis of recurrent pericarditis (RP) and reduction of risk of recurrence in adults **AND** children 12 years or older.

Note: Arcalyst will not be covered in combination with another biologic drug. Before Arcalyst is covered, the patient must meet all of the General Criteria for Arcalyst 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.

Arikayce

Products Affected

- Arikayce

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Arikayce (amikacin oral inhalation)

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

- Diagnosis of mycobacterium avium complex (MAC) lung disease (sputum culture supporting diagnosis must be submitted to Priority Health); **AND**
- Failure to obtain a negative sputum culture after a minimum of 6 consecutive months of a multidrug background regimen for MAC lung disease such as clarithromycin (or azithromycin), rifampin, and ethambutol; **AND**
- Be used as part of a multi-drug regimen and will not be approved for use as a single agent treatment; **AND**
- Prescribed by or in consultation with an infectious disease specialist.

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

- Documentation of a negative sputum culture obtained within the last 30 days; **AND**
- Be compliant in taking the medication as scheduled; **AND**
- Be tolerating the medication; **AND**
- Responded to treatment as determined by the prescribing physician.

Duration of Approval: 12 months

Note: The ATS/IDSA guidelines state that patients should continue to be treated until they have negative cultures for 1 year. Patients that have had negative cultures for 1 year will not be approved for continued treatment.

Benlysta

Products Affected

- Benlysta Subcutaneous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Besremi

Products Affected

- Besremi
- Besremi Pen

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Besremi (ropeginterferon alfa- 2b)

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

- Have a diagnosis of high-risk polycythemia vera (supporting documentation must be submitted to Priority Health); **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by or in consultation with a hematologist or oncologist; **AND**
- Trial and failure to hydroxyurea AND pegylated interferon-alfa 2a; **AND**
- Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2; **AND**
- Not have an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73m2.

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

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

Duration of Approval: 12 months

Bimzelx

Products Affected

- Bimzelx

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Bimzelx (bimekizumab)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **Plaque Psoriasis** requests:
  - 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:
    - adalimumab, Cosentyx, Enbrel, Otezla/XR, or ustekinumab, each for a period of at least 3 months.
- For **Hidradenitis Suppurativa** requests:
  - Patient has tried at least **ONE** other agent for this condition (e.g., intralesional or oral corticosteroids, or systemic antibiotics, or isotretinoin); **AND**
  - Patient has tried at least **TWO** of the following:
    - Cosentyx, adalimumab, infliximab, each for a period of at least 3 months.
- 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).
    - Patient has tried at least **TWO** of the following:
        - Cimzia, Cosentyx, 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.

Note: Bimzelx will not be covered in combination with another biologic drug. Before Bimzelx is covered, the patient must meet all of the General Criteria for Bimzelx and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Cablivi

Products Affected

- Cablivi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Cablivi (caplacizumab)

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

- Have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP), which includes thrombocytopenia and microscopic evidence of red blood cell fragmentation; **AND**
- Patient is at least 18 years of age; **AND**
- Cablivi will be administered in addition to plasma exchange and immunosuppressive therapy and continued for 30 days after discontinuation of plasma exchange.

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

- Patient has received Cablivi in combination with plasma exchange and immunosuppressive therapy during plasma exchange and for 30 days beyond the last plasma exchange; **AND**
- Patient has sign(s) of persistent underlying disease such as suppressed ADAMTS13 activity levels; **AND**
- Treatment will be extended for a maximum of 28 days.

Duration of Approval:

- Initial: approval duration of 30 days with a quantity limit of 31 vials per 30 days.
- Continuation: approval duration of 28 days with a quantity limit of 28 vials per 28 days.

Cardiac Myosin Inhibitors

Products Affected

- Camzyos
- Myqorzo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Cardiac Myosin Inhibitors

Preferred Agent(s):

- Camzyos (mavacamten)
- Myqorzo (aficamten)

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 symptomatic NYHA class II or III obstructive hypertrophic cardiomyopathy; **AND**
- Patient is at least 18 years of age; **AND**
- Have a left ventricular ejection fraction of at least 55%; **AND**
- Prescribed by or in consultation with a cardiologist; **AND**
- Has a history of trial and failure (at least 30 days), intolerance/contraindication, or intolerance to both of the following medications:
  - Beta blocker (e.g., metoprolol); **AND**
  - Calcium channel blocker (e.g., verapamil, diltiazem).

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

- Documentation that the patient has experienced a positive clinical response to Camzyos compared to baseline (e.g., improvement in patient reported symptoms, improvement in NT-proBNP, decreased shortness of breath); **AND**

- Improvement of pVO2 by at least 1.5 mL/kg/min **PLUS** at least one NYHA class reduction or at least a 3 mL/kg/min pVO2 improvement with stable NYHA class.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Camzyos and Myqorzo are not covered in combination with one another.

Carglumic acid

Products Affected

- Carglumic Acid

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Carglumic acid (generic Carbaglu)

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

- Patient has a diagnosis of deficiency of N -acetylglutamate synthase (NAGS); **AND**
- Has acute or chronic hyperammonemia.

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

- Clinical documentation, including chart notes, of disease stability or improvement must be provided.

Duration of Approval: 12 months

Cayston

Products Affected

- Cayston

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Cayston (aztreonam inhalation)

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

- Patient has a diagnosis of cystic fibrosis confirmed by appropriate diagnostic or genetic testing (documentation of cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health); **AND**
- Patient is at least 7 years of age; **AND**
- Confirmation of Pseudomonas aeruginosa in cultures of the airways confirmed by a copy of positive sputum culture; **AND**
- Susceptibility results showing aztreonam is the only inhaled antibiotic to which the Pseudomonas aeruginosa is sensitive **OR** at least one of the following:
  - Previous use of tobramycin inhalation solution and experienced a clinically significant adverse drug reaction or unsatisfactory therapeutic response.
  - Contraindication/intolerance to tobramycin inhalation solution.
  - Culture shows resistance to tobramycin.

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

- Continues to require treatment of Pseudomonas aeruginosa infection; **AND**
- Documentation of stabilization or improvement by pulmonologist or CF specialist.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Coverage for Cayston is to be used for 28 days, following 28 days off.

Cholbam

Products Affected

- Cholbam

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Cholbam (cholic acid)

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

- Patient has a diagnosis of bile acid synthesis disorder due to single enzyme defects (SED) or peroxisomal disorder (PD); **AND**
- Provide a serum very long chain fatty acid value (VLCFA); **AND**
- Provide baseline liver function tests.

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

- Body weight increased by 10 percent or is stable of at least the 50th percentile; **AND**
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is less than 50 U/L or baseline levels reduced by 80 percent; **AND**
- Total bilirubin level reduced to less than or equal to 1mg/Dl; **AND**
- Not have evidence of cholestasis on liver biopsy.

Duration of Approval: 12 months

Cibinqo

Products Affected

- Cibinqo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Cibinqo (abrocitinib)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **atopic dermatitis** requests:
  - Patient has moderate to severe atopic dermatitis; **AND**
  - Patient has tried **ONE** of the following:
    - One medium to high potency topical corticosteroid for a period of at least 3 months; **OR**
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months; **AND**
  - Patient has tried at least **TWO** of the following:
    - Dupixent, Adbry, Nemluvio each for a period of at least 3 months.

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

- Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL).

Duration of Approval: 12 months

Note: Cibinqo is not covered in combination with other biologic drug therapy. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in

the FDA label.

Cimzia

Products Affected

- Cimzia (1 Syringe)
- Cimzia (2 Syringe)
- Cimzia-Starter

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Cobenfy

Products Affected

- Cobenfy
- Cobenfy Starter Pack

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Cobenfy (xanomeline / trospium)

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

- Have a diagnosis of schizophrenia; **AND**
- Patient is at least 18 years of age; **AND**
- Have tried and failed, or have intolerance/contraindication to 2 atypical antipsychotic drugs, used for at least 28 days each; **AND**
- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

Duration of Approval: 12 months

Cosentyx

Products Affected

- Cosentyx (300 MG Dose)
- Cosentyx Sensoready (300 MG)
- Cosentyx Sensoready Pen
- Cosentyx Subcutaneous
- Cosentyx UnoReady

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Cosentyx (secukinumab)

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.
- 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.
- For **Ankylosing Spondylitis** requests:
  - There are no Specific Induction Criteria for this indication. Cosentyx is covered for any patient who meets the General Initiation Criteria.
- For **non-radiographic axial spondyloarthritis (nr-axSpA)** requests:
  - 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 **Hidradenitis Suppurativa** requests:
  - Patient has tried at least **ONE** other agent for this condition (e.g., intralesional or oral corticosteroids, or systemic antibiotics, or isotretinoin).

Note: Cosentyx will not be covered in combination with another biologic drug. Before Cosentyx is covered, the patient must meet all of the General Criteria for Cosentyx and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Crenessity

Products Affected

- Crenessity

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Crenessity (crinecerfont)

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

- Have a diagnosis of classic Congenital Androgen Hyperplasia (CAH) confirmed by genetic testing showing 21-hydroxylase deficiency (21OHD); **AND**
- Patient is at least 4 years of age; **AND**
- Be stable and compliant on current dose of glucocorticoid for at least 1 month and receiving a dose of more than 13 mg/m2/day of hydrocortisone equivalents; **AND**
- Demonstrate the inability to lower current GC dose (i.e. androstenedione or 17-OHP level > Upper Normal Limit (ULN) for patient age/sex; [assigned male at birth]: androstenedione level >0.5 x testosterone; [assigned female at birth]: symptoms of hyperandrogenism (hirsutism, acne, menstrual irregularities) despite above-normal androgen levels); **AND**
- Demonstrate medical necessity to lower current glucocorticoid dose (e.g. uncontrolled hypertension, diabetes, weight gain, bone mineral density loss) despite efforts to treat these conditions); **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 Crenessity as evidenced by a reduced daily glucocorticoid dose from baseline.

Duration of Approval:

- Initial: 6 months

- Continuation: 12 months

Note: Crenessity will not be covered in combination with CYP3A4 inducers (e.g, phenobarbital, phenytoin, rifampin, carbamazepine). Use of Crenessity oral solution is not covered in patients weighing more than 55kg unless documented inability to swallow capsule is provided.

Cresemba

Products Affected

- Cresemba Oral

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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: 6 months
- Continuation: 12 months

Cystic Fibrosis Agents (CFTR modulators)

Products Affected

- Alyftrek
- Kalydeco
- Orkambi
- Symdeko
- Trikafta

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Cystic Fibrosis Agents (CFTR modulators)

Preferred Agent(s):

- **Kalydeco (ivacaftor)**
- **Orkambi (lumacaftor/ivacaftor)**
- **Symdeko (tezacaftor/ivacaftor)**
- **Trikafta (elexacaftor/tezacaftor/ivacaftor, ivacaftor)**
- **Alyftrek (vanzacaftor/tezacaftor/deutivacaftor)**

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 cystic fibrosis (CF) (documentation of a CF ICD10 code within the last 12 months must be submitted to Priority Health). Approved ICD10 codes for CF include: E84.0, E84.11, E84.19, E84.8, E84.9; **AND**
- Drug formulation (i.e. granules, tablets) requested must match FDA label for age.

Dalfampridine ER

Products Affected

- Dalfampridine ER

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Dalfampridine ER (generic Ampyra)

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

- Have a diagnosis of multiple sclerosis (MS); **AND**
- Be receiving immunomodulatory therapy (unless immunomodulatory therapy is not indicated for patients MS type); **AND**
- Be between the ages of 18 to 70 years; **AND**
- Have significant and continuous walking impairment that impairs ability to complete normal daily activities (such as meal preparation, household chores, etc.) attributable to ambulation or functional status despite optimal treatment for MS; **AND**
- Patient does not require the use of a wheelchair (bilateral assistance is acceptable, such as a brace, cane, or crutch, if the patient can walk 20 meters without resting); **AND**
- Baseline timed 25-foot walk test (T25FW) is completed within 8 to 45 seconds **OR** patient has an Expanded Disability Status Scale (EDSS) score greater than or equal to 4.5 but less than 7.

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

- Documentation that the patient has met all the following requirements:
  - Maintain an 85% adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient; **AND**
  - Patients' functional impairment must resolve because of increased speed of ambulation resulting in the member being able to complete instrumental activities (meal preparation, household chores, etc.); **AND**

- Requires at least a 20% improvement in timed walking speed as documented by the T25FW test from pre-treatment baseline.

Duration of Approval:

- **Initial**: 6 months
- **Continuation**: 12 months

Note: Patient must not have a spinal cord injury, myasthenia gravis, or demyelinating peripheral neuropathies (such as Guillain-Barre syndrome), Alzheimer's disease, or Lambert Eaton myasthenic syndrome.

Daybue

Products Affected

- Daybue
- Daybue Stix

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Daybue (trofinetide)

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

- Have a diagnosis of classic/typical Rett syndrome with MCEP2 gene mutation (supporting documentation must be submitted to Priority Health); **AND**
- Provide documentation of baseline Rett Syndrome disease severity of behavior and/or functionality using an objective measure or tool (e.g., Clinical Global Impression (CGI) score, Rett Syndrome Behavior Questionnaire (RSBQ), Motor-Behavior Assessment [MBA], Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale); **AND**
- Have undergone an in-depth behavioral assessment by a neurologist, geneticist, or developmental pediatrician; **AND**
- Patient is at least 2 years of age; **AND**
- Prescriber is a specialist or has consulted with a neurologist, geneticist, or developmental pediatrician.

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

- Documentation of positive clinical response as evidenced by improvement in disease severity using an objective measure or tool (e.g., CGI, RSBQ, MBA).

Duration of Approval:

- Initial: 3 months
- Continuation: 3 months

Note: Daybue will not be covered for patients with atypical or variant Rett syndrome.

Diacomit

Products Affected

- Diacomit

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Diacomit (stiripentol)

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

- Patient has a diagnosis of Dravet syndrome and will be using Diacomit as adjunctive treatment for seizures; **AND**
- Patient is at least 2 years of age; **AND**
- Will use in combination with clobazam (there are no clinical data to support the use of Diacomit as monotherapy in Dravet syndrome); **AND**
- Have a trial and failure with valproate and clobazam.

Droxidopa

Products Affected

- Droxidopa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Droxidopa (generic Northera)

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

- Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by one of the following:
  - Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, and pure autonomic failure);
  - Dopamine beta-hydroxylase deficiency; **OR**
  - Non-diabetic autonomic neuropathy; **AND**
- Diagnosis excludes other causes of orthostatic hypotension (e.g., congestive heart failure, fluid restriction, malignancy); **AND**
- Patient has tried at least two of the following non-pharmacologic interventions:
  - Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates), alpha-adrenergic antagonists, and antidepressants];
  - Raising the head of the bed 10 to 20 degrees;
  - Compression garments to the lower extremities or abdomen;
  - Physical maneuvers to improve venous return (e.g., regular modest-intensity exercise);
  - Increased salt and water intake, if appropriate;
  - Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing); **AND**
- Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist; **AND**
- Has a history of trial and failure (at least 30 days), intolerance/contraindication, or intolerance to both of the following medications:
  - Midodrine; **AND**

- Fludrocortisone.

