

Priority Health Medicare Part B

Prior Authorization and Step Therapy Criteria December 2024



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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 Part B 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 provide as 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) <i>solution vial</i> | Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. 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 | 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 |
|-------------------------------------|---|---|
| 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-awwa) | 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 | <p>For initial and reauthorization requests: Medical records supporting the request must be provided, including the patient's current weight for dosing purposes.</p> <p>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%.</p> |
| | 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 | <p>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.</p> <p>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).</p> |
| | 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 |
|--|---|--|
| Alyglo (immune globulin) <i>intravenous</i> | 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: (1) 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 |
| Almysys (bevacizumab-maly) <i>injection</i> | 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) <i>injection</i> | Exclusion Criteria | Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Tegsedi, Onpattro) – AND – Patient must not have had a liver transplant. |
| | Required Medical Information | Medical records supporting the request must be provided – AND – Must have documentation of a transthyretin (TTR) mutation (e.g., V30M) – AND – Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2. |
| | 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 | Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.) – AND – For reauthorization, must have a positive clinical response to Amvuttra 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 | |
| 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) <i>intravenous</i> | 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: (1) 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 | |
| Avastin (bevacizumab) <i>Chemotherapy (J9035) only</i> | 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 | (1) Medical records supporting the request must be provided - AND - (2) Must have tried and failed (defined as an inability to improve symptoms or condition) generic testosterone cypionate or generic testosterone enanthate - AND - (3) Must have tried and failed (defined above) a generic topical testosterone therapy - AND - (4) For new (or restart) administrations of testosterone replacement therapy, must have confirmation of low testosterone that includes two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL - AND - clinical signs/symptoms other than erectile dysfunction or decreased libido (such as depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis). |
| | 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 also meet the following for coverage: (1) Patient is male - AND - (2) Patient has been screened for prostate cancer according to current guidelines. Exceptions may be made where necessary for gender dysphoria indications. |
| | 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 biological drugs or Otezla. |
| | 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 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 |
|--|---|---|
| Benlysta IV (belimumab) <i>vial</i> | Exclusion Criteria | Must not be used with another biologic drug or Lupkynis. |
| | Required Medical Information | <p>For all medically-accepted indications: Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.</p> <p>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.</p> <p>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.</p> |
| | 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 | <p>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.</p> <p>For SLE Reauthorization: Must have evidence of clinical improvement since starting Benlysta.</p> <p>For Lupus Nephritis Initial Coverage: Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid).</p> <p>For Lupus Nephritis Reauthorization: Must have evidence of clinical improvement including improved or stable eGFR.</p> |
| | 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) <i>intravenous</i> | 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: (1) 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 | |
| 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 | <p>(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.</p> <p>(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.</p> <p>- 1 - Chronic anal fissures: Must try and fail (defined as an inadequate response) conservative treatment such as topical nitrogen.</p> <p>- 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:</p> <ul style="list-style-type: none"> · Antidepressants (e.g., amitriptyline, nortriptyline) · Beta blockers (e.g., propranolol, metoprolol, timolol) · Anti-epileptics (e.g., valproate, topiramate) <p style="text-align: right;"><i>(continued on next page)</i></p> | |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|--|--|--|
| <p>botulinum toxins type A and type B (continued)</p> <p>Botox (onabotulinumtoxin A)</p> <p>Daxxify (daxibotulinumtoxinA-lanm)</p> <p>Dysport (abobotulinumtoxin A)</p> <p>Myobloc (rimabotulinumtoxin B)</p> <p>Xeomin (incobotulinumtoxin A)</p> | <p>Other Criteria (continued)</p> <p>Indications</p> <p>References & Summary of Evidence</p> | <p>- 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).</p> <p>- 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).</p> <p>- 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).</p> <p>- 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.</p> <p>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.</p> <p>Refer to the Priority Health Medicare Part B References & Summary of Evidence document</p> |
