Priority Health Medicare Part B

Prior Authorization and Step Therapy Criteria

July 2025

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Priority Health
Medicare Part B
Prior Authorization and Step Therapy Criteria

This document contains information regarding Priority Health Medicare Part B (medical) drugs requiring prior authorization and/or step therapy. For medical procedures, refer to the Medicare Coverage Database and Priority Health's Medical Policies for applicable coverage policies.

Priority Health Medicare complies with National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Article (LCA), and other coverage and benefit conditions included in Traditional Medicare law. When such coverage criteria do not exist or are not fully established, Priority Health Medicare may create coverage criteria based on CMS-approved compendium and current evidence in widely used treatment guidelines or clinical literature.

What is a Part B drug?
Outpatient prescription drugs and biologicals eligible for coverage under Medicare Part B. Part B drugs are usually limited to drugs or biologicals administered by infusion or injection furnished incident to a physician or provider service and not usually self-administered by the patient.

What is an NCD, LCD, and LCA?
NCD, LCDs, and LCAs contain coverage criteria set by the Centers of Medicare & Medicaid Services (CMS) or a Medicare Administrative Contractor (MAC) to determine if a drug is reasonable and necessary for the treatment of a condition.

What is a prior authorization?
Prior authorization (PA) means that certain criteria must be met before Priority Health Medicare may approve (cover) the drug. Prior authorization may also be required to determine if the drug is covered under the medical (Medicare Part B) or pharmacy (Medicare Part D) benefit (known as Part B vs Part D) or if a drug is used in a manner that exceeds other coverage limits as referenced on the Medical Benefit Drug List (MBDL).

What is step therapy?
Step Therapy (ST) means that trying a preferred or more cost-effective drug is required before taking a step up to a drug that is non-preferred. Step therapy for PartB drugs applies to members who are enrolled in a Medicare Advantage Prescription Drug (MAPD) plan and are not currently receiving the Part B drug.

What is a medically accepted indication (MAI)?

Medically accepted indications (MAIs) are defined by the Centers for Medicare and Medicaid Services (CMS) and depend on the benefit (Part D versus Part B) and whether the drug is used in an anti-cancer regimen.

For Part D: Refer to the Medicare Prescription Drug Benefit Manual Chapter 6, §10.6 – Medically Accepted Indication.

For Part B: If no NCD, LCD, LCA or other coverage policies exist, Part B drugs will be reviewed for a medically accepted indication. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.2 – Unlabeled Use of Drug. An unlabeled use of a drug may be covered if a Priority Health Clinical Reviewer or Medical Director determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

How does Priority Health Medicare determine criteria for a Part B drug?

Priority Health Medicare complies with NCDs, LCDs, LCAs, and general coverage and benefit conditions included in Traditional Medicare law. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. When such coverage and benefit criteria do not exist or are not fully established, Priority Health Medicare may create coverage criteria based on CMS-approved compendium and current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees, and providers. The coverage criteria are reviewed and approved by Priority Health's Pharmacy and Therapeutics (P&T) Committed prior to implementation (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

How do I know what criteria to use for a Part B drug?

First, check for applicable Medicare NCDs, LCDs, LCAs, and other Medicare guidance using the Medicare Coverage Database at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

Next, check for additional Priority Health Medicare coverage criteria using the Medical Benefit Drug List (MBDL) and this Priority Health Medicare Part B Prior Authorization and Step Therapy Criteria document. The MBDL lists most drugs available under the Part B (medical) benefit and any applicable coverage limits such as PA, ST, and/or Part B vs Part D determinations.

Providers are responsible for reviewing NCDs, LCDs and/or LCAs or other Medicare coverage guidance. Priority Health Medicare attempts to provideas much information as possible; however, if there is a conflict between this document and any Medicare coverage guidance, the Medicare coverage guidance will supersede.

How do I use this criteria document?

This criteria document is meant to be used alongside the Medical Benefit Drug List (MBDL), with the following prior authorization (PA) forms and websites:

- Medicare Part B vs Medicare Part D Drug Request form (general form used to request coverage for drugs that may be covered under Part B or Part D. Includes required information necessary for billing purposes.)
- Medicare Medical (Part B) Prior Authorization form (general form used to request coverage for Part B drugs that have PA and/or step therapy (ST). Includes required information necessary for billing purposes.)

- Oncology Drug Request form (general form used to request coverage for chemotherapeutic (cancer) medications requiring PA and/or ST under Part B. Includes required information necessary for billing purposes.)
- Medicare Coverage Database Search (website to search for National and Local Coverage Determinations and Coverage Articles [NCD, NCA, LCD, and LCAs]: https://www.cms.gov/medicare-coverage-database/search.aspx

Dose, frequency, place of administration and other billing information are required for appropriate billing and coverage of the requested drug(s). Please use the above forms to provide the necessary information and improve the timeliness of the request.

What if my request does not meet criteria and/or is not approved by the FDA?
You can request an exception to the coverage criteria including required indications and FDA-approved dose, frequency and/or route of administration.

Approval for exceptions require supporting evidence (i.e.,medical records; medical literature) that demonstrates the exception is medically necessary.

Approval for indications, dosing, or route of administration not approved by the FDA or recognized in Medicare-accepted compendia (e.g., DrugDex, AHFS, Clinical Pharmacology) requires supporting evidence for coverage including published peer-reviewed literature supporting the appropriateness of the drug, the dose, and/or route of administration for the requested indication.

What if I cannot find my drug on the Medical Benefit Drug List (MBDL) or this Prior Authorization/Step Therapy document?
Most drugs in this document are listed in alphabetical order according to their trade name unless the drug is available generically in which the drug will be listed by its generic name. Occasionally, when two or more drugs used to treat the same condition have the same coverage criteria, these may be grouped into one listing (e.g., botulinum toxins).

For new-to-market drugs not yet reviewed by the Priority Health Pharmacy and Therapeutics (P&T) Committee, the following criteria are required:
1. Use of the drug for a Medically Accepted Indication – and –
2. Use of all appropriate alternative covered Part D drugs (for plans with prescription drug coverage) and Part B drugs with evidence-based support for the requested indication

For other Part B drugs not found, use the Medicare Coverage Database tool at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx to review for applicable coverage policies (i.e., NCDs, LCDs or LCAs).