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

- Documentation of positive clinical response to droxidopa therapy; **AND**
- Member has experienced a sustained decrease in dizziness since initiation of therapy; **AND**
- Member has maintained an increase in systolic and diastolic blood pressure within 3 minutes of standing since the initiation of therapy.

Duration of Approval:

- Initial: 3 months
- Continuation: 6 months

Dupixent

Products Affected

- Dupixent

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Dupixent (dupilumab)

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

- For **atopic dermatitis** requests:
  - Patient has moderate to severe atopic dermatitis; **AND**
  - Patient has tried **ONE** of the following:
    - One medium to high potency topical corticosteroid for a period of at least 3 months; **OR**
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months.

- For **moderate-to-severe asthma** requests:
  - Eosinophilic asthma confirmed by a peripheral blood eosinophil count greater than 150 cells/mcL in the past 12 months; **OR** required dependence on daily oral corticosteroids; **AND**
  - 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 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 **moderate-to-severe 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 Dupixent; **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 **prurigo nodularis** requests:
  - Patient has moderate to severe prurigo nodularis (score of at least 7 on the Worst Itching Intensity Numerical Rating Scale (WI-NRS) and at least 20 nodular lesions); **AND**
  - Patient has tried **ALL** of the following:
    - One medium to high potency topical corticosteroid for a period of at least 3 months; **AND**
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months.

- For **eosinophilic esophagitis (EoE)** requests:
  - Eosinophilic esophagitis confirmed through biopsy (at least 15 intraepithelial eos/hpf); **AND**
  - Patient has tried and failed **ALL** of the following:
    - Dietary modification; **AND**
    - One proton pump inhibitor for a period of at least 2 months; **AND**
    - One topical corticosteroid (i.e., fluticasone, budesonide) for a period of at least 2 months.

- For **chronic urticaria** requests:
  - Patient is at least 12 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 **bullous pemphigoid** requests:
  - Patient has moderate to severe bullous pemphigoid (score of at least 24 on the Bullous Pemphigoid Disease Area Index and a weekly average Peak Pruritus NRS score of 4); **AND**
  - Patient has tried **ALL** of the following:
    - One medium to high potency topical corticosteroid for a period of at

least 3 months; **AND**
- One oral corticosteroid (i.e., prednisone) for a period of at least 3 months; **AND**
- One traditional non-biologic systemic agent (i.e., azathioprine, mycophenolate, methotrexate, doxycycline) for a period of at least 3 months.

Failure is defined as the inability to achieve and maintain remission of low or mild disease activity.

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

- For **atopic dermatitis** requests:
  - Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL).

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

- For **chronic rhinosinusitis with nasal polyp (CRSwNP)** requests:
  - 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 **moderate-to-severe 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 Dupixent.

- For **prurigo nodularis** requests:
  - Adherence to therapy including Dupixent; **AND**
  - Have positive clinical response (e.g., absolute change in Worst Itching Intensity Numerical Rating Scale (WI-NRS) and reduction in nodular lesions from baseline.

- For **eosinophilic esophagitis (EoE)** requests:
  - Adherence to therapy including Dupixent; **AND**
  - Have histological remission (defined as less than or equal to 6 eos/hpf); **AND**
  - Have positive clinical response (e.g., absolute change in Dysphagia Symptom Questionnaire (DSQ) score from baseline).

- For **chronic urticaria** requests:

    - Have a positive clinical response (reduction in the symptoms of urticaria).

- For **bullous pemphigoid** requests:
    - Adherence to therapy including Dupixent; **AND**
    - Have positive clinical response (e.g., reduction in disease severity from baseline).

Duration of Approval: 12 months

Note: Dupixent is not covered in combination with other biologic drug therapy (e.g., Fasenra, Tezspire, Xolair), Rhapsido, or with Ohtuvayre. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Dyspareunia Agents

Products Affected

- Imvexxy Maintenance Pack
- Imvexxy Starter Pack
- Intrarosa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Dyspareunia Agents

Preferred Agent(s):

- **Imvexxy (estradiol)**
- **Intrarosa (prasterone)**

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 moderate to severe dyspareunia caused by vulvovaginal atrophy; **AND**
- Plan documents must have sexual dysfunction rider; **AND**
- Documented trial with an OTC vaginal lubricant for at least 90 days; **AND**
- Documented trial of a vaginal estrogen product for at least 90 days.

Enbrel

Products Affected

- Enbrel
- Enbrel Mini
- Enbrel SureClick

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Enbrel (etanercept)

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.
- 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.
- For **Ankylosing Spondylitis** requests:
  - There are no Specific Induction Criteria for this indication. Enbrel is covered for any patient who meets the General Initiation Criteria.
- For **Rheumatoid Arthritis** requests:
  - Patient has tried at least one traditional non-biologic systemic agent (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine) for a period of at least 3 months.
- For **Juvenile Idiopathic Arthritis** requests:
  - Patient has tried at least **ONE** other agent for this condition (e.g., methotrexate, sulfasalazine, leflunomide, nonsteroidal anti-inflammatory

drug; **OR**

- Patient will be starting on Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide; **OR**
- Patient has aggressive disease, as determined by the prescribing physician.

Note: Enbrel will not be covered in combination with another biologic drug. Before Enbrel is covered, the patient must meet all of the General Criteria for Enbrel and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Enspryng

Products Affected

- Enspryng

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Enspryng (satralizumab)

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

- Patient has a diagnosis of Neuromyelitis optica spectrum disorder (NMOSD) (supporting documentation must be submitted to Priority Health); **AND**
- Anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided); **AND**
- Have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Have progressive disease on a therapeutic trial of rituximab; **AND**
- Expanded Disability Status Scale (EDSS) score of less than or equal to 7.

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

- Have a positive clinical response to Enspryng as evidenced by a documented decrease in relapse rate

Duration of Approval: 12 months

Entyvio SC

Products Affected

- Entyvio Pen
- Entyvio Subcutaneous Solution Pen-Injector 108 MG/0.68ML

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Entyvio SC (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).

Eohilia

Products Affected

- Eohilia

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Eohilia (budesonide oral suspension)

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

- Patient has a diagnosis of eosinophilic esophagitis (EOE) confirmed through biopsy (at least 15 intraepithelial eos/hpf); **AND**
- Patient has tried and failed **ALL** of the following:
  - Dietary modification; **AND**
  - One proton pump inhibitor for a period of at least 2 months; **AND**
  - One topical corticosteroid (i.e., fluticasone, budesonide) for a period of at least 2 months.
- Patient is at least 1 year of age; **AND**
- Prescribed by or in consultation with a gastroenterologist or allergist.

Duration of Approval: 12 weeks

Note: Eohilia is not covered in combination with biologic drug therapy. Failure is defined as the inability to achieve and maintain remission of low or mild disease activity.

Epidiolex

Products Affected

- Epidiolex

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Epidiolex (cannabidiol)

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

- Patient has a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex (documentation must be submitted to Priority Health); **AND**
- Be using Epidiolex as an adjunctive treatment for seizures associated with one of the above diagnoses; **AND**
- Patient is at least 1 year of age; **AND**
- Has tried and failed, or have intolerance/contraindication to at least two generic anticonvulsants.

Evrysdi

Products Affected

- Evrysdi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Evrysdi (risdiplam)

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.

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: Evrysdi will only be authorized in accordance with FDA-approved dosing for SMA.

Evrysdi is considered experimental and investigational for non-5q-spinal muscular atrophy disorders.

Evrysdi will not be authorized for use in patients previously treated with Zolgensma and will not be authorized for coverage in combination with Spinraza.

Fasenra

Products Affected

- Fasenra Pen

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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 **Hypereosinophilic Syndrome (HES)** requests:
  - Diagnosis of HES without an identifiable secondary non-hematologic cause; **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) OR have a blood eosinophil count of at least 1,000 cells/mcL; **AND**

- Be stable on standard therapy for HES including steroid therapy (e.g. prednisone) **OR** other immunosuppressive therapies (e.g., methotrexate, hydroxyurea).

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].

- 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).

Duration of Approval: 12 months

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

Fentanyl citrate lozenge

Products Affected

- fentaNYL Citrate Buccal Lozenge On A Handle 1200 MCG, 200 MCG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: **Fentanyl citrate lozenge** (generic Actiq)

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

- Patient is at least 16 years of age; **AND**
- Be using to manage breakthrough pain in cancer patients; **AND**
- Be receiving and tolerant to around-the-clock opioid therapy for persistent cancer pain.

Note: Limited to 120 lozenges per 30 days.

To request an Opioid Quantity Limit exception, click and complete the Opioid Quantity/Dose Limit exception request form.

Filsuvez

Products Affected

- Filsuvez

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Filsuvez (birch triterpenes)

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

- Diagnosis of recessive dystrophic epidermolysis (RDEB) with documentation of genetic testing confirming mutation(s); **AND**
- Have presence of open, partial thickness skin wounds; **AND**
- Application is limited to open, partial thickness skin wounds only during dressing change; **AND**
- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

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

- Documentation that Filsuvez is providing clinical benefit (e.g. complete wound closure, decrease in wound size, reduced body surface area affected by wounds, increase in granulation tissue, decrease in pain and/or infection

Duration of Approval:

- Initial: 3 months
- Continuation: 6 months

Note: Filsuvez is not covered when used in combination with Vyjuvek or Zevaskyn.

Fintepla

Products Affected

- Fintepla

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Fintepla (fenfluramine)

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

- Patient has a diagnosis of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome (documentation must be submitted); **AND**
- Patient is at least 2 years of age; **AND**
- Have tried and failed two of the following drugs alone or in combination:
  - clobazam, valproate/divalproex, or topiramate; **AND**
- Have tried and failed, or have contraindication to Diacomit (stiripentol)Dravet Syndrome only.

Firdapse

Products Affected

- Firdapse

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Firdapse (amifampridine)

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

- Patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) confirmed by one of the two electrodiagnostic studies and the antibody test as follows:
  - Patient has a normal sensory study with a reproducible post-exercise (i.e., 10 seconds of maximal
    isometric muscle activation) increase in compound motor action potential (CMAP) amplitude (post- exercise facilitation) of at least 60% compared to pre-exercise baseline **OR** a similar increment using high-frequency repetitive nerve stimulation (RNS); **AND**
  - Positive anti-P/Q type voltage-gated calcium channel (VGCC) antibody test
- Have clinical symptoms of LEMS (i.e., proximal lower extremity weakness) that interfere with daily activities; **AND**
- Be ambulatory; **AND**
- Provide a baseline disease severity score using the Quantitative Myasthenia Gravis (QMG) or the Triple- Timed Up-And-Go (3TUG) test; **AND**
- For adult patients only, have tried and failed pyridostigmine (fail is defined as taking the medication as prescribed and at an appropriate dose for the condition); **AND**
- If the patient has a cancer diagnosis associated with LEMS (e.g., small cell lung cancer), the cancer has been appropriately treated prior to starting Firdapse.

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

- Have disease response indicated by an improvement or stabilization from baseline

in subjective measures (e.g., symptoms such as muscle weakness, improvement in daily activities, walking); **AND**
- Have disease response indicated by an improvement or stabilization from baseline in objective measures using the 3TUG test.

Duration of Approval:

- Initial: 4 weeks
- Continuation: 12 months

Note: The covered quantity of amifampridine is limited to the FDA-approved dose for the drug and depends upon the age and weight of the member

Gabapentin extended release

Products Affected

- Gabapentin (Once-Daily)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Gabapentin extended release (generic Gralise)

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

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

Galafold

Products Affected

- Galafold

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Galafold (miglastat)

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

- Patient has a diagnosis of Fabry disease, and an amenable galactosidase alpha gene variant based on in-vitro assay data (supporting documentation must be submitted to Priority Health); **AND**
- Patient is at least 18 years of age.

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

- Have a continued response to treatment (e.g. reduction in plasma glycosphingolipid GL-3 levels compared to baseline, decline in GFR or progression to end stage renal disease) as determined by the prescribing physician; **AND**
- The patient is compliant in taking the medication as scheduled.

Duration of Approval: 12 months

Note: Galafold is not covered when used in combination with enzyme replacement therapy (ERT), thus combination use with Fabrazyme is not covered.

Gattex

Products Affected

- Gattex

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Gattex (teduglutide)

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

- Diagnosis of short bowel syndrome dependent on parenteral support. Please provide the following information:
  - Patient's current body mass index;
  - How long the patient has received parenteral support;
  - Total daily volume of parenteral support; **AND**
- Patient's body mass index is 15 kg/m2 or greater; **AND**
- If the patient has inflammatory bowel disease, he or she must not have taken immunosuppressant drugs within 3 months before starting Gattex and not used a biologic drug within 6 months before starting Gattex; **AND**
- If the patient has their large intestine intact, a colonoscopy must be completed within 6 months before starting Gattex; **AND**
- A reasonable expectation the patient will be removed from parenteral support within 6 months; **AND**
- Patient must not have a history of:
  - Colorectal or gastrointestinal malignancy
  - Radiation enteritis
  - Cancer within 5 years before starting Gattex
  - Use of human growth hormone within 6 months before starting Gattex
  - Treatment for active Crohn's disease within 12 weeks before starting Gattex
  - More than 4 admissions within 12 months before starting Gattex

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

- The patient is compliant in taking the medication as scheduled; **AND**
- The patient had a 50% reduction in parenteral support volume; **AND**
- With continued treatment, the patient can be removed from parenteral support within the next 6 months.

Duration of Approval:

- Initial: 6 months
- Continuation: 6 months (one time continuation approval only)

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

Products Affected

- Mounjaro Subcutaneous Solution Pen-Injector 10 MG/0.5ML, 12.5 MG/0.5ML, 15 MG/0.5ML, 2.5 MG/0.5ML, 5 MG/0.5ML, 7.5 MG/0.5ML
- Trulicity Subcutaneous Solution Pen-Injector 0.75 MG/0.5ML, 1.5 MG/0.5ML, 3 MG/0.5ML, 4.5 MG/0.5ML

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

Preferred Agent(s):

- **Trulicity (dulaglutide)**
- **Mounjaro (tirzepatide)**

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

- Patient has a diagnosis of Type 2 diabetes mellitus; **AND**
- Trial and failure of, or intolerance of at least 2 antidiabetic agents.

Note: Medications in this category are only covered for type 2 diabetes mellitus.

Hemophilia Products, Factor IX

Products Affected

- AlphaNine SD
- Alprolix
- BeneFIX
- Idelvion
- Ixinity
- Rebinyn
- Rixubis

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Hemophilia Products, Factor IX

Preferred Agent(s):

- **Alprolix, BeneFIX, Ixinity**

Non-Preferred Agent(s):

- **AlphaNine, Idelvion, Rebinyn, Rixubis**

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

- Diagnosis of severe Hemophilia B (factor IX level of less than 1%) has been confirmed by blood coagulation testing; **OR** diagnosis of moderate Hemophilia B with at least two documented episodes of spontaneous bleeding into joints (supporting documentation must be submitted to Priority Health); **AND**
- Be used for at least one of the following:
  - Control and prevention of acute bleeding episodes, **OR**
  - Perioperative management, **OR**
  - Routine prophylaxis to prevent/reduce the frequency of bleeding episodes.
- Prescribed by a hematologist or other specialist; **AND**
- NOT to be used for induction of immune tolerance in patients with hemophilia B; **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to a preferred product.