| <p>Breyanzi (lisocabtagene maraleucel)</p> | <p>Exclusion Criteria</p> <p>Required Medical Information</p> <p>Age Restrictions</p> <p>Prescriber Restrictions</p> <p>Coverage Duration</p> <p>Other Criteria</p> <p>Indications</p> <p>References & Summary of Evidence</p> | <p>N/A</p> <p>Medical records supporting the request must be provided.</p> <p>N/A</p> <p>N/A</p> <p>In accordance with the FDA-approved labeling or accepted standards of medical practice.</p> <p>Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).</p> <p>All Medically-Accepted Indications</p> <p>Refer to the Priority Health Medicare Part B References & Summary of Evidence document</p> |

| 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 |
|--|---|--|
| <p>Casgevy (exagamglogene autotemcel injection, suspension)</p> | <p>Exclusion Criteria</p> | <p>Casgevy is not covered in patients with prior HSCT or prior gene therapy.</p> |
| | <p>Required Medical Information</p> | <p>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 $\beta S/\beta S$, $\beta S/\beta 0$, or $\beta S/\beta +$ 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).</p> <p>FOR BETA THALESSEMIA REQUESTS: 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.</p> |
| | <p>Age Restrictions</p> | <p>Patient is at least 12 years of age.</p> |
| | <p>Prescriber Restrictions</p> | <p>Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider.</p> |
| | <p>Coverage Duration</p> | <p>6 months authorization duration with a limit of one dose (treatment) per lifetime.</p> |
| | <p>Other Criteria</p> | <p>N/A</p> |
| | <p>Indications</p> | <p>All FDA-Approved Indications</p> |
| <p>References & Summary of Evidence</p> | <p>Refer to the Priority Health Medicare Part B References & Summary of Evidence document</p> | |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---------------------------------------|---|---|
| Cimzia (certolizumab pegol) | Exclusion Criteria | Must not be used in combination with other biologic drugs or Otezla. |
| | 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 | <p>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, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.</p> <p>Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz, adalimumab-fkjp, and Hadlima.</p> |
| | 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. |
| | 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 Takhzyro. |
| | 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 or Otezla. |
| | 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|--|---|--|
| 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 |
| 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|---|
| 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 - AND - (3) Documentation supporting patient is ambulatory (e.g. able to walk with or without assistance, not wheelchair dependent). |
| | Age Restrictions | Patient is 4 to 7 years old. |
| | 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 | Some 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 |
|-------------------------------------|---|--|
| 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 | Must have confirmed diagnosis of cold agglutinin disease (CAD) – AND – Must have documentation of at least one blood transfusion within 6 months of starting Enjaymo – AND – 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 – 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 biological drugs or Otezla. |
| | 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 |
|---|--|--|
| 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 | <p>For initial coverage of severe eosinophilic asthma:</p> (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 at therapy start - 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 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). <p>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).</p> |
| | 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 | <p>For reauthorization of severe eosinophilic asthma: (1) Medical records supporting the request must be provided - AND - (2) Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).</p> <p>For reauthorization of 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).</p> |
| | 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 |
|--|---|--|
| Fynetra (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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|--|
| Gel-One (hyaluronan/ hyaluronic acid) <i>for intra-articular injection</i> | 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 |
| GenVisc 850 (hyaluronan/ hyaluronic acid) <i>for intra-articular injection</i> | 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 |
|---|---|--|
| 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 |
| 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: <ul style="list-style-type: none"> · 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 · Patient has one of the following: <ul style="list-style-type: none"> o Current use of factor IX prophylaxis therapy; OR o Patient has current or historical life-threatening hemorrhage; OR o Patient has had repeated, serious spontaneous bleeding episodes · 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|--|
| 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 |
| 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 |

| 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) <i>for intra-articular injection</i> | 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) <i>for intra-articular injection</i> | 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 |
|--|---|--|
| 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|---|
| 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 |
| Ilumya (tildrakizumab) | Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| | 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 | Prrovider 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 | <p>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, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.</p> <p>Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz, adalimumab-fkjp, and Hadlima.</p> |
| | 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) <i>intravitreal implant</i> | 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 |
| infliximab injection (excludes biosimilar, 10 mg, J1745) | Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| | 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 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| 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 |