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Abecma (idecabtagene vicleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Actemra IV (tocilizumab) *solution vial*	**Exclusion Criteria**	Must not be used in combination with other biological drugs, Otezla, or Janus Kinase Inhibitor (JAKis). SSc-ILD is not approved for intravenous administration.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Provider is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Tyenne.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Adakveo (crizanlizumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try hydroxyurea for 6 months or have an intolerance or contraindication.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Aduhelm (aducanumab-avwa)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	N/A
	Other Criteria	Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of ALZHEIMER's Disease (AD).
	Indications	In accordance with NCD 200.3.
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Adzynma (ADAMTS13, recombinant-krhn)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial and reauthorization requests:** Medical records supporting the request must be provided, including the patient's current weight for dosing purposes. **For initial requests:** Must also have (1) genetic testing confirming the diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP); and (2) ADAMTS13 activity less than 10%.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist for the disease state.
	Coverage Duration	**Initial:** 12 months. **Reauthorization:** 12 months. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial requests:** The initial dosing frequency for prophylactic use must be every 2 weeks. The frequency may be adjusted to once weekly based on prior prophylactic dosing regimen or clinical response and supporting documentation is required. **For reauthorization requests:** Must demonstrate 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).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Alhemo (concizumab-mtci)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial requests for Hemophilia A:** Medical records supporting the request must be provided and include documentation of the following: (1) Alhemo is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Patient has hemophilia A without factor VIII inhibitors; AND (3) Patient has tried and failed Hemlibra. **For initial requests for Hemophilia B:** Medical records supporting the request must be provided and include documentation of the following: (1) Alhemo is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Patient has hemophilia B with factor IX inhibitors.
	Age Restrictions	Patient is at least 12 years of age
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or other specialist.
	Coverage Duration	**Initial and reauthorization:** 12 months. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization of hemophilia A and B:** (1) Patient continues to use Alhemo for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Documentation of clinical benefit (e.g., less bleeding episodes; less use of factor VIII or factor IX replacement therapy or bypassing agents) has been provided.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Alyglo (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** Must first try two preferred IVIG products (e.g., Gammagard Liquid, Gamunex-C, Privigen). Refer to the Medicare Part B vs Medicare Part D Drug Request form. Additional criteria may apply as required by LCD L34771 (Immune Globulins) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Alymsys (bevacizumab-maly) *injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Mvasi **AND** Zirabev. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Amvuttra (vutrisiran) *injection*	**Exclusion Criteria**	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Onpattro)
	Required Medical Information	**For initial requests of hATTR-PN:** Medical records supporting the request must be provided and include all of the following: (1) Patient has a transthyretin (TTR) mutation (e.g., V30M) – AND – (2) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb - AND - (3) Patient has clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). **For initial requests of ATTR-CM:** Medical records supporting the request must be provided and include all of the following: (1) Patient has New York Heart Association (NYHA) class 1 , 2, or 3 heart failure with current clinical manifestations or prior hospitalization for HF - AND - (2) Patient has an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness) - AND - (3) Diagnosis confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) - AND - (4) if the diagnosis was confirmed by radionuclide imaging, coverage also requires documentation of Grade 2 or 3 cardiac uptake.
	Age Restrictions	Must be at least 18 years of age.
	Prescriber Restrictions	N/A
	Coverage Duration	**Initial and reauthorization:** 1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Amvuttra will not be approved if the patient has primary (light-chain) amyloidosis. **For reauthorization of hATTR-PN:** Documentation demonstrating a positive clinical response to Amvuttra compared to baseline must be provided (e.g., improved neuropathy symptoms, motor function, quality of life; slowing of disease progression). **For reauthorization of ATTR-CM**: Documentation demonstrating a positive clinical response to Amvuttra compared to baseline must be provided (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Anzemet (dolasetron) tablet	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination**. **For Part B requests:** Must first try both oral granisetron and oral ondansetron. Refer to the Medicare Part B vs Medicare Part D Drug Request form for criteria and billing requirements.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Asceniv (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** Must first try two preferred IVIG products (e.g., Gammagard Liquid, Gamunex-C, Privigen). Refer to the Medicare Part B vs Medicare Part D Drug Request form. Additional criteria may apply as required by LCD L34771 (Immune Globulins) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Aucatzyl Bag (Obecabtagene Autoleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided. Aucatzyl follows Medicare's National Coverage Determination (NCD) Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	N/A
	Other Criteria	N/A
	Indications	N/A
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Avastin (bevacizumab) *Chemotherapy (J9035) only*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Mvasi **AND** Zirabev. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Aveed (testosterone undecanoate)	**Exclusion Criteria**	N/A
	Required Medical Information	**For hypogonadism, medical records supporting the request must be provided and include the following:** (1) Must have tried and failed (defined as an inability to improve symptoms or testosterone levels) generic testosterone cypionate or generic testosterone enanthate - AND - (2) Must have tried and failed (defined above) a generic topical testosterone therapy - AND - (3) Must have two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL or that are low as defined by the laboratory reference values - AND - (4) Must have clinical signs and symptoms consistent with testosterone deficiency other than erectile dysfunction or decreased libido (such as depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis) - AND - (5) Patient was assigned male at birth. **For gender dysphoria, medical records supporting the request must be provided and include the following:** (1) Must have tried and failed (defined as an inability to improve symptoms or testosterone levels) generic testosterone cypionate or generic testosterone enanthate - AND - (2) Must have tried and failed (defined above) a generic topical testosterone therapy.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Avsola (infliximab-axxq)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Inflectra **AND** Renflexis.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Azmiro (testosterone cypionate) *IM injection*	**Exclusion Criteria**	N/A
	Required Medical Information	**For hypogonadism, medical records supporting the request must be provided and include the following:** (1) Must have tried and failed (defined as an inability to improve symptoms or testosterone levels) generic testosterone cypionate - AND - (2) Must have two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL or that are low as defined by the laboratory reference values - AND - (3) Must have clinical signs and symptoms consistent with testosterone deficiency other than erectile dysfunction or decreased libido (such as depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis) - AND - (4) Patient was assigned male at birth. **For gender dysphoria, medical records supporting the request must be provided and include the following:** Must have tried and failed (defined as an inability to improve symptoms or testosterone levels) generic testosterone cypionate.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Benlysta IV (belimumab) *vial*	**Exclusion Criteria**	Must not be used with another biologic drug or Lupkynis.
	Required Medical Information	**For all medically-accepted indications:** Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. **For SLE Initial Coverage:** Must also have a SELENA-SLEDAI score of 6 or more before starting Benlysta - **AND** - either an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80. **For Lupus Nephritis Initial Coverage:** Must also have a confirmed diagnosis of SLE - **AND** - a kidney biopsy confirming class 3, 4, and/or 5 disease.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be a specialist in treating the condition or have consulted with a specialist.
	Coverage Duration	1 year initial coverage; 2 years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For SLE Initial Coverage:** Must be taking standard of care that includes TWO of the following drugs together for at least 12 weeks each: a steroid, immunosuppressant, hydroxychloroquine. **For SLE Reauthorization:** Must have evidence of clinical improvement since starting Benlysta. **For Lupus Nephritis Initial Coverage:** Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid). **For Lupus Nephritis Reauthorization:** Must have evidence of clinical improvement including improved or stable eGFR.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Beqvez (fidanacogene elaparvovec-dzkt)	**Exclusion Criteria**	Beqvez is not covered in patients who have received a previous treatment course of Beqvez or another adeno-associated virus vector-based gene therapy. The safety and effectiveness of repeat administration have not been evaluated.
	Required Medical Information	The following are required for approval: (1) Medical records supporting the request; AND (2) Patient has a diagnosis of moderate to severe hemophilia B (defined as a factor IX activity level less than or equal to 2 IU/dL or less than or equal to 2% of normal); **AND** (3) Patient does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test; **AND** (4) Patient has one of the following: Current use of factor IX prophylaxis therapy; **OR** Patient has current or historical life-threatening hemorrhage; **OR** Patient has had repeated, serious spontaneous bleeding episodes
	Age Restrictions	Must be at least 18 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist.
	Coverage Duration	One lifetime dose.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Bivigam (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** Must first try two preferred IVIG products (e.g., Gammagard Liquid, Gamunex-C, Privigen). Refer to the Medicare Part B vs Medicare Part D Drug Request form. Additional criteria may apply as required by LCD L34771 (Immune Globulins) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Bkemv (eculizumab-aeeb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	For NMSOD and myasthenia gravis: Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	Initial: 1 year. Reauthorization: 2 years. Dose will be approved in accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For neuromyelitis optica spectrum disorder (NMOSD):** (1) Patient has anti-aquaporin-4 (AQP4) antibody positive disease - AND - (2) Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions - AND - (3) Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna AND Enspryng - AND - (4) No use in combination with Ultomiris, Uplizna, Enspryng, or other medications for NMOSD - AND - (5) For reauthorization requests: (a) No use in combination with Ultomiris, Uplizna, Enspryng, or other medications for NMOSD; AND (b) Documentation of a decrease in relapse rate must be provided. *(continued on next page)*

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Bkemv (eculizumab-aeeb) *continued*	**Other Criteria** *(continued)*	**For myasthenia gravis:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or more - **AND** - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - **AND** - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - **AND** - (4) Trial of Vyvgart with an intolerance or inadequate response - **AND** - (5) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq. (Eculizumab has not been studied and there is no data to support use in combination with other medications used to treat MG) - **AND** - (6) For reauthorization requests: (a) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq; **AND** (b) Must have documentation of improvement in the MG-ADL total score from baseline. **For atypical hemolytic uremic syndrome (aHUS):** (1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - **AND** - (2) For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine). **For paroxysmal nocturnal hemoglobinuria (PNH):** (1) Must have diagnosis confirmed by flow cytometry – **AND** – (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – **AND** – (3) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli. (Eculizumab has not been studied and there is no data to support use in combination with other medications used for PHN) - **AND** - (4) For reauthorization requests: (a) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli; **AND** (b) Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - **AND** - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Boniva IV (ibandronate sodium)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try one generic product.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
botulinum toxins type A and type B **Botox** (onabotulinumtoxin A) **Daxxify** (daxibotulinumtoxinA-lanm) **Dysport** (abobotulinumtoxin A) **Myobloc** (rimabotulinumtoxin B) **Xeomin** (incobotulinumtoxin A)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of a covered diagnosis, dose and frequency of injections, clinical effectiveness of the injections, and specific site(s) injected.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. It is usually considered not medically necessary to give injections for spastic conditions more frequently than every 12 weeks.
	Other Criteria	(1) Review applicable Medicare National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other Medicare guidance using the Medicare Coverage Database at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. (2) Meet the following criteria based on the supported indication for the drug requested. Note that supported indications for individual botulinum toxin type A and toxin type B differ. The indications below do not indicate the requested drug is supported for the indication. It is the responsibility of providers to use each drug in accordance with the supported indications. **- 1 - Chronic anal fissures:** Must try and fail (defined as an inadequate response) conservative treatment **- 2 - Chronic migraines:** (1) Must have chronic migraines defined as a headache occurring on 15 or more days a month for more than three months, which, on at least eight days/month have the features of migraine headache - AND - (2) Must try and fail (defined as an inadequate response or intolerance) any two of the following drugs: • Antidepressants (e.g., amitriptyline, nortriptyline) • Beta blockers (e.g., propranolol, metoprolol, timolol) • Anti-epileptics (e.g., valproate, topiramate) *(continued on next page)*

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
botulinum toxins type A and type B *(continued)* **Botox** (onabotulinumtoxin A) **Daxxify** (daxibotulinumtoxinA-lanm) **Dysport** (abobotulinumtoxin A) **Myobloc** (rimabotulinumtoxin B) **Xeomin** (incobotulinumtoxin A)	**Other Criteria** *(continued)*	**- 3 - Detrusor over activity associated with a neurologic condition:** (1) Must have documentation of the underlying neurological condition that is the cause of detrusor activity (e.g., spinal cord injury or multiple sclerosis) - **AND** - (2) Must try and fail (defined as an inadequate response or intolerance) one urinary anticholinergic (e.g., oxybutynin, trospium). **- 4 - Hyperhidrosis:** (1) Must have hyperhidrosis that significantly affect patient's quality of life – **AND** – (2) Your condition cannot be controlled adequately on topical agents such as aluminum chloride (Drysol). **- 5 - For sialorrhea (excessive salivation):** Must try and fail (defined as an inadequate response or intolerance) one anticholinergic drug (e.g., glycopyrrolate, scopolamine patch, benztropine). **- 6 - Urge incontinence/overactive bladder:** Must try and fail (defined as an inadequate response or intolerance) one urinary anticholinergic (e.g., oxybutynin, trospium) – **AND** - Myrbetriq.
	Indications	Coverage is limited to the spastic conditions listed under "Codes that Support Medical Necessity" of the Billing and Coding: Botulinum Toxin Type A & Type B (A57474) article.
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Breyanzi (lisocabtagene maraleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Carvykti (ciltacabtagene autoleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Casgevy (exagamglogene autotemcel injection, suspension)	**Exclusion Criteria**	Casgevy is not covered in patients with prior HSCT or prior gene therapy.
	Required Medical Information	**FOR SICKLE CELL REQUESTS**: Before the drug is covered, the patient must meet the following requirements: (1) Medical records supporting the request must be provided; **AND** (2) Patient has a diagnosis of Sickle Cell Disease (SCD) with βS/βS, βS/β0, or βS/β+ genotype confirmed by genetic testing; **AND** (3) Patient has a history of at least 2 severe vaso-occlusive events per year in the previous 2 years; **AND** (4) Patient's current weight has been provided; **AND** (5) Patient has adequate organ function and is eligible for HSCT (stem cell transplant); **AND** (6) Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment; **AND** (7) Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine). **FOR BETA THALESSEMIA REQUEST**S: Before the drug is covered, the patient must meet the following requirements: (1) Medical records supporting the request must be provided; **AND** (2) Must have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 mL/kg/year or 10 units/year of packed red blood cells (pRBC) in the previous 2 years); **AND** (3) Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; **AND** (4) Provider attests that, in the absence of a known or available HLA-matched family donor, the patient would be otherwise clinically stable and eligible to undergo HSCT.
	Age Restrictions	Patient is at least 12 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider.
	Coverage Duration	6 months authorization duration with a limit of one dose (treatment) per lifetime.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Cimzia (certolizumab pegol)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For all medically accepted indications:** Must first try and fail (defined as an intolerance or inability to improve symptoms) two of the following drugs with a supported use for the requested condition: a preferred adalimumab product, Rinvoq, Skyrizi, Tyenne, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Yesintek/Selarsdi, or Enbrel. Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz and Hadlima.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Cinqair (reslizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs.
	Required Medical Information	(1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - **AND** - (2) Patient's current weight must be provided - **AND** - (3) For initial coverage of severe eosinophilic asthma, must have an elevated eosinophil level greater than or equal to 150 cells/mcL at therapy start - **OR** - greater than or equal to 300 cells/mcL in the previous 12 months.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	**Initial:** 2 years; **reauthorization:** 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For severe eosinophilic asthma:** (1) Must try and fail 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - **AND** - (2) For reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Cinryze (C-1 esterase inhibitor [human])	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Haegarda.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Cosentyx IV (secukinumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice
	Other Criteria	Must first try Inflectra, Renflexis **OR** Simponi Aria.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Docivyx (docetaxel) vial for intravenous injection	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try generic docetaxel (Taxotere, J9171).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Durysta (bimatoprost) *intraocular implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation or prior therapies and response to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must try two of the following: latanoprost, bimatoprost, travoprost.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Elevidys (delandistrogene moxeparvovec-rokl)	**Exclusion Criteria**	N/A
	Required Medical Information	Before the drug is covered, the patient must meet all of the following requirements: (1) Documentation of Duchenne muscular dystrophy (DMD) confirmed by genetic mutation in the DMD gene that is not a deletion in exon 8 or exon 9 - **AND** - (2) An anti-AAVrh74 titer <1:400.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist or other specialist with experience treating DMD.
	Coverage Duration	**Initial and Reauthorization:** 1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Enjaymo (sutimlimab-jome)	**Exclusion Criteria**	Must not be used in combination with biologic drugs.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - **AND** - Must provide patient's current weight - **AND** - baseline hemoglobin level.
	Age Restrictions	Must be at least 18 years old.
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist.
	Coverage Duration	Initial 6 months; Reauthorization 12 months
	Other Criteria	(1) Must have confirmed diagnosis of cold agglutinin disease (CAD) – **AND** – (2) Must have documentation of at least one blood transfusion within 6 months of starting Enjaymo – **AND** – (3) Must have 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** – (4) Must have documented trial and failure with a rituximab-containing regimen – **AND** – **For reauthorization:** Must have documented clinical benefit evidenced by an increase in Hgb level and decrease in blood transfusions compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Entyvio (vedolizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Initial coverage: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Inflectra **OR** Renflexis. **For reauthorization**: Must have a positive clinical response to Entyvio (e.g., decrease in bowel movements per day, no blood in stool, decrease in oral steroid use, decrease in inflammatory markers such as fecal calprotectin, C-reactive protein, etc.).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Epogen (epoetin alpha)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required.** For Part B, non-ESRD requests: Must first try Procrit **AND** Retacrit. Criteria will be applied consistent with LCD L34633 - Erythropoiesis Stimulating Agents (ESAs).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Epysqli (eculizumab-aagh)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	For NMSOD and myasthenia gravis: Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	Initial: 1 year. Reauthorization: 2 years. Dose will be approved in accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For neuromyelitis optica spectrum disorder (NMOSD):** (1) Patient has anti-aquaporin-4 (AQP4) antibody positive disease - AND - (2) Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions - AND - (3) Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna AND Enspryng - AND - (4) No use in combination with Ultomiris, Uplizna, Enspryng, or other medications for NMOSD - AND - (5) For reauthorization requests: (a) No use in combination with Ultomiris, Uplizna, Enspryng, or other medications for NMOSD; AND (b) Documentation of a decrease in relapse rate must be provided. (continued on next page)