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

- Have evidence of efficacy (i.e., less breakthrough bleeds as documented in the treatment log and/or chart notes).

Duration of Approval:

- Perioperative management (1 month)
- acute bleeding management (see below)
- routine prophylaxis (12 months)

Note: Dosing should be provided through the nearest available vial size and/or dosing interval that will produce the least amount of waste per dose. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label. Additionally, when approved, Hemophilia Products should be obtained from a participating Hemophilia Specialty Pharmacy as noted in Medical Policy 91569.

For acute bleeding management:

Limited to a total of five on-hand doses. Each additional fill requires documentation of the patient's use of the previous supply of factor product. Information regarding cumulative quantities of on-hand factor must be provided when requesting for acute bleeding management.

Hemophilia Products, Factor VIII

Products Affected

- Advate
- Adynovate
- Afstyla
- Altuviiio
- Eloctate
- Esperoct
- Hemofil M
- Jivi
- Koate
- Kogenate FS Intravenous Kit 1000 UNIT, 2000 UNIT, 250 UNIT, 3000 UNIT, 500 UNIT
- Kovaltry
- Novoeight
- Nuwiq Intravenous Solution Reconstituted
- Recombinate
- Tretten
- Xyntha
- Xyntha Solofuse

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Hemophilia Products, Factor VIII

Preferred Agent(s):

- **Advate, Adynovate, Afstyla, Altuviiio, Eloctate, Esperoct, Hemofil, Jivi, Koate, Kogenate, Kovaltry, NovoEight, Nuwiq, Recombinate, Tretten, Xyntha**

Non-Preferred Agent(s):

- *Not applicable*

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

- Diagnosis of severe Hemophilia A (factor VIII level of less than 1%) has been confirmed by blood coagulation testing; **OR** diagnosis of moderate Hemophilia A with at least two documented episodes of spontaneous bleeding into joints (supporting documentation must be submitted to Priority Health); **AND**
- Be used for at least one of the following:
  - Control and prevention of acute bleeding episodes, **OR**
  - Perioperative management, **OR**
  - Routine prophylaxis to prevent/reduce the frequency of bleeding episodes.
- Prescribed by a hematologist or other specialist; **AND**

- NOT to be used for induction of immune tolerance in patients with hemophilia A; **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to a preferred product.

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

- Have evidence of efficacy (i.e., less breakthrough bleeds as documented in the treatment log and/or chart notes).

Duration of Approval:

- Perioperative management (1 month)
- acute bleeding management (see below)
- routine prophylaxis (12 months)

Note: Dosing should be provided through the nearest available vial size and/or dosing interval that will produce the least amount of waste per dose. Please provide rationale when requesting any dose or dosing interval not listed in the FDA label. Additionally, when approved, Hemophilia Products should be obtained from a participating Hemophilia Specialty Pharmacy as noted in Medical Policy 91569.

For acute bleeding management:

Limited to a total of five on-hand doses. Each additional fill requires documentation of the patient's use of the previous supply of factor product. Information regarding cumulative quantities of on-hand factor must be provided when requesting for acute bleeding management.

Hemophilia Products, Miscellaneous

Products Affected

- Alhemo
- Hemlibra
- Hympavzi
- Qfitlia

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Hepatitis C Antivirals

Products Affected

- Ledipasvir-Sofosbuvir
- Sofosbuvir-Velpatasvir
- Sovaldi
- Vosevi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Hepatitis C Antivirals, Direct Acting agents

Preferred Agent(s): *Prior authorization not required if Hep C ICD-10 codes are on file.*

- **Mavyret (glecaprevir/pibrentasvir)**
- **Sofosbuvir/velpatasvir (generic Epclusa)**

Non-Preferred Agent(s): *See criteria below*

- **Sovaldi (sofosbuvir)**
- **Vosevi (sofosbuvir/velpatasvir/voxilaprevir)**
- **Ledipasvir/sofosbuvir (generic Harvoni)**

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

- Have a diagnosis of chronic hepatitis C (ICD-10 codes: B18.2, B19.2, and B19.21) **OR** acute hepatitis C (ICD-10 codes: B17.10 and B17.11 for Mavyret only); **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to Mavyret or sofosbuvir/velpatasvir.

Hepcludex

Products Affected

- Hepcludex

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Hepcludex (bulevirtide)

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

- Have a positive hepatitis delta virus (HDV) antibody test or HDV RNA polymerase chain reaction (PCR) within 6 months prior to start of treatment; **AND**
- Have a current positive HDV RNA PCR result; **AND**
- Have an alanine aminotransferase (ALT) level of greater than 1-times to less than 10-times the upper limit of normal (ULN); **AND**
- Have no history of decompensated liver disease (Child-Pugh Class B or C); **AND**
- Patient is at least 18 years of age; **AND**
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.

For continuation of coverage:

- Must have documented therapeutic benefit (e.g., evidence of a virologic response (undetectable HDV RNA or ≥2 log10 IU/mL decline in HDV RNA over baseline), ALT decline, decrease in liver stiffness, or HBsAg response (HBsAg loss or HBsAg decrease by ≥1 log10 IU/mL) compared to pre-treatment levels.

Duration of Approval: 12 months

Hereditary Angioedema Agents, Acute Treatment

Products Affected

- Berinert
- Icatibant Acetate
- Kalbitor

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Hereditary Angioedema Agents, Acute Treatment

Preferred Agent(s):

- **Berinert (C1 esterase inhibitor)**
- **Icatibant**

Non-Preferred Agent(s):

- **Kalbitor (ecallantide)**

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

- Diagnosis of Hereditary angioedema (HAE) Type I or Type II with two sets of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis (supporting documentation must be submitted to Priority Health); **AND**
- Prescribed by an allergist, immunologist, hematologist, or other specialist experienced in treating HAE; **AND**
- Follow age-appropriate use as listed in FDA-approved label for each drug; **AND**
- Documentation of patient attacks affecting upper airways, **OR** involving the face, neck, or abdomen, OR resulting in debilitation or dysfunction; **AND**
- Patient has received training for self-administration; **AND**
- Patient is not on an angiotensin-converting enzyme (ACE) inhibitor.

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

- If use of an acute agent is required to treat on average more than 3 attacks per

month, Priority Health may require a second opinion of your HAE treatment plan, as noted in the plan documents.
- The WAO/EAACI recommends that a patient's HAE treatment plan and use of prophylactic and acute therapies be reviewed and evaluated at least yearly to gauge efficacy, safety, and dosing.

Duration of Approval:

- Icatibant: Limited to a total of three syringes on-hand. Each additional fill requires documentation of the patient's use of the previous supply of icatibant, as well as documentation of symptom relief with use. For example, if the member has two syringes on hand, then Priority Health will authorize a fill of one syringe to total three syringes on hand if icatibant showed benefit for the patient.
- Berinert: Limited to one fill of 20 units/kg (supplied in 500 unit vials). Each additional fill requires documentation of the patient's use of the previous supply of Berinert, as well as documentation of symptom relief with use.
- Kalbitor: Limited to a total of six injections (two doses of 30mg given as three 10mg injections) on-hand. Each additional fill requires documentation of the patient's use of the previous supply of Kalbitor, as well as documentation of symptom relief with use. For example, if the patient has one dose of 30 mg (three 10 mg syringes) on hand, then Priority Health will authorize one dose of 30 mg to provide a total on hand supply of
two 30 mg doses if Kalbitor showed benefit for the patient.

Note: As noted in the plan documents, Priority Health may require a second opinion confirming the diagnosis. Two or more acute-use agents (Firazyr, Berinert, and Kalibtor) are not covered in combination.

Hereditary Angioedema Agents, Preventative Treatment

Products Affected

- Haegarda MG/2ML
- Orladeyo
- Takhzyro
- Takhzyro Subcutaneous Solution 300

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Hereditary Angioedema Agents, Preventative Treatment

Preferred Agent(s):

- **Orladeyo (berotralstat)**
- **Takhzyro (lanadelumab)**

Non-Preferred Agent(s):

- **Haegarda (C1 esterase inhibitor)**

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

- Diagnosis of Hereditary angioedema (HAE) Type I or Type II with two sets of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis (supporting documentation must be submitted to Priority Health); **AND**
- Prescribed by an allergist, immunologist, hematologist, or other specialist experienced in treating HAE; **AND**
- Follow age-appropriate use as listed in FDA-approved label for each drug; **AND**
- Documentation of severe (e.g. airway swelling, debilitating attacks of the face, neck, or abdomen) acute attacks occurring at least twice per month; **AND**
- Documentation that on-demand/acute therapy (e.g. Firazyr, Berinert, Kalbitor) did not provide adequate symptom control; **AND**
- Patient has received training for self-administration (Takhzyro and Haegarda); **AND**
- Patient is not on an angiotensin-converting enzyme (ACE) inhibitor.

- Non-preferred drug product:
    - Trial and failure, or intolerance/contraindication to a preferred product.

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

- Submission and review of patient's HAE treatment plan; **AND**
- Compliance on therapy; **AND**
- Documentation of a decrease in the frequency of acute attacks from baseline (prior to treatment); **AND**
- The WAO/EAACI recommends that a patient's HAE treatment plan and use of prophylactic and acute therapies be reviewed and evaluated at least yearly to gauge efficacy, safety, and dosing.

Duration of Approval:

- Takhzyro: Limited to either 150mg or 300mg (one vial) every 2 weeks. Duration of each authorization is limited to 6 months. Patients who are attack-free after 6 months of treatment with Takhzyro are authorized for 300mg (one vial) every 4 week for 12 months.
- Haegarda: Limited to 60units/kg (in combinations of 3,000- & 2,000-unit vials) every 3 days for 12 months.
- Orladeyo: 12-month authorization

Note: As noted in the plan documents, Priority Health may require a second opinion confirming the diagnosis. Two or more prophylactic agents (i.e. Takhyzro, Haegarda, Orladeyo) are not covered in combination.

Human Growth Hormone

Products Affected

- Genotropin
- Genotropin MiniQuick
- Omnitrope Subcutaneous Solution Cartridge

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Human Growth Hormone

Preferred Agent(s):

- **Genotropin**
- **Omnitrope**

FOR PATIENTS LESS THAN 18 YEARS OF AGE

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

- Prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, pediatric nephrologist); **AND**
- Meet one of the following diagnoses and the applicable criteria for each diagnosis below.

- For **Growth Hormone Deficiency (GHD)** requests:
  - Meet one of the following:
    - Height is at least 2.5 SD below the mean for chronological age and sex; **OR**
    - Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile; **OR**
    - Using for neonatal hypoglycemia associated with growth hormone deficiency; **AND**
  - Growth plates must be open; **AND**
  - Meet one of the following:

        - Documented GH deficiency via 2 growth hormone (GH) stimulation tests below 10 ng/mL; **OR**
        - GH stimulation test level below 15 ng/mL, and IGF-1 and IGF-PB3 levels below normal for bone age and gender; **OR**
        - One GH stimulation test below 10 ng/mL for children with defined CNS pathology (ex. pituitary surgery, radiation therapy, precocious puberty); **OR**
        - If using for neonatal hypoglycemia associated with GHD, one random GH level less than 20 ng/mL.

- For **Idiopathic Short Stature (ISS)** requests:
    - Meet one of the following:
        - Height is at least 2.5 SD below the mean for chronological age and sex; **OR**
        - Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile.

- For **Turner's syndrome, SHOX gene variant, Prader-Willi Syndrome, or Noonan Syndrome** requests:
    - Growth plates must be open; **AND**
    - Diagnosis must be confirmed by genetic testing.

- For **Pre-transplant chronic renal insufficiency** requests:
    - Meet one of the following:
        - Height is at least 2.5 SD below the mean for chronological age and sex; **OR**
        - Height is between 2.0 and 2.5 SDs below the mean for chronological age and sex with decreased growth rate measured as growth velocity over one year below 25th percentile; **AND**
    - Patient is receiving weekly dialysis or creatinine clearance is less than 75 ml/min; **AND**
    - No evidence of active malignancy; **AND**
    - Growth plates must be open.

- For **Small for Gestational Age (SGA)** requests:
    - Child born small for gestational age, defined as birth weight or length less than 10th percentile of birth weight for gestational age; **AND**
    - Child fails to manifest catch up growth by age of 2 years, defined as height 2 or more SDs below the mean for age and sex; **AND**
    - Growth plates must be open.

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

- Growth velocity on treatment is at least 2.5 cm/year (must submit documentation of previous and current heights with dates).
- **Note:** HGH will no longer be covered when growth velocity is less than 2 cm/year and bone age in those who are assigned male at birth is 16 years, bone age in those who are assigned female at birth is 14 years.

Duration of Approval: 12 months

Note: The following conditions are not covered for patients less than 18 years of age: constitutional growth delay, familial short stature, and those with acute or chronic catabolic illness.

FOR PATIENTS 18 YEARS OF AGE AND OLDER

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

- Prescribed by a specialist in the condition being treated (e.g., pediatric endocrinologist, pediatric nephrologist); **AND**
- Meet one of the following diagnoses and the applicable criteria for each diagnosis below.

- For **Growth hormone deficiency (GHD)** requests:
  - GHD documented by one of the following:
    - suboptimal response (less than 3 mcg/L) to a hypoglycemic challenge (if contraindicated, another acceptable method is allowed); **OR**
    - at least 2 other pituitary-related hormone deficiencies **AND** an abnormally low IGF; **AND**
  - Patient has one of the following:
    - hypothalamic pituitary disease resulting from tumor or infarct
    - history of cranial irradiation during childhood or adulthood resulting in GH deficiency
    - Pituitary surgery resulting in GH deficiency
    - Continuing treatment of childhood onset GH deficiency
    - History of head trauma or subarachnoid hemorrhage

- For **Short bowel syndrome** requests:
  - Be receiving total parenteral nutrition (TPN); **AND**
  - Be participating in a program that manages dietary intake and hydration.

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

- Low IGF-1 (within the past 12 months), but dose is being increased; **OR**
- IGF-1 (within the past 12 months) within appropriate range for age and sex

Duration of Approval: 12 months

Note: The following conditions are not covered for patients at least 18 years of age: treated during childhood without documented evidence of persistent growth hormone deficiency; physiologic reductions in growth hormone related to aging; and treatment of Turner's syndrome or cystinosis.

Immunoglobulin A Nephropathy Agents

Products Affected

- Filspari
- Tarpeyo
- Vanrafia

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Immunoglobulin A Nephropathy Agents

Preferred Agent(s):

- **Filspari (sparsentan)**
- **Tarpeyo (budesonide)**
- **Vanrafia (atrasentan)**

Non-Preferred Agent(s):

- *Not applicable*

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

- Diagnosis of biopsy-verified primary immunoglobulin A nephropathy (documentation must be submitted to Priority Health); **AND**
- Patient has tried and failed **ALL** of the following:
  - Maximally tolerated dose of ACE inhibitor or ARB (minimum of 3 months); **AND**
  - SGLT2 inhibitor (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**
- Prescriber is a specialist or has consulted with a specialist for the condition being treated; **AND**
- Patient is at least 18 years of age; **AND**
- Patient is not currently receiving dialysis and has not undergone kidney transplant.

