Priority Health Choice

Medical Drug
Prior Authorization Criteria

This document contains prior authorization criteria for physician-administered medications administered in outpatient, non-emergent settings. These medications are covered under the medical benefit of Priority Health Choice Medicaid, Medicaid CSHCS, and Healthy MI plans.

What is a prior authorization?
When a medication requires prior authorization, it means that certain clinical criteria must be met before the medication can be covered. Clinical prior authorizations should be completed *prior* to administration of the drug.

How to know when a physician-administered medication requires prior authorization
To know when a medication requires prior authorization, use the Medical Benefit Drug List (MBDL), posted on the Medicaid Approved Drug List (ADL). Prescribers should use the Medicaid Medical Authorization form, along with the criteria in this document, to request prior authorization. Providers are responsible for understanding if a drug HCPCS codes is included in the fee schedule applicable to their claims and whether the NDC dispensed is payable per MDHHS policy.

Not all physician-administered medications are covered by this plan
There are certain physician-administered drugs that are not covered. Some medications are carved-out to Fee-For-Service Medicaid. MDHHS maintains a list of these drugs. Providers should contact Fee-For-Service Medicaid regarding coverage of carve-out drugs. Additionally, medications that are excluded from coverage by the members Certificate of Coverage will not be covered.

Priority Health

Drug Name	HCPCS Code	Criteria
Actemra IV (tocilizumab)	J3262	**Approved Diagnosis:** • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Systemic Juvenile Idiopathic Arthritis (SJIA) • Giant Cell Arteritis • Cytokine Release Syndrome **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** age 2 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Rheumatoid Arthritis (RA) • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab Juvenile Idiopathic Arthritis (Polyarticular & Systemic) • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight Giant Cell Arteritis • Patient has tried one systemic corticosteroid Cytokine Release Syndrome • Patient is experiencing a severe or life-threatening T-cell induced reaction; **AND** • The IV formulation of Actemra is being used for treatment; **AND** • A maximum of 4 doses is requested **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:** • The subcutaneous form of this drug will not be covered under the medical benefit. Refer to the Approved Drug List (ADL) for coverage under the pharmacy benefit. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Adakveo (crizanlizumab-tmca)	J0791	**Approved Diagnosis:** • Sickle Cell Disease **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Age Limitation:** Must be age 16 years or older **Initial Criteria:** • Documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Documented 6-month trial with hydroxyurea , or record of contraindication or intolerance, **AND** • Documentation of at least two vaso-occlusive crises (VOCs) in the last year **Continuation Criteria:** • Documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Documentation showing the patient has experienced a reduction in vaso-occlusive crises while on Adakveo therapy. **Additional Information:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Adzynma (ADAMTS13, recombinant-krhn)	J7171	**Approved Diagnosis:** • congenital thrombotic thrombocytopenic purpura (cTTP) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by or in consultation with a specialist for the disease state **Age Limitation:** Must be age 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must have a diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by genetic testing; **AND** • Documentation of ADAMTS13 activity must be provided **and** is less than 10%; **AND** • Documentation of current weight; **AND** • Initial dosing frequency for prophylactic use is not to exceed every 2 weeks **Continuation Criteria:** • Documentation showing patient has demonstrated a beneficial response to therapy (e.g. decrease in acute and subacute TTP events, improvement in platelet count from baseline, decrease in microangiopathic hemolytic anemia episodes) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Aldurazyme (laronidase)	J1931	**Approved Diagnosis:** • Mucopolysaccharidosis I (MPS I) ○ Hurler form ○ Hurler-Scheie form ○ Scheie form with moderate to severe symptoms **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis, **AND** • Documentation of patient's current weight **Continuation Criteria:** • Continuation criteria only applies if the member is not able to safely receive the medication by home infusion, **AND** • Documentation confirming diagnosis, **AND** • Documentation of patient's current weight, **AND** • Documentation showing the patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: ○ Stabilization, OR ○ improvement in FVC and/or 6MWT **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Alpha-1 Proteinase Inhibitor – human Aralast Aralast NP Prolastin Prolastin-C Zemaira Glassia	J0256 (J0257 Glassia)	**Approved Diagnosis:** • congenital alpha1-antitrypsin deficiency **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of clinically evident emphysema, **AND** • Documentation of patient's current weight, **AND** • A predicted FEV1 value between 30% and 65%, **AND** • Patient must be a non-smoker, **AND** • Labs confirming baseline serum alpha1-antitrypsin (AAT) level less than 11 mmol/L ○ 11 mmol/L is equal to 80 mg/dL if measured by radial immunodiffusion ○ 11 mmol/L is equal to 50 mg/dL if measured by nephelometry **Continuation Criteria:** • Documentation of clinically evident emphysema, **AND** • Documentation of patient's current weight, **AND** • A predicted FEV1 value between 30% and 65%, **AND** • Patient must be a non-smoker, **AND** • Pretreatment baseline labs must be included showing serum alpha1-antitrypsin (AAT) level less than 11 mmol/L, **AND** • Current labs must be included showing serum alpha1-antitrypsin (AAT) level greater than 11 mmol/L **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Amvuttra (vutrisiran)	J0225	**Approved Diagnosis:** • polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with a cardiologist or neurologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** **hATTR-PN** • Documentation confirming diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy **AND** • Documentation of genetic testing that confirms a transthyretin (TTR) mutation **AND** • Must have presence of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.) **AND** • Must have documentation of one of the following: o Baseline polyneuropathy disability (PND) score ≤ IIIb; OR o Baseline FAP Stage 1 or 2 **AND** • Patient has not had a liver transplant **ATTR-CM** • Documentation confirming diagnosis o ATTR-CM must be confirmed by genetic testing, tissue biopsy, or radionuclide imaging (99mTcPYP, 99mTc- DPD, or 99mTc-HMDP scan); **AND** • Medical history of heart failure that includes one of the following o at least one prior hospitalization of heart failure **OR** o clinical evidence of heart failure **AND** • Must not currently have, or have history of: o New York Heart Association (NYHA) Class 4 heart failure o Primary (light-chain) amyloidosis o Prior liver or heart transplant or an implanted cardiac device **AND** • Will not be used concurrently with Amvuttra, Onpattro, Wainua, Vyndaqel, or Vyndamax **AND** • Trial and failure or Intolerance/contraindication to one of the following: Attruby (acoramidis), Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis **Continuation Criteria:** • Documentation confirming diagnosis **AND** • Documentation that the patient has experienced a positive clinical response to Amvuttra compared to baseline (e.g., improved neurologic improvement, motor function, quality of life, slowing of disease progression) **AND** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered in an outpatient hospital infusion center. • Amvuttra will not be covered in combination with tafamidis (Vyndaqel, Vyndamax), Onpattro, Wainua or Attruby

Benlysta IV (belimumab)	J0490	**Approved Diagnosis:** • Systemic lupus erythematosus (SLE) • Lupus nephritis **Approval Timeframe:** • Initial authorization: 24 weeks • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** Must be age 5 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Systemic lupus erythematosus (SLE) • Must provide documentation confirming diagnosis of active, autoantibody-positive systemic lupus erythematosus (SLE) with one of the following: ○ Anti-nuclear antibody (ANA) titer ≥ 1:80; **OR** ○ Anti-double-stranded DNA (anti-dsDNA) level ≥ 30 IU/mL; **AND** • Must have a SELENA-SLEDAI score of 6 or more while on treatment with standard therapy (e.g., corticosteroids, immunosuppressants, hydroxychloroquine) for at least 12 weeks each before starting Benlysta; **AND** • Must not have central nervous system manifestations; **AND** • Must not be using in combination with any other biologic drug (e.g. rituximab) or Lupkynis (voclosporin); **AND** • Documentation of patient's current weight Lupus nephritis • Must provide documentation confirming diagnosis of biopsy-proven lupus nephritis Class III through V; **AND** • Be autoantibody-positive with one of the following: ○ Anti-nuclear antibody (ANA) titer ≥ 1:80, **OR** ○ Anti-double-stranded DNA (anti-dsDNA) level ≥ 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) <30 mL/min/1.73m2 **Continuation Criteria:** Systemic lupus erythematosus (SLE) • Must provide documentation confirming diagnosis; **AND** • Documentation of patient's current weight; **AND** • Patient must meet 3 of the following: ○ Must have a SELENA-SLEDAI score point reduction of 4 or more based on a 30-day assessment; **OR** ○ Must have a Physician Global Assessment change indicating showing no disease progression (worsening) compared to baseline treatment with Benlysta; **OR** ○ Must have a British Lupus Assessment Group (BILAG) score of zero in Category A (very active disease) –and– a score of one or less in Category B (moderately active, in any organ system in the last 4 weeks); **OR** ○ A reduction in dose of steroid therapy; **OR** ○ A negative seroconversion or a 20% reduction in autoantibody levels from baseline; **OR** ○ Free of significant clinical flares that require steroid boost treatment with Benlysta Lupus nephritis • Must have evidence of efficacy (defined as urinary protein creatinine ratio ≤0.7, eGFR ≤20% below the pre-flare or at least 60mL/min/1.73m2), and no use of rescue therapy for treatment failure **Additional Information:** • The subcutaneous form of this drug will not be covered under the medical benefit. Refer to the Approved Drug List (ADL) for coverage under the pharmacy benefit. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Botulinum Toxin Botox Dysport Myobloc Xeomin Daxxify	 J0585 J0586 J0587 J0588 J0589	**Approved Diagnosis:** • Bladder Dysfunction ○ Overactive Bladder ○ Detrusor Overactivity associated with a Neurologic Condition • Chronic Migraine • Spasticity or Dystonia associated with: ○ Cerebral Palsy ○ Demyelinating diseases of the CNS and copus callosum including Leukodystrophy ○ Esophageal achalasia ○ Facial nerve VII disorder (facial myokymia, Melkersson's syndrome, facial/hemifacial spasms) ○ Hereditary spastic paraplegia ○ Laryngeal spasm, Laryngeal adductor spastic dysphonia or stradulus ○ Multiple Sclerosis ○ Neuromyelitis optica ○ Orofacial dyskinesia ○ Schilder's disease ○ Strabismus ○ Cervical Dystonia ○ Focal hand dystonia (i.e. organic writer's cramp) ○ Jaw-closing oromandibular dystonia ○ Lingual dystonia ○ Spastic hemiplegia due to stroke or brain injury ○ Torsion dystonia, idiopathic and symptomatic ○ Torticollis • Primary Axillary Hyperhidrosis • Palmar Hyperhidrosis • Blepharospasm • Anal Fissures • Ptyalism/sialorrhea **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis Anal Fissures • Documentation of minimum 8-week trial, and subsequent therapeutic fail, with: ○ nitroglycerin ointment, OR ○ topical diltiazem • Patient declines, or is not a candidate for surgical intervention Detrusor Overactivity associated with a Neurologic Condition • Documentation of the underlying neurological condition that is the cause of detrusor activity (e.g. spinal cord injury or multiple sclerosis) • Documentation of trail, and subsequent therapeutic failure with an anticholinergic drug • Requested dose must not exceed 200 units intramuscularly for each treatment, once every 90 days Primary Axillary Hyperhidrosis • Documentation that the patient is unable to achieve satisfactory results using aluminum chloride (generic for Drysol) or other extra-strength (more than 20%) antiperspirants or be intolerant to these therapies because of severe rash. Palmar Hyperhidrosis • Documentation that the patient is unable to achieve satisfactory results using aluminum chloride (generic for Drysol).

Botulinum Toxin Botox Dysport Myobloc Xeomin Daxxify	 J0585 J0586 J0587 J0588 J0589	Chronic Migraine • Documentation that headaches are disabling and occur on 15 days or more each month, lasting four hours each day or longer. • Patient has tried and failed at least one-month of any two of the following oral medications: ○ Antidepressants (e.g., amitriptyline, nortriptyline) ○ Beta blockers (e.g., propranolol, metoprolol, timolol) ○ Anti-epileptics (e.g., valproate, topiramate) Overactive bladder • Documentation of therapeutic trial and failure with two or more anticholinergic drugs. • Maximum dose is 100 units intramuscularly for each treatment, once every 90 days Ptyalism/sialorrhea • Documentation of therapeutic trial and failure on anticholinergic therapy. **Continuation Criteria:** • Documentation confirming diagnosis • Documentation showing the patient has demonstrated a beneficial response to therapy • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information** • No authorization required when drug is billed by a provider with one of the following specialties: Rehabilitation Medicine, Physical Medicine & Rehab, or Neurology • The following conditions are not covered: ○ Botulinum toxin for the treatment of anal spasm, irritable colon, biliary dyskinesia, craniofacial wrinkles or any treatment of other spastic conditions not listed as covered on this prior authorization form are considered experimental (including the treatment of smooth muscle spasm). ○ Botulinum toxin for patients receiving aminoglycosides ○ Botulinum toxin for patients with chronic paralytic strabismus, except to reduce antagonistic contractor with surgical repair ○ Treatment exceeding accepted dosage parameters unless supported by individual medical record review as well as treatments where the goal is to improve appearance rather than function. ○ Use of botulinum toxin A or botulinum toxin B for all other conditions not listed as a covered benefit. ○ Plantar hyperhidrosis ○ Cluster, tension, and cervicogenic headaches • If approved, authorization will be for one dose every 90 days for two years. It is usually not considered medically necessary to give botulinum toxin injection more frequently than every 90 days. An exception is for migraine prophylaxis, which will be authorized for one dose every 84 days. The maximum cumulative dose should generally not exceed 400 units in a 3-month interval when treating one or more indications. Requests exceeding 400 units in a 3-month interval must be explained by the provider and are subject to Priority Health's medical necessity review.