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Epysqli (eculizumab-aagh) *continued*	**Other Criteria** *(continued)*	**For myasthenia gravis:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or more - **AND** - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - **AND** - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - **AND** - (4) Trial of Vyvgart with an intolerance or inadequate response - **AND** - (5) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq. (Eculizumab has not been studied and there is no data to support use in combination with other medications used to treat MG) - **AND** - (6) For reauthorization requests: (a) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq; **AND** (b) Must have documentation of improvement in the MG-ADL total score from baseline **For atypical hemolytic uremic syndrome (aHUS):** (1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - **AND** - (2) For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine). **For paroxysmal nocturnal hemoglobinuria (PNH):** (1) Must have diagnosis confirmed by flow cytometry – **AND** – (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – **AND** – (3) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli. (Eculizumab has not been studied and there is no data to support use in combination with other medications used for PHN) - **AND** - (4) For reauthorization requests: (a) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli; **AND** (b) Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - **AND** - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Erzofri (paliperidone palmitate) *extended-release injectable suspension, for intramuscular use*	**Exclusion Criteria**	N/A
	Required Medical Information	Must first try Invega Sustenna, Invega Trinza, **OR** Invega Hayfera.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	N/A
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Evenity (romosozumab-aqqg)	**Exclusion Criteria**	Cumulative use of Evenity of more than 12 months is not covered.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - **AND** - documentation confirming your diagnosis (such as the results from your bone scan)
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by endocrinologist.
	Coverage Duration	12 months per lifetime.
	Other Criteria	Must try and fail alendronate, risedronate, or ibandronate - **AND** - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, new fracture while on therapy **OR** a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Evkeeza (evinacumab-dgnb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice
	Other Criteria	Must first try Repatha (trial with Repatha is not required for children 5 through 9 years of age).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Fasenra (benralizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs
	Required Medical Information	**For initial coverage of severe eosinophilic asthma:** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - **AND -** (2) Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within 6 weeks (prior to the immediate start of treatment with Fasenra) - OR - greater than or equal to 300 cells/mcL in the previous 12 months - **AND** (3) Must try and fail 1 ICS/LABA inhaler drug in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks). **For initial coverage of eosinophilic granulomatosis with polyangiitis (EGPA):** Medical records supporting the request must be provided and include documentation that the patient has non-severe EGPA (defined as absence of life or organ-threatening manifestations).
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	**Initial:** 1 year; **reauthorization:** 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization requests for severe eosinophilic asthma**: (1) Medical records supporting the request must be provided - AND - (2) Must have documentation of clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). **For reauthorization requests for EGPA:** (1) Medical records supporting the request must be provided - AND - (2) Must have documentation of clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Fylnetra (pegfilgrastim-pbbk)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Gel-One (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
GenVisc 850 (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Granix (tbo-filgrastim)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Nivestym **AND** Zarxio.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Hemgenix (etranacogene dezaparvovec-drlb)	**Exclusion Criteria**	Hemgenix is not covered in patients who have received a previous treatment course of Hemgenix or another adeno-associated virus vector-based gene therapy. The safety and effectiveness of repeat administration have not been evaluated.
	Required Medical Information	The following is required for approval: (1) Patient has a diagnosis of moderate to severe hemophilia B (a factor IX activity level less than or equal to 2 IU/dL or less than or equal to 2% of normal); **AND** (2) Patient has one of the following: (a) Current use of factor IX prophylaxis therapy; **OR** (b) Patient has current or historical life-threatening hemorrhage; **OR** (c) Patient has had repeated, serious spontaneous bleeding episodes (3) Medical records supporting the request have been provided.
	Age Restrictions	Must be at least 18 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist.
	Coverage Duration	One lifetime dose
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Herceptin (trastuzumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Herceptin Hylecta (trastuzumab and hyaluronidase)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Hercessi (trastuzumab-strf)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Additional criteria may be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Herzuma (trastuzumab-pkrb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Hyalgen (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Hymovis (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Hympavzi (marstacimab-hncq injection, solution)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial requests for Hemophilia A:** Medical records supporting the request must be provided and include documentation of the following: (1) Hympavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Patient has moderate or severe hemophilia A (a clotting factor level <1% or between 1%-5%) without factors; AND (3) Patient has tried and failed Hemlibra. **For initial requests for Hemophilia B:** Medical records supporting the request must be provided and include documentation of the following: (1) Hympavzi is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Patient has moderate or severe hemophilia B (a clotting factor level <1% or between 1%-5%) without factors.
	Age Restrictions	Patient is at least 12 years of age
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or other specialist.
	Coverage Duration	Initial and reauth: 12 months. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization of hemophilia A and B:** (1) Patient continues to use Hympavzi for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Documentation of clinical benefit (e.g., less bleeding episodes; less use of factor VIII replacement therapy or bypassing agents) has been provided.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
iDose TR (travoprost intracameral implant)	**Exclusion Criteria**	The requested eye for treatment must not have received prior treatment with IDOSE TR.
	Required Medical Information	(1) Medical records supporting the request must be provided; AND (2) Patient has open angle glaucoma or ocular hypertension; AND (3) Patient meets one of the following (a or b): (a) Patient has tried and failed one generic topical prostaglandin eye drop such as latanoprost, bimatoprost, or travoprost - and - Durysta; OR (b) Patient is not able to use Durysta and has tried and failed two generic topical prostaglandin eye drops. Failed is defined as a trial with an inadequate response or intolerance, or a trial with demonstrated compliance issues with glaucoma eye drops.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One-time administration as indicated per the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Iheezo 3% (chloroprocaine hcl/ pf gel eye drops)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try two other topical anesthetics such as Akten (lidocaine ophthalmic gel), proparacaine ophthalmic solution, and tetracaine ophthalmic solution.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ilaris (canakinumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs.
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be a specialist or consulted with a specialist for the condition being treated.
	Coverage Duration	**Gout**: Initial coverage limited to 1 dose with authorization given for 12 weeks; and reauthorization is 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. **For all others (excludes gout):** Intial and Reauthorization 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial coverage of acute gout flares:** Must try and fail (defined as an inadequate response or intolerance to adequate and/or maximally tolerated doses) colchicine, non-steroidal anti-inflammatory drugs (NSAIDs), AND systemic corticosteroids. **For reauthorization of acute gout flares:** Patient must be established on maintenance therapy with urate-lowering agents such as allopurinol, febuxostat and/or probenecid.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ilumya (tildrakizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For all medically accepted indications:** Must first try and fail (defined as an intolerance or inability to improve symptoms) two of the following drugs with a supported use for the requested condition: a preferred adalimumab product, Rinvoq, Skyrizi, Tyenne, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Yesintek/Selarsdi, or Enbrel. *Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz and Hadlima.*
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Iluvien (fluocinolone acetonide) *intravitreal implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Imuldosa IV (ustekinumab-srlf)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - **AND** - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek AND Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
infliximab injection (excludes biosimilar, 10 mg, J1745)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Inflectra **AND** Renflexis.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Infugem (gemcitabine hcl)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try generic gemcitabine injection (Gemzar).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Ivra (melphalan hydochloride)	**Exclusion Criteria**	N/A
	Required Medical Information	Coverage requires: (1) Trial with generic melphalan IV powder for solution; and (2) Medical records supporting the request, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Izervay (avacincaptad pegol sodium/PF)	**Exclusion Criteria**	GA (geographic atrophy) secondary to a condition other than AMD (age-related macular degeneration) is not covered. Izervay must not be used in combination with Syfovre or any other medication for GA (Izervay has not been studied and there is no data to support use in combination with other medications used to treat GA).
	Required Medical Information	Medical records supporting the request must be provided. For initial requests, must also have documentation confirming the diagnosis.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with an ophthalmologist.
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Documentation showing the patient had a measurable improvement or stabilization in the condition compared to pre-treatment baseline (such as GA lesion size reduction, improved visual acuity, or improved/stable disease as seen on fundus autofluorescence or OCT) must be provided.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Kanjinti (trastuzumab-anns)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Kebilidi vial (eladocagene exuparvovec-tneq)	**Exclusion Criteria**	N/A
	Required Medical Information	Documentation must be provided confirming the following: (1) The diagnosis – AND - (2) The patient does not have high anti-AAV2 neutralizing antibodies (defined as a titer greater than 1:1200 per the clinical study or a titer that precludes use based on current clinical evidence).
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	6 months authorization with limit of 1 treatment per lifetime
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Kimyrsa (oritavancin)	**Exclusion Criteria**	N/A
	Required Medical Information	Must provide culture and sensitivity results, or If not available, must specify the suspected organism(s) being treated.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist.
	Coverage Duration	N/A
	Other Criteria	Must try all other susceptible antibiotics (e.g., vancomycin) as determined by culture and sensitivity or as indicated for empiric therapy (e.g., beta-lactam, macrolide, fluoroquinolone).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Kisunla (donanemab-azbt) *injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of registry participation and follow-up.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	6 months initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Coverage will be provided consistent with CMS's National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of ALZHEIMER's Disease (AD) which includes the following: (1) Patient is diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia; AND (2) Patient's physician is participating in a registry (attestation required).
	Indications	All FDA-approved indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Krystexxa (pegloticase)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try allopurinol. If allopurinol is contraindicated, must first try febuxostat.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Kymriah (tisagenlecleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lamzede (velmanase alfa-tycv)	**Exclusion Criteria**	Lamzede is not covered for patients with CNS disease manifestations or rapidly progressive disease, patients who cannot walk without support, and/or patients with a history of a HSCT or bone marrow transplant.
	Required Medical Information	Medical records supporting the request must be provided. For alpha-mannosidosis, documentation of the diagnosis confirmed by one of the following must also be provided: • biallelic pathogenic variants in MAN2B1 gene **OR** • enzyme assay demonstrating alpha-mannosidase activity <10% of normal activity.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a physician who specializes in the management of patients with alphamannosidosis, or in the administration of other enzyme replacement therapies for lysosomal storage disorders.
	Coverage Duration	Initial coverage and reauthorization: 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must have documentation that the patient is using Lamzede for the treatment of non-central nervous system disease manifestations (e.g. has mild to moderate disease, able to ambulate independently). **For reauthorization:** Must have documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (e.g. motor function, FVC, rate of infections, serum oligosaccharides, etc.) compared to the predicted natural history trajectory of disease; **AND** the patient continues to have an absence of exclusion criteria.
	Indications	All FDA-approved indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lantidra (donislecel-jujn solution)	**Exclusion Criteria**	N/A
	Required Medical Information	The following are required for approval: (1) Medical records supporting the request - **AND** - (2) Diagnosis of type 1 diabetes - **AND** - (3) Patient has had intensive insulin management that includes the appropriate use of a CGM (i.e., with insulin pump or with an automated insulin delivery system) - **AND** - (4) Patient has been unable to reach target HbA1c despite intensive diabetes education and insulin management due to current, repeated episodes of severe hypoglycemia defined by the ADA as Level 3 hypoglycemia (a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery, regardless of glucose level) - **AND** - (5) Lantidra must be taken with concomitant immunosuppressants - **AND** - (6) Approval of the patient's islet cell transplant must be on file prior to determination of Lantidra's use in any patient.
	Age Restrictions	Patient is at least 18 years of age.
	Prescriber Restrictions	N/A
	Coverage Duration	**Initial:** 1 infusion. **Reauthorization:** up to 2 additional infusions.
	Other Criteria	**For reauthorization:** Patient has not achieved independence from exogenous insulin within one year of infusion - or - within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion. There are no data regarding the effectiveness or safety for patients receiving more than three infusions.
	Indications	All FDA-approved indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lenmeldy (atidarsagene autotemcel)	**Exclusion Criteria**	Lenmeldy is not covered in patients who have received prior gene therapy.
	Required Medical Information	Medical records supporting the request must be provided and include the following (1 and 2): (1) Diagnosis of metachromatic leukodystrophy (MLD) confirmed by the following: - Genetic testing showing two disease-causing arylsulfatase A gene (ARSA) alleles; **AND** - ARSA enzyme activity below normal range; **AND** - In patients with novel ARSA variant(s), presence of sulfatides in a 24-hour urine collection (2) Must have one of the following MLD subtypes per the FDA-approved indication: - Pre-symptomatic late infantile (PSLI); **OR** - Pre-symptomatic early juvenile (PSEJ); **OR** - Early symptomatic early juvenile (ESEJ)
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition.
	Coverage Duration	One lifetime dose (safety and effectiveness of repeat administration have not been evaluated).
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Leqembi (lecanemab-irmb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of registry participation and follow-up.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	**Initial and reauthorization:** 6 months.Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Coverage will be provided consistent with CMS's National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of ALZHEIMER's Disease (AD) which includes the following: (1) Patient is diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia; AND (2). Patient's physician is participating in a registry (attestation required).
	Indications	All FDA-approved indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Leqvio (inclisiran)	**Exclusion Criteria**	Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet.
	Required Medical Information	Must submit most recent LDL-C level. Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist.
	Coverage Duration	**Initial Coverage:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	(1) Patient has tried Repatha and LDL-C remains greater than or equal to 70mg/dL – **AND** – (2) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70mg/dL – **OR** – (3) Patient is statin intolerant demonstrated by experiencing statin associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin - **AND** - (4) For reauthorization, documentation confirming patient has improved and maintained an improved LDL compared to baseline must be provided.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lumizyme (alglucosidase alfa)	**Exclusion Criteria**	Must not be used in combination with another ERT (e.g., Nexviazyme, Pombiliti)
	Required Medical Information	Medical records supporting the request must be provided, including the following: (1) Patient's current weight - **AND** - (2) For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician).
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have documented response to therapy evidenced by improvement or stabilization in condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lyfgenia (lovotibeglogene autotemcel suspension)	**Exclusion Criteria**	Lyfgenia is not covered in patients with prior HSCT or prior gene therapy.
	Required Medical Information	Before the drug is covered, the patient must meet the following requirements: (1) Patient has a diagnosis of Sickle Cell Disease (SCD) with βS/βS, βS/β0, or βS/β+ genotype confirmed by genetic testing; **AND** (2) Patient has a history of at least 4 severe vaso-occlusive events within the previous 2 years; **AND** (3) Patient's current weight has been provided; **AND** (4) Patient has adequate organ function and is eligible for HSCT (stem cell transplant); **AND** (5) Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment; **AND** (6) Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine).
	Age Restrictions	Patient is at least 12 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider.
	Coverage Duration	6 months authorization duration with a limit of one dose (treatment) per lifetime.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Margenza (margetuximab-cmkb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Monovisc (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Neupogen (filgrastim)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Nivestym **AND** Zarxio.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Nexviazyme (avalglucosidase alfa-ngpt)	**Exclusion Criteria**	Must not be used in combination with another ERT (e.g. Lumizyme, Pombiliti)
	Required Medical Information	Medical records supporting the request must be provided, including the following: (1) Patient's current weight - **AND** - (2) For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician).
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have a documented response to therapy evidenced by improvement or stabilization in condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Niktimvo (axatilimab-csfr)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial coverage:** (1) Trial and failure of at least two prior lines of systemic therapy; AND (2) Must follow current NCCN guidance for chronic graft versus host disease; AND (3) Must weigh at least 40 kilograms (kg); AND (4) Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Initial and reauthorization: 1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization requests**: (1) Must follow current NCCN guidance for chronic graft versus host disease; and (2) must weigh at least 40 kilograms (kg); and (3) Must have documentation of clinical benefit.
	Indications	All Medically Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Nucala (mepolizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs.
	Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. **For initial coverage of severe eosinophilic asthma:** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within 6 weeks (prior to the immediate start of treatment with Nucala) - OR - greater than or equal to 300 cells/mcL in the previous 12 months - AND - (3) Must try and fail 1 ICS/LABA inhaler drug in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks). **For reauthorization requests for severe eosinophilic asthma:** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). **For initial coverage of Hypereosinophilic Syndrome (HES):** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have a blood eosinophil count at least 1,000 cells/mcL - AND - (3) Must have had HES for at least 6 months - AND - (4) Must have had at least 2 flares of HES in the past year defined as symptoms requiring a steroid or increase in current steroid - AND - (5) The provider attests that there is NO identifiable non-hematologic secondary cause of HES - AND - (6) Must try and fail (defined as an inability to improve symptoms) a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea). **For reauthorization requests for Hypereosinophilic Syndrome (HES):** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	**Initial:** 1 year; **reauthorization:** 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. *(continued on next page)*