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

- 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:

- **Filspari, Vanrafia:**
  - Initial: 9 months
  - Continuation: 12 months
- **Tarpeyo:** 10 months (total).

Note: Filspari, Tarpeyo and Vanrafia are not covered in combination with each other.

Impavido

Products Affected

- Impavido

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Impavido (miltefosine)

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

- Patient has a diagnosis of visceral, mucosal, or cutaneous leishmaniasis caused by one of the following: Leishmania donovani, Leishmania braziliensis, Leishmania guyanensis or Leishmania panamensis (supporting documentation must be submitted to Priority Health).

Duration of Approval: 1 month

Increlex

Products Affected

- Increlex

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Increlex (mecasermin)

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

- Patient has a diagnosis of severe primary insulin-like growth factor-1 (IGF-1) deficiency or primary growth hormone deficiency caused by growth hormone gene deletions with development of neutralizing antibodies to growth hormone (supporting documentation must be submitted to Priority Health); **AND**
- Patient is 2 to 65 years of age; **AND**
- Prescribed by, or after consultation with, a pediatric endocrinologist; **AND**
- Have the following:
  - Baseline height less than 3rd percentile or greater than 2 standard deviations (SD) below the mean for gender and age
  - IGF-1 at least 3 SD below the normal range for age and sex
  - History of lower-than-normal growth velocity
  - Epiphyses are open (must be confirmed for patients 10 years of age and older, submit radiograph)
  - Patient's bone age must be less than 16 years for those who are assigned male at birth, less than 14 years for those who are assigned female at birth

- For severe primary insulin-like growth factor deficiency additional criteria includes:
  - Documentation of growth hormone concentration is normal or increased, **OR** by molecular genetic testing of growth hormone receptor mutations.

- For primary growth hormone deficiency caused by growth hormone gene deletion additional criteria includes:
  - Documentation of prior treatment with growth hormone (typically 3-6 month trial) and subsequent antibody development.

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

- Epiphyses are open; **AND**
- Rate of growth with Increxlex is greater than pretreatment rate of growth; **AND**
- Patient's bone age must be less than 16 years for those who are assigned male at birth, less than 14 years for those who are assigned female at birth.

Duration of Approval: 12 months

Iron-based Phosphate Binders

Products Affected

- Auryxia
- Ferric Citrate
- Velphoro

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Iron-based Phosphate Binders

- **Auryxia (ferric citrate)**
- **Velphoro (sucroferric oxyhydroxide)**

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

- For hyperphosphatemia in patients with chronic kidney disease (CKD):
  - Require dialysis to control disease; **AND**
  - Patient has tried and failed at least **TWO** of the following:
    - calcium acetate, sevelamer, lanthanum; **AND**
  - Current adherence to dietary restriction of phosphate as defined by the KDOQI/KDIGO guidelines.

- For iron-deficiency anemia in CKD (Auryxia only):
  - Not be on dialysis; **AND**
  - Have an estimated GFR of less than 60 ml/min; **AND**
  - Trial and failure on therapeutic doses of oral iron supplements; **AND**
  - Have a hemoglobin (Hgb) between 9 g/dL and 11.5 g/dL; **AND**
  - Have a serum ferritin no greater than 200 ng/mL and transferrin saturation (TSAT) less than 25%

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

- For iron-deficiency anemia in CKD (Auryxia only):
  - Not require dialysis to control CKD; **AND**
  - Be free of the need for additional therapy with erythropoiesis-stimulating

agents (ESA), intravenous iron, or blood transfusions.

Duration of Approval:

- Initial: 4 months (for CKD anemia)
- Continuation: 12 months

Irritable Bowel Syndrome with Diarrhea Agents

Products Affected

- Alosetron HCl
- Viberzi
- Xifaxan Oral Tablet 550 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Irritable Bowel Syndrome with Diarrhea Agents

Preferred Agent(s):

- **Alosetron HCl (generic Lotronex)**
- **Viberzi**
- **Xifaxan 550mg tablet**

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

- Patient has a diagnosis of irritable bowel syndrome (IBS) with diarrhea; **AND**
- Have failed conventional treatment with lifestyle and dietary modification which may include exclusion of gas-producing foods, diet low in fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs), and in select cases avoidance of lactose and gluten (detailed documentation of lifestyle changes tried for at least 1 month must be faxed to Priority Health); **AND**
- Trial of at least three of the following (tried for at least 1 month each):
  - Loperamide
  - Antispasmodic (ex. Dicyclomine)
  - Bile acid sequestrant (cholestyramine, colestipol or colesevelam)
  - Tricyclic antidepressant (ex. nortriptyline)

Note: Xifaxan, Viberzi, alosetron HCl are not covered in combination with each other. For hepatic encephalopathy, Xifaxan 550mg tablet is covered for patients with an ICD-10 code of K76.82. For the diagnosis of irritable bowel syndrome with diarrhea (IBS-D), the quantity of Xifaxan 550mg tablet is limited to one tablet given 3 times daily for 14 days, may be retreated up to 2 times with the same dosing regimen if symptoms recur within a 6 month period. For the diagnosis of hepatic encephalopathy recurrence, the

quantity is limited to one 550 mg tablet given 2 times daily.

Isturisa

Products Affected

- Isturisa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Isturisa (osilodrostat)

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

- Have a diagnosis of Cushing's disease (documentation must be faxed to Priority Health); **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by an endocrinologist; **AND**
- Documentation of failed pituitary surgery or contraindication to pituitary surgery; **AND**
- Documentation of treatment failure on two of the following: ketoconazole, Lysodren, cabergoline, and/or Signifor/LAR.

Joenja

Products Affected

- Joenja

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Joenja (leniolisib)

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

- Have a diagnosis of activated phosphoinositide 3-kinase delta syndrome which was confirmed with either biochemical or molecular genetic testing (supporting documentation must be submitted to Priority Health); **AND**
- Have nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g. lung, liver); **AND**
- Patient is at least 4 years of age; **AND**
- Prescriber is a specialist or has consulted with a specialist for the condition being treated (APDS).

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

- Documentation of positive clinical response in signs and manifestations of APDS.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Keveyis

Products Affected

- Dichlorphenamide
- Keveyis

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Keveyis (dichlorphenamide)

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

- Patient has a diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants (supporting documentation must be submitted to Priority Health); **AND**
- Diagnosis confirmed by **ONE** of the following:
  - Genetic testing
  - Established family history
  - Provocative testing
  - Electromyography; **AND**
- Baseline and periodic monitoring of serum potassium and bicarbonate levels; **AND**
- Documentation that lifestyle modifications, dietary restrictions and exercise restrictions have been maximally challenged; **AND**
- Have tried and failed, or have intolerance/contraindication to acetazolamide.

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

- Documentation that the patient has had a reduction in the number of paralytic attacks.

Duration of Approval:

- Initial: 2 months
- Continuation: 12 months

Kevzara

Products Affected

- Kevzara

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Kevzara (sarilumab)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **Rheumatoid Arthritis** requests:
  - 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 **TWO** of the following:
    - tocilizumab, Enbrel, adalimumab, or Xeljanz/XR, each 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 **Polymyalgia Rheumatica** requests:
  - Patient has tried one systemic corticosteroid.

Note: Kevzara will not be covered in combination with another biologic drug. Before Kevzara is covered, the patient must meet all of the General Criteria for Kevzara and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide

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

Kineret

Products Affected

- Kineret

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Kineret (anakinra)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **Rheumatoid Arthritis** requests:
  - 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 **TWO** of the following:
    - tocilizumab, Enbrel, adalimumab, or Xeljanz/XR, each for a period of at least 3 months.

Note: Kineret will not be covered in combination with another biologic drug. Before Kineret is covered, the patient must meet all of the General Criteria for Kineret and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Livtencity

Products Affected

- Livtencity

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Livtencity (maribavir)

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

- Has a diagnosis of post-transplant (hematopoietic stem cell or solid organ transplantation) cytomegalovirus (CMV) infection/disease (supporting documentation must be submitted to Priority Health); **AND**
- Have baseline CMV DNA level (e.g., PCR); **AND**
- Have documentation of trial and failure with ganciclovir or valganciclovir; **AND**
- Not be used concomitantly with other CMV antivirals (e.g., ganciclovir, valganciclovir); **AND**
- Patient is at least at least 18 years of age; **AND**
- Patient weight is greater than 35 kilograms.

Duration of Approval: 8 weeks

Note: Livtencity 200 mg tablet has a quantity limit of 112 tablets per 28 days (400 mg twice daily). For patients requiring higher dosages, such as those taking selected interacting drugs, please provide rationale as to which co- administered drugs are being used.

Lupkynis

Products Affected

- Lupkynis

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Lupkynis (voclosporin)

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

- For biopsy-proven lupus nephritis Class III through V:
  - 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 45 mL/min/1.73m2; **AND**
  - Have tried and failed Benlysta.

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

- For biopsy-proven lupus nephritis Class III through V:
  - 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: Lupkynis is not covered in combination with other biologic drug therapy (e.g. Benlysta, Gazyva, rituximab).

Mavenclad

Products Affected

- Cladribine (10 Tabs)
- Cladribine (4 Tabs)
- Cladribine (5 Tabs)
- Cladribine (6 Tabs)
- Cladribine (7 Tabs)
- Cladribine (8 Tabs)
- Cladribine (9 Tabs)
- Mavenclad (10 Tabs)
- Mavenclad (4 Tabs)
- Mavenclad (5 Tabs)
- Mavenclad (6 Tabs)
- Mavenclad (7 Tabs)
- Mavenclad (8 Tabs)
- Mavenclad (9 Tabs)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Mavenclad (cladribine)

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

- Patient has a diagnosis of relapsing-remitting multiple sclerosis (MS) or active secondary progressive MS; **AND**
- Have had an inadequate response to at least **TWO** other disease modifying therapies for MS, one of which must be glatiramer, dimethyl fumarate, fingolimod, teriflunomide; **AND**
- Not have concurrent use with other MS disease modifying drugs; **AND**
- Not have clinically isolated syndrome (CIS); **AND**
- Patient is at least 18 years old.

Duration of Approval: 2 years

Note: Mavenclad is limited to a maximum of 20 tablets per year, and 40 tablets total treatment. Treatment duration is limited to two courses (4 cycles) over 2 years. Priority Health will not cover any other MS disease modifying drug therapies for 2 years after the first course of Mavenclad for patients who have completed 4 cycles of therapy.

Mifepristone

Products Affected

- miFEPRIStone Oral Tablet 300 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Mifepristone (generic Korlym)

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

- Patient has a diagnosis of hyperglycemia secondary to hypercortisolism in patients with endogenous Cushing's syndrome; **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by an endocrinologist; **AND**
- Have a diagnosis of endogenous Cushing's syndrome **AND** type II diabetes mellitus (DM) or glucose intolerance secondary to hypercortisolism; **AND**
- Have failed surgical treatment or are not a candidate for surgery; **AND**
- Have tried maximally titrated dosages of insulin and other agents used to treat DM for at least 3 months, and have been unable to achieve adequate diabetes control.

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

- Have documentation of an improvement in hyperglycemia control.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Miglustat

Products Affected

- migLUstat
- Yargesa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Miglustat (generic Zavesca)

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

- Patient has a diagnosis of mild to moderate type 1 Gaucher disease (must fax documentation of diagnostic testing confirming disease (i.e. genotyping) to Priority Health); **AND**
- Patient is at least 18 years of age; **AND**
- Patient must not be a candidate for enzyme replacement therapy (i.e. because of allergy, hypersensitivity).

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

Myalept

Products Affected

- Myalept

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Myalept (metreleptin)

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

- Patient has a diagnosis of acquired or congenital generalized lipodystrophy resulting in leptin deficiency complications (supporting documentation must be submitted to Priority Health); **AND**
- Provide laboratory leptin assay results confirming leptin deficiency:
  - Serum leptin levels less than the 7th percentile of normal values reported by the 3rd National Health and Nutrition Examination survey (less than 7.0 ng/mL in those assigned female at birth and less than 3.0 ng/mL in those assigned male at birth); **AND**
- Patient has **ONE** of the following metabolic abnormalities:
  - Type 2 diabetes mellitus
  - Triglyceride level more than 200 mg/dL
  - Hyperinsulinemia (defined by fasting serum insulin greater than 30 microunits/mL

Note: Myalept is not covered in the following conditions: HIV, infectious liver disease, acquired lipodystrophy with hematologic abnormalities. Limited to maximum weight based daily dosing per FDA label.

Myfembree

Products Affected

- Myfembree

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Myfembree (relugolix/estradiol/ norethindrone)

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

- Have a diagnosis of either:
  - heavy menstrual bleeding associated with uterine fibroids; **OR**
  - moderate to severe pain associated with endometriosis; **AND**
- Have a trial and failure of Oriahnn (elagolix/estradiol/norethindrone) or Orilissa (elagolix) used for at least 3 months.

Duration of Approval: 24 months total

Nemluvio

Products Affected

- Nemluvio

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Nemluvio (nemolizumab)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **atopic dermatitis** requests:
  - Patient has moderate to severe atopic dermatitis; **AND**
  - Patient has tried **ONE** of the following:
    - One medium to high potency topical corticosteroid for a period of at least 3 months; **OR**
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months.
- For **prurigo nodularis** requests:
  - Patient has moderate to severe prurigo nodularis (score of at least 7 on the Worst Itching Intensity Numerical Rating Scale (WI-NRS) and at least 20 nodular lesions); **AND**
  - Patient has tried **ALL** of the following:
    - One medium to high potency topical corticosteroid for a period of at least 3 months; **AND**
    - One topical calcineurin inhibitor (tacrolimus or pimecrolimus) for a period of at least 3 months.
- **For continuation of coverage, the patient must have met the following requirements:**

- For **atopic dermatitis** requests:
  - Have a positive clinical response (e.g., clinical reduction in body surface area (BSA) affected from baseline, reduction in pruritus severity and flares, improvement in ADL).

- For **prurigo nodularis** requests:
  - Adherence to therapy including Nemluvio; **AND**
  - Have positive clinical response (e.g., absolute change in Worst Itching Intensity Numerical Rating Scale (WI-NRS) and reduction in nodular lesions from baseline.

Duration of Approval: 12 months

Note: Nemluvio is not covered in combination with other biologic drug therapy. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Nexletol & Nexlizet

Products Affected

- Nexletol
- Nexlizet

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug(s):

- **Nexletol (bempedoic acid)**
- **Nexlizet (bempedoic acid/ezetimibe)**

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 Repatha (evolocumab) or Praluent (alirocumab); **AND**
- Patient's most recent LDL-C laboratory report must be submitted with authorization request; **AND**
- Patient must continue to receive maximally tolerated statin therapy or have a intolerance/contraindication to or intolerance of statin therapy*; **AND**
- Requires documentation of compliant use with at least one high-intensity statin (rosuvastatin at least 20 mg daily or atorvastatin at least 40 mg daily) in combination with ezetimibe for at least 8 consecutive weeks with failure to achieve

LDL-C less than 70 mg/dL in patients with history of CVD, or LDL-C less than 100 mg/dL in patients without history of CVD. If one high-intensity statin is not tolerated, a trial of a second statin is required.