| 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| 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) <i>injection</i> | 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: <ol style="list-style-type: none"> 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 |
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| 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 |
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| 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: <ul style="list-style-type: none"> · 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 alphasannosidosis, 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 |
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| 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 |
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| Lenmeldy (atidarsagene autotemcel) | Exclusion Criteria | Lenmeldy is not covered in patients who have received prior gene therapy. |
| | Required Medical Information | <p>Medical records supporting the request must be provided and include the following (1 and 2):</p> <p>(1) Diagnosis of metachromatic leukodystrophy (MLD) confirmed by the following:</p> <ul style="list-style-type: none"> - Genetic testing showing two disease-causing arylsulfatase A gene (ARSA) alleles; <p>AND</p> <ul style="list-style-type: none"> - ARSA enzyme activity below normal range; AND - In patients with novel ARSA variant(s), presence of sulfatides in a 24-hour urine collection <p>(2) Must have one of the following MLD subtypes per the FDA-approved indication:</p> <ul style="list-style-type: none"> - 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 | 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 |
|---|--|---|
| 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 | <p>(1) Patient has tried Repatha and LDL-C remains greater than or equal to 70mg/dL – AND –</p> <p>(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 –</p> <p>(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 -</p> <p>(4) For reauthorization, documentation confirming patient has improved and maintained an improved LDL compared to baseline must be provided.</p> |
| | 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 |
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| 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 |
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| 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 β^S/β^S , β^S/β^0 , or β^S/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 |
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| 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) <i>for intra-articular injection</i> | 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 |
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| 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 |
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| <p>Nucala (mepolizumab)</p> | <p>Exclusion Criteria</p> | <p>Must not be used in combination with other biologic drugs.</p> |
| | <p>Required Medical Information</p> | <p>For all medically-accepted indications: Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.</p> <p>For initial coverage of severe eosinophilic asthma: Must also 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.</p> <p>For initial coverage of Hypereosinophilic Syndrome (HES): Must also have blood eosinophil count at least 1,000 cells/mcL.</p> |
| | <p>Age Restrictions</p> | <p>N/A</p> |
| | <p>Prescriber Restrictions</p> | <p>Prescriber is a specialist or has consulted with a specialist for the condition being treated.</p> |
| | <p>Coverage Duration</p> | <p>Initial: 2 years; reauthorization: 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice</p> |
| | <p>Other Criteria</p> | <p>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).</p> <p>For eosinophilic granulomatosis with polyangiitis (EGWP): (1) Must try and fail (defined as an intolerance or inability to improve symptoms) with one traditional, non-biologic immunomodulator (e.g., azathioprine, cyclophosphamide) - AND - (2) For reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).</p> <p>For Hypereosinophilic Syndrome (HES): (1) 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 - (2) Must try and fail (defined as an inability to improve symptoms) a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea) - AND - (3) For reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).</p> <p>For chronic rhinosinusitis with nasal polyps: (1) Must try and fail (defined as an inability to improve symptoms for least 4 weeks) with intranasal steroids - AND - (2) Must be used in combination with an intranasal steroid - AND - (3) For reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).</p> <p style="text-align: right;"><i>(continued on next page)</i></p> |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| Nucala (mepolizumab) <i>continued</i> | Indications | All Medically-Accepted Indications |
| | References & Summary of Evidence | Refer to the Priority Health Medicare Part B References & Summary of Evidence document |
| 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| 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 |
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| Ohtuvayre (ensifentrine) <i>inhalation suspension</i> | Exclusion Criteria | Must not be used in combination with roflumilast. |
| | Required Medical Information | <p>Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit.</p> <p>For initial requests, medical records supporting the request must be provided and include the following:</p> <p>(1) Diagnosis of moderate-to-severe COPD defined as an FEV1 between 30-70% - AND -</p> <p>(2) Within the past year, the patient has had two or more COPD exacerbations that required the use of oral steroids - OR - 1 COPD exacerbation that required hospitalization or an emergency room visit – AND –</p> <p>(3) 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).</p> <p>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.</p> |
| | 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 |
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| OmvoH (mirikizumab-mrkz) IV | Exclusion Criteria | Must not be used in combination with other biologic drugs or Otezla. |
| | 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: adalimumab, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia 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 |