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Nucala (mepolizumab) *continued*	**Other Criteria**	**For initial coverage of eosinophilic granulomatosis with polyangiitis (EGPA):** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Patient has non-severe disease defined as absence of life or organ-threatening manifestations. (3) Patient has tried and failed (defined as an intolerance or inability to improve symptoms) one traditional, non-biologic immunomodulator (e.g., azathioprine, methotrexate, mycophenolate). **For reauthorization requests for eosinophilic granulomatosis with polyangiitis (EGPA):** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). **For initial coverage of chronic rhinosinusitis with nasal polyps:** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have experienced 2 or more of the following symptoms for at least 12 weeks despite management: nasal congestion or obstruction, nasal drainage, reduction or loss of smell - **AND** - (3) Must try and fail (defined as an inability to improve symptoms for least 4 weeks) with intranasal steroids - **AND** - (4) Must be used in combination with an intranasal steroid. **For reauthorization requests for chronic rhinosinusitis with nasal polyps:** (1) Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Nulojix (belatacept)	**Exclusion Criteria**	Must not be administered in the patient's home.
	Required Medical Information	N/A
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try tacrolimus **AND** cyclosporine – **AND** – Must follow LCD L33824 (Immunosuppressive Drugs) and LCA A52474 (Immunosuppressive Drugs- Policy Article). All NCDs and LCDs can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Nypozi (filgrastim-txid)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Nivestym **AND** Zarxio
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ohtuvayre (ensifentrine) *inhalation suspension*	**Exclusion Criteria**	Must not be used in combination with roflumilast.
	Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. For initial requests, medical records supporting the request must be provided and include the following: (1) Diagnosis of moderate-to-severe COPD defined as an FEV1 between 30-70% - AND - (2) Trial and failure of dual or triple therapy in the past 6 months that included a LABA/LAMA therapy (e.g., Trelegy Ellipta, Anoro Ellipta, Stiolto Respimat). Failure is defined as no improvement, worsening of the condition, or an intolerance after trying the required therapy at the maximum dosages for at least 4 weeks consistently.
	Age Restrictions	Patient is at least 18 years of age.
	Prescriber Restrictions	Prescriber is or has consulted a pulmonologist.
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization**, documentation supporting a decrease in symptoms, improvement in lung function, and/or reduced COPD exacerbations with Ohtuvayre compared to baseline must be provided.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Omvoh IV (mirikizumab-mrkz)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	Patient is at least 18 years of age
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Three induction doses (week 0, week 4 and week 8) will be covered. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For all medically accepted indications:** Must first try and fail (defined as an intolerance or inability to improve symptoms) two of the following drugs with a supported use for the requested condition: a preferred adalimumab product, Rinvoq, Skyrizi, Tyenne, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Yesintek/Selarsdi, or Enbrel.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Onpattro (patisiran)	**Exclusion Criteria**	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Amvuttra) – **AND** – Patient must not have had a liver transplant.
	Required Medical Information	(1) Medical records supporting the request must be provided – **AND** – (2) Must provide patient's current weight – **AND** – (3) Must have documentation of a transthyretin (TTR) mutation (e.g., V30M) – **AND** – (4) Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2 **- AND -** (5) Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.).
	Age Restrictions	Must be at least 18 years of age.
	Prescriber Restrictions	N/A
	Coverage Duration	1 year initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have a positive clinical response to Onpattro compared to baseline (e.g., improved neuropathy symptoms, motor function, quality of life; slowing of disease progression).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ontruzant (trastuzumab-dttb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Ogivri. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Orbactiv (oritavancin)	**Exclusion Criteria**	N/A
	Required Medical Information	Must provide culture and sensitivity results, or If not available, must specify the suspected organism(s) being treated.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist.
	Coverage Duration	N/A
	Other Criteria	Must try all other susceptible antibiotics (e.g., vancomycin) as determined by culture and sensitivity or as indicated for empiric therapy (e.g., beta-lactam, macrolide, fluoroquinolone).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Orencia IV (abatacept)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice
	Other Criteria	Must first try Inflectra **OR** Renflexis.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Orthovisc (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Otulfi IV (ustekinumab-aauz)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - **AND** - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek **AND** Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Oxlumo (lumasiran) *injection*	**Exclusion Criteria**	Coverage will not be provided in the following situations: (1) Patient has a history of kidney or liver transplant; AND (2) Patient will be using in combination with Rivfloza.
	Required Medical Information	(1) Medical records supporting the request must be provided; AND (2) Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis; AND (3) For reauthorization requests, must have documented clinical benefit with Oxlumo compared to baseline.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or urologist.
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Ozurdex (dexamethasone) *intravitreal implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Panzyga (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** Must first try two preferred IVIG products (e.g., Gammagard Liquid, Gamunex-C, Privigen). Refer to the Medicare Part B vs Medicare Part D Drug Request form. Additional criteria may apply as required by LCD L34771 (Immune Globulins) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Parsabiv (etelcalcetide)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	**Part B vs Part D** – Use the Medicare Part B vs Medicare Part D Drug Request form for criteria and billing requirements.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Pemfexy (pemetrexed, J9304)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try generic pemetrexed.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Pemrydi RTU (pemetrexed disodium), J9324 100 mg/10 mL vial	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try generic pemetrexed.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
PiaSky (crovalimab-akkz) *vial*	**Exclusion Criteria**	Patient is not receiving PiaSky in combination with another complement inhibitor for the treatment of PNH (Empaveli, Soliris, Ultomiris, Fabhalta, Voydeya).
	Required Medical Information	For initial coverage, medical records supporting the request must be provided and include the following: (1) Diagnosis confirmed by flow cytometry – AND – (2) Hemolysis-associated symptoms (thrombosis, organ dysfunction, pain, dyspnea, hemoglobin <10 g/dL etc.) – AND - (3) Patient's body weight is at least 40 kg.
	Age Restrictions	Must be at least 13 years of age.
	Prescriber Restrictions	N/A
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have documentation confirming a positive clinical response to PiaSky including a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Pombiliti (cipaglucosidase alfa-atga)	**Exclusion Criteria**	Must not be used in combination with another ERT (such as Lumizyme or Nexviazyme)
	Required Medical Information	Medical records supporting the request must be provided, including the following: (1) Patient's current weight - **AND** - (2) For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing
	Age Restrictions	Must be at least 18 years old.
	Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician).
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must be used in combination with Opfolda. For reauthorization, must also have documented response to therapy evidenced by improvement or stabilization in the condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Pyzchiva IV (ustekinumab-ttwe)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek **AND** Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Qalsody (tofersen)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided including the following: (1) Documentation confirming the diagnosis; and (2) Documentation confirming the superoxide dismutase 1 (SOD1) gene mutation; and (3) Documentation of the patient's baseline neurofilament light chain (NfL) level
	Age Restrictions	Must be 18 years of age or older
	Prescriber Restrictions	Must be prescribed by a neurologist
	Coverage Duration	**Initial and reauthorization:** 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial approval:** Must have weakness associated with ALS – AND - Must have a vital capacity ≥50% (or ≥45% if the vital capacity has been stable defined as not declining more than 5% in the previous 6 months). **For reauthorization:** Must have documentation of a decrease in plasma neurofilament light chains from baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Qfitla (fitusiran injection, solution)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial requests for Hemophilia A:** Medical records supporting the request must be provided and include documentation of the following: (1) Qfitlia is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Patient has moderate or severe hemophilia A (a clotting factor level <1% or between 1%-5%) without factors; AND (3) Patient has tried and failed Hemlibra. **For initial requests for Hemophilia B:** Medical records supporting the request must be provided and include documentation of the following: (1) Qfitlia is being used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Patient has moderate or severe hemophilia B (a clotting factor level <1% or between 1%-5%).
	Age Restrictions	Patient is at least 12 years of age
	Prescriber Restrictions	Prescribed by a hematologist or other specialist.
	Coverage Duration	Initial and reauthorization: 1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization of hemophilia A and B:** (1) Patient continues to use Qfitlia for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND (2) Documentation of clinical benefit (e.g., less bleeding episodes; less use of factor VIII replacement therapy or bypassing agents) has been provided.
	Indications	All Medically Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Qutenza (capsaicin) *8% patch*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For diabetic peripheral neuropathy of the feet:** Must try and fail (defined as an inadequate response or intolerance) two of the following generic medications, each from a different class: lidocaine 5% patch, duloxetine, venlafaxine, pregabalin, gabapentin, or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline). **For postherpetic neuralgia:** Must try and fail (defined as an inadequate response or intolerance) two of the following generic medications: lidocaine 5% patch, pregabalin, gabapentin, or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Quzyttir (cetirizine) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try injectable diphenhydramine and injectable hydroxyzine.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Reblozyl (luspatercept-aamt) vial for injection	**Exclusion Criteria**	Must not be used in combination with imetelstat (Reblozyl has not been studied and there is no data to support use in combination with imetelstat [Rytelo]).
	Required Medical Information	**For Beta Thalassemia initial coverage, documentation to support the following is required:** (1) Use of Reblozyl for the treatment of anemia in an adult with beta thalassemia who requires regular blood transfusions defined as at least 6 red blood cell (RBC) units in the previous 24 weeks (6 months) prior to Reblozyl - **AND** - (2) The patient's current weight. **For Myelodysplastic Syndrome initial coverage, documentation to support the following is also required:** (1) Use of Reblozyl for very low- to intermediate-risk myelodysplastic syndromes as defined by IPSS-R risk score - AND - (2) The patient's current weight - AND - (3) Use of Reblozyl follows current National Comprehensive Cancer Network (NCCN) Guidelines.