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

Nitisinone

Products Affected

- Nitisinone

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Nitisinone (generic Orfadin)

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

- Have a diagnosis of hereditary tyrosinemia, type 1 (HT-1) that is confirmed by elevated urinary or plasma succinylacetone (SA) levels or a mutation in the fumarylacetoacetate hydrolase (FAH) gene (supporting documentation must be submitted to Priority Health); **AND**
  - Patient is at least 5 years of age; **AND**
  - Requested drug will be used in combination with dietary restriction of tyrosine and phenylalanine; **AND**
  - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders.
- Have a diagnosis of alkaptonuria (AKU) that is confirmed by elevated urinary homogentisic acid (HGA) levels or a mutation in the homogentisate 1,2 dioxygenase (HGD) gene (supporting documentation must be submitted to Priority Health); **AND**
  - Patient is at least 18 years of age; **AND**
  - Requested drug will be used in combination with dietary restriction of tyrosine; **AND**
  - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders.

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

- Meet one of the following:
  - HT-1: Urinary or plasma SA levels have decreased from baseline.
  - AKU: Urinary HGA levels have decreased from baseline.

Duration of Approval:

- Initial: 3 months
- Continuation: 12 months

Note: Nitisinone is typically dosed at 2mg/day (max 10mg/day) for AKU and 0.5mg/kg to 1 mg/kg twice daily (max 2mg/kg/day) for HT-1.

Nourianz

Products Affected

- Nourianz

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Nourianz (istradefylline)

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

- Have a diagnosis of advanced Parkinson's disease (supporting documentation must be submitted to Priority Health); **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, a neurologist; **AND**
- Patient is experiencing acute, intermittent hypomobility (defined as “off” episodes characterized by muscle stiffness, slow movements, or difficulty starting movements); **AND**
- Patient is receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release tablets and multiple daily dosing); **AND**
- Therapeutic trial and failure of, or contraindication to, adjunctive therapy with at least one medication in each of the drug classes listed below:
  - 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 have met the following requirements:

- Have a positive clinical response to Nourianz

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Nuedexta

Products Affected

- Dextromethorphan-quiNIDine
- Nuedexta

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Nuedexta (dextromethorphan/ quinidine)

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

- Patient has a diagnosis of pseudobulbar affect caused by a structural neurologic condition (e.g. amyotrophic lateral sclerosis [ALS], multiple sclerosis [MS], or stroke); **AND**
- Prescribed by, or in consultation with, a neurologist; **AND**
- Patient has not had an exacerbation of the underlying neurologic condition in the two months before starting Nuedexta; **AND**
- Patient does not have a history of Alzheimer's or other dementia, major psychiatric disturbance (e.g. bipolar disorder, major depression, schizophrenia), substance abuse or drug-seeking behavior, or recent falls/be at risk for falls; **AND**
- Patient has at least 10 episodes of inappropriate laughing or crying per day before therapy; **AND**
- Documented trial with one tricyclic antidepressant and one selective serotonin reuptake inhibitor (SSRI) for a total of 6 months.

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

- Documentation of a 50 percent decrease in number of episodes of laughing or crying compared to baseline (before Nuedexta was started)

Duration of Approval:

- Initial: 3 months
- Continuation: 12 months

Ofev

Products Affected

- Nintedanib Esylate
- Ofev

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Ofev (nintedanib)

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

- Patient is a current non-smoker; **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, a specialist for the condition being treated; **AND**
- Have one of the following diagnoses:
  - Idiopathic Pulmonary Fibrosis (IPF)
    - Prescriber must rule out: other known causes of interstitial lung disease; **AND**
    - Have presence of a UIP pattern on High Resolution Computer Tomography (HRCT) in patients not subjected to surgical lung biopsy; and possibly surgical lung biopsy
  - Chronic, progressive fibrosing interstitial lung disease (PF-ILD)
    - Be confirmed by HRCT; **AND**
    - Extent of fibrotic disease in the lung must be at least 10%; **AND**
    - Forced Vital Capacity (FVC) decline of greater than 10%.
    - If FVC decline is at least 5% but less than 10%, must have:
      - Experiencing worsening respiratory symptoms; **OR**
      - Exhibiting increasing extent of fibrotic changes on chest imaging.
  - Systemic sclerosis (SSc) related Interstitial Lung Disease (ILD) (SSc-ILD)
    - Be confirmed by HRCT; **AND**
    - Extent of fibrotic disease in the lung must be at least 10%; **AND**
    - Forced Vital Capacity (FVC) must be at least 40% of predicted normal; **AND**
    - SSc disease onset (defined by first non-Raynaud symptom) within 7

past years; **AND**

- Carbon Monoxide Diffusion Capacity (DLCO) 30% to 89% of predicted normal; **AND**
- Disease progression (e.g., at least10 percent decline in FVC or DLCO) on trials of mycophenolate mofetil and/or cyclophosphamide at maximally tolerated doses, or medical contraindication; **AND**
- Patient is being adequately treated for any complications of SSc (e.g., pulmonary hypertension) and comorbid disease (e.g., chronic obstructive pulmonary disease [COPD]).

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

- Documentation of stable FVC (recommended to discontinue if there is more than a 10% decline in FVC over a 12 month period, indicating disease progression) for IPF.

Duration of Approval: 12 months

Note: Ofev will not be covered in combination with tocilizumab or pirfenidone.

Ohtuvayre

Products Affected

- Ohtuvayre

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Ohtuvayre (ensifentrine)

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

- Have a diagnosis of moderate-to-severe COPD (FEV1/FVC less than 0.7 AND FEV1 between 30-70%); **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 Ohtuvayre; **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 at least 18 years of age; **AND**
- Patient is a current non-smoker; **AND**
- Fail to reduce exacerbations while on roflumilast; **AND**
- Prescribed by, or in consultation with, a specialist for the condition being treated.

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

- 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 Ohtuvayre.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Ohtuvayre is not covered in combination with biologic drug therapy (e.g., Dupixent, Nucala.)

Olumiant

Products Affected

- Olumiant Oral Tablet 1 MG, 2 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Olumiant (baricitinib)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **Rheumatoid Arthritis** requests:
  - 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, one of which must be a TNF inhibitor:
    - tocilizumab, Enbrel, adalimumab, or Xeljanz/XR each for a period of at least 3 months.

Note: Olumiant will not be covered in combination with another biologic drug **OR** for alopecia areata. Before Olumiant is covered, the patient must meet all of the General Criteria for Olumiant and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Omalizumab

Products Affected

- Omlyclo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Omalizumab

Preferred Agents:

- **Xolair Solution (omalizumab) - Medical Benefit Drug**
- **Xolair Syringe (omalizumab) - Pharmacy and Medical Benefit Drug**
- **Xolair Auto-Injector (omalizumab) - Pharmacy Benefit Drug**
- **Omlyclo Syringe (omalizumab) - Pharmacy and Medical 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 and Omlyclo are not covered in combination with other biologic drug therapy (e.g. Nucala, Cinqair, Fasenra, Dupixent) or Rhapsido.

Omvoh

Products Affected

- Omvoh (300 MG Dose)
- Omvoh Subcutaneous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Omvoh (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.

Oncology Agents

Products Affected

- Akeega
- Alecensa
- Alunbrig
- Augtyro
- Ayvakit
- Balversa
- Bexarotene Oral
- Bosulif
- Bosutinib
- Braftovi
- Brukinsa
- Cabometyx
- Calquence
- Caprelsa
- Cometriq (100 MG Daily Dose)
- Cometriq (140 MG Daily Dose)
- Cometriq (60 MG Daily Dose)
- Copiktra
- Cotellic
- Danziten
- Dasatinib
- Daurismo
- Erivedge
- Erleada
- Erlotinib HCl
- Everolimus Oral Tablet 10 MG, 2.5 MG, 5 MG, 7.5 MG
- Everolimus Oral Tablet Soluble
- Farydak Oral Capsule 10 MG, 15 MG, 20 MG
- Fotivda
- Fruzaqla
- Gavreto
- Gefitinib
- Gilotrif
- Gleostine
- Gomekli
- Hernexeos
- Hyrnuo
- Ibrance
- Ibtrozi
- Iclusig
- IDHIFA
- Imatinib Mesylate Oral
- Imbruvica
- Inluriyo
- Inlyta
- Inqovi
- Inrebic
- Itovebi
- Iwilfin
- Jakafi
- Jakafi XR
- Jaypirca
- Jideytro
- Kisqali (200 MG Dose)
- Kisqali (400 MG Dose)
- Kisqali (600 MG Dose)
- Komzifti
- Koselugo
- Krazati
- Lapatinib Ditosylate
- Lazcluze
- Lenvima (10 MG Daily Dose)
- Lenvima (12 MG Daily Dose)
- Lenvima (14 MG Daily Dose)
- Lenvima (18 MG Daily Dose)
- Lenvima (20 MG Daily Dose)
- Lenvima (24 MG Daily Dose)
- Lenvima (4 MG Daily Dose)
- Lenvima (8 MG Daily Dose)
- Lifyorli (125 MG DOSE)
- Lifyorli (150 MG DOSE)
- Lomustine
- Lonsurf
- Lorbrena
- Lumakras
- Lynparza
- Lysodren
- Lytgobi (12 MG Daily Dose)
- Lytgobi (16 MG Daily Dose)
- Lytgobi (20 MG Daily Dose)

- Matulane
- Mekinist
- Mektovi
- methylTESTOSTERone Oral
- Modeyso
- Nerlynx
- Nilotinib D-Tartrate Oral Capsule 150 MG, 200 MG, 50 MG
- Nilotinib HCl
- Ninlaro
- Nubeqa
- Odomzo
- Ogsiveo
- Ojemda
- Ojjaara
- Onureg
- Orgovyx
- Orserdu
- PAZOPanib HCl
- Pemazyre
- Piqray (200 MG Daily Dose)
- Piqray (250 MG Daily Dose)
- Piqray (300 MG Daily Dose)
- Pomalidomide
- Qinlock
- Retevmo
- Revuforj
- Rezurock
- Romvimza
- Rozlytrek
- Rubraca
- Rydapt
- SORAfenib Tosylate
- Stivarga
- SUNItinib Malate
- Tabrecta
- Tafinlar
- Tagrisso
- Talzenna
- Tazverik Oral Tablet 200 MG
- Temozolomide
- Tibsovo
- Tretinoin Oral
- Truqap Oral Tablet 160 MG, 200 MG
- Tukysa
- Turalio
- Vanflyta
- Venclexta
- Venclexta Starting Pack
- Veppanu
- Verzenio
- Vitrakvi
- Vizimpro Oral Tablet 15 MG, 30 MG, 45 MG
- Vonjo
- Voranigo
- Welireg
- Xalkori
- Xospata
- Xpovio (100 MG Once Weekly)
- Xpovio (40 MG Once Weekly) Oral Tablet Therapy Pack 40 MG
- Xpovio (40 MG Twice Weekly)
- Xpovio (60 MG Once Weekly)
- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)
- Xtandi
- Zejula
- Zelboraf
- Zolinza
- Zydelig
- Zykadia

Criteria Details

Click and complete the Employer Group & MyPriority Plans Pharmacy Oral Oncology drug request form or Electronic prior authorization (ePA).

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

Products Affected

- Orencia ClickJect
- Orencia Subcutaneous

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Orencia (abatacept)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

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

Oriahnn

Products Affected

- Oriahnn

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Oriahnn (elagolix/estradiol/ norethindrone)

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

- Have a diagnosis of heavy menstrual bleeding associated with uterine fibroids; **AND**
- Have a trial and failure of an oral contraceptive (estrogen/progestin or progestin only) used for at least 3 months

Duration of Approval: 24 months total

Orilissa

Products Affected

- Orilissa

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Orilissa (elagolix)

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

- Have a diagnosis of moderate to severe pain associated with endometriosis; **AND**
- Have a trial and failure of a non-steroidal anti-inflammatory drug (NSAID) and an oral contraceptive used for at least 3 months each.

Duration of Approval: Orilissa 150 mg once daily dose is limited to a maximum duration of treatment of 24 months; Orilissa 200 mg twice daily dose is limited to a maximum duration of treatment of 6 months.

Otezla/XR

Products Affected

- Otezla
- Otezla XR
- Otezla/Otezla XR Initiation Pk

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Otezla/XR (apremilast)

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.
- 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.
- For **Behcet's disease** requests:
  - The patient has oral ulcers or other mucocutaneous involvement (provide chart note documentation); **AND**
  - The patient has tried at least **ONE** other systemic therapy (e.g., colchicine, systemic corticosteroids, azathioprine, tumor necrosis factor inhibitors).

Note: Otezla/XR will not be covered in combination with another biologic drug. Before Otezla/XR is covered, the patient must meet all of the General Criteria for Otezla/XR and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please

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

Oxervate

Products Affected

- Oxervate

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Oxervate (cenegermin)

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

- Patient has a diagnosis of neurotrophic keratitis (supporting documentation must be submitted); **AND**
- Covered only for stage 2 or stage 3 neurotrophic keratitis

Duration of Approval: 8 weeks total treatment

Palforzia

Products Affected

- Palforzia (1 MG Daily Dose) Oral 1 x 1 MG
- Palforzia (12 MG Daily Dose) Oral 2 x 1 MG & 10 MG
- Palforzia (120 MG Daily Dose) Oral 20 MG & 100 MG
- Palforzia (160 MG Daily Dose) Oral 3 x 20 MG & 100 MG
- Palforzia (20 MG Daily Dose) Oral 20 MG
- Palforzia (200 MG Daily Dose) Oral 2 x 100 MG
- Palforzia (240 MG Daily Dose) Oral 2 x 20 MG & 2 x 100 MG
- Palforzia (3 MG Daily Dose) Oral 3 x 1 MG
- Palforzia (300 MG Maintenance) Oral Packet 300 MG
- Palforzia (300 MG Titration) Oral Packet 300 MG
- Palforzia (40 MG Daily Dose) Oral 2 x 20 MG
- Palforzia (6 MG Daily Dose) Oral 6 x 1 MG
- Palforzia (80 MG Daily Dose) Oral 4 x 20 MG
- Palforzia Initial Dose 1-3yrs Oral 0.5 & 1 & 1.5 & 3 MG
- Palforzia Initial Escalation Oral 0.5 & 1 & 1.5 & 3 & 6 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

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

- 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: Only the first kit (Initial Dose Escalation kit containing the first 5 doses) may be covered under the medical benefit. All other doses are covered under pharmacy benefit.

Palynziq

Products Affected

- Palynziq

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Palynziq (pegvaliase)

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

- Have a diagnosis of phenylketonuria (supporting documentation must be submitted); **AND**
- Patient is at least 12 years of age; **AND**
- Prescribed by a metabolic disease specialist; **AND**
- Current adherence to dietary restriction of phenylalanine defined as an average of 65 grams of protein per day [from combination of medical foods that supply approximately 75 percent of protein requirements (except phenylalanine) and natural foods]; **AND**
- Continue phenylalanine restricted diet if approved for Palynziq; **AND**
- Baseline/current phenylalanine levels provided showing current levels are greater than 600 micromole/L; **AND**
- Clinical trial and failure of sapropterin in combination with phenylalanine restricted diet
    - Clinical trial defined as 4 weeks treatment with Kuvan 20mg/kg/day
    - Failure is defined as blood phenylalanine levels greater than 600mcmol/L with combination therapy
    - Patients with mutation analysis documenting two null mutations in trans (i.e. mutations resulting in complete absence of phenylalanine hydroxylase enzyme activity) are not required to trial Kuvan; **AND**
- Palynziq is not covered in combination with Sapropterin (Kuvan). Sapropterin must be stopped within 14 days of beginning therapy on Palynziq.