Brineura (celiponase alfa)	J0567	**Approved Diagnosis:** • Late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 6 months **Prescriber Specialty Requirement:** Must be prescribed by a neurologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must have a diagnosis of late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease which was confirmed by tripeptidyl peptidase 1 (TPP1) deficiency (testing must be included with submission); **AND** • Patient must be symptomatic; **AND** • Treatment is being given to slow the loss of ambulation in a patient with a baseline motor-language CLN2 clinical rating scale (CRS) greater than or equal to 3 **Continuation Criteria:** • Patient must meet all of the initial requirements; **AND** • Patient has a score of 1 or higher in the motor domain of the CLN2 clinical rating scale; **AND** • Clinical documentation, including chart notes, of disease stability or improvement must be provided

Briumvi (Ublituximab-xiiy)	J2329	**Approved Diagnosis:** • Primary Progressive MS • Relapsing-remitting MS **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** Neurologist or specialist in MS **Age Limitation:** age 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of: ○ Primary Progressive Multiple Sclerosis (PPMS) ○ Relapsing-Remitting [RRMS] or Secondary Progressive multiple sclerosis **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Briumvi will not be approved in combination with any other disease modifying therapy for multiple sclerosis

Byooviz (ranibizumab-nuna)	Q5124	**Approved Diagnosis:** • Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Myopic Choroidal Neovascularization (mCNV) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Patients currently receiving treatment with Byooviz and who have demonstrated an adequate response are not required to try Avastin. Neovascular (wet) age-related macular degeneration (AMD): • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid ○ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. Macular edema following retinal vein occlusion (RVO) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic macular edema (DME) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic retinopathy (DR) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Myopic Choroidal Neovascularization (mCNV) • Byooviz for mCNV may be authorized for a maximum of 1 injection per month up to a maximum of 3 months **Continuation Criteria:** • Documentation confirming diagnosis • Documentation showing the disease response as indicated by ○ stabilization of visual acuity, or ○ improvement in BCVA score when compared to baseline. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Cerezyme (imiglucerase)	J1786	**Approved Diagnosis:** • Diagnosis of Non-neuropathic Gaucher's disease, chronic, symptomatic **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1-year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Documentation of patient's current weight **Continuation Criteria:** • Continuation criteria only applies if the member is not able to safely receive the medication by home infusion • Documentation confirming diagnosis • Documentation showing the patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: clinically significant reduction in spleen or liver volume, increase in platelet or hemoglobin values • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Cimerli (ranibizumab-eqrn)	Q5128	**Approved Diagnosis:** • Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Myopic Choroidal Neovascularization (mCNV) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Patients currently receiving treatment with Cimerli and who have demonstrated an adequate response are not required to try Avastin. Neovascular (wet) age-related macular degeneration (AMD): • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid ○ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. Macular edema following retinal vein occlusion (RVO) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic macular edema (DME) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic retinopathy (DR) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Myopic Choroidal Neovascularization (mCNV) • Cimerli for mCNV may be authorized for a maximum of 1 injection per month up to a maximum of 3 months **Continuation Criteria:** • Documentation confirming diagnosis • Documentation showing the disease response as indicated by ○ stabilization of visual acuity, or ○ improvement in BCVA score when compared to baseline. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Cimzia (certolizumab pegol)	J0717	**Approved Diagnosis:** • Non-radiographic Axial Spondyloarthritis • Ankylosing Spondylitis • Crohn's Disease • Plaque Psoriasis • Psoriatic Arthritis • Rheumatoid Arthritis • polyarticular Juvenile Idiopathic Arthritis (pJIA) **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** • pJIA: age 2 years or older • All other indications: age 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab unless prescribed for non-radiographic axial spondyloarthritis **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Cinqair (reslizumab)	J2786	**Approved Diagnosis:** • Severe, Eosinophilic Asthma **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of patient's current weight • Labs confirming peripheral blood eosinophil count of > 150 cells/mcL in the past 12 months • Must have been compliant on **all** the following therapies for at least 3 consecutive months each: ○ High-dose inhaled corticosteroid (ICS)* ○ Long-acting beta agonist (LABA) ○ One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva) • Documentation showing the member experienced ≥ 2 asthma exacerbations in the previous year that required at least ONE of the following: ○ Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days ○ Hospitalization and/or ED visit • Must not currently use tobacco products • Must not use in combination with other biologics (e.g., Nucala, Dupixent, Fasenra, or Xolair) **Continuation Criteria:** • Must have been compliant on therapy with Cinqair • Documentation of patient's current weight • Documentation showing the patient has experienced improvement or maintained stable clinical status. • Must not currently use tobacco products • Must not use in combination with other biologics (e.g., Nucala, Dupixent, Fasenra, Xolair, or Tezspire) • Documentation showing patient has had a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Cosela (trilaciclib)	J1448	**Approved Diagnosis:** • Extensive small cell lung cancer (SCLC) **Approval Timeframe:** • Initial authorization: 12 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of extensive small cell lung cancer (SCLC) • Patient is currently receiving ○ platinum/etoposide +/- immune checkpoint inhibitor; *or* ○ a topotecan-containing regimen • The patient has previously experienced severe neutropenia while using one of the regimens described above, despite use of G-CSF products (i.e. filgrastim, pegfilgrastim). **Continuation Criteria:** • Documentation showing that the patient has demonstrated a beneficial response to therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Crysvita (burosumab-twza)	J0584	**Approved Diagnosis:** • X-linked hypophosphatemia (XLH) • Tumor-induced osteomalacia (TIO) **Approval Timeframe:** • Initial authorization: 12 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** none **Age Limitation:** See diagnosis specific age limits below **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** X-linked hypophosphatemia (XLH) • Patient must be age 6 months or older; **AND** • Documentation of diagnosis confirmed by one of the following must be included ○ Genetic testing (PHEX-gene mutation); *or* ○ Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL; **AND** • Must have baseline serum phosphorus level below lower limit of laboratory reference range with current hypophosphatemia; **AND** • Documentation confirming the patient is exhibiting clinical signs and symptoms of XLH (e.g. rickets, growth retardation, musculoskeletal pain, bone fractures, etc.). Tumor-induced osteomalacia (TIO) • Patient must be age 2 years or older; **AND** • Must be used for treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized; **AND** • Must have baseline serum phosphorus level below lower limit of laboratory reference range with current hypophosphatemia. **Continuation Criteria:** • The patient is compliant in taking the medication as scheduled • Must have experienced normalization of serum phosphate while on therapy (documentation of laboratory levels must be submitted) • Documentation must be submitted showing patient experienced a positive clinical response to therapy (e.g. enhanced height velocity, improvement in skeletal deformities, reduction in bone fractures) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Dalvance (dalbavancin)	J0875	**Approved Diagnosis:** • Acute bacterial skin and skin structure infection (ABSSSI) **Approval Timeframe:** • Initial authorization: 1 month • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of culture and sensitivity results must be sent to Priority Health showing the patient's infection is not susceptible to alternative antibiotic treatments • Confirmation that Dalvance will be started in the hospital or other health care facility and will be continued in outpatient facility **NOTE:** Inpatient claims are not managed by PH Pharmacy Department • Must have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives.
Duopa (carbidopa 5 mg/levodopa 20 mg enteral suspension)	J7340	**Approved Diagnosis:** • Parkinson's disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a neurologist. **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of therapeutic failure after a one-month trial with carbidopa/levodopa ER tablet given at multiple daily dosing **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy

Elaprase (idursulfase)	J1743	**Approved Diagnosis:** • Hunter syndrome (Mucopolysaccharidosis II) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Hunter syndrome (Mucopolysaccharidosis II) • Documentation of patient's current weight **Continuation Criteria:** • Continuation criteria only applies if the member is unable to safely receive the medication by home infusion • Documentation confirming diagnosis • Documentation of patient's current weight • Documentation showing that the patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: ○ clinically significant reduction in spleen or liver volume ○ increase in platelet, or ○ hemoglobin values **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Elelyso (taliglucerase alfa)	J3060	**Approved Diagnosis:** • Gaucher's Disease (Type 1) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Gaucher's Disease (Type 1) • Documentation of patient's current weight **Continuation Criteria:** • Continuation criteria only applies if the member is unable to safely receive the medication by home infusion • Documentation confirming diagnosis • Documentation of patient's current weight • Documentation showing that the patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: ○ stabilization or improvement in FVC; and/or ○ stabilization or improvement of 6MWT **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Elfabrio (pegunigalsidase alfa-iwxj)	J2508	**Approved Diagnosis:** • Fabry disease **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** • Must be prescribed by a nephrologist, cardiologist, specialist in metabolic disorders or genetics **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of patient's current weight • Documentation confirming diagnosis of Fabry disease (e.g., alpha-Gal A activity in leukocytes or plasma, mutation analysis of the alpha-Gal A gene) • The patient is either a: ○ Classically affected male (i.e., male with very low or undetectable levels of alpha-galactosidase A [alphaGal A]): **OR** ○ Female carrier or male with atypical presentations (i.e., with marginal levels of alpha-Gal A) with clinical manifestations of Fabry disease (e.g., renal, neurologic, cardiovascular) present **Continuation Criteria:** Continuation criteria only applies if the member is unable to safely receive the medication by home infusion: • Documentation confirming diagnosis • Documentation of patient's current weight • Documentation showing a continued response to treatment (e.g., reduction in plasma glycosphingolipid GL-3 levels compared to baseline) • Patient has remained compliant with > 50 percent of treatments • Patient regularly attends follow-up visits • Patient has not developed ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV) • Patient does not have end-stage Fabry disease or other comorbidities with a life expectancy of < 1 year • Patient has not experienced severe cognitive decline **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Empaveli (pegcetacoplan)	J7799 C9399	**Approved Diagnosis:** • Paroxysmal Nocturnal Hemoglobinuria (PNH) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** • Hematology/Oncology **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis must be submitted; **AND** • Must have flow cytometric confirmation ≥10% granulocyte clone cells; **OR** • Have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage **Continuation Criteria:** • Documentation confirming diagnosis; **AND** • Must have a decrease disabling symptoms; **AND** • Hemoglobin levels must be stabilized; **AND** • Patient has experienced an improvement in fatigue and quality of life **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Encelto (revakinagene taroretcel-lwey)	J3590	**Approved Diagnosis:** • MacTel type 2 **Approval Timeframe:** • Initial authorization: Single implant per eye per lifetime • Continuation authorization: N/A **Prescriber Specialty Requirement:** Must be prescribed by an ophthalmologist (retinal specialist) **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation (test results) must be submitted confirming diagnosis of MacTel type 2 • Documentation must be submitted showing patient has evidence of fluorescein leakage and at least one of the following additional characteristics: ○ hyperpigmentation outside a 500-micron radius from the fovea center, retinal opacification, crystalline deposits, right-angle vessels, **OR** inner/outer lamellar cavities. • Patient must have IS/OS PR break (loss) in EZ between 0.16 and 2.00 mm^2 • Patient must have a BCVA score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart • Patient must not have evidence of neovascular MacTel type • Patient must not have previously received an Encelto implant.
Enjaymo (sutimlimab-jome)	J1302	**Approved Diagnosis:** • Cold Agglutinin Disease (CAD) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a hematologist **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of cold agglutinin disease (CAD); **AND** • Documentation of the patient's current weight and baseline hemoglobin level must be submitted; **AND** • Documentation of at least one blood transfusion within 6 months of starting Enjaymo; **AND** • Patient's hemoglobin must be ≤ 10 g/dL; **AND** • Must be a presence of one or more symptoms associated with CAD (e.g., symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event); **AND** • Must have a documented trial and failure with a rituximab-containing regimen **Continuation Criteria:** • Must have documented clinical benefit from use of Enjaymo as evidenced by: ○ an increase in baseline Hgb level; **AND** ○ no blood transfusions 5 weeks from initiation of therapy **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. If this medication is new to the patient, and if requested, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Entyvio IV (vedolizumab)	J3380	**Approved Diagnosis:** • Crohn's disease • Ulcerative Colitis **Approval Timeframe:** • Initial authorization: 14 weeks • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Mild Crohn's disease • Must have documented therapeutic failure with one of the following: o Corticosteroids o Mesalamine o Olsalazine o Sulfasalazine o Azathioprine o 6-mercaptopurine (6-MP) o Methotrexate; **AND** • Must have documented therapeutic failure with infliximab Moderate to Severe Crohn's disease • Patient has moderate to severe Crohn's disease; **AND** • Must have documented prior use of corticosteroids for treatment of Crohn's disease; **AND** • Must have documented therapeutic failure with infiximab Mild to Moderate Ulcerative Colitis • Must have documented therapeutic failure with two of the following: o 6-mercaptopurine (6-MP) o Azathioprine o Balsalazide o Corticosteroids o Mesalamine o Sulfasalazine; **AND**

		• Must have documented therapeutic failure with infliximab Severe Ulcerative Colitis • Patient has frequent loose bloody stools (≥6 per day) with severe cramps and evidence of systemic toxicity; **AND** • Must have documented prior use of corticosteroids for treatment of Ulcerative Collitis; **AND** • Must have documented therapeutic failure with infliximab **Continuation Criteria:** • Documentation confirming diagnosis; **AND** • Must have a positive clinical response to Entyvio as indicated by one of the following; decrease in bowel movements per day, no blood in stool, decrease in oral corticosteroid use, or decrease in inflammatory markers such as fecal calprotectin, C-reactive protein. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Epoprostenol Sodium Flolan Veletri	J1325	**Approved Diagnosis:** • Pulmonary arterial hypertension **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of pulmonary arterial hypertension to improve exercise capacity and delay clinical worsening • Patient must have a World Health Organization group 1 classification of pulmonary arterial hypertension **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Evenity (romosozumab-aqqg)	J3111	**Approved Diagnosis:** • Postmenopausal osteoporosis **Approval Timeframe:** • Initial authorization: 1 year (12 total doses) • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of postmenopausal osteoporosis • Documentation of a T-score less than or equal to -3 • Documentation of previous low-impact fracture • Must have a documented therapeutic failure** with an oral bisphosphonate (or documented intolerance or contraindication) despite a minimum, compliant 2-year trial • Must have a documented therapeutic failure** (or documented intolerance or contraindication) with zoledronic acid (generic Reclast) after a minimum 12-month trial **Additional Information:** • **Therapeutic failure is defined by: ○ new fracture while on treatment, *or* ○ reduction in bone mineral density (BMD) per recent DEXA scan. ○ If member has a new fracture while on a bisphosphonate, only a trial of one bisphosphonate (oral or IV) is required • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Evkeeza (evinacumab-dgnb)	J1305	**Approved Diagnosis:** • Homozygous Familial Hypercholesterolemia (HoFH) **Approval Timeframe:** • Initial authorization: 12 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation must be submitted confirming diagnosis of Homozygous Familial Hypercholesterolemia (HoFH), by one or more of the following: ○ Presence of two mutant alleles at the LDL receptor, Apolipoprotein B, or PCSK9 gene; *or* ○ An untreated LDL-C greater than 500 mg/dL (13 mmol/L) before treatment or greater than 300 mg/dL (7.76 mmol/L) despite treatment, and either have cutaneous or tendinous xanthoma before age 10 years or untreated LDL-C levels consistent with heterozygous familiar hypercholesterolemia in both parents (greater than 190 mg/dL) • Documentation of compliant use with at least one high-intensity statin (rosuvastatin at least 20 mg daily or atorvastatin at least 40 mg daily) in combination with ezetimibe AND a PCSK9 inhibitor (e.g. Repatha/evolocumab) for at least 8 consecutive weeks with failure to achieve LDL-C goal. ○ Patient must continue to receive maximally tolerated statin therapy or have a contraindication to or intolerance of statin therapy ○ If one high-intensity statin is not tolerated, a trial of a second statin is required • Requires documentation of failure to reach LDL-C goal using LDL apheresis • Not covered in combination with Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe), Juxtapid (lomitapide), or a PCSK9 inhibitor (Repatha, Praluent). **Continuation Criteria:** • Documentation must be submitting showing improved and maintained an improved LDL compared to baseline. • Not covered in combination with Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe), Juxtapid (lomitapide), or a PCSK9 inhibitor (Repatha, Praluent). • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

		Additional Information: • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Eylea **Eylea HD** (aflibercept)	J0178 J0177	**Approved Diagnosis:** • Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy • Retinopathy of Prematurity (ROP) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Patients currently receiving treatment with Eylea and who have demonstrated an adequate response are not required to try Avastin. Neovascular (wet) age-related macular degeneration (AMD): • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid ○ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. Macular edema following retinal vein occlusion (RVO) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic macular edema (DME) with baseline visual acuity 20/50 or worse • Documentation of baseline best-corrected visual acuity (BCVA) score must be included with request Diabetic macular edema (DME) with baseline visual acuity better than 20/50 • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic retinopathy • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Retinopathy of Prematurity (ROP)