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| Onpattro (patisiran) | Exclusion Criteria | Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Tegsedi, Amvuttra) – AND – Patient must not have had a liver transplant. |
| | Required Medical Information | Medical records supporting the request must be provided – AND – Must provide patient's current weight – AND – Must have documentation of a transthyretin (TTR) mutation (e.g., V30M) – AND – Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2. |
| | 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 | Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.) – AND – 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 |
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| 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 |
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| Orencia IV (abatacept) | Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| | 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 |
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| Oxlumo (lumasiran) <i>injection</i> | 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) <i>intravitreal implant</i> | 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) <i>intravenous</i> | 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: (1) 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 |
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| 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 |
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| Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf) | 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 OR Ogivri in combination with Perjeta. 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 |
| 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 |
|--|---|---|
| Pluvicto (lutetium lu 177 vipivotide tetraxetan) | 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 | Initial coverage: 4 doses. Reauthorization: 2 doses. The total number of doses (200 mCi/dose) authorized cannot exceed 6 doses. |
| | Other Criteria | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts. For reauthorization, must also have evidence of response (e.g., radiological, PSA, clinical benefit). 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| 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 |
| Prolia (denosumab) | 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 and fail (defined as a decrease in BMD or new fracture while on therapy) an oral bisphosphonate or zoledronic acid. If intolerant or contraindicated to an oral bisphosphonate, zoledronic acid is required. Coverage is also provided if the patient has a creatinine clearance less than 35 mL/min. |
| | 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 $\geq 50\%$ (or $\geq 45\%$ 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 |
|--|--|---|
| 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 | <p>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).</p> <p>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).</p> |
| | 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 |
|---|---|---|
| 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 Difucid (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 biological drugs or Otezla. |
| | 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 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) <i>intravitreal implant</i> | 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|--|---|---|
| Revcovi (elapegedemase-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 |
| 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|-----------------------------------|---|---|
| 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 |
| 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| 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 |
| 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/1.73m ² 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 |
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| 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 – AND (3) Patient is not female |
| | Required Medical Information | (1) Medical records supporting the request – AND (2) Patient's current weight – AND (3) 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 |
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| Ryplazim (plasminogen, human-tvmh) | Exclusion Criteria | N/A |
| | Required Medical Information | Must have documentation of a baseline plasminogen activity level $\leq 45\%$ - 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 | <p>For initial coverage, must have:</p> (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 - AND - (4) Trial of Vyvgart with an inadequate response or intolerance. Vyvgart trial is not required for patients with MuSK anti-body positive disease. <p>For initial and reauthorization: Medical records supporting the request must be provided.</p> |
| | 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 | <p>For Reauthorization: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.</p> |
| | 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 |
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| 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 | <p>For systemic lupus erythematosus (SLE):</p> (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 | |
| 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 | <p>For acromegaly: Must first try Sandostatin LAR. For Cushing's syndrome: Must first try ketoconazole.</p> |
| | 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 biological drugs or Otezla. |
| | 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 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 biological drugs or Otezla. |
| | 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, 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 | <p>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).</p> <p>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).</p> |
| | 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 |
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| 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 (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 a biologic male – 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 |