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

- Documented compliant maintenance therapy on Palynziq; **AND**
- Continued adherence to a phenylalanine-restricted diet; **AND**
- Achieved at least a 20 percent reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration no greater than 600 micromole/L.

Duration of Approval: up to 12 months (coverage duration may depend on dose requested)

Note: Palynziq is not covered in combination with sapropterin (Kuvan). Initial approval is limited to a maximum of one year (includes minimum 9- week titration and maximum of 24- weeks maintenance therapy) at a maximum dose of 20mg daily. For requests to exceed 20mg Palynziq daily, the patient must meet the following requirements: 1. Must have compliant maintenance therapy on Palynziq 20mg daily for a minimum of 24 weeks. 2. Have failed to achieve a 20 percent reduction in blood phenylalanine concentration from baseline or a blood phenylalanine concentration no greater than 600 micromol/L by week 24 of 20mg daily Palynziq maintenance therapy. Coverage for Palynziq 40mg daily is limited to an initial duration of 16 weeks.

Parathyroid Hormone Analogs

Products Affected

- Bonsity
- Teriparatide
- Tymlos

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Parathyroid Hormone Analogs

Preferred Agent(s):

- **Tymlos (abaloparatide)**

Non-Preferred Agent(s):

- **Teriparatide (generic Forteo)**
- **Bonsity (teriparatide)**

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

- For 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): **AND**
  - Non-preferred drug product:
    - Trial and failure, or intolerance/contraindication to the preferred product.

- For 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; **AND**

- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to the preferred product.

*Contraindication examples to oral bisphosphonate therapy include the following:

- Documented inability to sit or stand upright for at least 30 minutes
- Documented pre-existing gastrointestinal disorder such as inability to swallow, esophageal stricture, or achalasia

**Ineffective response is defined as one of the following:

- Decrease in T-score in comparison to previous T-score from DEXA scan
- New fracture while on therapy.

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

- Have a positive clinical response (i.e., T-score stable or improved, **OR** no new fractures have occurred while using PTH analog).

Duration of Approval: 12 months

Note: PTH analogs are not covered in combination with other injectable drugs for the treatment of osteoporosis (e.g., denosumab, Evenity). When criteria are met, parathyroid hormone treatment may be authorized for up to a total of two years in a lifetime as additional efficacy beyond two years has not been established. For example, Priority Health will not authorize Forteo/Tymlos if another parathyroid hormone has already been used for two years.

Penicillamine

Products Affected

- penicillAMINE Oral Tablet

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Penicillamine (generic Depen)

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

- Patient has a diagnosis of Wilson's disease (hepatolenticular degeneration) or cystinuria; **AND**
- For cystinuria, a trial with conservative measures (i.e. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated (supporting documentation of conservative measures failure must be submitted to Priority Health).

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

- Documented compliant maintenance therapy on penicillamine; **AND**
- Continued adherence to conservative measures listed above for cystinuria.

Duration of Approval: 12 months

Note: Quantity limit of 120 tablets per 30 days. For approval over the quantity limit, documentation proving conservative measures have continued in combination with Depen Titratabs or penicillamine 250 mg oral tablet, and that member has been compliant with these measures must be faxed to Priority Health.

Peripherally-Acting Opioid Antagonists

Products Affected

- Movantik
- Symproic

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Peripherally-Acting Opioid Antagonists

Preferred Agent(s):

- **Movantik**

Non-Preferred Agent(s):

- **Symproic**

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

- Have a diagnosis of opioid-induced constipation; **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance/contraindication to the preferred product.

Pirfenidone

Products Affected

- Pirfenidone Oral Capsule
- Pirfenidone Oral Tablet 801 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Pirfenidone (generic Esbriet)

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

- Patient has a diagnosis of Idiopathic pulmonary fibrosis; **AND**
- Prescribed by, or in consultation with, a pulmonologist; **AND**
- Prescriber has ruled out other known causes of interstitial lung disease; **AND**
- Have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy; and possibly surgical lung biopsy; **AND**
- Be a current non-smoker.

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

- Be a current non-smoker; **AND**
- Documentation of stable FVC (recommended to discontinue if there is a greater than 10 percent decline in FVC over a 12 month period, indicating disease progression); **AND**
- Be adherent to Esbriet.

Duration of Approval: 12 months

Note: Esbriet is not covered in combination with Ofev.

Pombiliti + Opfolda

Products Affected

- Opfolda

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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 Oral

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Primary Biliary Cholangitis Agents

Products Affected

- Iqirvo
- Livdelzi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Primary Biliary Cholangitis Agents

Preferred Agent(s):

- **Elafibranor (Iqirvo)**
- **Seladelpar (Livdelzi)**

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

- Patient has a diagnosis of primary biliary cholangitis; **AND**
- Have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol; **AND**
- Have one of the following: alkaline phosphatase level at least 1.67 times the upper limit of normal (ULN) or total bilirubin at least 1 time the ULN but less than 2 times the ULN; **AND**
- Patient is at least 18 years of age; **AND**
- Prescriber is a specialist or has consulted with a gastroenterologist or hepatologist; **AND**
- Patient must not have any of the following:
  - Clinically significant hepatic decompensation (e.g. known esophageal varices, poorly controlled or diuretic resistant ascites, history of variceal bleeds or related interventions);
  - Severe pruritus;
  - Inadequate response to ursodiol due to patient adherence; **OR**
  - Superimposed liver disease (e.g. hepatitis C, alcoholic liver disease).

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

- Documentation of stable disease as evidenced by no progression to decompensated cirrhosis, an ALP less than 1.67 times the ULN with at least a 15% reduction in ALP, and a total bilirubin less than or equal to the ULN; **AND**
- Maintain an 85% adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient.

Duration of Approval: 12 months

Note: Iqirvo and Livdelzi will not be covered in combination with each other.

Pulmonary Arterial Hypertension (PAH), Activin Signaling Inhibitor

Products Affected

- Winrevair

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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), Endothelin Receptor Antagonists

Products Affected

- Ambrisentan
- Bosentan
- Macitentan

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Pulmonary Arterial Hypertension (PAH), Endothelin Receptor Antagonists

Preferred Agent(s):

- **Ambrisentan (Letairis)**
- **Bosentan (Tracleer)**

Non-Preferred Agent(s):

- **Opsumit (macitentan)**
- **Opsynvi (macitentan-tadalafil)**

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); **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance to ambrisentan or bosentan.

Note: If requesting Tracleer (bosentan) tablet for suspension formulation, you must be 12 years of age or younger.

Pulmonary Arterial Hypertension (PAH), Nitric oxide-cyclic guanosine monophosphate enhancers

Products Affected

- Adempas
- Sildenafil Citrate Oral Suspension Reconstituted
- Sildenafil Citrate Oral Tablet 20 MG
- Tadalafil Oral Tablet 20 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Pulmonary Arterial Hypertension (PAH), Nitric oxide-cyclic guanosine monophosphate enhancers

Preferred Agent(s):

- **Sildenafil (Revatio)**
- **Tadalafil**

Non-Preferred Agent(s):

- **Adempas (riociguat)**

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 to Priority Health); **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance to sildenafil or tadalafil.

For diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) must be World Health Organization (WHO) Group 4, that is either recurrent or persistent after documented pulmonary endarterectomy (PEA), **OR** inoperable (supporting documentation must be submitted). (Adempas only).

Pulmonary Arterial Hypertension (PAH), Other

Products Affected

- Orenitram
- Orenitram Month 1
- Orenitram Month 2
- Orenitram Month 3
- Tyvaso
- Tyvaso DPI Institutional Kit
- Tyvaso DPI Maintenance Kit Inhalation Powder 112 x 32MCG & 112 x64MCG, 112 x 48MCG & 112 x64MCG, 112 x 48MCG & 112 x80MCG
- Tyvaso DPI Titration Kit
- Tyvaso Refill Kit
- Tyvaso Starter Kit
- Uptravi Oral
- Uptravi Titration
- Ventavis Inhalation Solution 10 MCG/ML, 20 MCG/ML

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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).

Pulmozyme

Products Affected

- Pulmozyme

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Pulmozyme (dornase alfa)

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

- Have a diagnosis of cystic fibrosis (ICD10 codes: E84.0, E84.11, E84.19, E84.8, E84.9).

Pyrimethamine

Products Affected

- Pyrimethamine Oral

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Pyrimethamine (generic Daraprim)

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

- Have diagnosis of toxoplasmosis, used for either primary prophylaxis or treatment of active disease; **AND**
- Have diagnosis of HIV infection and CD4 count less than 100 cells/mm3 (if using for prophylaxis): **AND**
- Be used in combination with a sulfonamide (e.g., sulfadiazine) and leucovorin; **AND**
- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

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

- For chronic maintenance following initial therapy for active disease: must have a CD4 count less than or equal to 200 cells/mm3 at any time in the previous 6 months;
- For primary prophylaxis: must have a CD4 count less than or equal to 200 cells/mm3 at any time in the previous 3 months;
- Adherent to antiretroviral therapy as evidenced by claims data.

Duration of Approval: 8 weeks (treatment); 6 months (prophylaxis).

Note: Pyrimethamine tablets are not covered for malaria, chemoprophylaxis or treatment.

Pyrukynd

Products Affected

- Pyrukynd
- Pyrukynd Taper Pack Oral Tablet Therapy Pack 7 x 20 MG & 7 x 5 MG, 7 x 50 MG & 7 x 20 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Pyrukynd (mitapivat)

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

- Treatment of hemolytic anemia in adults with pyruvate kinase deficiency; **WITH**
  - Genetic testing confirming diagnosis; **AND**
  - Current hemoglobin less than or equal to 10g/dL; **AND**
  - At least six red blood cell (RBC) transfusion episodes within the previous year
- Patient is at least 18 years of age; **AND**
- Prescribed by or in consultation with a hematologist.

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

- Have documented benefit defined as hemoglobin response of at least 1.5mg/dL over baseline and/or reduction in transfusion burden.

Duration of Approval:

- Initial: 3 months
- Continuation: 12 months

Note: Not covered for the following patients: Homozygous for R479H mutation, 2 non-missense variants in PKLR gene, Not regularly transfused.

Radicava

Products Affected

- Radicava ORS

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Ravicti

Products Affected

- Glycerol Phenylbutyrate

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Ravicti (glycerol phenylbutyrate)

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

- Have a diagnosis of chronic hyperammonemia because of a urea cycle disorder; **AND**
- Patient is at least 2 months of age; **AND**
- Patient's condition cannot by managed by dietary protein restriction; **AND**
- Patient's condition cannot be managed by amino acid supplementation; **AND**
- Patient has tried and failed sodium phenylbutyrate.

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

- Clinical documentation, including chart notes, of disease stability or improvement must be provided.

Duration of Approval: 12 months

Redemplo

Products Affected

- Redemplo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Redemplo (plozasiran)

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

- Patient has a diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic testing OR North American FCS (NAFCS) Score of ≥60 OR clinical factors outlined by the AACE (supporting documentation must be submitted to Priority Health); **AND**
- Patient has a fasting triglyceride level >10 mmol/L or 880 mg/dL; **AND**
- Use in addition to dietary management of FCS, including a low-fat diet of ≤20 grams of fat per day; **AND**
- Have a trial and failure with or intolerance to all the following:
  - Six continuous months of lifestyle modification including diet and exercise (low-fat diet of ≤20 g of fat per day, avoidance of alcohol and processed, sugary foods) and not achieving a positive clinical response (e.g., improvement of triglyceride levels); **AND**
  - Fenofibrate, fenofibric acid, or gemfibrozil for at least 12 weeks; **AND**
  - Omega-3-acid ethyl esters or icosapent ethyl for at least 12 weeks; **AND**
- Prescribed by or in consultation with a provider specializing in the treatment of lipid disorders.

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

- Must have documented benefit from use of Redemplo (e.g. biochemical response and reduction in symptoms, such as episodes of acute pancreatitis).

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Revcovi

Products Affected

- Revcovi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Rezdiffra

Products Affected

- Rezdiffra

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Rezdiffra (resmetirom)

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

- Have a diagnosis of metabolic dysfunction associated steatohepatitis (MASH) or nonalcoholic steatohepatitis (NASH), supporting documentation must be submitted to Priority Health; **AND**
- Have fibrosis stage of F2 or F3; **AND**
- Patient is at least 18 years of age; **AND**
- Trial and failure of 6 continuous months of a lifestyle modification program including diet and exercise (as defined below) and not achieving a positive clinical response (e.g., improvement of stabilization from baseline in objective measures including fibrosis scoring and NAFLD Activity Scoring); **AND**
- Patient will use in conjunction with lifestyle modification including diet, exercise, and reduced alcohol consumption; **AND**
- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

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

- Have a positive clinical response (e.g., improvement or stabilization from baseline in objective measures including fibrosis scoring and NAFLD Activity Scoring); **AND**
- Have fibrosis stage of F3 or less; **AND**
- Continued use in conjunction with lifestyle modification.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Provider must submit documentation of active participation for a minimum of 6 months in a covered PH lifestyle modification program or an alternative concurrent lifestyle modification program (e.g. recent food diaries, exercise logs, program receipts, app participation, etc.) if member does not have access to a covered PH program.

Rhapsido

Products Affected

- Rhapsido

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Rhapsido (remibrutinib)

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

- For **chronic urticaria** requests:
  - Prescriber is an allergist, immunologist or has consulted with a specialist for the condition being treated; **AND**
  - Patient is at least 18 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; **AND**
  - First try Dupixent or Xolair.

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

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

Duration of Approval: 12 months

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

Rufinamide

Products Affected

- Banzel
- Rufinamide

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Rufinamide (generic Banzel)

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

- Patient has a diagnosis of Lennox-Gastaut syndrome (documentation must be submitted to Priority Health); **AND**
- Be using as an adjunctive treatment for seizures associated with LGS.

Rytary

Products Affected

- Carbidopa-Levodopa ER Oral Capsule Extended Release
- Rytary

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Rytary (levodopa-carbidopa)

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 Rytary therapy.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Sapropterin

Products Affected

- Sapropterin Dihydrochloride

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Sapropterin (generic Kuvan)

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

- Patient has a diagnosis of phenylketonuria (supporting documentation must be submitted to Priority Health); **AND**
- Patient is at least 1 month of age; **AND**
- Prescribed by a metabolic disease specialist; **AND**
- Be adherent to current dietary restriction of phenylalanine defined as an average of 65 grams of protein per day [from combination of medical foods that supply approximately 75 percent of protein requirements (except phenylalanine) and natural foods]; **AND**
- Continue phenylalanine restricted diet if approved for Kuvan; **AND**
- Tetrahydrobiopterin (BH4) deficiency has been ruled out; **AND**
- Baseline blood phenylalanine levels must be provided.

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

- Documented compliant maintenance therapy on Kuvan; **AND**
- Continued adherence to a phenylalanine-restricted diet; **AND**
- Achieved a 30 percent or greater reduction in phenylalanine (Phe) blood levels from baseline.