		• Diagnosis of Retinopathy of Prematurity (ROP) **Continuation Criteria:** • Documentation confirming diagnosis • Documentation showing the disease response as indicated by: ○ stabilization of visual acuity, or ○ improvement in BCVA score when compared to baseline.
Fabrazyme (agalsidase beta)	J0180	**Approved Diagnosis:** • Fabry disease **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** • Must be prescribed by a nephrologist, cardiologist, specialist in metabolic disorders or genetics **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of patient's current weight • Documentation confirming diagnosis of Fabry disease ○ (e.g. alpha-Gal A activity in leukocytes or plasma, mutation analysis of the alpha-Gal A gene) • The patient is either a: ○ Classically affected person assigned male at birth (i.e. a person assigned male at birth with very low or undetectable levels of alpha-galactosidase A [alphaGal A]), **OR** ○ A person assigned female at birth who is a carrier, or a person assigned male at birth with atypical presentations (i.e. with marginal levels of alpha-Gal A) with clinical manifestations of Fabry disease (e.g. renal, neurologic, cardiovascular) present **Continuation Criteria:** • Continuation criteria only applies if the member is unable to safely receive the medication by home infusion • Documentation confirming diagnosis • Documentation of patient's current weight • Documentation showing a continued response to treatment (e.g. reduction in plasma glycosphingolipid GL-3 levels compared to baseline) • Patient has remained compliant with >50 percent of treatments • Patient regularly attends follow-up visits • Patient has not developed ESRD, without an option for renal transplantation, in combination with advanced heart failure (New York Heart Association class IV) • Patient does not have end-stage Fabry disease or other comorbidities with a life expectancy of <1 year • Patient has not experienced severe cognitive decline **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home

		infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.
Fasenra prefilled syringe (benralizumab)	J0517	**Approved Diagnosis:** • For treatment of moderate to severe asthma with an eosinophilic phenotype • For the treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** • Must be prescribed by, or in consultation (consultation notes must be submitted) with: o a pulmonologist o an allergist o an immunologist o a rheumatologist **Age Limitation:** see below **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** **Moderate to severe asthma with an eosinophilic phenotype** • Patient must be age 6 years or older • Must have an eosinophilic count ≥150 cells/mcL in the past 12 months; **AND** • Patient must have been compliant on all the following therapies for at least 3 months: o High-dose inhaled corticosteroid (ICS) o Long-acting beta agonist (LABA) o One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva); **AND** • Patient must have had ≥ 2 asthma exacerbations in the previous year that required at least one of the following: o Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days o Hospitalization and/or ED visit; **AND** • Must not currently use tobacco products; **AND** • Must not use in combination with other biologics (e.g., Nucala, Dupixent, Cinqair, or Xolair) **Eosinophilic Granulomatosis with Polyangiitis (EGPA)** • Patient must be age 18 years or older; **AND** • Have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) **Continuation Criteria:** • Must have been compliant on therapy with Fasenra, **AND** • Must not currently use tobacco products; **AND** • Must not use in combination with other biologics (e.g., Nucala, Dupixent, Cinqair, Xolair, or Tezspire); **AND**

		• Documentation showing patient has had a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use) **Additional Information** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy • Fasenra will not be approved if used in combination with other biologics (ex. Dupixent, Cinqair, Xolair, Tezspire, Nucala) • Fasenra Syringes will only be approved under the medical benefit. Please reference the patient's pharmacy benefits for coverage of Fasenra Pen Autoinjector • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Gamifant (emapalumab-lzsg)	J9210	**Approved Diagnosis:** • Primary hemophagocytic lymphohistiocytosis (HLH) **Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 3 months **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis must be submitted; **AND** • Patient must have previously tried and experienced clinical failure with conventional therapy (e.g. etoposide, dexamethasone, cyclosporine) **Continuation Criteria:** • Documentation confirming diagnosis must be submitted; **AND** • Patient must have previously tried and experienced clinical failure with conventional therapy (e.g. etoposide, dexamethasone, cyclosporine); **AND** • Documentation showing objective evidence of response to therapy (i.e. normalization of HLH abnormalities) must be submitted; **AND** • Request must include an update and/or plan for hematopoietic stem cell transplant (HSCT) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Givlaari (givosiran)	J0223	**Approved Diagnosis:** • Acute hepatic porphyria, including: ○ Acute intermittent porphyria (AIP) ○ Hereditary coproporphyria (HCP) ○ Variegate porphyria (VP) ○ ALA dehydratase deficient porphyria. **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: up to 6 months **Prescriber Specialty Requirement:** none **Age Limitation:** Must be age 18 years or older

		Dose & Frequency: Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis must be submitted; **AND** • Patient must have active disease, defined as 2 documented porphyria attacks within the past 6 months (including hospitalization, urgent care visits or, IV hemin administration at home). **Continuation Criteria:** • Documentation confirming stabilization of the disease or absence of disease progression (reduction in attacks from baseline) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Ilaris (canakinumab)	J0638	**Approved Diagnosis:** • Cryopyrin-Associated Periodic Syndromes (CAPS) ○ Familial Cold Autoinflammatory Syndrome (FCAS) ○ Muckle-Wells Syndrome (MWS) • Periodic Fever Syndromes ○ Familial Mediterranean Fever (FMF) ○ Hyper ImmunoglobulinD Syndrome (HIDS) ○ Mevalonate Kinase Deficiency (MKD) ○ Tumor Recrosis Receptor-Associated Periodic Syndrome (TRAPS) • Systemic Juvenile Idiopathic Arthritis (SJIA) • Adult-Onset Still's Disease (AOSD) i • Gout Flares **Approval Timeframe:** • Initial authorization: ○ CAPS, FCAS, MWS, FMF, HIDS, MKD, TRAPS, SJIA, AOSD = 1 year ○ Gout = single dose for 12 weeks • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** See below **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis Cryopyrin-Associated Periodic Syndromes (CAPS) • Patient must be 4 years or older Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD) • Patient must be 2 years or older Gout Flares • Has had three or more flares in the last 12 months; **AND** • Patient has tried lifestyle modifications such as reduced alcohol consumption, discontinuing or changing other medications known to precipitate gout attacks when possible; **AND** • Patient has tried and failed or has had an intolerance/contraindication with an adequate course of conventional therapy including colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), AND systemic corticosteroids. **Continuation Criteria:** • Continuation criteria only applies if member is unable to safely receive the medication by home infusion

		• For gout flares requiring treatment beyond the initial dose, patient must be established on maintenance therapy with urate-lowering agents such as allopurinol, febuxostat, and/or probenecid • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.
Ilumya (tildrakizumab)	J3245	**Approved Diagnosis:** • Plaque Psoriasis **Approval Timeframe:** • Initial authorization: 12 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Prescriber is a specialist or has consulted with a specialist for the disease being treated **Age Limitation:** age 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial, and subsequent therapeutic failure, with infliximab or Enbrel® **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. • Ilumya will not be covered in combination with another biologic drug.

Imaavy (nipocalimab-aahu)	J3590 C9399	**Approved Diagnosis:** • Generalized myasthenia gravis (gMG) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Prescribed by, or in consultation with, a neurologist **Age Limitation:** Patient must be 12 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation must be submitted confirming diagnosis; **AND** • Documentation showing patient has either anti-acetylcholine receptor antibody (AChR-Ab) positive **OR** anti-muscle-specific tyrosine kinase (MuSK) antibody positive disease; **AND** • Patient must have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV; **AND** • Patient must have a Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 6; **AND** • Documentation must be submitted showing baseline quantitative myasthenia gravis (QMG) total score; **AND** • Documentation of 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** • Documentation showing patient has required 2 or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control **Continuation Criteria:** • Documentation must be submitted showing 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) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Immune Globulin		**Approved Diagnosis:** • Hypogammaglobulinemia, unspecified • Selective IgM immunodeficiency

Primary Immunodeficiency Cutaquig Cuvitru Flebogamma Gammagard liquid Gammaplex Gamunex Hizentra HyQvia Octagam Privigen Xembify	 J1551 J1555 J1572 J1569 J1557 J1561 J1559 J1575 J1568 J1459 J1558	• Other selective immunoglobulin deficiencies • X-linked agammaglobulinemia • X-linked immunodeficiency with hyper IGM • Combined immunodeficiency (SCID) • Common variable hypoglobulinemia • Wiskott-Aldrich Syndrome **Approval Timeframe:** • Initial authorization: to be determined by clinical reviewer, up to 1 year • Continuation authorization: to be determined by clinical reviewer, up to 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis. Dose approved will be based on adjusted body weight if • BMI is 30 kg/m2; *or* • if actual body weight is 20% higher than his or her ideal body weight (IBW) **Initial Criteria:** • Documentation confirming diagnosis. Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings; **AND** • Documentation of the patient's current weight; **AND** • Must provide documentation of previous treatment failures; **AND** • Patient's IgG level is less than 200 mg/dL; **OR** • Patient has a history of multiple hard to treat infections. Multiple hard to treat infections means: ○ four or more ear infections within 1 year; ○ two or more serious sinus infections within 1 year; ○ two or more months of antibiotics with little effect; ○ two or more pneumonias within 1 year; ○ recurrent or deep skin abscesses; ○ need for intravenous antibiotics to clear infections; or ○ two or more deep-seated infection including septicemia; **AND** • The patient has a deficiency in producing antibodies in response to vaccination; **AND** • Baseline titers were drawn before challenging with vaccination; **AND** • Titers were draw between 4 and 8 weeks of vaccination (less than 70% of antigens are in protective range) **Continuation Criteria:** • Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug class is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires all intravenous immune globulin products to be infused in an outpatient hospital infusion center (this requirement does not apply to subcutaneous immune globulin). • In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect. *Continued >*

		• Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage. • Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary. • If improvement does not occur with IVIG, continued infusion may not be considered medically necessary. • The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the 'Approved Diagnosis' section of the prior authorization criteria.
Immune Globulin Secondary Immunodeficiency Cutaquig Cuvitru Flebogamma Gammagard liquid Gammaplex Gamunex Hizentra HyQvia Octagam Privigen Xembify	 J1551 J1555 J1572 J1569 J1557 J1561 J1559 J1575 J1568 J1459 J1558	**Approved Diagnosis:** For secondary immunodeficiency, immune globulin is covered when the patient's hypogammaglobulinemia is caused by; • solid organ transplant • extensive surgery • allograft rejection • hematological malignancy • extensive burns • collagen-vascular disease • chronic lymphoid leukemia (CLL) **Approval Timeframe:** • Initial authorization: to be determined by clinical reviewer, up to 1 year • Continuation authorization: to be determined by clinical reviewer, up to 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis. Dose approved will be based on adjusted body weight if • BMI is 30 kg/m2; *or* • if actual body weight is 20% higher than his or her ideal body weight (IBW) **Initial Criteria:** • Documentation confirming diagnosis. Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings; **AND** • Documentation of the patient's current weight; **AND** • Must provide documentation of previous treatment failures; Chronic Lymphoid Leukemia (CLL) • Patient has a history of multiple hard to treat infections. Multiple hard to treat infections means: ○ four or more ear infections within 1 year; ○ two or more serious sinus infections within 1 year; ○ two or more months of antibiotics with little effect; ○ two or more pneumonias within 1 year; ○ recurrent or deep skin abscesses; ○ need for intravenous antibiotics to clear infections; or ○ two or more deep-seated infection including septicemia; AND • The patient has a deficiency in producing antibodies in response to vaccination; AND • Baseline titers were drawn before challenging with vaccination; AND • Titers were draw between 4 and 8 weeks of vaccination (less than 70% of antigens are in protective range) *Continued >* **Continuation Criteria:**

		• Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug class is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires all intravenous immune globulin products to be infused in an outpatient hospital infusion center (this requirement does not apply to subcutaneous immune globulin). • In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect. • Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage. • Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary. • If improvement does not occur with IVIG, continued infusion may not be considered medically necessary. • The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the 'Approved Diagnosis' section of the prior authorization criteria.
Immune Globulin Hematologic Conditions Cutaquig Cuvitru Flebogamma Gammagard liquid Gammaplex Gamunex Hizentra HyQvia Octagam Privigen Xembify	 J1551 J1555 J1572 J1569 J1557 J1561 J1559 J1575 J1568 J1459 J1558	**Approved Diagnosis:** • primary thrombocytopenia • ITP in pregnancy and fetal alloimmune thrombocytopenia • Neonatal alloimmune thrombocytopenia • post-transfusion purpura • autoimmune hemolytic anemia • immune-mediated neutropenia • anemia due to pure red cell aplasia secondary to chronic parvovirus B19 infection • anemia due to pure red cell aplasia, immunologic subtype • allogeneic bone marrow or stem cell transplant • complications of transplanted solid organ (e.g. heart, kidney, liver, lung, pancreas) or bone marrow transplant • human immunodeficiency virus infection (HIV) **Approval Timeframe:** • Initial authorization: to be determined by clinical reviewer, up to 1 year • Continuation authorization: to be determined by clinical reviewer, up to 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis. Dose approved will be based on adjusted body weight if • BMI is 30 kg/m2; *or* • if actual body weight is 20% higher than his or her ideal body weight (IBW) *Continued >* **Initial Criteria:**

		• Documentation confirming diagnosis. Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings; **AND** • Documentation of the patient's current weight; **AND** • Must provide documentation of previous treatment failures; **AND** <u>Primary Thrombocytopenia</u> • For treatment of acute ITP, a rapid rise in platelet count must be medically necessary. Medically necessary means: o Immune globulin is used before surgery and the platelet count is less than 100,000/mm3; **OR** o Patient has acute bleeding and platelet count is less than 30,000/mm3; **OR** o Patient is at risk for intracerebral hemorrhage (i.e. platelet is less than 20,000/mm3 • For treatment of chronic ITP, the patient: o Must be age 10 or older; **AND** o Must have a platelet count less than 30,000/mm for children or less than 20,000/mm3 for adults; **AND** o Has illness present for more than six months; **AND** o Failed, has a contraindication to, or is intolerant to corticosteroid therapy <u>ITP in pregnancy and fetal alloimmune thrombocytopenia</u> • The patient is refractory to steroids with a platelet count less than 10,000/mm3 during her third trimester; OR • the platelet count is less than 30,000/mm3 and associated with bleeding prior to vaginal delivery or C-section; OR • The patient previously delivered infants with autoimmune thrombocytopenia; OR • At 20 weeks gestation or later, cordocentesis reveals fetal platelets less than 20,000/ mm3; OR • Screening reveals platelet alloantibodies <u>Neonatal alloimmune thrombocytopenia</u> (immune globulin is not covered for routine use) • The patient is severely thrombocytopenic (i.e. a platelet count less than 30,000/mm3) and/or symptomatic; **AND** • The neonate failed, has a contraindication to, or is intolerant to platelet transfusion <u>Post-transfusion purpura</u> • platelet count is less than 10,000/mm3; **OR** • the patient experienced bleeding complications due to thrombocytopenia <u>Autoimmune hemolytic anemia</u> (immune globulin is not covered for routine use) • the patient has warm-type AIHA; **AND** • the patient has failed, has a contraindication to, or intolerance to corticosteroid therapy; **AND** • the patient had a splenectomy or is the patient at high risk for post-splenectomy sepsis <u>Immune-mediated neutropenia</u> (immune globulin not covered for routine use) • The patient has a serious clinical infection related to neutropenia; **AND** • The patient failed to respond to both (1) corticosteroids and (2) filgrastim or pegfilgrastim therapies <u>Anemia due to pure red cell aplasia secondary to chronic parvovirus B19 infection</u> • The patient has severe, refractory anemia;**AND** • The patient has documented erythrovirus B19 viremia; **AND** • The patient was evaluated for underlying conditions that could lead to aplasia <u>Anemia due to pure red cell aplasia, immunologic subtype</u> • The patient failed, has a contraindication to, or is intolerant to corticosteroid therapy; **AND** • The patient has failed, has a contraindication to, or is intolerant to cyclosporine; **AND** • The patient has failed, has a contraindication to, or is intolerant to cyclophosphamide <u>Allogeneic bone marrow or stem cell transplant</u> • Immune globulin is used for prevention of acute graft-versus-host disease or infection (e.g. cytomegalovirus); **AND** • The transplant was between 0 to 99 days before starting immune globulin

		• Immune globulin is approved for allogeneic bone marrow or stem cell transplant for 3 months. <u>Complications of transplanted solid organ (e.g. heart, kidney, liver, lung, pancreas) or bone marrow transplant</u> • Immune globulin is being used to: ○ suppress panel reactive anti-HLA antibodies prior to transplantation; **OR** ○ treat antibody mediated rejection of solid organ transplantation; **OR** ○ prevent cytomegalovirus-induced pneumonitis <u>Human immunodeficiency virus infection (HIV)</u> • immune globulin is covered for patients with HIV to reduce significant bacterial infections in patients age 13 or younger who also have evidence of a humoral immunologic defect* with presence of bacterial infections. • Humoral immunologic defect means: ○ recurrent serious bacterial infections despite appropriate prophylactic antibiotic therapy; or ○ demonstrated antibody deficiency to common antigens (i.e. measles, pneumococcal, and/or H. flue type B vaccine) as demonstrated by poor antibody titers; or ○ bronchiectasis suboptimally responsive to antimicrobial and pulmonary therapy; or ○ HIV-associated thrombocytopenia despite antiretroviral therapy **<u>Continuation Criteria:</u>** • Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. <u>Primary Thrombocytopenia</u> • For renewals, achievement and maintenance of a platelet count equal to or greater than 50 x 10^9/L. <u>Allogeneic bone marrow or stem cell transplant</u> • the patient's IgG is less than or equal to 400 mg/dL; **AND** • treatment duration does not exceed 360 days measured from the date of the transplant **<u>Additional Information:</u>** • This drug class is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires all intravenous immune globulin products to be infused in an outpatient hospital infusion center (this requirement does not apply to subcutaneous immune globulin). • In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect. • Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage. • Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary. • If improvement does not occur with IVIG, continued infusion may not be considered medically necessary. • The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the 'Approved Diagnosis' section of the prior authorization criteria.