	Age Restrictions	Patient is at least 18 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist or oncologist.
	Coverage Duration	Initial and reauthorization: 1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For Beta Thalassemia reauthorization, documentation to support the following is required:** (1) Patient's current weight - AND - (2) Patient is receiving benefit from therapy defined as achieving or maintaining a reduction in red blood cell transfusion burden. **For Myelodysplastic Syndrome reauthorization, documentation to support the following is required:** (1) Patients current weight - AND - (2) Response and continued use of Reblozyl follows current National Comprehensive Cancer Network (NCCN) Guidelines
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rebyota (fecal microbiota, live-jslm)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 treatment course per FDA label and/or accepted standards of medical practice.
	Other Criteria	Must have been treated for 2 recurrent CDI episodes – **AND** – Must have tried Dificid (fidaxomicin) **AND** vancomycin.
	Indications	FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Releuko (filgrastim-ayow)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Nivestym **AND** Zarxio.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Remicade (infliximab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Inflectra **AND** Renflexis.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Rethymic (allogeneic processed thymus tissue–agdc)	**Exclusion Criteria**	Rethymic is not covered for the treatment of severe combined immunodeficiency (SCID).
	Required Medical Information	Before the drug is covered, medical records supporting the request must be provided and include confirmation of the diagnosis of congenital athymia by a specialist for this condition (such as a pediatric immunologist).
	Age Restrictions	FDA-Approved age
	Prescriber Restrictions	Must be prescribed by a specialist for the condition.
	Coverage Duration	6 months authorization period with a limit of one dose/treatment for the life of member. **Reauthorization:** N/A.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Retisert (fluocinolone acetonide) *intravitreal implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try and fail Ozurdex **AND** Yutiq. For reauthorization, must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Revcovi (elapegademase-lvlr injection)	**Exclusion Criteria**	N/A
	Required Medical Information	Must provide the following: (1) Trough plasma ADA activity, (2) trough dAXP levels, (3) patient's current weight, (4) requested dose, and (5) medical records supporting the request.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	**Initial coverage:** 1 year. **Reauthorization:** 2 years.
	Other Criteria	Provider attestation that treatment will follow FDA-approved labeling with dose adjusted to maintain trough ADA activity over 30 mmol/hr/L, trough dAXP level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rezzayo (rezafungin acetate)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records - and - culture & sensitivities must be provided that support the patient has limited or no alternative options for the treatment of candidemia and invasive candidiasis.
	Age Restrictions	Must be 18 years or older.
	Prescriber Restrictions	N/A
	Coverage Duration	Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Riabni (rituximab-arrx)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Truxima **AND** Ruxience. For chemotherapy requests, criteria will also be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rituxan (rituximab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Truxima **AND** Ruxience. For chemotherapy requests, criteria will also be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Rituxan Hycela (rituximab/ hyaluronidase)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Truxima **AND** Ruxience. For chemotherapy requests, criteria will also be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rivfloza (nedosiran injection, solution)	**Exclusion Criteria**	Coverage will not be provided in the following situations: (1) Patient has a history of kidney or liver transplant; AND (2) Patient will be using in combination with Oxlumo.
	Required Medical Information	(1) Medical records supporting the request must be provided; AND (2) Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis; AND (3) Must have preserved kidney function with an estimated glomerular filtrate rate (eGFR) of 30 mL/min/1.73m2 or more; AND (4) For reauthorization requests, must have documented clinical benefit with Rivfloza compared to baseline.
	Age Restrictions	Patient is at least 9 years of age.
	Prescriber Restrictions	Prescribed by or in consultation with a nephrologist or urologist.
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Rivfloza vials are only covered for children 9 to 11 years old weighing less than 50 kilograms per the FDA-approved labeling.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Roctavian (valoctocogene roxaparvovc-rvox)	**Exclusion Criteria**	(1) Patient must not have any detectable antibodies to adeno-associated virus serotype 5 (AAV5) – AND - (2) Patient must not have any FVIII inhibitors.
	Required Medical Information	Medical records supporting the request must be provided and include documentation of the following: (1) Patient's current weight – AND - (2) Confirmatory diagnosis of severe hemophilia A with a factor VIII activity level showing < 1 IU/dL
	Age Restrictions	Must be 18 years of age or older.
	Prescriber Restrictions	N/A
	Coverage Duration	One lifetime dose in accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Rolvedon (eflapegrastim-xnst)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ryoncil (remestemcel-L-rknd)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial requests for aGVHD:** Medical records supporting the request must be provided and include the following: (1) Patient has diagnosis of grade B–D aGVHD with symptoms involving skin, liver, and/or GI tract (excluding skin-only grade B aGVHD); AND (2) Patient has steroid refractory disease (progression within 3 days or no improvement within 7 days of consecutive treatment with 2 mg/kg/day of methylprednisolone or equivalent); AND (3) Patients over 12 years of age must have documented failure or intolerance with Jakafi.
	Age Restrictions	Must be at least 2 months to 17 years of age
	Prescriber Restrictions	Must be prescribed by, or in consultation with, an oncologist, hematologist, or other qualified specialist
	Coverage Duration	Initial: 4 weeks (8 doses). Reauthorization: 4 weeks (8 doses)
	Other Criteria	**For Reauthorization of aGVHD:** (1) Patient has partial response (organ improvement of ≥1 stage without worsening of any other organ), or mixed response (improvement in ≥1 organ stage with worsening in another), or aGVHD flare (grade B–D progression after achieving complete response); AND (2) Documentation showing symptom improvement while on therapy has been provided.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ryplazim (plasminogen, human-tvmh)	**Exclusion Criteria**	N/A
	Required Medical Information	Must have documentation of a baseline plasminogen activity level ≤45% - **AND** –patient's current weight – **AND** - genetic testing confirming diagnosis of PLGD type 1.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist.
	Coverage Duration	12 weeks initial; 12 months reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial approval:** Must have documented lesions (external and/or internal) – **AND** – symptoms consistent with disease. **For reauthorization:** Must have documentation of improvement in the number and/or size of lesions.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rystiggo (rozanolixizumab-noli)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Zilbrysq. (Rystiggo has not been studied and there is no data to support use in combination with other medications used to treat MG)
	Required Medical Information	**For initial coverage, must have:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 3 – AND - (2) Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive or anti-muscle-specific tyrosine kinase [MuSK] anti-body positive - AND - (3) Trial of 1 non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance **For initial and reauthorization:** Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For Reauthorization**: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Saphnelo (anifrolumab-fnia)	**Exclusion Criteria**	Must not be used with another biologic drug (e.g., Benlysta) or Lupkynis.
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a rheumatologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For systemic lupus erythematosus (SLE):** (1) Must have tried and failed (defined as an inability to taper the steroid dose and/or have frequent relapses) two of the following in combination: steroid, immunosuppressant, and/or hydroxychloroquine; (2) Must have tried and failed (defined above) Benlysta; (3) Must have a baseline SELENA-SLEDAI score of 6 or more; and (4) for reauthorization, must have documentation of clinical benefit compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Selarsdi IV (ustekinumab-aekn)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For Crohn's disease:** Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Signifor LAR (pasireotide)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For acromegaly**: Must first try Sandostatin LAR. **For Cushing's syndrome**: Must first try ketoconazole.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Simponi Aria (golimumab) *IV*	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Inflectra **OR** Renflexis.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Sivextro (tedizolid)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try all other susceptible antibiotics as determined by culture and sensitivity.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Skyrizi IV (risankizumab-rzaa) *600 mg/10 mL vial*	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Three IV induction will be approved. Subsequent maintenance doses must be approved under the pharmacy benefit.
	Other Criteria	**For Crohn's disease:** Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). **For Ulcerative Colitis:** Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Skysona (elivaldogene autotemcel)	**Exclusion Criteria**	Must not have history of hematopoietic stem cell transplant (HSCT) – and – must not have had previous gene therapy for any diagnosis.
	Required Medical Information	For approval, the following documentation must be provided: (1) Medical records supporting the request, including any imaging or tests. (2) Genetic testing confirming ABCD1 mutation (3) Early, active cerebral adrenoleukodystrophy (CALD) confirmed by the following: (a) Elevated very long chain fatty acids (VLCFA) values; and (b) Active, CNS disease established by central radiographic review of brain MRI demonstrating: (i) Loes score equal to or between 0.5 and 9 on the 34-point scale (ii) Gadolinium enhancement on MRI of demyelinating lesions (4) Neurologic Function Score (NFS) less than or equal to 1
	Age Restrictions	Must be 4 to 17 years of age.
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist, hematologist/oncologist, or transplant specialist
	Coverage Duration	One lifetime dose (safety and effectiveness of repeat administration have not been evaluated).
	Other Criteria	For approval, the following must be met: (1) Patient must be assigned male at birth – **AND** – (2) Patient does NOT have hepatitis B – **AND** – (3) Patient is NOT HIV positive – **AND** – (4) Transplant specialist has attested that the patient does not have a known or available HLA-matched family donor – and – the patient would otherwise be clinically stable and eligible to undergo myeloablative conditioning and HSCT
	Indications	FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Soliris (eculizumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	For NMSOD and myasthenia gravis: Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For neuromyelitis optica spectrum disorder (NMOSD):** (1) Patient has anti-aquaporin-4 (AQP4) antibody positive disease - **AND** - (2) Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions - **AND** - (3) Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna **AND** - (4) Patient has tried and failed (defined above) Enspryng - **AND** - (5) Must have an Expanded Disability Status Scale (EDSS) score of ≤7 - **AND** - (6) Soliris will not be used in combination with Ultomiris, Uplizna, Enspryng, or other medications to treat neuromyelitis optica spectrum disorder (NMOSD) - **AND** - (7) For reauthorization requests: (a) Soliris will not be used in combination with Ultomiris, Uplizna, Enspryng, or other medications for neuromyelitis optica spectrum disorder (NMOSD); **AND** (b) documentation of a decrease in relapse rate must be provided. *(continued on next page)*