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| 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 | <p>For neuromyelitis optica spectrum disorder (NMOSD):</p> <p>(1) Patient has anti-aquaporin-4 (AQP4) antibody positive disease - AND -</p> <p>(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 -</p> <p>(3) Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna AND -</p> <p>(4) Patient has tried and failed (defined above) Enspryng - AND -</p> <p>(5) Must have an Expanded Disability Status Scale (EDSS) score of ≤ 7 - AND -</p> <p>(6) Soliris will not be used in combination with Ultomiris, Uplizna, Enspryng, or other medications to treat neuromyelitis optica spectrum disorder (NMOSD) - AND -</p> <p>(7) For reauthorization requests:</p> <p>(a) Soliris will not be used in combination with Ultomiris, Uplizna, Enspryng, or other medications for neuromyelitis optica spectrum disorder (NMOSD); AND</p> <p>(b) documentation of a decrease in relapse rate must be provided.</p> <p style="text-align: right;">(Continued on next page)</p> |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|---|
| <p>Soliris (eculizumab) <i>continued</i></p> | | <p>For myasthenia gravis:</p> <p>(1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or more - AND -</p> <p>(2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - AND -</p> <p>(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 -</p> <p>(4) Trial of Vyvgart with an intolerance or inadequate response - AND -</p> <p>(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 -</p> <p>(6) For reauthorization requests:</p> <p>(1) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq; AND</p> <p>(2) Must have documentation of improvement in the MG-ADL total score from baseline.</p> |
| | <p>Other Criteria <i>(continued)</i></p> | <p>For atypical hemolytic uremic syndrome (aHUS):</p> <p>(1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - AND -</p> <p>(2) For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine)</p> <p>For atypical hemolytic uremic syndrome (aHUS):</p> <p>(1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - AND -</p> <p>(2) For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine).</p> <p>For paroxysmal nocturnal hemoglobinuria (PNH):</p> <p>(1) Must have diagnosis confirmed by flow cytometry – AND –</p> <p>(2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – AND –</p> <p>(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 -</p> <p>(4) For reauthorization requests:</p> <p>(a) Must not be used in combination with other complement drug therapy including Fabhala, Ultomiris, Empaveli; AND</p> <p>(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.</p> |
| | <p>Indications</p> | <p>All FDA-Approved Indications</p> <p style="text-align: right;"><i>(continued on next page)</i></p> |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| Soliris (eculizumab) <i>continued</i> | References & Summary of Evidence | Refer to the Priority Health Medicare Part B References & Summary of Evidence document |
| Spevigo (spesolimab-sbzo) 450 MG/7.5 ML VIAL | Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. No more than 2 infusions are covered. |
| | 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 | Up to 2 infusions total as indicated per the FDA approved labeling and accepted standards of medical practice. Reauth: N/A. |
| | 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 |
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| 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 | <p>For initial requests for the treatment of Major Depressive Disorder with acute suicidal ideation:</p> <p>(1) Medical records supporting the request must be provided; AND</p> <p>(2) Spravato must be used in combination with an oral antidepressant.</p> <p>For initial requests for the diagnosis of Treatment-Resistant Depression:</p> <p>(1) Medical records supporting the request must be provided; AND</p> <p>(2) Spravato must be used in combination with an oral antidepressant; AND</p> <p>(3) Must try and fail 2 different generic antidepressants of an adequate dose, each from a different class, for at least 6 weeks; AND</p> <p>(4) 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).</p> |
| | Age Restrictions | Must be at least 18 years of age. |
| | Prescriber Restrictions | Must be prescribed by or in consultation with a psychiatrist. |
| | Coverage Duration | <p>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).</p> <p>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.</p> |
| | 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 biological drugs or Otezla. |
| | 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 | <p>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, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.</p> <p>Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz, adalimumab-fkjp, and Hadlima.</p> |
| | Indications | All Medically-Accepted Indications |
| | References & Summary of Evidence | Refer to the Priority Health Medicare Part B References & Summary of Evidence document |
| 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 |
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| Supprelin LA (histrelin acetate) <i>implant</i> | 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 | <p>For initial coverage: Must try and be unable to continue Lucentis.</p> <p>For reauthorization: Must have disease response indicated by stable or improved BCVA score compared to baseline.</p> |
| | 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 |
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| 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 |
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| Synjoynt (hyaluronan or derivative) <i>for intra-articular injection</i> | 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 |
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| Synvisc/Synvisc One (hyaluronan/ hyaluronic acid) <i>for intra-articular injection</i> | 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 |
| Tecartus (brexucabtagene autoleucl) | 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 |
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| 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) <i>implant</i> | Exclusion Criteria | N/A |