Immune Globulin Neurological Conditions Cutaquig Cuvitru Flebogamma Gammagard liquid Gammaplex Gamunex Hizentra HyQvia Octagam Privigen Xembify	 J1551 J1555 J1572 J1569 J1557 J1561 J1559 J1575 J1568 J1459 J1558	**Approved Diagnosis:** • Guillain-Barré syndrome • Myasthenia gravis • Eaton-Lambert syndrome • Polyneuropathy (chronic inflammatory demyelinating) • Multifocal motor neuropathy • Stiff-man syndrome **Approval Timeframe:** • Initial authorization: to be determined by clinical reviewer, up to 1 year • Continuation authorization: to be determined by clinical reviewer, up to 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis. Dose approved will be based on adjusted body weight if • BMI is 30 kg/m2; *or* • if actual body weight is 20% higher than his or her ideal body weight (IBW) **Initial Criteria:** • Documentation confirming diagnosis. Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings; **AND** • Documentation of the patient's current weight; **AND** • Must provide documentation of previous treatment failures; **AND** Guillain-Barre syndrome • The patient has severe disease and is requiring aid to stand and/or walk; **AND** • Immune globulin is started within 4 weeks of symptom onset • A maximum of two doses are covered for this diagnosis (1 initial dose & 1 continuation dose) Myasthenia gravis (MG) • Immune globulin is not covered for routine use. Coverage is limited to patients with severe MG to treat acute, severe decompensation; defined as; ○ having myasthenic crisis (i.e. impending respiratory or bulbar compromise); *and* ○ is experiencing disease exacerbation and/or decompensation, such as difficulty swallowing, acute respiratory failure, major functional disability responsible for the discontinuation of physical activity • other treatments have been unsuccessful or are contraindicated; **AND** • given concomitantly with either glucocorticoids or other immunosuppressive therapy (e.g. azathioprine, cyclosporine) When immune globulin is used to bridge immunosuppressive therapies, immune globulin is only covered until the immunosuppressive therapy takes effect, and the patient is: • unable to use or tolerate glucocorticoid therapy; **AND** • being started on immunosuppressive therapies, such as azathioprine, mycophenolate, or cyclosporine Eaton-Lambert syndrome • The patient has failed, has a contraindication to, or has an intolerance to cholinesterase inhibitors used in combination with guanidine or an aminopyridine; **AND** • The patient has failed, has a contraindication to, or has an intolerance to corticosteroid therapy and immunosuppressive therapy (e.g. azathioprine, cyclosporine) *Continued >*

		Polyneuropathy (chronic inflammatory demyelinating) • 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 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; b. distal CMAP duration increase in one or more nerves plus one other demyelination criterion listed in (a) or (c)-(g) in one or more other nerves; c. abnormal temporal dispersion conduction must be present in two or more motor nerves; d. reduced conduction velocity in two or more motor nerves; e. prolonged distal motor latency in two or more motor nerves; f. absent F wave in two or more motor nerves plus one other demyelination criterion listed in (a)-(e) or (g) in one or more other nerves; or prolonged F wave latency in two or more motor nerves Multifocal motor neuropathy • The patient has progressive, symptomatic multifocal motor neuropathy (characterized limb weakness or motor involvement having a motor nerve distribution in at least two nerves); **AND** • Electrophysiological findings rule out other possible conditions that may not respond to immune globulin; **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) Stiff-man syndrome • Patient must have severe active illness, defined as; patient is positive for anti-glutamic acid decarboxylase (GAD) antibody • A baseline physical examination is documented in the medical record • Other treatment interventions have been unsuccessful or intolerable, meaning the patient failed, has a contraindication, or intolerance to: ○ two or more benzodiazepine therapies; and ○ baclofen; and ○ corticosteroid therapy *Continued >*

		Continuation Criteria: • Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. Guillain-Barre syndrome • A maximum of two doses are covered for this diagnosis (1 initial dose & 1 continuation dose); **AND** • The second dose is covered when the patient has an inadequate response to the first dose of immune globulin and will be given within 3 weeks of the first dose. **Additional Information:** • This drug class is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires all intravenous immune globulin products to be infused in an outpatient hospital infusion center (this requirement does not apply to subcutaneous immune globulin). • In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect. • Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage. • Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary. • If improvement does not occur with IVIG, continued infusion may not be considered medically necessary. • The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the 'Approved Diagnosis' section of the prior authorization criteria.

Immune Globulin Autoimmune Disorders Cutaquig Cuvitru Flebogamma Gammagard liquid Gammaplex Gamunex Hizentra HyQvia Octagam Privigen Xembify	 J1551 J1555 J1572 J1569 J1557 J1561 J1559 J1575 J1568 J1459 J1558	**Approved Diagnosis:** • Dermatomyositis • Polymyositis • Systemic sclerosis dermatomyositis overlap syndrome • Kawasaki disease • severe vasculitic syndrome **Approval Timeframe:** • Initial authorization: to be determined by clinical reviewer, up to 1 year • Continuation authorization: to be determined by clinical reviewer, up to 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis. Dose approved will be based on adjusted body weight if • BMI is 30 kg/m2; *or* • if actual body weight is 20% higher than his or her ideal body weight (IBW) **Initial Criteria:** • Documentation confirming diagnosis. Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings; **AND** • Documentation of the patient's current weight; **AND** • Must provide documentation of previous treatment failures; **AND** Dermatomyositis and Polymyositis • A baseline physical examination is documented in the medical record • The condition is confirmed by biopsy; **AND** • The patient has severe active disease state; **AND** • The patient has muscle weakness in all upper and/or lower limbs; **AND** • The patient failed, has a contraindication to, or intolerance to corticosteroid therapy; **AND** • The patient failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine Systemic sclerosis dermatomyositis overlap syndrome • The patient failed, has a contraindication to, or intolerance to corticosteroid therapy; **AND** • The patient failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine, methotrexate, cyclophosphamide, and cyclosporine; **AND** • The prescriber must indicate in advance what objective clinical endpoints will be used to determine efficacy of immune globulin therapy (Priority Health will use this criteria to evaluate ongoing effectiveness of treatment. Kawasaki disease • Fever is present in patient for at least 5 days; **AND** • Treatment is initiated within 10 days of onset of fever; **AND** • Concomitant aspirin treatment be given with immune globulin Severe vasculitic syndrome • Provider must specify which syndrome the patient has: ○ systemic (polyarteritis nodosa) ○ Churg-Strauss Vasculitis ○ livedoid vasculitis (atrophie blanche) **Continuation Criteria:** • Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. *Continued >*

		Dermatomyositis and Polymyositis • A baseline physical examination is documented in the medical record. Requests for continuation of therapy must show documented improvement over baseline per physical exam and improvement in CPK. **Additional Information:** • This drug class is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires all intravenous immune globulin products to be infused in an outpatient hospital infusion center (this requirement does not apply to subcutaneous immune globulin). • In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect. • Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage. • Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary. • If improvement does not occur with IVIG, continued infusion may not be considered medically necessary. • The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the 'Approved Diagnosis' section of the prior authorization criteria.
Immune Globulin Dermatologic Conditions Cutaquig Cuvitru Flebogamma Gammagard liquid Gammaplex Gamunex Hizentra HyQvia Octagam Privigen Xembify	 J1551 J1555 J1572 J1569 J1557 J1561 J1559 J1575 J1568 J1459 J1558	**Approved Diagnosis:** • Toxic epiderma necrolysis • Stevens-Johnson Syndrome, with or without toxic epidermal necrolysis overlap syndrome • Pyoderma gangrenosum, but only when the patient: ○ failed, has a contraindication to, or intolerance to corticosteroid therapy ○ failed, has a contraindication to, or intolerance to cyclosporine ○ first tried two of the following other treatments: ▪ conventional immunosuppressive medications (in addition to cyclosporine) ▪ Dapsone ▪ minocycline ▪ TNF-alpha inhibitors • Autoimmune mucocutaneous blistering disease • Mucous membrane pemphigold without ocular involvement • Mucous membrane pemphigold with ocular involvement • Epidermolysis bullosa • linear IgA dermatosis **Approval Timeframe:** • Initial authorization: to be determined by clinical reviewer, up to 1 year • Continuation authorization: to be determined by clinical reviewer, up to 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis. Dose approved will be based on adjusted body weight if • BMI is 30 kg/m2; *or* • if actual body weight is 20% higher than his or her ideal body weight (IBW) *Continued >*

		Initial Criteria: • Documentation confirming diagnosis. Diagnosis of the disorder must be reasonably certain, and based on a thorough history and examination, and appropriate laboratory testing (e.g. electromyography (EMG), spinal fluid tests, serum tests and biopsy findings; **AND** • Documentation of the patient's current weight; **AND** • Must provide documentation of previous treatment failures; **AND** • A baseline physical examination is documented in the medical record (requests for continuation of therapy must show documented improvement over baseline per physical exam); **AND** • The patient's condition: ○ is rapidly progressing, extensive, or debilitating; *and* ○ has been confirmed by a biopsy; **AND** • The patient failed, has a contraindication to, or intolerance to corticosteroid therapy; **AND** • The patient failed, has a contraindication to, or intolerance to immunosuppressive therapies, such as azathioprine **Continuation Criteria:** • Each continuation request for immune globulin previously approved by Priority Health must include clinical progress notes providing the patient's response to immune globulin therapy. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug class is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires all intravenous immune globulin products to be infused in an outpatient hospital infusion center (this requirement does not apply to subcutaneous immune globulin). • In some situations, IVIG may be used for medically necessary indications listed on this prior authorization form for a person that has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, give IVIG therapy along with conventional treatment(s), but continued administration of IVIG is not medically necessary when conventional therapy takes effect. • Any metric assessment used for objective monitoring of progress is accepted, such as the Medical Research Council (MRC) scale (most commonly used for muscle strength), INCAT Disability scale, and activities of daily living (ADL) measurements. Changes in these measures must be clearly documented. Subjective or experiential improvement alone is generally insufficient to continue IVIG or to expect coverage. • Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory Clinical monitoring takes clear precedence over laboratory monitoring. If clinical improvement is evident, then laboratory monitoring solely to guide IVIG therapy is not medically necessary. • If improvement does not occur with IVIG, continued infusion may not be considered medically necessary • The use of intravenous immunoglobulin therapy is considered medically necessary by Priority Health for the conditions specified in the 'Approved Diagnosis' section of the prior authorization criteria

Kanuma (sebelipase alfa)	J2840	**Approved Diagnosis:** • lysosomal acid lipase (LAL) deficiency **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of diagnosis of Wolman disease or Cholesteryl ester storage disease (CESD) (later-onset disease) • Diagnosis must be confirmed by genetic testing with evidence of LIPA mutation (genetic testing results must be submitted) **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Kimyrsa (oritavancin)	J2406	**Approved Diagnosis:** • Acute bacterial skin and skin structure infection (ABSSSI) **Approval Timeframe:** • Initial authorization: 1 month • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of culture and sensitivity results must be sent to Priority Health showing the patient's infection is not susceptible to alternative antibiotic treatments • Must have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives.

Korsuva (difelikefalin acetate)	J0879	**Approved Diagnosis:** • moderate to severe, treatment-resistant pruritis in patients with chronic kidney disease (CKD) **Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of moderate to severe, treatment-resistant pruritis in patients with chronic kidney disease (CKD) on hemodialysis at least 3 days per week; **AND** • Documentation showing any existing hyperparathyroidism, hyperphosphatemia, and/or hypermagnesemia has been treated to optimal target values; **AND** • Must first have a therapeutic trial and failure of at least 4 weeks with **THREE** of the following therapies: ○ topical analgesic (e.g. capsaicin, pramoxine) ○ oral antihistamine (e.g. hydroxyzine, diphenhydramine) ○ gabapentin or pregabalin ○ montelukast ○ Phototherapy (UVA or UVB) **Continuation Criteria:** • Documentation confirming diagnosis of moderate to severe, treatment-resistant pruritis in patients with chronic kidney disease (CKD) on hemodialysis at least 3 days per week; **AND** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Krystexxa (pegloticase)	J2507	**Approved Diagnosis:** • treatment-failure gout (TFG) **Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of chronic, treatment-failure gout (TFG) • Patient must have three or more flares in the last 12 months • Patient must first try allopurinol using a daily dose of 900 mg for 6 months (or probenecid or febuxostat if allopurinol is contraindicated) and be unable to maintain a serum uric acid level less than or equal to 6 mg/dL • Patient must have gout tophus or gouty arthritis • Patient has tried lifestyle modifications such as reduced alcohol consumption, discontinuing or changing other medications known to precipitate gout attacks when possible); **AND** • Patient must **not** have: ○ unstable angina ○ uncontrolled arrhythmia ○ non-compensated heart failure ○ uncontrolled blood pressure (a blood pressure higher than 150/95 mmHg) ○ received an organ transplant ○ glucose-6-phosphate dehydrogenase deficiency ○ a need to receive dialysis **Continuation Criteria:** • After 3 months of Krystexxa therapy, the patient's serum uric acid level must remain at or below 6mg/dL • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Leqvio (inclisiran)	J1306	**Approved Diagnosis:** • Heterozygous familial hypercholesterolemia (HeFH) • Very high risk clinical atherosclerotic cardiovascular disease (ASCVD) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: **Prescriber Specialty Requirement:** Must be prescribed by a cardiologist, endocrinologist, or board-certified lipidologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming 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** • Patient's most recent LDL-C laboratory report must be submitted with authorization request • Must try and fail two formulary PCSK9 inhibitors (Repatha AND Praluent) • 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 • Patient must continue to receive maximally tolerated statin therapy or have a contraindication to, or intolerance of, statin therapy • Patient must not be using in combination with a PCSK9 inhibitor, Nexletol (bempedoic acid), or Nexlizet (bempedoic acid/ezetimibe) **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered in an outpatient hospital infusion center.