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Soliris (eculizumab) *continued*	**Other Criteria** *(continued)*	**For myasthenia gravis:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or more - **AND** - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - **AND** - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - **AND** - (4) Trial of Vyvgart with an intolerance or inadequate response - **AND** - (5) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq. (Soliris has not been studied and there is no data to support use in combination with other medications used to treat MG) - **AND** - (6) For reauthorization requests: (a) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq; **AND** (b) Must have documentation of improvement in the MG-ADL total score from baseline. **For atypical hemolytic uremic syndrome (aHUS):** (1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - **AND** - (2) For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine). **For paroxysmal nocturnal hemoglobinuria (PNH):** (1) Must have diagnosis confirmed by flow cytometry – **AND** – (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – **AND** – (3) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli. (Soliris has not been studied and there is no data to support use in combination with other medications used for PHN) - **AND** - (4) For reauthorization requests: (a) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli; **AND** (b) Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - **AND** - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Spevigo (spesolimab-sbzo) 450 MG/7.5 ML VIAL	**Exclusion Criteria**	Must not be used in combination with other biologic or targeted DMARDS or with Otezla.
	Required Medical Information	**For GPP requests:** (1) Medical records supporting the request must be provided; **AND** (2) Patient has a diagnosis of generalized pustular psoriasis (GPP) confirmed by a skin biopsy, presence of systemic symptoms such as fever and fatigue, **AND** relapsing episodes (history of GPP flares); **AND** (3) Patient is experiencing a GPP flare of moderate-to-severe intensity defined by all the following (a, b, c, and d): (a) a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or more; (b) New or worsening pustules; (c) a GPPPGA pustulation sub-score of 2 or more; and (d) 5% of more of body surface area (BSA) with erythema and pustules; **AND** (4) Must first try and fail (defined as an inability to improve flares) one traditional non-biologic immunomodulator drug or a generic retinoid (ex: cyclosporine, acitretin, isotretinoin); **AND** (5) Must try and fail (defined above) a biologic DMARD with evidence for use in GPP (ex: infliximab).
	Age Restrictions	Must be age 12 or older
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	**Initial:** 12 weeks. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Spinraza (nusinersen sodium)	**Exclusion Criteria**	N/A
	Required Medical Information	For initial requests: (1) Confirmation of spinal muscular atrophy (SMA) by genetic testing; and (2) documentation supporting a trial and failure with Evrysdi.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Documentation of a positive response to therapy compared to the predicted natural history and progression.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Spravato (esketamine)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial requests for the treatment of Major Depressive Disorder with acute suicidal ideation:** (1) Medical records supporting the request must be provided; **AND** (2) Spravato must be used in combination with an oral antidepressant. **For initial requests for the diagnosis of Treatment-Resistant Depression:** (1) Medical records supporting the request must be provided; **AND** (2) Must try and fail 2 different generic antidepressants of an adequate dose, each from a different class, for at least 6 weeks; **AND** (3) Must try and fail one augmentation therapy of an adequate dose for at least 6 weeks (augmentation therapy includes but is not limited to lithium, antipsychotics, or anticonvulsants).
	Age Restrictions	Must be at least 18 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a psychiatrist.
	Coverage Duration	**Acute suicidal ideation**: 6 month authorization period with a limit of 4 weeks of treatment (safety and efficacy of use beyond the initial 4 weeks has not been established). **TRD**: 6 months initial and 1 year reauth. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization for Treatment-Resistant Depression:** Must have documentation supporting an improvement in depression symptoms compared to baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Stelara IV (ustekinumab) *130 mg/26 ml vial*	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - **AND** - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek AND Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Steqeyma IV (ustekinumab-stba)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - **AND** - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek AND Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Stimufend (Pegfilgrastim-FPGK)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Supprelin LA (histrelin acetate) *implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Lupron.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Susvimo (ranibizumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Baseline Best-Corrected Visual Acuity (BCVA) score must be provided – **AND** – Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial coverage:** Must try and be unable to continue Lucentis. **For reauthorization:** Must have disease response indicated by stable or improved BCVA score compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Syfovre (pegcetacoplan intravitreal injection)	**Exclusion Criteria**	GA (geographic atrophy) secondary to a condition other than AMD (age-related macular degeneration) is not covered. Must not be used in combination with Izervay or any other medication for GA (Syfovre has not been studied and there is no data to support use in combination with other medications used to treat GA).
	Required Medical Information	Medical records supporting the request must be provided. For initial coverage, must also have documentation confirming the diagnosis.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with an ophthalmologist.
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dosing is limited to a frequency of every 60 days.
	Other Criteria	**For reauthorization:** Documentation showing the patient has had measurable improvement or stabilization in the condition compared to pre-treatment baseline (such as GA lesion size reduction, improved visual acuity, or improved/stable disease as seen on fundus autofluorescence or OCT) must be provided.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Synojoynt (hyaluronan or derivative) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Synvisc/Synvisc One (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Tecartus (brexucabtagene autoleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tepezza (teprotumumab-trbw)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try a systemic corticosteroid for at least 4 weeks.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Testopel (testosterone) *implant*	**Exclusion Criteria**	N/A
	Required Medical Information	**For hypogonadism, medical records supporting the request must be provided and include the following:** (1) Must have tried and failed (defined as an inability to improve symptoms or testosterone levels) generic testosterone cypionate or generic testosterone enanthate - AND - (2) Must have tried and failed (defined above) a generic topical testosterone therapy - AND - (3) Must have two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL or that are low as defined by the laboratory reference values - AND - (4) Must have clinical signs and symptoms consistent with testosterone deficiency other than erectile dysfunction or decreased libido (such as depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis) - AND - (5) Patient was assigned male at birth. **For gender dysphoria, medical records supporting the request must be provided and include the following:** (1) Must have tried and failed (defined as an inability to improve symptoms or testosterone levels) generic testosterone cypionate or generic testosterone enanthate - AND - (2) Must have tried and failed (defined above) a generic topical testosterone therapy.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tezspire (tezepelumab-ekko)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	**Initial:** 1 year; **reauthorization:** 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For asthma:** (1) Must try and fail with 1 ICS/LABA inhaler drug in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - **AND** - (2) For reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use)
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Tofidence (tocilizumab-bavi) vial for intravenous injection Biosimilar to ACTEMRA® (tocilizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Tyenne.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tremfya IV (guselkumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Three IV induction doses will be approved in accordance with the FDA-approved labeling. Subsequent maintenance doses must be approved under the pharmacy benefit.
	Other Criteria	**For all medically accepted indications:** Must first try and fail (defined as an intolerance or inability to improve symptoms) two of the following drugs with a supported use for the requested condition: a preferred adalimumab product, Rinvoq, Skyrizi, Tyenne, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Yesintek/Selarsdi, or Enbrel. Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz and Hadlima. Alternatives with a supported use for ulcerative colitis currently include Skyrizi, Yesintek/Selarsdi, adalimumab, Xeljanz/XR, and Rinvoq.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Triluron (hyaluronan/hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Trivisc (hyaluronan/hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tyenne IV (tocilizumab-aazg) vial for intravenous injection Biosimilar to ACTEMRA® (tocilizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	For all medically-accepted indications (except cytokine release syndrome, giant cell arteritis, and treatment of COVID-19): Must first try Inflectra **OR** Renflexis.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tyvaso (treprostinil) inhalation	**Exclusion Criteria**	N/A
	Required Medical Information	**Part B vs Part D determination required.** Refer to the Medicare Part B vs Medicare Part D Drug Request form.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	**For PAH**: 2 years initial and reauthorization. **For PH-ILD:** 1 year initial and 2 years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization of PAH:** Documentation supporting the patient has had a positive clinical response to Tyvaso compared to baseline must be provided. **For reauthorization of PH-ILD:** Documentation supporting that patient has had a positive clinical response that includes an improved 6MWT compared to baseline must be provided.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Tzield (teplizumab-mzww) vial	**Exclusion Criteria**	Must not have a history of type 2 diabetes.
	Required Medical Information	Medical records supporting the request must be provided, including autoantibody test results – AND – Must provide patient's current weight.
	Age Restrictions	Must be 8 years of age or older.
	Prescriber Restrictions	Must be prescribed by, or in consultation with, an endocrinologist.
	Coverage Duration	One, 14-day course in accordance with the FDA-approved labeling.
	Other Criteria	For approval, the following must be met:
	Indications	FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Udenyca (pegfilgrastim-cbqv)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ultomiris (ravulizumab-cqvz)	**Exclusion Criteria**	N/A
	Required Medical Information	**For neuromyelitis optica spectrum disorder (NMOSD):** (1) Patient has anti-aquaporin-4 (AQP4) antibody positive disease; **AND** (2) Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND** (3) Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna; **AND** (4) Patient has tried and failed (defined above) Enspryng; **AND** (5) Ultomiris will not be used in combination with Soliris, Uplizna, Enspryng, or other medications for NMOSD; **AND** (6) Must have an Expanded Disability Status Scale (EDSS) score of ≤7; **AND** (7) Medical records supporting the request must be provided; **AND** (8) For reauthorization: Ultomiris must not be used in combination with Soliris, Uplizna, Enspryng, or other medications for neuromyelitis optica spectrum disorder (NMOSD); AND Documentation of a decrease in relapse rate must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	For NMSOD: Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	1 year (initial); 2 years (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For myasthenia gravis:** (1) Must have a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more; **AND** (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive; **AND** (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance; **AND** (4) Trial of Vyvgart with an intolerance or inadequate response; **AND** (5) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soliris, Rystiggo, or Zilbrysq. (Ultomiris has not been studied and there is no data to support use in combination with (6) Medical records supporting the request must be provided; AND (7) For reauthorization, must have documentation of improvement in the MG-ADL total score from baseline - AND - must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soliris, Rystiggo, or Zilbrysq. (continued on next page)