Duration of Approval:

- Initial: 2 months
- Continuation: 12 months

Note: Sapropterin (Kuvan) is not covered in combination with Palynziq.

Scemblix

Products Affected

- Scemblix

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy Oncology drug request form or Electronic prior authorization (ePA).

Drug: Scemblix (asciminib)

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

- Have one of the following diagnoses:
  - Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs).
  - Ph+ CML in CP with the T315I mutation, previously treated with Iclusig (ponatinib); **AND**
- Prescribed by an oncologist, hematologist, or another board-certified prescriber with qualifications to treat specified cancer type; **AND**
- Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2 (must be submitted within past 30 days).

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

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

Duration of Approval: 12 months

- For Ph+ CML CP without the T315I mutation:
  - Initial: 6 months
  - Continuation: 12 months
- For Ph+ CML CP with the T315I mutation:

- Initial: 3 months
- Continuation: 6 months

Serostim

Products Affected

- Serostim

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Serostim (somatropin)

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

- Patient has a diagnosis of HIV-associated wasting or cachexia.

Signifor

Products Affected

- Signifor

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Signifor (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.

Duration of Approval: 12 months

Siliq

Products Affected

- Siliq

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Siliq (brodalumab)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **Plaque Psoriasis** requests:
  - 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: Siliq will not be covered in combination with another biologic drug. Before Siliq is covered, the patient must meet all of the General Criteria for Siliq and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Simponi

Products Affected

- Simponi

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Simponi (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 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.

Skyclarys

Products Affected

- Skyclarys

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Skyclarys (omaveloxolone)

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

- Have a diagnosis of Friedreich's ataxia (FA) with genetic confirmation (supporting documentation must be submitted to Priority Health); **AND**
- Provide documentation of modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 to 80; **AND**
- Be ambulatory; **AND**
- Patient is between 16 to 40 years of age; **AND**
- Prescriber is a neurologist or has consulted with a neurologist.

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

- Documentation of positive clinical response as evidenced by improvement of modified Friedreich's Ataxia Rating Scale (mFARS).

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Skyrizi

Products Affected

- Skyrizi Subcutaneous Solution Cartridge

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Skyrizi (risankizumab)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

- For **Crohn's disease** requests:
  - 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.

Sodium Oxybate

Products Affected

- Sodium Oxybate

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Sodium Oxybate (generic Xyrem)

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

- Prescribed by, or in consultation with, a board-certified sleep specialist or neurologist; **AND**
- MSLT plus polysomnogram must meet requirements according to International Classification of Sleep Disorders- Third Edition (ICSD-3*) for the diagnosis of narcolepsy. Must fax MSLT plus polysomnogram results to Priority Health; **AND**
- Xyrem will not be covered in patients who use other sedative hypnotics, drink alcohol when using Xyrem; **AND**
- Meet diagnosis specific criteria below:
- For treatment of excessive daytime sleepiness in patients with narcolepsy
    - Have a documented therapeutic trial with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others, with all of the following:
        - Amphetamine salts, dextroamphetamine or methylphenidate
        - Modafinil
        - Armodafinil
        - Sunosi; **AND**
- Patient is at least 18 years of age.
- For treatment of cataplexy substantial enough to warrant treatment
    - Have a documented 6-week trial with continued cataplexy on one of the following: fluoxetine, venlafaxine ER, or Strattera; **AND**
    - Patient is at least 7 of years of age.

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

- Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline **OR** reduced frequency of cataplexy attacks from pre-treatment baseline if patient has cataplexy

Duration of Approval: 12 months

Note: Xyrem is limited to a maximum dose of 9 grams per night (558 ml every 31 days). Xyrem will not be covered in combination with Wakix.

Sodium phenylbutyrate

Products Affected

- Buphenyl
- Sodium Phenylbutyrate Oral

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Sodium phenylbutyrate (generic Buphenyl)

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

- Patient has a diagnosis of chronic hyperammonemia because of a urea cycle disorder; **AND**
- Patient's condition cannot be managed by dietary protein restriction; **AND**
- Patient's condition cannot be managed by amino acid supplementation.

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

- Clinical documentation, including chart notes, of disease stability or improvement must be provided.

Duration of Approval: 12 months

Sohonos

Products Affected

- Sohonos

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Sohonos (palovarotene)

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

- Patient has a diagnosis of fibrodysplasia ossificans progressive (FOP) with a ACVR1 R206H mutation (supporting documentation must be submitted to Priority Health); **AND**
- Patient is between at least 8 years of age (assigned female at birth) **OR** at least 10 years of age (assigned male at birth); **AND**
- Patients of reproductive potential: attestation that the patient is not pregnant and appropriate contraception methods will be used at least 1 month before treatment, during treatment, and 1 month after the last dose; **AND**
- Prescribed by or in consultation with a specialist in rare connective tissue diseases.

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

- Documentation of positive clinical response (e.g., no new or minimal new heterotropic ossification).

Duration of Approval: 6 months

Somavert

Products Affected

- Somavert

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Somavert (pegvisomant)

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

- Patient has a diagnosis of acromegaly; **AND**
- Have an inadequate response to surgery or radiation therapy, unless those therapies are not an option; **AND**
- Have had a trial and failure to a somatostatin analog (e.g. Signifor).

Sotyktu

Products Affected

- Sotyktu

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Sotyktu (deucravacitinib)

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.
- 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.

Note: Sotyktu will not be covered in combination with another biologic drug. Before Sotyktu is covered, the patient must meet all of the General Criteria for Sotyktu and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide

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

Sporanox oral suspension

Products Affected

- Itraconazole Oral Solution

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Sporanox oral suspension (itraconazole)

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

- For the treatment of **invasive fungal disease** (i.e. Aspergillus spp., Blastomycosis, Histoplasmosis)
  - Prescribed or recommended by an infectious disease specialist; **AND**
  - Have a trial and failure of itraconazole capsules.
- For the treatment of **oropharyngeal and esophageal candidiasis**
  - Prescribed or recommended by an infectious disease specialist; **AND**
  - Have had a trial and failure, or intolerable side effect to clotrimazole troches, nystatin suspension, fluconazole and itraconazole capsule.

Duration of Approval:

- For invasive fungal disease or prophylaxis of invasive Aspergillosis/Candida) initial authorization for a maximum of 3 months.
- For oropharyngeal candidiasis limited to 4 weeks.
- For esophageal candidiasis limited to 6 weeks.

Strensiq

Products Affected

- Strensiq

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Strensiq (asfotase alfa injection)

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

- Patient has a diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia including radiographic evidence (supporting documentation must be submitted to Priority Health); **AND**
- Clinical manifestations consistent with hypophosphatasia must be present; **AND**
- Diagnosis confirmed with both biochemical and molecular genetic testing; **AND**
- A second opinion may be required by Priority Health from a Specialist Provider we choose to help us determine whether Strensiq is medically necessary.

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

- Documentation that the patient has had a positive clinical response (e.g., clinical symptoms, Radiographic Global Impression of Change).

Duration of Approval:

- Initial: 6 months
- Continuation: 12 month

Note: The FDA-approved labeling allows for Strensiq to be injected three times per week or six times per week. Strensiq is only covered as a three times per week injection.

Taltz

Products Affected

- Taltz

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Taltz (ixekizumab)

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 **THREE** 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).
  - Patient has tried at least **TWO** of the following:
    - Cimzia, Cosentyx, 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 **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.

Note: Taltz will not be covered in combination with another biologic drug. Before Taltz is covered, the patient must meet all of the General Criteria for Taltz and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Tasimelteon

Products Affected

- Tasimelteon

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Tasimelteon (generic Hetlioz)

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

- Patient has a diagnosis of Non-24-hour Sleep-Wake Disorder; **AND**
- Patient must be totally blind; **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by a sleep specialist; **AND**
- Have tried and failed at least a 6-month trial with melatonin or Rozerem (documentation of the medication's inability to improve the patients overall sleep quality must be submitted); **AND**
- Have tried and failed eszopiclone or zolpidem.

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

- The patient's use of Hetlioz must be continuous without any gaps in treatment. Hetlioz will only continue to be covered for patients with a proportion of days covered greater than or equal to 95 percent (must fill the prescription to have enough medication at least 28.5days or more for each month); **AND**
- Prescriber must provide an objective evaluation of the patient's sleep quality, including documentation of an improvement in overall sleep quality while taking Hetlioz.

Duration of Approval: 6 months

Tavneos

Products Affected

- Tavneos

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Tavneos (avacopan)

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

- Patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA]) (supporting documentation must be submitted to Priority Health); **AND**
- Patient is at least 18 years of age; **AND**
- Patient does not currently require dialysis or have a kidney transplant, and has not received plasma exchange in the past 12 weeks; **AND**
- Prescribed by or in consultation with a specialist; **AND**
- Have documentation of the following:
  - Active, organ or life-threatening disease; **AND**
  - eGFR at least 15 mL/min/1.72 m2; **AND**
  - Positive test for either anti-PR3 or anti-MPO.

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

- Have a positive clinical response to Tavneos as evidenced by experiencing disease stability or improvement from baseline as assessed by one objective measure (e.g., improvement in the Birmingham Vasculitis Activity Score (BVAS), estimated GFR, decrease in urinary albumin creatinine ratio); **AND**
- Have a reduction in steroid dose.

Duration of Approval:

- Initial: 6 months

- Continuation: 12 months

Note: Tavneos must be used as adjunctive (add-on) therapy in combination with standard therapy including cyclophosphamide, rituximab, and glucocorticoids (such as methylprednisolone or prednisone) **AND** patient must have a medical need to reduce steroid use if not previously relapsed (i.e. infection, osteoporosis).

Testosterone Replacement Products

Products Affected

- Kyzatrex
- Testosterone Transdermal Gel 1.62 %, 12.5 MG/ACT (1%), 20.25 MG/ACT (1.62%), 25 MG/2.5GM (1%), 50 MG/5GM (1%)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Tezspire

Products Affected

- Tezspire Subcutaneous Solution Auto-Injector

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Tezspire Pre-Filled Pen (tezepelumab)

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

- For **severe persistent asthma** requests:
  - Have a diagnosis of severe asthma requiring a biologic; **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 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 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 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: Tezspire is not covered in combination with other biologic drug therapy.

Thiola, Thiola EC

Products Affected

- Tiopronin

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug(s):

- **Thiola**
- **Thiola EC (tiopronin)**

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

- Patient has a diagnosis of severe homozygous cystinuria using tiopronin to prevent cystine stone formation (supporting documentation must be submitted to Priority Health); **AND**
- Documentation of a trial with conservative measures (i.e. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated.

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

- Documented compliant maintenance therapy on tiopronin; **AND**
- Continued adherence to conservative measures listed above.

Duration of Approval: 12 months

Note: For approval over quantity limit restriction, documentation proving conservative measures have continued in combination with Thiola and that member has been compliant with these measures must be faxed to Priority Health.

Thrombopoietic Agents

Products Affected

- Alvaiz
- Eltrombopag Olamine
- Tavalisse
- Wayrilz

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Thrombopoietic Agents

Preferred Agent(s):

- **Promacta (eltrombopag olamine)**
- **Alvaiz (eltrombopag choline)**
- **Tavalisse (fostamatinib)**
- **Wayrilz (rilzabrutinib)**

Non-Preferred Agent(s):

- *Not applicable*

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

- For chronic immune (idiopathic) thrombocytopenic purpura (ITP):
  - Have had an insufficient response to corticosteroids, immunoglobulin, or splenectomy; **AND**
  - Have documentation of a treatment-limiting adverse drug reaction to corticosteroids or immunoglobulin; **AND**
  - Current platelet count less than 50 x 109/L with a clinical risk of bleeding

- For aplastic anemia (Promacta/Alvaiz only):
  - Have had an insufficient response to one immunosuppressive agent; **AND**
  - Baseline platelet count must be less than 30 x 109/L

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

- For immune (idiopathic) thrombocytopenia must 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)

- For aplastic anemia must have a hematologic response defined as one of the following:
  - Platelet count increase to 20 x 109/L above baseline or stable platelet counts with transfusion independence for a minimum of 8 weeks; **OR**
  - Hemoglobin increase of greater than 1.5 g/dL or a reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks; **OR**
  - ANC increase of 100% or an ANC increase greater than 500/µL.

Duration of Approval:

- All diagnoses:
  - Initial: 6 months
  - Continuation: 12 months

Note: Eltrombopag, Tavalisse, and Wayrilz are not covered in combination with each other or in combination with Nplate. The maximum daily dose of eltrombopag for treatment of ITP is 75 mg per day (Alvaiz is 54 mg/day), and the maximum daily dose for treatment of aplastic anemia is 150 mg per day (Alvaiz is 108 mg/day).

Tobramycin Inhalation

Products Affected

- Bethkis
- Kitabis Pak (w/ nebulizer)
- Tobi
- Tobi Podhaler
- Tobramycin Inhalation

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Tobramycin Inhalation

Preferred Agent(s):

- **Tobramycin inhalation nebulization 300mg/4mL (generic Bethkis)**
- **Tobramycin inhalation nebulization 300mg/5mL (generic Kitabis)**
- **Kitabis inhalation nebulization 300mg/5mL**

Non-Preferred Agent(s):

- **Bethkis inhalation nebulization 300mg/4mL**
- **Tobi inhalation nebulization 300mg/5mL**
- **Tobi Podhaler**

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

- Patient has a diagnosis of cystic fibrosis confirmed by appropriate diagnostic or genetic testing (documentation of cystic fibrosis ICD10 code within the last 12 months must be submitted to Priority Health); **AND**
- Confirmation of Pseudomonas aeruginosa in cultures of the airways confirmed by a copy of positive sputum culture; **AND**
- Patient is at least 6 years of age; **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance to **ONE** preferred formulation.

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

- Continues to require treatment of Pseudomonas aeruginosa infection; **AND**

- Documentation of stabilization or improvement by pulmonologist or CF specialist.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Coverage for tobramycin inhalation nebulization products is to be used for 28 days, following 28 days off.

Tocilizumab

Products Affected

- Avtozma Subcutaneous
- Tyenne Subcutaneous

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) - Medical Benefit Drug**
- **Avtozma prefilled syringe and IV (tocilizumab-anoh) - Medical Benefit Drug**
- **Avtozma auto-injector (tocilizumab-anoh) - Pharmacy Benefit Drug**

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.
- 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.
- 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.

Tolvaptan

Products Affected

- Tolvaptan
- Tolvaptan (Hyponatremia)

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Tolvaptan (generic Jynarque)

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

- Patient is between 18 to 65 years of age; **AND**
- Patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed via ultrasound (supporting documentation must be submitted to Priority Health); **AND**
- Prescribed by, or in consultation with, a nephrologist; **AND**
- Have an estimated glomerular filtration rate (eGFR) of 25-90 mL/min/1.73m2; **AND**
- Have disease that is rapidly progressing or likely to rapidly progress as evidenced by:
  - Total kidney volume (TKV) of at least 750mL, **OR**
  - Rapid loss of eGFR of at least 2.5mL/min/1.73m2 per year; **AND**
- Hypertension, if present, must be adequately controlled (to 130/80mmHg or less).