Lucentis (ranibizumab)	J2778	**Approved Diagnosis:** • Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Myopic Choroidal Neovascularization (mCNV) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Patients currently receiving treatment with Lucentis and who have demonstrated an adequate response are not required to try Avastin. Neovascular (wet) age-related macular degeneration (AMD): • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid ○ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. Macular edema following retinal vein occlusion (RVO) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic macular edema (DME) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic retinopathy (DR) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Myopic Choroidal Neovascularization (mCNV) • Lucentis for mCNV may be authorized for a maximum of 1 injection per month up to a maximum of 3 months **Continuation Criteria:** • Documentation confirming diagnosis • Documentation showing the disease response as indicated by ○ stabilization of visual acuity, or ○ improvement in BCVA score when compared to baseline. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Lumizyme (alglucosidase alfa)	J0221	**Approved Diagnosis:** • Pompe disease **Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders. **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency) that is supported by enzyme assay or DNA testing (documentation must be submitted) • Documentation of patient's current weight • Documented baseline values for one or more of the following: ○ **Infantile-onset disease:** muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6-minute walk test (6MWT); OR ○ **Late-onset (non-infantile) disease:** FVC and/or 6 MWT **Continuation Criteria:** Continuation criteria only applies if the member is not able to safely receive the medication by home infusion, • Documentation that patient cannot safely receive the medication by home infusion; **AND** • Documentation confirming diagnosis of Pompe disease (acid alpha-glucosidase [GAA] deficiency) that is supported by enzyme assay or DNA testing (documentation must be submitted); **AND** • Documentation of patient's current weight; **AND** • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: (Baseline and current values must be submitted) ○ **Infantile-onset disease:** muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6-minute walk test (6MWT); **OR** ○ **Late-onset (non-infantile) disease:** FVC and/or 6 MWT; **AND** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established. • For adult patients, doses should be rounded down to the nearest vial size within 10% of the calculated dose • Lumizyme will not be covered in combination with Nexviazyme®

Naglazyme (galsulfase)	J1458	**Approved Diagnosis:** • Maroteaux-Lamy syndrome **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Maroteaux-Lamy syndrome, **AND** • Documentation of the patient's current weight **Continuation Criteria:** Continuation criteria only applies if the member is not able to safely receive the medication by home infusion; • Documentation that patient cannot safely receive the medication by home infusion; **AND** • Documentation confirming diagnosis; **AND** • Documentation of patient's current weight; **AND** • Documentation showing the patient has demonstrated a beneficial response to therapy by at least one of the following: ○ Disease stabilization ○ Improvement in 12-minute walk test **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Nexviazyme (avalglucosidase alfa-ngpt)	J0219	**Approved Diagnosis:** • late-onset Pompe disease **Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders. **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of late-onset Pompe disease (acid alpha-glucosidase[GAA] deficiency) that is supported by enzyme assay or DNA testing (documentation must be submitted) • Documentation of patient's current weight • Documented baseline values for FVC and/or 6 MWT **Continuation Criteria:** Continuation criteria only applies if the member is not able to safely receive the medication by home infusion; • Documentation that the patient cannot safely receive the medication by home infusion • Documentation confirming diagnosis of late-onset Pompe disease (acid alpha-glucosidase[GAA] deficiency) that is supported by enzyme assay or DNA testing (documentation must be submitted) • Patient has demonstrated a beneficial response to therapy compared to pretreatment baselinein FVC and/or 6 MWT (Baseline and current values must be submitted) • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established. • For adult patients, doses should be rounded down to the nearest vial size within 10% of the calculated dose. • Nexviazyme® will not be covered in combination with Lumizyme®

Nplate (romiplostim)	J2802	**Approved Diagnosis:** • chronic immune (idiopathic) thrombocytopenic purpura (ITP) • severe, persistent, or recurrent ITP **Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis; **AND** • Documentation of the patient's current weight Chronic immune (idiopathic) thrombocytopenic purpura (ITP) • platelet count <30,000/microL; **AND** • significant bleeding symptoms severe, persistent or recurrent ITP • platelet count <20,000/microL; **AND** • an insufficient response to corticosteroids, immunoglobulin, or splenectomy, **OR** • patient is not a candidate for splenectomy or immunoglobulin therapy **Continuation Criteria:** • Documentation confirming diagnosis, **AND** • Documentation of patient's current weight, **AND** • Documentation showing the patient has demonstrated a beneficial response to therapy by one of the following: ○ Platelet count has increased to at least 50,000/microL; **OR** ○ If platelet count is less than 50,000/microL, must have documented response to therapy (i.e., reduction in clinically significant bleeding events) **Additional Information:** • Nplate (romiplostim) is not covered in combination with another thrombopoietin receptor agonist [e.g., Promacta (eltrombopag)] **AND** cannot be used in an attempt to normalize platelet counts

Nulibry (fosdenopterin hydrobromide)	C9399 J3490	**Approved Diagnosis:** • Reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** specialist in inborn errors of metabolism **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation must be submitted confirming diagnosis of MoCD Type A by genetic testing • Must be prescribed by a specialist in inborn errors of metabolism **Continuation Criteria:** • Documentation of a positive clinical response to Nulibry (neurological function, gross motor function, developmental milestones, etc.) • Documentation showing patient is tolerating therapy • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Ocrevus (ocrelizumab) **Ocrevus Zunovo** (ocrelizumab and hyaluronidase-ocsq)	J2350 J2351	**Approved Diagnosis:** • Primary Progressive MS • Relapsing-remitting MS **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** Neurologist or specialist in MS **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of: ○ Primary Progressive Multiple Sclerosis (PPMS) ○ Relapsing-Remitting [RRMS] or Secondary Progressive multiple sclerosis **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Ocrevus will not be approved in combination with any other disease modifying therapy for multiple sclerosis

Omvoh (mirikizumab-mrkz)	J2267	**Approved Diagnosis:** • Ulcerative Colitis **Approval Timeframe:** • Initial authorization: 3 months (3 doses) • Continuation authorization: N/A **Prescriber Specialty Requirement:** Prescribed by or in consultation with a gastroenterologist **Age Limitation:** Must be age 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of moderately to severely active ulcerative colitis (UC); **AND** • Must have a documented trial and documented therapeutic failure with Humira; **AND** • Must provide documentation of patient's current weight **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • When used for 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. Refer to the Medicaid Approved Drug List for coverage

Onapgo (apomorphine hydrochloride)	J3490 C9399	**Approved Diagnosis:** • Advanced Parkinson's disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Prescribed by or in consultation with a neurologist **Age Limitation:** 18 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Diagnosis of Parkinson's disease that is levodopa-responsive; **AND** • Patient is receiving optimal carbidopa/levodopa containing therapy (e.g., has tried extended-release tablets and multiple daily dosing); **AND** • Prescriber attests that the patient is experiencing persistent motor fluctuations with a minimum of 3 hours of "off" time per day despite optimized carbidopa/levodopa therapy; **AND** • Therapeutic trial and failure of, or intolerance/contraindication to, adjunctive therapy with a dopamine agonist (e.g. pramipexole, ropinirole) **Continuation Criteria:** • Documentation that the patient has experienced a positive clinical response compared to baseline • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Onpattro (patisiran)	J0222	**Approved Diagnosis:** • Hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy **Approval Timeframe:** • Initial authorization: 12 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis must be submitted; **AND** • Genetic testing confirms a transthyretin (TTR) mutation (e.g., V30M); **AND** • Must have presence of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.); **AND** • Must have documentation of one of the following: ○ Baseline polyneuropathy disability (PND) score ≤ IIIb ○ Baseline FAP Stage 1 or 2; **AND** • Patient is not receiving Onpattro in combination with tafamidis (Vyndaqel, Vyndamax), Wainua, Amvuttra or Attruby; **AND** • Patient has not had a liver transplant **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Documentation that the patient continues to have one of the following: ○ Polyneuropathy disability (PND) score ≤ IIIb, *or* ○ FAP Stage 1 or 2; **AND** • Documentation that the patient has experienced a positive clinical response to Onpattro compared to baseline (e.g., improved neurologic improvement, motor function, quality of life, slowing of disease progression); **AND**

		• Patient is not receiving Onpattro in combination with tafamidis (Vyndaqel, Vyndamax), Wainua, Amvuttra or Attruby; **AND** • Patient has not had a prior liver transplant **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Opfolda (miglustat)	J1202	**Approved Diagnosis:** • late-onset Pompe disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialist, neurologist, cardiologist, pediatrician) **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must have a diagnosis of late-onset Pompe disease (LOPD) that is supported by enzyme assay or DNA testing (supporting documentation must be submitted to Priority Health) • Documentation of the patient's current weight must be submitted • Documentation of baseline percent-predicted forced vital capacity (FVC) and 6-minute walk test (6MWT) must be submitted • Opfolda must be used in combination with Pombiliti • Patient must not require the use of invasive or noninvasive ventilation support for > 6 hours/day while awake **Continuation Criteria:** • Documentation of response to therapy, as evidenced by an improvement, stabilization, or slowing of progression of percent-predicted FVC and/or 6MWT **Additional Information:** • Opfolda is not covered in combination with Lumizyme or Nexviazyme

Orbactiv (oritavancin)	J2407	**Approved Diagnosis:** • Acute bacterial skin and skin structure infection (ABSSSI) **Approval Timeframe:** • Initial authorization: 1 month • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of culture and sensitivity results must be sent to Priority Health showing the patient's infection is not susceptible to alternative antibiotic treatments • Must have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives.
Orencia IV (abatacept)	J0129	**Approved Diagnosis:** • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Psoriatic Arthritis (PsA) • Prophylaxis of acute graft versus host disease (aGVHD) **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** • RA: age 18 years and older • PJIA: age 2 years and older • PsA: age 18 years and older • aGVHD: age 2 years and older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Rheumatoid Arthritis (RA) & Psoriatic Arthritis (PsA) • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab Polyarticular Juvenile Idiopathic Arthritis • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight Prophylaxis of acute graft versus host disease (aGVHD) • must be used in combination with a calcineurin inhibitor and methotrexate; **AND** • the member is undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor

		Continuation Criteria: • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • The subcutaneous form of this drug will not be covered under the medical benefit. Refer to the Approved Drug List (ADL) for coverage under the pharmacy benefit. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Oxlumo (lumasiran)	J0224	**Approved Diagnosis:** • Primary Hyperoxaluria Type 1 (PH1) with AGXT (alanine:glyoxylate aminotransferase gene) mutation **Approval Timeframe:** • Initial authorization: 12 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation must be submitted confirming diagnosis of PH1 with AGXT mutation • Patient must not have history of kidney or liver transplant • Documentation showing the patient has made efforts to increase fluid intake to at least 3 L/m2 BSA per day. • Patient has completed a trial of at least 3 consecutive months with pyridoxine resulting in no significant improvement observed (e.g. <30% reduction in urine oxalate concentration after at least 3 months of therapy) **Continuation Criteria:** • Documentation must be submitted confirming diagnosis of PH1 with AGXT mutation • Patient must not have history of kidney or liver transplant • Documentation that the patient is tolerating therapy and there was an improvement in urinary oxalate excretion from baseline. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:**

		• This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Pavblu (aflibercept-ayyh)	Q5147	**Approved Diagnosis:** • Neovascular (wet) age-related macular degeneration (AMD) • Macular edema following retinal vein occlusion (RVO) • Diabetic macular edema (DME) • Diabetic retinopathy • Retinopathy of Prematurity (ROP) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Patients currently receiving treatment with Pavblu and who have demonstrated an adequate response are not required to try Avastin Neovascular (wet) age-related macular degeneration (AMD): • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid ○ Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome Macular edema following retinal vein occlusion (RVO) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic macular edema (DME) with baseline visual acuity 20/50 or worse

		• Documentation of baseline best-corrected visual acuity (BCVA) score must be included with request Diabetic macular edema (DME) with baseline visual acuity better than 20/50 • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic retinopathy • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Retinopathy of Prematurity (ROP) • Diagnosis of Retinopathy of Prematurity (ROP) **Continuation Criteria**: • Documentation confirming diagnosis • Documentation showing the disease response as indicated by: ○ stabilization of visual acuity, or ○ improvement in BCVA score when compared to baseline
PiaSky (crovalimab-akkz)	J1307	**Approved Diagnosis:** • Paroxysmal Nocturnal Hemoglobinuria (PNH) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** 13 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Patient must have a body weight of >40 kg • Documentation must be submitted confirming diagnosis of PNH by both of the following: ○ Flow cytometry analysis confirming presence of PNH clones AND ○ Laboratory results, signs, and/or symptoms attributed to PNH (e.g. LDH >1.5 × ULN, Hb <10 g/dL, abdominal pain, anemia, dyspnea, extreme fatigue, unexplained/unusual thrombosis, etc.) **Continuation Criteria:** • Documentation of positive clinical response to PiaSky therapy including an increased or stabilization of Hb levels, reduction in transfusions, or improvement in hemolysis. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established. • PiaSky will not be covered in combination with another complement inhibitor for the treatment of PNH (Empaveli, Soliris, Ultomiris, Fabhalta, Voydeya)

Pombiliti (cipaglucosidase alfa)	J1203	**Approved Diagnosis:** • late-onset Pompe disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialist, neurologist, cardiologist, pediatrician) **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must have a diagnosis of late-onset Pompe disease (LOPD) that is supported by enzyme assay or DNA testing (supporting documentation must be submitted to Priority Health) • Documentation of the patient's current weight must be submitted • Documentation of baseline percent-predicted forced vital capacity (FVC) and 6-minute walk test (6MWT) must be submitted • Pombiliti must be used in combination with Opfolda • Patient must not require the use of invasive or noninvasive ventilation support for > 6 hours/day while awake **Continuation Criteria:** • Documentation of response to therapy, as evidenced by an improvement, stabilization, or slowing of progression of percent-predicted FVC and/or 6MWT **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered in an outpatient hospital infusion center. • Pombiliti is not covered in combination with Lumizyme or Nexviazyme

Prolia (denosumab)	J0897	**Approved Diagnosis:** • Osteoporosis • Increase bone mass in patients with cancer **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must have a diagnosis of osteoporosis (a person assigned male at birth or postmenopausal person assigned female at birth with T-score of ≤-2.5 or T-score > -2.5 with fragility fracture); **AND** ○ Must have a documented treatment failure or ineffective response** to a minimum of a 12-month trial with an oral bisphosphonate (e.g., alendronate, risedronate or ibandronate) OR zoledronic acid (generic Reclast); **OR** ○ Must have a documented contraindication* to BOTH oral bisphosphonates (e.g., alendronate, risedronate or ibandronate) AND zoledronic acid (generic Reclast); **OR** • Must have prostate cancer and used to increase bone mass in a person assigned male at birth taking androgen deprivation therapy or have breast cancer and used to increase bone mass in a person assigned female at birth taking adjuvant aromatase inhibitor therapy; **AND** ○ Must have a documented treatment failure or ineffective response** to a minimum of a 12-month trial with an oral bisphosphonate (e.g., alendronate, risedronate or ibandronate) OR zoledronic acid (generic Reclast); **OR** ○ Must have a documented contraindication* to BOTH oral bisphosphonates (e.g., alendronate, risedronate or ibandronate) AND zoledronic acid (generic Reclast) ***Contraindication to oral bisphosphonate therapy include the following:** • Documented inability to sit or stand upright for at least 30 minutes; **OR**