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ultomiris (ravulizumab-cqvz) *(continued)*	**Other Criteria** *(continued)*	**For atypical hemolytic uremic syndrome (aHUS):** (1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must **For paroxysmal nocturnal hemoglobinuria (PNH):** (1) Must have diagnosis confirmed by flow cytometry; AND (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain); AND (3) Must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli. (Ultomiris has not been studied and there is no data to support use in combination with other medications used for PHN); AND (4) Medical records supporting the request must be provided; AND (5) For reauthorization: Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - AND - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline - AND - must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Uplizna (inebilzumab-cdon)	**Exclusion Criteria**	N/A
	Required Medical Information	**For neuromyelitis optica spectrum disorder (NMOSD):** (1) Medical records supporting the request must be provided - AND - (2) Must first try rituximab AND Enspryng. **For IgG4 Related Disease (IgG4-RD) initial requests:** (1) Medical records supporting the request must be provided - AND - (2) Must have a confirmed diagnosis of IgG4-RD - AND - (3) Must have tried and failed glucocorticoids (including resistance to or inability to reduce dose sufficiently) - AND - (4) Must have tried and failed rituximab - AND - (5) Must not be used in combination with rituximab, Soliris, Ultomiris, or other therapies for the condition.
	Age Restrictions	N/A
	Prescriber Restrictions	**For IgG4 Related Disease:** Must be prescribed or in consultation with a specialist for the condition.
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For IgG4 Related Disease (IgG4-RD) reauthorization requests:** (1) Medical records supporting the request must be provided - AND - (2) Must not be used in combination with rituximab, Soliris, Ultomiris, or other therapies for the condition - AND - (3) Must have documentation demonstrating a decrease in the number of disease flares.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
ustekinumab IV (unbranded)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek **AND** Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
ustekinumab-ttwe IV	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek **AND** Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vegzelma (bevacizumab-abcd)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Mvasi **AND** Zirabev. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ventavis (iloprost) inhalation	**Exclusion Criteria**	N/A
	Required Medical Information	**Part B vs Part D determination required.** Refer to the Medicare Part B vs Medicare Part D Drug Request form. **For initial coverage of PAH (WHO Group 1):** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - (2) Must have confirmation of diagnosis by right heart catheterization - AND - (3) Must have a trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND endothelin receptor antagonist (e.g., ambrisentan or bosentan).
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization of PAH:** Documentation supporting the patient has had a positive clinical response to Ventavis compared to baseline must be provided.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Veopoz (pozelimab-bbfg) *400 MG/2 ML vial*	**Exclusion Criteria**	Must not be used in combination with eculizumab.
	Required Medical Information	Medical records supporting the request must be provided and include the following: (1) clinical diagnosis of CHAPLE disease that includes symptoms of the condition (such as diarrhea, vomiting, abdominal pain, etc.) and a low serum albumin; (2) confirmation of CD55 loss-of function mutation by genetic testing; (3) baseline serum albumin; and (4) patient's current weight.
	Age Restrictions	Must be at least 1 year of age
	Prescriber Restrictions	Must be prescribed by or in consultation with hematologists, gastroenterologists, or those who specialize in rare genetic hematologic diseases
	Coverage Duration	**Initial:** 1 year; **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization**, documentation of a positive clinical response must be provided.
	Indications	All FDA-Approved indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vibativ (telavancin)	**Exclusion Criteria**	N/A
	Required Medical Information	Must provide culture and sensitivity results, or If not available, must specify the suspected organism(s) being treated.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist.
	Coverage Duration	N/A
	Other Criteria	Must try all other susceptible antibiotics (e.g., vancomycin) as determined by culture and sensitivity or as indicated for empiric therapy (e.g., beta-lactam, macrolide, fluoroquinolone).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Visco-3 (hyaluronan/hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, **OR** Supartz FX. Additional criteria may apply as required by LCD L39529 (Intraarticular Knee Injections of Hyaluronan) found at: https://www.cms.gov/medicare-coverage-database/search.aspx.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vivimusta IV (Bendamustine)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try two of the following: J9033, J9034, J9036 (inj., treanda, inj., bendeka or inj. belrapzo/bendamustine). Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyalev (foscarbidopa and foslevodopa) *injection, for subcutaneous use*	**Exclusion Criteria**	N/A
	Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. Vyalev falls under the Local Coverage Determination (LCD) L33374 External Infusion Pumps. Vyalev also requires medical records to support the request, including documentation of the following: (1) Patient has levodopa-responsive advanced PD with clearly defined "on" periods; AND (2) Patient is receiving optimal carbidopa/levodopa therapy; AND (3) Patient has persistent motor fluctuations despite therapy with the following: levodopa or levodopa-carbidopa AND one other class of anti-Parkinson's therapy including dopamine agonists (e.g. pramipexole, ropinirole), MAO-B inhibitors (e.g. rasagiline, selegiline), COMT inhibitors (e.g. entacapone).
	Age Restrictions	Patient is at least 18 years of age
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	**Initial:** 1 year. **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Documentation of positive clinical response to Vyalev therapy.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyepti (eptinezumab-jjmr)	**Exclusion Criteria**	Must not be used in combination with other CGRP antagonist therapy
	Required Medical Information	**For initial requests:** (1) Medical records supporting the request must be provided; AND (2) Patient must be evaluated for and determined not to have medication overuse headache (MOH); (3) must first try 2 of the following for at least 3 months each and be unable to adequately reduce migraine headaches: Aimovig, Nurtec ODT, and/or Emgality.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	6 months initial coverage; 2 years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice
	Other Criteria	**For reauthorization:** Must provide evidence of clinical improvement including a reduction in monthly migraine days compared to baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyjuvek Gel topical (beremagene geperpavec-svdt)	**Exclusion Criteria**	Patients with any of the following will not be approved for coverage: (1) Current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; **OR**, (2) Active infection in the area to be treated; **OR,** (3) Skin graft in the past 3 months.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of a diagnosis of DEB and documentation of genetic testing confirming mutation(s) in the COL7A1 gene.
	Age Restrictions	Patient is at least 6 months of age.
	Prescriber Restrictions	Prescribed by or in consultation with a dermatologist who specializes in DEB management
	Coverage Duration	6 months initial and reauthorization
	Other Criteria	**Initial**: Must have presence of open DEB skin wounds - **AND** - application is limited to open DEB skin wounds only. **Reauthorization**: Clinical documentation must be provided to confirm that initial criteria are met and that the Vyjuvek is providing clinical benefit (e.g. complete wound closure, decrease in wound size, increase in granulation tissue).
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyvgart (efgartigimod alfa-fcab)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Rystiggo, or Zilbrysq. (Vyvgart has not been studied and there is no data to support use in combination with other medications used to treat MG)
	Required Medical Information	**For initial coverage, must have:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 5 - **AND** - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - **AND** - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - **AND** - (4) Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	**Exclusion Criteria**	Must not be used in combination with similar therapies for the requested condition including immune globulins, Soliris, Ultomiris, Rystiggo, or Zilbrysq.
	Required Medical Information	**For initial coverage of Myasthenia Gravis (MG), documentation of the following is required:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 5 - AND - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - AND - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - AND - (4) Medical records supporting the request. **For initial coverage of chronic inflammatory demyelinating polyneuropathy (CIDP), documentation of the following is required:** (1) Confirmed diagnosis by electrodiagnostic testing - AND - (2) Trial and failure with an intravenous immune globulin (IVIG) or subcutaneous immune globulin (SCIG) product (failure is defined as inability to improve the condition) - AND - (3) Medical records supporting the request.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization of myasthenia gravis:** Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Wezlana IV (ustekinumab-auub)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Yesintek **AND** Selarsdi.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Winrevair (sotatercept-csrk)	**Exclusion Criteria**	N/A
	Required Medical Information	For initial requests, documentation of the following is required: (1) Must have a confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1, by right heart catheterization; **AND** (2) Must have WHO functional class II or III symptoms; **AND** (3) Must have tried and failed (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) **AND** an endothelin receptor antagonist (e.g., ambrisentan or bosentan); **AND** (4) Winrevair will be initiated as add on therapy to at least 2 other PAH agents (e.g. ERA, PDE5i, prostaglandins).
	Age Restrictions	Patient is at least 18 years of age.
	Prescriber Restrictions	Must be prescribed by or in consultation with a specialist for the condition.
	Coverage Duration	**Initial:** 1 year; **Reauthorization:** 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization requests:** Documentation must be provided demonstrating that the patient has had a beneficial response to Winrevair compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, or 6MWD.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xenleta (lefamulin)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try all other susceptible antibiotics as determined by culture and sensitivity (e.g., moxifloxacin, azithromycin, doxycycline, linezolid).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xenpozyme (olipudase-alfa-rpcp) *20 MG VIAL*	**Exclusion Criteria**	Patient must not have ASMD Type A.
	Required Medical Information	Must provide medical records supporting the request and patient's current weight and height. For initial coverage, must also provide the following: (1) Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B (2) Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls) (3) Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO) and splenomegaly (4) Baseline DLCO
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist familiar with the treatment of lysosomal storage disorders.
	Coverage Duration	**Initial coverage and reauthorization:** 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Documentation of a clinical response to therapy compared to pretreatment baseline in one or more of the following: reduction in spleen or liver volume, improvement in lung function (e.g., DLCO) or improvement in symptoms (shortness of breath, fatigue, etc.).
	Indications	FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xgeva (denosumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Doses will be approved according to the FDA- approved labeling or within accepted standards of medical practice.
	Other Criteria	For all medically-accepted indications except bone metastases from breast, prostate, and lung cancer: Must first try zoledronic acid (generic Zometa)
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xolair (omalizumab) vial/prefilled syringe	**Exclusion Criteria**	Must not be used in combination with other biologic drugs (e.g., Dupixent, Nucala, Fasenra).
	Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. **For initial coverage of asthma:** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have tried and failed 1 ICS/LABA inhaler in combination with 1 other asthma controller drug in the past 6 months (failed is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks); AND (3) Must provide patient's current weight and baseline IgE level - AND - (4) A baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels) - AND - (5) A baseline (defined above) positive skin test or in vitro reactivity to a perennial aeroallergen. **For reauthorization requests for asthma:** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must provide patient's current weight and baseline IgE level - AND - (2) Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). **For initial coverage of chronic urticaria:** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Patient has a confirmed diagnosis of chronic urticaria defined as urticaria occurring for more than 6 weeks - AND - (3) Must try and fail (defined as inability to improve symptoms) with at least two H1 antihistamines (e.g., levocetirizine, desloratadine) - OR - one H1 antihistamine and at least 1 of the following: H2 antihistamine (e.g., famotidine), oral steroid, or leukotriene modifier. **For reauthorization requests for chronic urticaria:** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).
	Age Restrictions	N/A