| | Required Medical Information | (1) Medical records supporting the request must be provided - AND - (2) Must have tried and failed (defined as an inability to improve symptoms or condition) generic testosterone cypionate or generic testosterone enanthate - AND - (3) Must have tried and failed (defined above) a generic topical testosterone therapy - AND - (4) For new (or restart) administrations of testosterone replacement therapy, must have confirmation of low testosterone that includes two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL - AND - clinical signs/symptoms other than erectile dysfunction or decreased libido (such as depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis). |
| | 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 also meet the following for coverage: (1) Patient is male - AND - (2) Patient has been screened for prostate cancer according to current guidelines. Exceptions may be made where necessary for gender dysphoria indications. |
| | 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 |
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| 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 | 2 years initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. |
| | Other Criteria | For all asthma indications: (1) Must try and fail with 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 |
| Tofidence (tocilizumab-bavi) vial for intravenous injection Biosimilar to ACTEMRA® (tocilizumab) | Exclusion Criteria | Must not be used in combination with other biologic drugs or Otezla. |
| | 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 | <p>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, Stelara, 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, Stelara, adalimumab, Xeljanz/XR, and Rinvoq.</p> |
| | 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 |
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| Triluron (hyaluronan/hyaluronic acid) <i>for intra-articular injection</i> | 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 |
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| Trivisc (hyaluronan/hyaluronic acid) <i>for intra-articular injection</i> | 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 | |
| Tyenne IV (tocilizumab-aazg) vial for intravenous injection Biosimilar to ACTEMRA® (tocilizumab) | Exclusion Criteria | Must not be used in combination with other biologic drugs or Otezla. |
| | 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 | 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 |
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| Tyvaso (treprostinil) inhalation | Exclusion Criteria | N/A |
| | Required Medical Information | <p>For PAH (WHO Group 1): Medical records supporting the request must be provided including confirmation of diagnosis by right heart catheterization and documentation of prior therapies and responses to treatment.</p> <p>For PH-ILD (WHO Group 3): Medical records supporting the request must be provided including confirmation of diagnosis by right heart catheterization - and - baseline 6-minute walk test (6MWT) - and - patient's associated condition (IPF, CTD, CPFE).</p> |
| | 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: Up to 2 years. For PH-ILD: 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 | <p>Part B vs Part D determination required. Refer to the Medicare Part B vs Medicare Part D Drug Request form.</p> <p>For PAH (WHO Group 1): (1) 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).</p> <p>For PH-ILD (WHO Group 3): (1) Only covered for PH-ILD associated with IPF, CTD, or combined IPF and emphysema (CPFE); and (2) For reauthorization, documentation that patient has had a positive clinical response as determined by the provider and includes improvement in the 6MWT compared to baseline.</p> |
| | 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 |
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| 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: (1) Must have documentation of at least 2 of the following autoantibodies: <ul style="list-style-type: none"> - Glutamic acid decarboxylase 65 (GAD) autoantibody: - Insulin autoantibody (IAA) - Insulinoma-associated antigen 2 autoantibody (IA-2A) - Zinc transporter 8 autoantibody (ZnT8A) - Islet cell autoantibody (ICA) (2) Must have documentation of dysglycemia defined as meeting one of the following: <ul style="list-style-type: none"> - A fasting glucose level of 110 to 125 mg/dL – or – - A 2-hour postprandial plasma glucose level of at least 140 mg/dL but less than 200 mg/dL – or – - A postprandial glucose level more than 200 mg/dL on two occasions |
| | 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 |
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| 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 |
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| Ultomiris (ravulizumab-cqvz) | Exclusion Criteria | N/A |
| | Required Medical Information | <p>For neuromyelitis optica spectrum disorder (NMOSD):</p> <p>(1) Patient has anti-aquaporin-4 (AQP4) antibody positive disease; AND</p> <p>(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</p> <p>(3) Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna; AND</p> <p>(4) Patient has tried and failed (defined above) Enspryng; AND</p> <p>(5) Ultomiris will not be used in combination with Soliris, Uplizna, Enspryng, or other medications for NMOSD; AND</p> <p>(6) Must have an Expanded Disability Status Scale (EDSS) score of ≤ 7; AND</p> <p>(7) Medical records supporting the request must be provided; AND</p> <p>(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.</p> |
| | 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 | <p>For myasthenia gravis:</p> <p>(1) Must have a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more; AND</p> <p>(2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive; AND</p> <p>(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</p> <p>(4) Trial of Vyvgart with an intolerance or inadequate response; AND</p> <p>(5) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Soloris, Rystiggo, or Zilbrysq. (Ultomiris has not been studied and there is no data to support use in combination with other medications used to treat MG); AND</p> <p>(6) Medical records supporting the request must be provided; AND</p> <p>(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, Soloris, Rystiggo, or Zilbrysq.</p> <p style="text-align: right;">(continued on next page)</p> |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|---|