		• 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; **OR** • New fracture while on therapy **Continuation Criteria:** • Must have a positive clinical response to Prolia as one of the following: ○ T-score is stable or improved while using Prolia; **OR** ○ No new fractures have occurred while using Prolia; **AND** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be administered in an outpatient hospital infusion center. • Prolia is not covered in combination with other injectable drugs for the treatment of osteoporosis (e.g., Evenity, Tymlos, Forteo).
Qutenza (capsaicin)	J7336	**Approved Diagnosis:** • Neuropathic pain associated with postherpetic neuropathy • Pain associated with diabetic peripheral neuropathy **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** age 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must have tried ALL the following for at least a period of 3 months ○ Gabapentin ○ Lyrica ○ One generic tricyclic antidepressant (amitriptyline, amoxapine, doxepin, imipramine, nortriptyline, protriptyline, or trimipramine) ○ Oxycodone CR or morphine CR or Lidocaine 5% Patch
Radicava (edaravone)	J1301	**Approved Diagnosis:** • "definite" or "probable" amyotrophic lateral sclerosis (ALS) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 6 months **Prescriber Specialty Requirement:** Prescribed by or in consultation with a neurologist **Age Limitation:** 20-75 years **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis

		Initial Criteria: • Clinical documentation confirming diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial World Federation of Neurology/Arlie House criteria • Living independently • Baseline ALS functional rating scale (ALSFRS-R); ○ Completed copy of ALSFRS-R must be included with request • Forced vital capacity (FVC) ≥ 80% • Must be used in combination with riluzole unless there is documentation of intolerance or contraindication to riluzole **Continuation Criteria:** • Documentation that the patient has experienced a positive clinical response compared to baseline (e.g., slowing of disease progression) • FCV of greater than or equal to 30%, does not require tracheostomy/artificial ventilation, and is not on continuous Bilevel Positive Airway Pressure (BiPAP) • Ambulatory (able to walk with or without assistance) • Able to self-feed • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Reblozyl (luspatercept-aamt)	J0896	**Approved Diagnosis:** • anemia due to beta-thalassemia • myelodysplastic syndromes (MDS) **Approval Timeframe:** • Initial authorization: 12 weeks • Continuation authorization: 12 months **Prescriber Specialty Requirement:** an oncologist/hematologist OR another board-certified prescriber with qualifications to treat the specified disease **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must be used for the treatment of transfusion-dependent* adult patients with anemia due to beta-thalassemia or myelodysplastic syndromes (MDS) who require red blood cell transfusions.*Defined as 6 to 20 RBC units in the 24 weeks prior to treatment and no transfusion-free period for at least 35 days during that period. **Continuation Criteria:** • Patient has experienced a reduction in transfusion requirements from pretreatment baseline of at least 2 units PRBC while receiving Reblozyl; **AND** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Reblozyl will not be covered in combination with imetelstat (Rytelo)
Remodulin (treprostinil)	J3285	**Approved Diagnosis:** • pulmonary arterial hypertension (PAH)

		Approval Timeframe: • Initial authorization: 1 year • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of pulmonary arterial hypertension (PAH), (World Health Organization Group 1), AND ○ Member has WHO functional Class II or greater symptoms prior to therapy initiation ○ Documentation to support diagnosis, such as pre-treatment right heart catheterization with the following results: ▪ MPAP ≥ 25mmHg ▪ PCWP ≤ 15 mmHg ▪ PVR > 3 Wood units **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Rethymic (allogeneic processed thymus tissue–agdc)	C9399 J3590	**Approved Diagnosis:** • congenital athymia **Approval Timeframe:** • Initial authorization: One time per life of member • Continuation authorization: N/A **Prescriber Specialty Requirement:** • Must be prescribed by a specialist for the condition **Age Limitation:** < 3 years **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of congenital athymia with confirmation from specialist (pediatric immunologist) and surgery conducted by surgeon with experience with Rethymic • Must have documentation of anti-human leukocyte antigen (HLA) antibody screening ○ Patients testing positive for anti-HLA antibodies should receive Rethymic from a donor who does not express those HLA alleles • For patients who have received prior hematopoietic cell transplantation (HCT) or solid organ transplant, HLA matching is required ○ To minimize risk of graft-versus-host-disease, confirm HLA matching of Rethymic to recipient alleles that were not expressed in the HCT donor. **Additional Information:** • Rethymic will not be covered for patients with pre-existing cytomegalovirus infection • Rethymic is not approved to treat SCID
Rezzayo (rezafungin)	J0349	**Approved Diagnosis:** • Candidemia • invasive candidiasis

		Approval Timeframe: • Initial authorization: Maximum of 4 weeks • Continuation authorization: N/A **Prescriber Specialty Requirement:** • Must be prescribed by, or in consultation with, an oncologist, infectious disease specialists, or an internal medicine specialists **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must provide documentation confirming diagnosis: • Must have documentation of culture & sensitivities that support that the patient has limited or no alternative options for the treatment of candidemia and invasive candidiasis, including ruling out the use of oral fluconazole **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Ryoncil (remestemcel-L-rknd)	C9399 J3590	**Approved Diagnosis:** • grade B–D aGVHD **Approval Timeframe:** • Initial authorization: 4 weeks (8 doses) • Continuation authorization: up to 4 weeks (8 doses) **Prescriber Specialty Requirement:** • Must be prescribed by, or in consultation with, a clinically appropriate provider (oncologist, hematologist, BMT specialist, or other qualified prescriber.) **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must provide documentation confirming diagnosis of grade B–D aGVHD confirmed by: ○ symptoms involving skin, liver, and/or GI tract (excluding skin-only grade B aGVHD); AND ○ Steroid resistant (progression within 3 days or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone or equivalent; AND • If patient is ≥ 12 years of age, must have a documented failure to Jakafi (Not applicable to those ≥ 2 months of age to <12 years of age) **Continuation Criteria:** • Documentation of partial response (organ improvement of ≥1 stage without worsening of any other organ) **OR** mixed response (improvement in ≥1 evaluable organ stage with worsening in another); **OR** • Documentation of complete response (CR) with aGVHD flare (grade B–D progression after achieving CR); **AND** • Documentation must be submitted showing symptom improvement while on therapy **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Ryplazim (plasminogen, human-tvmh)	J2998	**Approved Diagnosis:** • Plasminogen deficiency type 1 (hypoplasminogenemia) **Approval Timeframe:** • Initial authorization: 12 weeks • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by or in consultation with a hematologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Genetic testing confirming diagnosis of PLGD type 1 (supporting documentation must be submitted to Priority Health) • Documentation of patient's baseline plasminogen activity level (≤45%) must be submitted • Documentation showing lesions (external and/or internal) and symptoms are present **Continuation Criteria:** • Continuation criteria only applies if the member is not able to safely receive the medication by home infusion • Documentation that patient cannot safely receive the medication by home infusion • Documentation of improvement in the number and/or size of lesions • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414- Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.

Rystiggo (rozanolixizumab-noli)	J9333	**Approved Diagnosis:** • generalized Myasthenia Gravis (gMG) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** • Prescribed by or in consultation with a neurologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must provide documentation confirming diagnosis: ○ Anti-acetylcholine receptor antibody [AChR-Ab]; **OR** ○ Anti-muscle-specific tyrosine kinase [MuSK] anti-body positive disease; **AND** • Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV; **AND** • Documentation of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 3; **AND** • Documentation of baseline quantitative myasthenia gravis (QMG) total score; **AND** • Documentation of 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** • Documented trial and clinical failure of Vyvgart IV (may bypass if MuSK anti-body positive) **Continuation Criteria:** • . Must have documented response as evidenced by BOTH of the following: ○ Improved MG-ADL total score from baseline (≥ a 2-point reduction) ○ Improved (QMG) total score from baseline (≥ a 3-point improvement) **Additional Information:**

		• This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Rystiggo will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Soliris, Ultomiris, or Vyvgart.
Scenesse (afamelanotide implant)	J7352	**Approved Diagnosis:** • erythropoietic protoporphyria (EPP) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must be using for a diagnosis of erythropoietic protoporphyria (EPP). • Genetic testing must be included with request confirming diagnosis of EPP • Must have characteristic symptoms of EPP phototoxicity • Will not be covered in patients with the following: ○ current basal cell carcinoma ○ squamous cell carcinoma, or other malignant or premalignant skin lesions or personal history of melanoma; or in any other photodermatosis (i.e. solar uticaria, polymorphic light eruption, discoid lupus erythematosus). **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • Covered for a maximum of 4 implants per year • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Signifor LAR (pasireotide)	J2502	**Approved Diagnosis:** • Acromegaly • Cushing's disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: N/A **Prescriber Specialty Requirement:** none

		Age Limitation: none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Must be used for treatment of acromegaly ○ Must have inadequate response to surgery, unless surgery is not an option ○ Must first try Sandostatin LAR • Must have a diagnosis of Cushing's disease ○ Documentation of failed pituitary surgery or contraindication to surgery ○ Documented trial and failure with ketoconazole to reduce cortisol secretion **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Simponi ARIA (golimumab)	J1602	**Approved Diagnosis:** • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Psoriatic Arthritis (PsA) • Ankylosing Spondylitis (AS) **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** age 2 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Rheumatoid Arthritis (RA) • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight Psoriatic Arthritis (PsA) • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab Ankylosing Spondylitis (AS) • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:**

		• The subcutaneous form of this drug will not be covered under the medical benefit. Refer to the Approved Drug List (ADL) for coverage under the pharmacy benefit. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Sivextro IV (tedizolid)	J3090	**Approved Diagnosis:** • Bacterial skin and skin structure infections due to gram-positive organisms **Approval Timeframe:** • Initial authorization: 6 doses • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Diagnosis of non-purulent cellulitis: o Trial, failure, or intolerance to linezolid, AND o Trial, failure, or intolerance to first line beta-lactam therapy, AND o Trial, failure, or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (SMZ/TMP), tetracycline (minocycline or doxycycline), OR o Culture and sensitivity results demonstrate resistance to first line agents, OR o Contraindication or intolerance to all other treatment options • Diagnosis of purulent cellulitis, abscess, or wound infection: o Trial, failure, or intolerance to linezolid, AND o Trial, failure, or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (SMZ/TMP), tetracycline (minocycline or doxycycline), OR o Culture and sensitivity results demonstrate resistance to first line agents, OR o Contraindication or intolerance to all other treatment options

Skyrizi IV (risankizumab-rzaa)	J2327	**Approved Diagnosis:** • Crohn's Disease • Ulcerative Colitis **Approval Timeframe:** • Initial authorization: 2 months, total of 3 doses • Continuation authorization: N/A **Prescriber Specialty Requirement:** • prescribed by, or in consultation with, a gastroenterologist or rheumatologist **Age Limitation:** age 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis; **AND** • Must have a documented trial and documented therapeutic failure with Humira **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • When used for Crohn's disease OR Ulcerative Colitis, three IV induction doses will be covered under the medical benefit. Subsequent maintenance doses will only be covered under the pharmacy benefit – see Medicaid Approved Drug List for coverage details.

Soliris (eculizumab)	J1299	**Approved Diagnosis:** • Atypical hemolytic uremic syndrome (aHUS) • Paroxysmal nocturnal hemoglobinuria (PNH) • Refractory generalized myasthenia gravis (MG) • Neuromyelitis optica spectrum disorder (NMOSD) **Approval Timeframe:** • Initial authorization: 6 months (12 weeks for myasthenia gravis) • Continuation authorization: 1 year **Prescriber Specialty Requirement:** see below **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis Paroxysmal nocturnal hemoglobinuria (PNH) • Must have flow cytometric confirmation ≥10% granulocyte clone cells; **OR** • Have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage) Atypical hemolytic uremic syndrome (aHUS) • Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out Refractory generalized myasthenia gravis (MG) • Must meet all the following criteria with documentation provided: ○ Anti-acetylcholine receptor antibody (AChR-Ab) positive disease ○ Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II – IV ○ Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 6 ○ Provide baseline quantitative myasthenia gravis (QMG) total score ○ Progressive disease on a therapeutic trial of at least TWO or more of the following over the course of 12 months: ▪ Azathioprine ▪ Cyclosporine ▪ mycophenolate mofetil ▪ tacrolimus ▪ methotrexate ▪ cyclophosphamide ○ 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** ○ Patient has documented trial and clinical failure of Vyvgart; **AND**

Soliris (eculizumab)	J1299	○ Prescribed by or in consultation with a neurologist Neuromyelitis optica spectrum disorder (NMOSD) • Documentation confirming diagnosis of neuromyelitis optica spectrum disorder (NMOSD) • Must be anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided) • Must have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years. • Must be prescribed by or in consultation with a neurologist • Must have progressive disease on a therapeutic trial of rituximab, inebilizumab (Uplizna) AND satralizumab (Enspryng). • Expanded Disability Status Scale (EDSS*) score of ≤7. **Continuation Criteria:** Paroxysmal nocturnal hemoglobinuria (PNH) • Must have a decrease in disabling symptoms • Hemoglobin levels must be stabilized • Patient has experienced an improvement in fatigue and quality of life *continued >* Atypical hemolytic uremic syndrome (aHUS) • Must have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine) Refractory generalized myasthenia gravis (MG) • Must have documented response as evidenced by BOTH of the following: ○ Improved MG-ADL total score from baseline ○ Improved (QMG) total score from baseline Neuromyelitis optica spectrum disorder (NMOSD) • Documentation of a decrease in relapse rate. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. • Soliris will not be covered in combination with Ultomiris Intravenous/subcutaneous Immune Globulin, Rystiggo, or Vyvgart.