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DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xolair (omalizumab) vial/prefilled syringe *(continued)*	**Prescriber Restrictions**	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	1 year initial and reauth for food allergy; 1 year initial and 2 years reauth for all others. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial coverage of nasal polyps:** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Patient has a baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels) - AND - (3) Must try and fail (defined as an inability to improve symptoms for least 4 weeks) intranasal steroids - AND - (4) Must be used in combination with an intranasal steroid - AND - (4) Must provide patient's current weight and baseline IgE level. **For reauthorization requests for nasal polyps:** (1) Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided - AND - (2) Must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use) - AND - (3) Must provide patient's current weight and baseline IgE level - AND - (4) Must continue to be used in combination with an intranasal steroid **For initial coverage of food allergy:** (1) Medical records supporting the request must be provided - AND - (2) Patient has a diagnosis of an IgE-mediated food allergy confirmed by both a positive in vitro test for IgE to the specified foods AND a positive skin prick test to the specified foods - AND - (3) Patient has a clinical history of a significant allergic reaction to the specified foods - AND - (4) Patient has a baseline IgE level of at least 30 IU/mL - AND - (5) Xolair must be used in conjunction with a food allergen-avoidant diet - AND - (6) Patient's current weight and baseline IgE level have been provided - AND - (7) Patient is at least 1 year of age. **For reauthorization requests for food allergy:** (1) Medical records supporting the request must be provided - AND - (2) Xolair must continue to be used in conjunction with a food allergen-avoidant diet - AND - (3) The patient's current weight and baseline IgE level must be provided.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Yescarta (axicabtagene ciloleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Yesintek IV (ustekinumab-kfce)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One-time induction dose. Doses are approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For Crohn's disease:** Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Yupelri (revefenacin)	**Exclusion Criteria**	N/A
	Required Medical Information	(1) Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit.
	Age Restrictions	
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice
	Other Criteria	Must first try Spiriva **AND** Incruse Ellipta.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Yutiq (fluocinolone) *implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ziextenzo (pegfilgrastim-bmez)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Zilbrysq (zilucoplan injection, solution)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Rystiggo. (Zilbrysq has not been studied and there is no data to support use in combination with other medications used to treat MG).
	Required Medical Information	**For initial requests, must have:** (1) Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive – AND – (2) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more – AND – (3) Trial of Vyvgart or Rystiggo with an inadequate response or intolerance – AND – (4) Trial of Ultomiris with an inadequate response or intolerance. **For initial and reauthorization:** Medical records supporting the request must be provided.
	Age Restrictions	Must be at least 18 years old.
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	12 weeks (initial); 1 year (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Zolgensma (onasemnogene abeparvovec)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document
Zymfentra (infliximab-dyyb) injection	**Exclusion Criteria**	Must not be used in combination with other biologic drugs, Otezla, or Janus Kinase Inhibitor (JAKis).
	Required Medical Information	(1) Medical records supporting the request must be provided; AND (2) A diagnosis of moderately to severely active ulcerative colitis or moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously; AND (3) Trial and failure (defined as an intolerance or inability to improve symptoms) with two of the following drugs with a supported use for the requested condition: a preferred adalimumab product, Rinvoq, Skyrizi, Tyenne, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Yesintek/Selarsdi, or Enbrel. Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz and Hadlima.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Zynteglo (onasemnogene abeparvovec)	**Exclusion Criteria**	Must not have a prior hematopoietic stem cell transplant (HSCT) or history of previous gene therapy (the safety and efficacy of Zynteglo following a previous HSCT or gene therapy has not been established).
	Required Medical Information	(1) Medical records supporting the request must be provided; (2) Must have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 mL/kg/year of packed red blood cells (pRBC) in the previous 2 years OR at least 8 transfusions of pRBCs per year in the previous 2 years; (3) Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; AND (4) Provider attests that, in the absence of a known or available HLA-matched family donor, the patient would be otherwise clinically stable and eligible to undergo HSCT.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist, transplant specialist, or another board-certified prescriber with qualifications to treat specified condition.
	Coverage Duration	One lifetime dose (safety and effectiveness of repeat administration have not been evaluated).
	Other Criteria	N/A
	Indications	FDA-Approved Indications
	References & Summary of Evidence	Refer to the Priority Health Medicare Part B References & Summary of Evidence document