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

- Show signs of declining rate of progression in CKD via increase in total kidney volume of less than 5% per year or decline in eGFR by less than 2.5mL/min/1.73m2; **AND**
- Maintain an 85 percent adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient.

Duration of Approval: 12 months

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

Products Affected

- Attruby Injector
- Vyndamax
- Vyndaqel Oral Capsule 20 MG
- Wainua Subcutaneous Solution Auto-

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.

Trientine

Products Affected

- Trientine HCl

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Trientine (generic Syprine)

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

- Patient has a diagnosis of Wilson's disease (supporting documentation must be submitted to Priority Health); **AND**
- Prescribed by, or in consultation with, a gastroenterologist; **AND**
- Have had a trial and failure, or intolerance, to penicillamine.

Ustekinumab

Products Affected

- Imuldosa Subcutaneous Prefilled Syringe 45 MG/0.5ML
- Selarsdi Subcutaneous Solution Prefilled Syringe
- Steqeyma Subcutaneous Solution Prefilled Syringe
- Starjemza Subcutaneous Solution
- Yesintek Subcutaneous Solution Prefilled Syringe
- Starjemza Subcutaneous Solution

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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**

- **Imuldosa Prefilled Syringe (ustekinumab-srlf) - Pharmacy Benefit Drug**
- **Imuldosa Solution (ustekinumab-srlf) - 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.

Valchlor

Products Affected

- Valchlor

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Valchlor (mechlorethamine gel)

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

- Patient has a diagnosis of stage 1A or 1B mycosis fungoides (MF) type cutaneous T-cell lymphoma (CTCL); **AND**
- Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2 (must be submitted within past 30 days); **AND**
- Have a trial of at least two of the following:
  - Topical corticosteroid
  - Topical chemotherapy
  - Topical retinoid
  - Imiquimod
  - Local radiation therapy
  - Phototherapy

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

- Positive clinical responses to Valchlor including clinical reduction in body surface area (BSA) affected from baseline, 50 percent reduction in Composite Assessment of Index Lesion Severity (CAILS) from baseline, or 50 percent improvement in Severity Weighted Assessment Tool (SWAT) from baseline

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Velsipity

Products Affected

- Velsipity

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Velsipity (etrasimod)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.
- For **ulcerative colitis** requests:
  - 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, 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: Velsipity will not be covered in combination with another biologic drug. Before Velsipity is covered, the patient must meet all of the General Criteria for Velsipity 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.

Verquvo

Products Affected

- Verquvo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Verquvo (vericiguat)

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

- Have confirmed diagnosis of symptomatic worsening chronic heart failure (NYHA Class II-IV), defined as one of the following:
  - History of previous heart failure (HF) hospitalization within the last 6 months
  - Outpatient intravenous diuretic for HF within the previous 3 months; **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, a cardiologist; **AND**
- Patient has been using at least 3 of the following HF medications at goal doses for HF treatment or maximally tolerated dosing:
  - ACEI, ARB, or sacubitril/valsartan (Entresto)
  - Bisoprolol, carvedilol or sustained release metoprolol
  - Spironolactone
  - Diuretic (i.e. furosemide); **AND**
- Ejection Fraction less than 45% assessed within the previous 12 months; **AND**
- Documentation of an elevated brain natriuretic peptide (BNP) or NT-proBNP level within the previous 30 days.

Note: Vequvo is not covered in combination with Kerendia.

Vesicular monoamine transporter type 2 (VMAT2)

Products Affected

- Austedo
- Austedo XR
- Austedo XR Patient Titration
- Ingrezza
- Tetrabenazine

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Group Description: Vesicular monoamine transporter type 2 (VMAT2)

Preferred Agent(s):

- **Tetrabenazine**
- **Ingrezza**

Non-Preferred Agent(s):

- **Austedo**

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

- For **chorea associated with Huntington's disease**:
  - Documentation confirming diagnosis must be submitted to Priority Health; **AND**
  - Patient is at least 18 years of age; **AND**
  - Non-preferred drug product:
    - Trial and failure, or intolerance to tetrabenazine used at maximally tolerated doses.
- For **moderate to severe tardive dyskinesia**:
  - Provide documentation of current Abnormal Involuntary Movement Scale (AIMS) score with a minimum score of 3 on item 8 (severity of abnormal movements overall); **AND**
  - Have tried and failed a dose reduction, tapering, and/or discontinuation of the offending agent(s); **AND**

- Be 18 years of age; **AND**
- Non-preferred drug product:
  - Trial and failure, or intolerance to Ingrezza.

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

- Medical documentation submitted confirming a positive response to therapy:
  - Chorea symptoms have improved or stabilized; **OR**
  - Decreased AIMS score (items 1 to 7) from baseline.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Notes:

- For tetrabenazine doses greater than 50mg/day, must have CYP2D6 genotype provided.
- Austedo, Ingrezza, and tetrabenazine will not be covered in combination with one another.

Vigabatrin

Products Affected

- Vigabatrin Oral Packet
- Vigadrone Oral Packet
- Vigafyde
- Vigpoder Oral Packet 500 MG

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Vigabatrin (generic Sabril, Vigadrone, Vigafyde, Vigpoder)

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

- Have a diagnosis of infantile spasms; **OR**
- Have a diagnosis of refractory complex partial seizure and have had a trial and failure with two generic anticonvulsants.

Vijoice

Products Affected

- Vijoice

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Vijoice (alpelisib)

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

- Physician confirmed/documented diagnosis of PROS; **AND**
- Patient has at least one target lesion identified on imaging and target lesion volume is documented; **AND**
- Documented evidence of a mutation in the PIK3CA; **AND**
- Patient is at least 2 years of age; **AND**
- Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2 (must be submitted within past 30 days).; **AND**
- Patient's condition is severe or life-threatening and treatment is deemed necessary as determined by the treating physician.

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

- Documentation of positive response to therapy, as evidenced by at least a 20% reduction in the sum of measurable target lesion volume (one to three lesions, via central review of imaging scans), confirmed by at least one subsequent imaging assessment provided that none of the individual target lesions had at least 20% increase from baseline, nontarget lesions had not progressed, and there were no new lesions; **AND**
- Documentation that the member is tolerating therapy.

Duration of Approval:

- Initial: 6 months

- Continuation: 12 months

Note: For adult patients requiring a 250mg daily dose of alpelisib for PROS, the covered formulation is Piqray.

Voxzogo

Products Affected

- Voxzogo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Voxzogo (vosoritide)

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

- Patient has a diagnosis of achondroplasia confirmed by genetic testing for variants in the fibroblast growth factor receptor 3 (FGFR3) gene (supporting documentation must be submitted to Priority Health); **AND**
- Have documentation of member's current annualized growth velocity (AGV) and the patient has open epiphyses; **AND**
- Prescriber attests that there are no plans for the member to have limb-lengthening surgery and the member has not had limb-lengthening surgery in the past 18 months; **AND**
- Member has not received previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids in the 6 months prior to request; **AND**
- Prescribed by or in consultation with a board-certified geneticist, endocrinologist, neurologist, orthopedic surgeon, or specialist with experience in treating achondroplasia.

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

- Adherence to therapy at least 85% of the time as verified by the prescriber or patient medication fill history; **AND**
- Documentation confirming current open epiphyses; **AND**
- Documentation of positive clinical response as demonstrated by improvement or stabilization in annualized growth velocity and increase in AGV is at least 1.5 centimeters/year from baseline.

Duration of Approval: 12 months (initial and maintenance)

Voydeya

Products Affected

- Voydeya

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Voydeya (danicopan)

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

- Have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); **AND**
- Be receiving active treatment with Ultomiris or Soliris/Epysqli and considered stable (treatment >6 months); **AND**
- Patient is at least 18 years of age; **AND**
- Have symptomatic Extravascular Hemolysis (EVH) defined as:
  - Fatigue or dyspnea **AND**
  - Hgb less than 9.5g/dL **OR**
  - Absolute Reticulocyte Count greater than 120 x 109/L

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

- Patient must be receiving active treatment with Ultomiris or Soliris/Epysqli; **AND**
- Have clinical signs have improved (e.g. hemoglobin levels have increased, reduction in transfusions, improvement in hemolysis, or increased reticulocyte count); **AND**
- Have improvement in fatigue and quality of life; **AND**
- Documentation of compliance to therapy.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 Months

Note: Voydeya is not covered in combination with Fabhalta or PiaSky or Empaveli.

Vyvgart Hytrulo

Products Affected

- Vyvgart Hytrulo Subcutaneous Solution Prefilled Syringe

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

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.

Wakix

Products Affected

- Wakix

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Wakix (pitolisant)

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

- Prescribed by, or in consultation with, a board-certified sleep specialist or neurologist; **AND**
- MSLT plus polysomnogram must meet requirements according to International Classification of Sleep Disorders- Third Edition (ICSD-3) for the diagnosis of narcolepsy. Must fax MSLT plus polysomnogram results to Priority Health; **AND**
- Wakix will not be covered in patients who use other sedative hypnotics, drink alcohol when using Wakix; **AND**
- Patient is at least 6 years of age; **AND**
- Meet diagnosis specific criteria below:

- For treatment of excessive daytime sleepiness in patients with narcolepsy:
  - Have a documented therapeutic trial with persistent sleepiness that significantly impairs the ability to function or poses a danger to them or others, with all of the following:
    - Amphetamine salts, dextroamphetamine or methylphenidate
    - Modafinil
    - Armodafinil
    - Sunosi

- For treatment of cataplexy substantial enough to warrant treatment:
  - Have a documented 6-week trial with continued cataplexy on one of the following:
    - fluoxetine, venlafaxine ER, or Strattera

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

- Response to therapy with a reduction in excessive daytime sleepiness from pre-treatment baseline **OR** reduced frequency of cataplexy attacks from pre-treatment baseline if patient has cataplexy

Duration of Approval: 12 months

Note: Wakix will not be covered in combination with sodium oxybate.

Xdemvy

Products Affected

- Xdemvy

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Xdemvy (lotilaner)

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

- Have a diagnosis of Demodex blepharitis as evidenced by:
  - Presence of at least mild erythema of the upper eyelid margin; **AND**
  - Presence of mite on examination of eyelashes by light microscopy or presence of collarettes on slit lamp examination; **AND**
- Patient is at least 18 years of age; **AND**
- Prescribed by or in consultation with an optometrist or ophthalmologist; **AND**
- First try ivermectin for the current blepharitis condition.

Duration of Approval: 1 fill (10 mL bottle) per 12 months

Xeljanz/XR

Products Affected

- Tofacitinib Citrate ER
- Tofacitinib Citrate Oral
- Xeljanz
- Xeljanz XR

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Xeljanz/XR (tofacitinib)

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

- Prescriber is a specialist or has consulted with a specialist for the condition being treated.

- For **Ankylosing Spondylitis** requests:
  - Patient has tried at least **ONE** tumor necrosis factor inhibitor (TNFI) 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 **ONE** tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months.

- For **Juvenile Idiopathic Arthritis** requests:
  - Patient has tried at least **ONE** tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months.

- For **Psoriatic Arthritis** requests:
  - Patient will use Xeljanz/Xeljanz XR along with methotrexate or another conventional synthetic DMARD; **AND**
  - 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 **ONE** tumor necrosis factor inhibitor (TNFI) 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** tumor necrosis factor inhibitor (TNFI) for a period of at least 3 months.

Note: Xeljanz/XR will not be covered in combination with another biologic drug. Before Xeljanz/XR is covered, the patient must meet all of the General Criteria for Xeljanz/XR and all of the Specific Criteria for the treatment diagnosis. If these criteria are not met, the prescriber must provide an explanation of why an exception to the criteria is necessary. Coverage for a diagnosis not listed above will be considered on a case by case basis. Please provide rationale for use and all pertinent patient information. Please provide rationale when requesting coverage for use (e.g., indication, dose) not listed in the FDA label.

Xermelo

Products Affected

- Xermelo

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Xermelo (telotristat)

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

- Patient has a diagnosis of carcinoid syndrome diarrhea; **AND**
- Patient is at least 18 years of age; **AND**
- Have been receiving stable dose SSA therapy (either long-acting release [LAR], depot, or infusion pump) for at least 3 months; **AND**
- Xermelo will be used in combination with a somatostatin analog (SSA); **AND**
- Have an Eastern Cooperative Oncology Group (ECOG) score between 0 and 2; **AND**
- Be experiencing 4 or more bowel movements per day; **AND**
- Not have any of the following:
  - 12 or more watery bowel movements per day
  - History of short bowel syndrome
  - Clinically significant elevations in liver function tests
  - Recently undergone tumor directed therapy.

Duration of Approval: 12 months

Yorvipath

Products Affected

- Yorvipath

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Yorvipath (palopegteriparatide)

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

- Have a confirmed diagnosis of hypoparathyroidism; **AND**
- Provide documentation of serum parathyroid hormone, calcium, magnesium, and phosphate levels (all drawn together); **AND**
- Have tried and failed calcium supplementation (at least 2,000mg/day of elemental calcium) and vitamin D supplementation (e.g., calcitriol dose of at least 2 mcg/day) and be unable to maintain adequate control of calcium levels; **AND**
- Be concurrently taking a calcium supplement and a vitamin D supplement (e.g., calcitriol); **AND**
- Patient is at least 18 years of age; **AND**
- Prescriber is an endocrinologist or has consulted with an endocrinologist.

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

- Have documented benefit from use of Yorvipath that includes an improved serum calcium; **AND**
- Continue to take calcium and vitamin D supplementation.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

Note: Yorvipath is not covered in combination with other PTH analogs (e.g., teriparatide, abaloparatide). Yorvipath will not be covered for acute postsurgical

hypoparathyroidism.

Zilbrysq

Products Affected

- Zilbrysq

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Zilbrysq (zilucoplan)

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 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**
- Progressive disease on a therapeutic trial of Vyvgart or Rystiggo AND Ultomiris; **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: 3 months
- Continuation: 12 months

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

Ztalmy

Products Affected

- Ztalmy

Criteria Details

Priority Health

Click and complete the Employer Group & MyPriority Plans Pharmacy (Non-Oncology) drug request form or Electronic prior authorization (ePA).

Drug: Ztalmy (ganaxolone)

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

- Patient has a diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder and will be using Ztalmy as adjunctive treatment for seizures (documentation must be submitted to PH); **AND**
- Patient is at least 2 years of age; **AND**
- Prescribed by a neurologist; **AND**
- Documented therapeutic failure of at least 2 previous antiepileptic drugs; **AND**
- Member's current weight provided; **AND**
- Documentation of baseline monthly seizure frequency.

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

- Confirmation of a sustained reduction in monthly seizure frequency.

Duration of Approval:

- Initial: 6 months
- Continuation: 12 months

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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）。

ⵜⵉⵙⵏⴰⵙ : ⵎⴰⵙ ⵜⵙⵏⵙⵉⵡⵉⵜ ⵜⵉⵎⵣⵡⵔⵜ ⵏⵜⵜⴰⵡⵉⵔⵉⵜ ⵉⵙ ⵜⵣⵎⵔⵜ (ⵜⴰⵡⴰⵙⵜ) ⵜⵉⵎⵣⵡⵔⵜ ⵏⵜⵜⴰⵡⵉⵔⵉⵜ ⵉⵙ ⵜⵣⵎ

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