Supprelin LA (histrelin acetate implant)	J9226	**Approved Diagnosis:** • Central Precocious Puberty (CPP) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** • minimum age: 2 years • maximum age: ○ for a person assigned female at birth: 11 years ○ for a person assigned male at birth: 12 years **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis **Continuation Criteria:** • Documentation confirming diagnosis • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be given in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Syfovre (pegcetacoplan intravitreal injection)	J2781	**Approved Diagnosis:** • Geographic atrophy of the macula secondary to age-related macular degeneration **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** must be prescribed by, or in consultation with, an ophthalmologist **Age Limitation:** none

		Dose & Frequency: Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis must be submitted • Visual acuity in the affected eye(s) must be 20/320 or better **Continuation Criteria:** • Documentation must be submitted showing disease responses as indicated by: ○ reduction in GA lesion growth • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • Initial coverage dosing frequency of every 60 days for one year. Requests for increased frequency will need to demonstrate failure on every other month dosing
Sylvant (siltuximab)	J2860	**Approved Diagnosis:** • multicentric Castleman disease (MCD) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of multicentric Castleman disease (MCD) • Must be HIV negative • Must be human herpesvirus (HHV) negative **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Synagis (palivizumab)	90378	**Approved Diagnosis:** • Prematurity • Chronic Lung Disease • Heart Disease • Neuromuscular Disease, congenital airway anomaly, or pulmonary abnormality • Immunocompromised **Approval Timeframe:** • Initial authorization: maximum of 5 doses per RSV season (typically October 1 to May 1) • Continuation authorization: will be determined by clinical reviewer **Prescriber Specialty Requirement:** none **Age Limitation:** Patient must be age 24 months or younger **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** **For patients age 0 to 12 months:** • Children who have not had a dose of Beyfortis™ (nirsevimab) in the current RSV season; **AND** • Mother did not receive vaccination against RSV in the 2nd or 3rd trimester; **AND** Prematurity • Documentation confirming that patient was born at 28 weeks, 6 days gestation or earlier during their first RSV season Chronic Lung Disease • Documentation confirming that patient was born at 31 weeks, 6 days gestation or earlier • Documentation confirming that patient required more than 21% oxygen for at least 28 days after birth • NICU discharge summary must be included Heart Disease • Documentation confirming that patient has hemodynamically significant cyanotic CHD • Documentation confirming that patient has acyanotic CHD and is receiving medication for CHF • NICU discharge summary must be included Neuromuscular Disease / Congenital Airway Anomaly / Pulmonary Abnormality • Documentation confirming that disease impairs patient's ability to clear secretions from the lower airways • Please note, routine use in cystic fibrosis and Down Syndrome is not recommended Immunocompromised • Documentation confirming that patient will be profoundly immunocompromised because of chemotherapy or other conditions during the RSV season. **For patients age 12 to 24 months:** • Children who have not had a dose of Beyfortis™ (nirsevimab) in the current RSV season; **AND** Chronic Lung Disease • Documentation confirming that patient was born at 31 weeks, 6 days gestation or earlier • Documentation confirming that patient required 28+ days of supplemental oxygen after birth • Documentation that the patient continues to require medical support (supplemental oxygen, chronic corticosteroids, or diuretic therapy) within 6 months of the start of their second RSV season

		Immunocompromised • Documentation confirming that patient will be profoundly immunocompromised because of chemotherapy or other conditions during the RSV season. **Continuation Criteria:** • Considered in a case by case basis. If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%). **Additional Information** • The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly • This medication may be approved under either the pharmacy benefit or the medical benefit (not both)
Tepezza (teprotumumab-trbw)	J3241	**Approved Diagnosis:** • Grave's Disease **Approval Timeframe:** • Initial authorization: 6 months (total of 8 doses per lifetime) • Continuation authorization: N/A **Prescriber Specialty Requirement:** Prescriber must be (or working in consultation with) an ophthalmologist **Age Limitation:** Patient must be age 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Grave's disease and documentation that the patient has active moderate to severe TED (not sight-threatening but has an appreciable impact on daily life) with documentation of one or more of the following: ○ lid retraction of >2 mm ○ moderate or severe soft-tissue involvement ○ proptosis ≥3 mm above • Documentation of laboratory results indicating that the patient is euthyroid prior to starting Tepezza therapy • Documentation Clinical Activity Score (CAS) Report (score must be ≥4) in the most severely affected eye • Must not have had previous orbital surgery (i.e. orbital decompression, extraocular muscle surgery, eyelid repositioning/eyelid retraction, and cosmetic soft tissue redraping) or irradiation for TED prior to the start of therapy • Failure of an adequate trial of a systemic corticosteroid (a cumulative dose of at least 4.5 gm of methylprednisolone IV OR prednisone daily doses of at least 60 mg), unless contraindicated or clinically significant adverse effects are experienced (e.g. poorly-controlled diabetes) **Additional Information:** • The recommended dose is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for 7 additional infusions. Tepezza is limited to a total of 8 doses per lifetime. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be given in an outpatient hospital infusion center.

Testopel (testosterone 75mg pellet)	S0189 J3490	**Approved Diagnosis:** • Hypogonadism • Gender Dysphoria **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Hypogonadism • Patient has evidence of hypogonadism, shown by both of the following: ○ Clinical signs and symptoms consistent with androgen deficiency (requests for coverage to treat fatigue and 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 submitted with request); **AND** • Must first try injectable testosterone enanthate or injectable testosterone cypionate (e.g. testosterone enanthate 150 to 200 mg every two weeks) for a minimum of two months with failure to improve symptoms and failure to increase total serum testosterone above 300ng/dL ○ If patient experiences fluctuations in energy, mood, or libido, after two months or more, the dosage can be changed (e.g. testosterone enanthate 100 mg once a week); **AND** • After a trial and failure with generic injectable testosterone, must then first try generic topical testosterone for a minimum of two months with failure to improve symptoms and failure to increase total serum testosterone above 300ng/dL Gender Dysphoria • Patient has been diagnosed with Gender Dysphoria and documentation of diagnosis must be submitted; **AND** • Must have first tried and failed generic injectable testosterone, either testosterone enanthate or testosterone cypionate; **AND** • After a trial and failure with generic injectable testosterone, must have then first tried and failed generic topical testosterone **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • "Needle phobia" or "needle fatigue" is not considered an intolerance or contraindication to injectable testosterone therapy.

Tezspire (tezepelumab-ekko)	J2356	**Approved Diagnosis:** • add-on maintenance treatment of severe asthma **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** Patient must be 12 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Patient must not currently use tobacco products; **AND** • Patient must have been compliant on all the following therapies for at least 3 months: ○ High-dose inhaled corticosteroid (ICS) ○ Long-acting beta agonist (LABA) ○ One additional asthma controller medication (e.g. leukotriene receptor antagonist, Spiriva); **AND** • Patient must have had ≥ 2 asthma exacerbations in the previous year that required at least one of the following: ○ Systemic steroids (or an increase in the current steroid maintenance dose) for at least 3 days ○ Hospitalization and/or ED visit; **AND** • Patient must have tried and failed one preferred biologic (Xolair, Dupixent,, Fasenra, Cinqair); **AND** • Must not use in combination with other biologics (e.g., Nucala, Dupixent, Cinqair, or Xolair) **Continuation Criteria:** • Documentation showing patient has had a positive clinical response (e.g., decrease in exacerbation frequency, improvement in asthma symptoms, decrease in oral corticosteroid use); **AND** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • Tezspire will not be covered in combination with other biologic drug therapy

Tofidence (tocilizumab-bavi)	Q5133	**Approved Diagnosis:** • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Systemic Juvenile Idiopathic Arthritis (SJIA) • Giant Cell Arteritis • Cytokine Release Syndrome **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** age 2 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Rheumatoid Arthritis (RA) • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab Juvenile Idiopathic Arthritis (Polyarticular & Systemic) • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight Giant Cell Arteritis • Patient has tried one systemic corticosteroid Cytokine Release Syndrome • Patient is experiencing a severe or life-threatening T-cell induced reaction; **AND** • The IV formulation of Tofidence is being used for treatment; **AND** • A maximum of 4 doses is requested **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:** • Any subcutaneous form of this drug will not be covered under the medical benefit. Refer to the Approved Drug List (ADL) for coverage under the pharmacy benefit. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Tremfya IV (guselkumab)	J1628	**Approved Diagnosis:** • Crohn's disease • Ulcerative Colitis **Approval Timeframe:** • Initial authorization: 2 months, total of 3 doses • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** Patient must be 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of moderate to severe active ulcerative colitis; **OR** • Documentation confirming diagnosis of moderately to severely active Crohn's disease (CD); **AND** • Must have a documented trial and documented therapeutic failure with Humira **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • When used for Ulcerative Colitis or Crohn's Disease, three IV induction doses will be covered under the medical benefit. Subsequent maintenance doses will only be covered under the pharmacy benefit – see Medicaid Approved Drug List for coverage details

Tyenne IV (tocilizumab-aazg)	Q5135	**Approved Diagnosis:** • Rheumatoid Arthritis (RA) • Polyarticular Juvenile Idiopathic Arthritis (PJIA) • Systemic Juvenile Idiopathic Arthritis (SJIA) • Giant Cell Arteritis • Cytokine Release Syndrome **Approval Timeframe:** • Initial authorization: 2 years • Continuation authorization: 2 years **Prescriber Specialty Requirement:** none **Age Limitation:** age 2 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Rheumatoid Arthritis (RA) • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must have a documented trial and documented therapeutic failure with infliximab Juvenile Idiopathic Arthritis (Polyarticular & Systemic) • Must provide documentation confirming diagnosis, **AND** • Must provide patient's current weight Giant Cell Arteritis • Patient has tried one systemic corticosteroid Cytokine Release Syndrome • Patient is experiencing a severe or life-threatening T-cell induced reaction; **AND** • The IV formulation of Tyenne is being used for treatment; **AND** • A maximum of 4 doses is requested **Continuation Criteria:** • Must provide documentation confirming diagnosis, **AND** • Must provide the patient's current weight, **AND** • Must provide documentation showing the patient has experienced improvement or maintained stable clinical status **Additional Information:** • The subcutaneous form of this drug will not be covered under the medical benefit. Refer to the Approved Drug List (ADL) for coverage under the pharmacy benefit. • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Tysabri (natalizumab)	J2323	**Approved Diagnosis:** • Relapsing–Remitting Multiple Sclerosis • Crohn's disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** Patient must be 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Relapsing–Remitting Multiple Sclerosis • Patient must have had a documented therapeutic trial and inadequate response to at least TWO other disease modifying therapies for MS, one of which must be: o Glatiramer o dimethyl fumarate o fingolimod; **OR** o teriflunomide Moderate to Severe active Crohn's disease • Patient has prior use of corticosteroids; **AND** • Patient must have a documented trial and documented therapeutic failure with **both** Humira and infliximab **Continuation Criteria:** • Must have a positive clinical response to Tysabri® as evidenced by experiencing disease stability or improvement • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Tysabri will not be covered in combination with another biologic drug or in combination with other drugs for the treatment of Multiple Sclerosis (e.g., Ocrevus, Gilenya, Betaseron).

Tzield (teplizumab-mzwv)	J9381	**Approved Diagnosis:** • Stage 2 Type 1 Diabetes **Approval Timeframe:** • Initial authorization: one time course (14 doses) • Continuation authorization: N/A **Prescriber Specialty Requirement:** must be prescribed by, or in consultation with, an endocrinologist **Age Limitation:** 8 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation showing a diagnosis of stage 2 type 1 diabetes • Must have documentation of at least 2 of the following autoantibodies: ○ Glutamic acid decarboxylase 65 (GAD) autoantibody ○ Insulin autoantibody (IAA) ○ Insulinoma-associated antigen 2 autoantibody (IA-2A) ○ Zinc transporter 8 autoantibody (ZnT8A) ○ Islet cell autoantibody (ICA) • Must submit documentation of patient's current weight AND autoantibodies testing results **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Ultomiris (ravulizumab-cwvz)	J1303	**Approved Diagnosis:** • Paroxysmal nocturnal hemoglobinuria (PNH) • Atypical hemolytic uremic syndrome (aHUS) • Refractory generalized myasthenia gravis (MG) • Neuromyelitis optica spectrum disorder (NMOSD) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** for refractory generalized myasthenia gravis (MG) only, must be prescribed by a neurologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Paroxysmal nocturnal hemoglobinuria (PNH) • Must have received meningococcal vaccine at least two weeks before starting Ultomiris treatment; **AND** • Must have flow cytometric confirmation ≥10% granulocyte clone cells or have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage) Atypical hemolytic uremic syndrome (aHUS) • Must have received meningococcal vaccine at least two weeks before starting Ultomiris treatment; **AND** • Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out Refractory generalized myasthenia gravis (MG) • 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** • Must have documented trial and clinical failure of Vyvgart; Neuromyelitis optica spectrum disorder (NMOSD) • Documentation confirming diagnosis of neuromyelitis optica spectrum disorder (NMOSD) • Must be anti-aquaporin-4 (AQP4) antibody positive (documentation must be provided) • Must have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years • Must be prescribed by or in consultation with a neurologist • Must have progressive disease on a therapeutic trial of rituximab, inebilizumab (Uplizna) **AND** satralizumab (Enspryng). • Expanded Disability Status Scale (EDSS*) score of ≤7 *continued >*

		Continuation Criteria: Paroxysmal nocturnal hemoglobinuria (PNH) • Must have a decrease disabling symptoms • Hemoglobin levels must be stabilized • Patient has experienced an improvement in fatigue and quality of life Atypical hemolytic uremic syndrome (aHUS) • Must have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine) Refractory generalized myasthenia gravis (MG) • Must have documented response as evidenced by BOTH of the following: improved MG-ADL total score from baseline, AND improved (QMG) total score from baseline. Neuromyelitis optica spectrum disorder (NMOSD) • Documentation of a decrease in relapse rate **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. • Ultomiris will not be covered in combination with Soliris, Intravenous/subcutaneous Immune Globulin, Rystiggo, or Vyvgart

Uplizna (inebilizumab-sdon)	J1823	**Approved Diagnosis:** • Neuromyelitis optica spectrum disorder (NMOSD) • Ig-G4 Related Disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Neurologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** **NMOSD** • Documentation provided confirming diagnosis of NMOSD and anti-aquaporin-4 (AQP4) antibody positive • Must have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years • Must have progressive disease on a therapeutic trial of rituximab AND satralizumab (Enspryng) • Must have expanded Disability Status Scale (EDSS) score of ≤7 **Ig-G4 Related Disease requests:** • Confirmed diagnosis of IgG4-RD (supporting documentation must be submitted to Priority Health); **AND** • Score of at least 20 on the 2019 ACR/EULAR classification criteria; **AND** • Patient is experiencing (or recently experienced) an IgG4-RD flare that requires initiation or continuation of glucocorticoid (GC) treatment; **AND** • IgG4-RD affecting at least 2 organs/sites; **AND** • Have progressive disease on a therapeutic trial of glucocorticoids AND rituximab; **AND** • Prescriber is a specialist or has consulted with a specialist for the condition being treated. **Continuation Criteria:** **NMOSD** • Documentation of a decrease in relapse rate **Ig-G4 Related Disease requests:** • Have documentation of a decrease in the number of disease flares **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.

Ustekinumab IV Otulfi Pyzchiva Selarsdi Steqeyma Ustekinumab Yesintek	Q9999 JA Q9997 Q9998 JA Q5099 JA J3358 Q5100 JA	**Approved Diagnosis:** • Crohn's Disease • Ulcerative Colitis **Approval Timeframe:** • Initial authorization: 1 month (one dose) • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** age 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis; **AND** • Must have a documented trial and documented therapeutic failure with Humira; **AND** • Must provide documentation of patient's current weight **Additional Information:** • When used for Crohn's disease or ulcerative colitis, a single IV induction dose will be covered under the medical benefit. Subcutaneous maintenance doses will only be covered under the pharmacy benefit.

Vabysmo (faricimab-svoa)	J2777	**Approved Diagnosis:** • Neovascular (wet) age-related macular degeneration (AMD) • Diabetic macular edema (DME) • Macular edema following retinal vein occlusion (RVO) **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis • Patients currently receiving treatment with Vabysmo and who have demonstrated an adequate response are not required to try Avastin. Neovascular (wet) age-related macular degeneration (AMD): • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid; **AND** • Must try Lucentis (ranibizumab), biosimilars of Lucentis, or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid; o Avastin is not required if patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome. Diabetic macular edema (DME) with baseline visual acuity 20/50 or worse • Documentation of baseline best-corrected visual acuity (BCVA) score must be included with request • Must try Lucentis (ranibizumab), biosimilars of Lucentis, or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Diabetic macular edema (DME) with baseline visual acuity better than 20/50 • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid; **AND** • Must try Lucentis (ranibizumab), biosimilars of Lucentis, or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid Macular edema following retinal vein occlusion (RVO) • Must first try Avastin (bevacizumab) for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid; **AND** • Must try Lucentis (ranibizumab), biosimilars of Lucentis, or aflibercept for at least 3 consecutive months with failure to effectively improve baseline visual acuity and/or reduce fluid **Continuation Criteria:** • Documentation confirming diagnosis • Documentation showing the disease response as indicated by: o stabilization of visual acuity, or o improvement in BCVA score when compared to baseline

Veopoz (pozelimab-bbfg)	J9376	**Approved Diagnosis:** • CD55-deficient protein-losing enteropathy (CHAPLE disease) **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by or in consultation with hematologists, gastroenterologists, or those who specialize in rare genetic hematologic diseases **Age Limitation:** 1 year of age or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of CHAPLE disease that includes symptoms of the condition (diarrhea, vomiting, abdominal pain, etc.) **and** a low serum albumin**; AND** • Documentation confirming CD55 loss-of function mutation by genetic testing; **AND** • Documentation of patient's current weight; **AND** • Documentation of patient's baseline serum albumin **Continuation Criteria:** • Documentation of a positive clinical response (e.g. improvement or no worsening in clinical symptoms, increase in or stabilization of albumin and IgG concentrations, increase in growth percentiles**)** **Additional Information:** • Veopoz is not covered in combination with Soliris/Ultomiris • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.
Vibativ (telavancin)	J3095	**Approved Diagnosis:** • Acute bacterial skin and skin structure infection (ABSSSI) **Approval Timeframe:** • Initial authorization: 1 month • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of culture and sensitivity results must be sent to Priority Health showing the patient's infection is not susceptible to alternative antibiotic treatments • Must have documented methicillin-resistant Staphylococcus aureus (MRSA) acute bacterial skin and skin structure infection (ABSSSI) that is resistant to all other MRSA sensitive antibiotics or be unable to tolerate alternatives.
Vpriv (velaglucerase alfa)	J3385	**Approved Diagnosis:** • Non-neuropathic Gaucher's disease **Approval Timeframe:**

		• Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of chronic Non-neuropathic Gaucher's disease **Continuation Criteria:** • Continuation criteria only applies if the member is unable to safely receive the medication by home infusion • Documentation confirming diagnosis of chronic Non-neuropathic Gaucher's disease • Patient has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following: ○ clinically significant reduction in spleen or liver volume ○ increase in platelet ○ hemoglobin values • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy. **Additional Information:** • This drug is included in Priority Health's medical policy 91414 – Infusion Services and Equipment, which requires medications to be administered by home infusion. Home infusion agencies must bill the drug to the pharmacy benefit. Note: if this medication is new to the patient, Priority Health may cover up to 3 months of treatment at an outpatient hospital infusion center until safety has been established.
Vyalev (foscarbidopa and foslevodopa)	J7356	**Approved Diagnosis:** • Parkinson's disease **Approval Timeframe:** • Initial authorization: 1 year • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a neurologist. **Age Limitation:** Patient is 18 years of age or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation of diagnosis of Parkinson's disease that is levodopa-responsive; **AND** • Documentation that the patient is experiencing persistent motor fluctuations with a minimum of 2.5 hours of "off" time per day despite optimized carbidopa/levodopa therapy **Continuation Criteria:** • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy
Vyepti	J3032	**Approved Diagnosis:** • Migraine Prevention

(eptinezumab-jjmr)		**Approval Timeframe:** • Initial authorization: 3 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** 18 years or older **Dose & Frequency:** Limited to initial dosing of 100mg given every 3 months. • For patients not responsive to the 100mg dose, a single authorization can be made for a 300mg dose which will be assessed for efficacy beyond that observed for the 100mg dose **Initial Criteria:** • Must experience 4 or more migraines per month • Must have tried and failed at least 1 agent in 2 of the following groups of prophylactic treatment options (minimum of 28 days for each): ○ Blood pressure agents: Propranolol, timolol, or metoprolol ○ Antidepressant agents: Amitriptyline or nortriptyline ○ Antiepileptic drugs: Topiramate or valproic acid and its derivatives • Trial and failure, or intolerance to Aimovig®, Emgality®, and Ajovy® for 3 continuous months each and not achieving adequate reduction in migraines. • Not covered in combination with any other branded prophylactic agent **Continuation Criteria:** • Must demonstrate effectiveness (>50% reduction in monthly migraine days) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Vyvgart Hytrulo	J9334	**Approved Diagnosis:** • generalized Myasthenia Gravis (gMG) • Chronic inflammatory demyelinating polyneuropathy (CIDP)

(efgartigimod alfa and hyaluronidase-qvfc)		**Approval Timeframe:** • Initial authorization: ○ gMG: 100 days (Limited to 2 cycles = 4 doses per cycle) ○ CIDP: 3 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a neurologist/ neuromuscular specialist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** **Generalized Myasthenia Gravis (gMG)** • Documentation confirming anti-acetylcholine receptor antibody (AChR-Ab) positive disease; **AND** • Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV; **AND** • Documentation of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 5; **AND** • Must provide baseline quantitative myasthenia gravis (QMG) total score; **AND** • Documentation confirming patient had 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. **Chronic inflammatory demyelinating polyneuropathy (CIDP)** • 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 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 (g) in one or more other nerves; **OR** ○ prolonged F wave latency in two or more motor nerves; **AND** • Patient has tried and failed on at least a 3-month trial of immunoglobulin (IG) OR has a documented intolerance/contraindication to IG *continued >* **Continuation Criteria:**

		• Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy **Generalized Myasthenia Gravis (gMG)** • Must have documented response as evidenced by **BOTH** of the following: ○ improved MG-ADL total score from baseline (≥ a 2-point reduction) ○ improved (QMG) total score from baseline (≥ a 3-point improvement) **Chronic inflammatory demyelinating polyneuropathy (CIDP)** • Documentation of significant clinical improvement in neurologic symptoms or stabilization of disease (measurement of response may include nerve conduction studies, objective clinical measurement tools (e.g. INCAT, Medical Research Council [MRC] sum score, grip strength, etc.) or physical exam showing improvement in neurological strength and sensation **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Vyvgart will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Soliris, Rystiggo, or Ultomiris
Vyvgart	J9332	**Approved Diagnosis:** • generalized Myasthenia Gravis (gMG)

(efgartigimod alfa-fcab)		**Approval Timeframe:** • Initial authorization: 100 days (Limited to 2 cycles = 4 doses per cycle) • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a neurologist **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming anti-acetylcholine receptor antibody (AChR-Ab) positive disease; **AND** • Documentation of Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV; **AND** • Documentation of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score greater than or equal to 5; **AND** • Must provide baseline quantitative myasthenia gravis (QMG) total score; **AND** • Documentation confirming patient had 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. **Continuation Criteria:** • Must have documented response as evidenced by **BOTH** of the following: ○ improved MG-ADL total score from baseline (≥ a 2-point reduction) ○ improved (QMG) total score from baseline (≥ a 3-point improvement) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • Vyvgart will not be covered in combination with Intravenous/Subcutaneous Immune Globulin, Soliris, Rystiggo, or Ultomiris
Winrevair (Sotatercept-csrk)	J3590 C9399	**Approved Diagnosis:** • Pulmonary Arterial Hypertension (PAH) **Approval Timeframe:**

		• Initial authorization: 6 months • Continuation authorization: 1 year **Prescriber Specialty Requirement:** Prescriber is a specialist or has consulted with a specialist for the condition being treated **Age Limitation:** 18 years of age or older **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming Diagnosis of PAH WHO group 1, functional class II or III; **AND** • Documented trial and failure of, or contraindication to, at least 2 months of combination therapy including one Phosphodiesterase 5 (PDE-5) inhibitor AND one Endothelin receptor antagonist (ERA); **AND** • Winrevair is being used as add on therapy to standard care (at least 2 other PAH agents such as an ERA, PDE5i, prostaglandins, etc.); **AND** • Platelet count of > 50,000/mm3 (> (>50x109/L), acceptable hemoglobin levels, and other labs in accordance with the product label. **Continuation Criteria:** • Documentation confirming diagnosis • Must provide documentation showing the patient has experienced benefit to therapy compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, exercise capacity (6MWD) **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be given in an outpatient hospital infusion center. • Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
Xenpozyme (olipudase alfa-rpcp)	J0218	**Approved Diagnosis:** • acid sphingomyelinase deficiency (ASMD) type A/B or type B **Approval Timeframe:** • Initial authorization: 6 months • Continuation authorization: 12 months **Prescriber Specialty Requirement:** Must be prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis must be submitted which includes: ○ ASM biochemical enzyme assay demonstrating low ASM enzyme activity (<10% of controls) • Documentation supporting the request must be submitted which includes the patient's current weight • For adults, diffusion capacity of the lungs for carbon monoxide (DLco) ≤70% of predicted normal • Spleen volume ≥6 multiples of normal (MN) for adults or ≥5 MN for patients less than 18 years old **Continuation Criteria:** • Documentation of a clinical response to therapy compared to pretreatment baseline in one or more of the following: ○ reduction in spleen or liver volume ○ increase in platelet count ○ improvement in lung function (e.g., DLco); OR

		○ improvement in symptoms (shortness of breath, fatigue, etc.). **Additional Information:** • Xenpozyme will not be covered if: ○ Patient has acute or rapidly progressive neurologic abnormalities ○ Patient requires use of invasive ventilatory support or requires noninvasive ventilatory support while awake and for greater than 12 hours a day ○ Patient's platelet count is <60 × 103/µL ○ Patient has an international normalized ratio (INR) >1.5 ○ Patient's alanine aminotransferase (ALT) or aspartate aminotransferase (AST) is >250 IU/L or total bilirubin is >1.5 mg/dL • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center.
Xiaflex (collagenase, clostridium histolyticum)	J0775	**Approved Diagnosis:** • Dupuytren's contracture • Peyronie's disease **Approval Timeframe:** • Initial authorization: See specific durations under criteria • Continuation authorization: N/A **Prescriber Specialty Requirement:** none **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Dupuytren's contracture with: ○ Flexion contracture of at least one finger, other than the thumb, of greater than or equal to 20 degrees at the MP or PIP joints; **AND** ○ Patient must be free of chronic muscular, neurological, or neuromuscular disorders affecting the hands; **AND** ○ Xiaflex is an alternative to surgical intervention. For coverage consideration, please provide the medical reason that surgery would not be an option for the patient. **NOTE:** Maximum dose is 3 injections per cord every 4 weeks, with a maximum of 2 injections per hand per visit (which may be administered as either 1 injection per cord on 2 cords affecting 2 different joints OR 2 injections on 1 cord affecting 2 joints). • Documentation confirming diagnosis of Peyronie's disease with: ○ Penile curvature of 30 degrees or more for 12 months or longer; **AND** ○ Erections must be painful **NOTE**: Priority Health covers up to 4 treatment cycles for Peyronie's disease. Each treatment cycle consists of two Xiaflex injections given one to three days apart. Each

		subsequent treatment cycle must be six-weeks apart and is only authorized if the patient's penile curvature is 15 degrees or more. **Additional Information:** • Priority Health considers Peyronie's disease cosmetic in the absence of painful erections.
Xolair (omalizumab)	J2357	**Approved Diagnosis:** • Asthma • Chronic Urticaria • Chronic rhinosinusitis with nasal polyp (CRSwNP) • IgE-mediated food allergy **Approval Timeframe:** • Initial authorization: see below • Continuation authorization: 1 year **Prescriber Specialty Requirement:** none **Age Limitation:** see below **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** Moderate to Severe Persistent Asthma • Must be at least 6 years of age • Initial authorization for 1 year • Must have been compliant on all of the following therapies for at least 3 months: ○ High-dose inhaled corticosteroid (ICS)* ○ Long-acting beta agonist (LABA) ○ One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva) • Compliant use of the above medications must not be effective as demonstrated by at least one of the following: ○ Oral or systemic steroid treatment or an increase in the current oral steroid maintenance dose ○ Hospitalization and/or ED visit ○ Increasing need for short-acting beta2-agonist • Must have a positive skin test or in-vitro reactivity to a perennial aeroallergen (lab results must be submitted) • Must be within the recommended dosing range based on current weight and baseline IgE level

Xolair (omalizumab)	J2357	• Must not currently use tobacco products • Must not use Xolair in combination with other biologics (e.g., Fasenra, Cinqair, Nucala) <u>Chronic Urticaria:</u> • Must be age 12 or older • Initial authorization for 1 year • Must first try two or more H1 antihistamines **OR** • Must first try one H1 antihistamine and one or more of the following: ○ H2 antihistamine ○ Oral corticosteroid ○ Leukotriene modifier <u>Chronic rhinosinusitis with nasal polyp (CRSwNP)</u> • Must be age 18 or older • Initial authorization for 6 months • Baseline Nasal Polyps Score (NPS) of at least 5, with a unilateral score of at least 2 for each nostril • Must be within the recommended dosing range based on current weight and baseline IgE level • Symptomatic disease that is persistent for a minimum of 12 weeks, including all of the following: ○ Nasal obstruction ○ Rhinorrhea (anterior/posterior) ○ Diminished or loss of smell • Member must have tried and failed all of the following: ○ At least one prior treatment course with a systemic corticosteroid ○ Minimum 3 months compliant treatment with an intranasal glucocorticoid ○ Minimum 1-month trial with either a non-sedating antihistamine or antileukotriene agent (e.g., montelukast) *continued >* <u>IgE-mediated food allergy</u> • Must be at least one year of age • Must have a confirmed diagnosis of an IgE-mediated food allergy • Must be prescribed by or in consultation with an allergist or immunologist • Must be used in conjunction with a food allergen-avoidant diet • Must be within the recommended dosing range based on current weight and baseline IgE level **<u>Continuation Criteria:</u>** <u>Moderate to Severe Persistent Asthma</u> • Peak flow improvement by: ○ greater than 20%, or FEV1 improved by greater than or equal to 12% OR ○ patient has experienced a reduction in symptoms (i.e. wheezing, shortness of breath, cough, chest tightness) • Decrease in the use of quick relief medications or corticosteroids (oral or inhaled) • Decrease in ER visits, hospitalizations, physician visits, or school/work absences due to acute asthma attacks • Must not currently use tobacco products • Must not use in combination with other biologics (e.g., Cinqair, Fasenra, or Xolair) <u>Chronic Urticaria:</u> • Adherence to therapy • Reduction in the symptom of urticaria documented by the prescriber (chart notes supporting symptom reduction must be submitted) <u>Chronic rhinosinusitis with nasal polyp (CRSwNP)</u> • Adherence to therapy including Xolair and intranasal steroid • Reduction in the symptom of rhinosinusitis with nasal polyp documented by the prescriber (chart notes supporting symptom reduction must be submitted to Priority Health) including, but not limited to: ○ 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 IgE-mediated food allergy • Continue food allergen-avoidant diet; **AND** • Continue to be prescribed by or in consultation with an allergist or immunologist **Additional Information:** • This drug is included in Priority Health's medical policy 91414 - Infusion Services and Equipment, which requires medications to be infused in an outpatient hospital infusion center. • This criteria applies to all Xolair formulations
Zevaskyn (prademagene zamikeracel)	C9399 J3590	**Approved Diagnosis:** • Recessive dystrophic epidermolysis bullosa (RDEB) **Approval Timeframe:** • Initial authorization: One time • Continuation authorization: N/A **Prescriber Specialty Requirement:** Prescribed by a qualified dermatologist specializing in EB at a Zevaskyn qualified treatment center (QTC) **Age Limitation:** none **Dose & Frequency:** Limited to FDA approved dose & frequency by diagnosis **Initial Criteria:** • Documentation confirming diagnosis of Recessive dystrophic epidermolysis bullosa (RDEB) with documentation of genetic testing confirming mutations in **both** COL7A1 genes • Documentation confirming presence of partial-thickness RDEB wounds open chronically for ≥ 6 months • Provider attests that Zevaskyn will only be applied to partial-thickness RDEB wounds open chronically for ≥ 6 months **Continuation Criteria:** • A new PA is required for any previously untreated areas **Additional Information:** • Vyjuvek or Filsuvez cannot be used on wounds treated or designated to be treated with Zevaskyn