| Ultomiris (ravulizumab-cqvz) (continued) | Other Criteria (continued) | <p>For atypical hemolytic uremic syndrome (aHUS):</p> <p>(1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out; AND</p> <p>(2) Medical records supporting the request must be provided; AND</p> <p>(3) For reauthorization, must have documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine).</p> <p>For paroxysmal nocturnal hemoglobinuria (PNH):</p> <p>(1) Must have diagnosis confirmed by flow cytometry; AND</p> <p>(2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain); AND</p> <p>(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</p> <p>(4) Medical records supporting the request must be provided; AND</p> <p>(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.</p> |
| | Indications | All FDA-Approved Indications |
| | References & Summary of Evidence | Refer to the Priority Health Medicare Part B References & Summary of Evidence document |
| Uplizna (inebilizumab-cdon) | 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 neuromyelitis optica spectrum disorder, must first try rituximab AND Enspryng. |
| | 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 |
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| 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 |
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| Ventavis (iloprost) inhalation | Exclusion Criteria | N/A |
| | Required Medical Information | For PAH (WHO Group 1): Medical records supporting the request must be provided, including confirmation of diagnosis by right heart catheterization - and - 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 | Part B vs Part D determination required – Refer to the Medicare Part B vs Medicare Part D Drug Request form. For PAH (WHO Group 1): 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). |
| | 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 |
| 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 |
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| Visco-3 (hyaluronan/hyaluronic acid) <i>for intra-articular injection</i> | 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 |
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| 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, Ajoovy, 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 |
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| 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 | <p>Initial: Must have presence of open DEB skin wounds - AND - application is limited to open DEB skin wounds only.</p> <p>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).</p> |
| | 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 |
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| 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 |
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| 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 | <p>For initial coverage of Myasthenia Gravis (MG), documentation of the following is required:</p> (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. <p>For initial coverage of chronic inflammatory demyelinating polyneuropathy (CIDP), documentation of the following is required:</p> (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 | <p>For reauthorization of myasthenia gravis: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.</p> <p>For reauthorization of CIDP: Must have a documented response to therapy evidenced by improvement of stabilization in the disease.</p> |
| | 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 |
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| 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 |
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| 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 |
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| 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 |
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| 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 |
| Xipere (triamcinolone) | 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 Triesence. For intermediate and posterior uveitis, must also try either Ozurdex or 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 |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
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| <p>Xolair (omalizumab) vial/prefilled syringe</p> | <p>Exclusion Criteria</p> | <p>Must not be used in combination with other biologic drugs (e.g., Dupixent, Nucala, Fasenra).</p> |
| | <p>Required Medical Information</p> | <p>For asthma requests:</p> <p>(1) Medical records supporting the request must be provided; AND</p> <p>(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</p> <p>(3) Must provide patient's current weight and baseline IgE level.</p> <p>For asthma reauthorization requests:</p> <p>(1) Must provide patient's current weight and baseline IgE level; AND</p> <p>(2) Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).</p> <p>For chronic urticaria requests:</p> <p>(1) Medical records supporting the request must be provided; AND</p> <p>(2) Must try and fail (defined as an intolerance or 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.</p> <p>For chronic urticaria reauthorization requests:</p> <p>Must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).</p> |
| | <p>Age Restrictions</p> | <p>N/A</p> |
| | <p>Prescriber Restrictions</p> | <p>Prescriber is a specialist or has consulted with a specialist for the condition being treated.</p> |
| | <p>Coverage Duration</p> | <p>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.</p> |
| <p>Other Criteria</p> | <p>For nasal polyp requests:</p> <p>(1) Medical records supporting the request must be provided; AND</p> <p>(2) Must try and fail (defined as an inability to improve symptoms for least 4 weeks) with intranasal steroids; AND</p> <p>(3) Must be used in combination with an intranasal steroid; AND</p> <p>(4) Must provide patient's current weight and baseline IgE level.</p> <p>For nasal polyp reauthorization requests:</p> <p>(1) Must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use); AND</p> <p>(2) Must provide patient's current weight and baseline IgE level; AND</p> <p>(3) Must continue to be used in combination with an intranasal steroid.</p> <p style="text-align: right;"><i>(continued on next page)</i></p> | |

| DRUG | PA/ST CRITERIA | CRITERIA DETAILS |
|---|---|--|
| Xolair (omalizumab) vial/prefilled syringe <i>(continued)</i> | Other Criteria <i>(continued)</i> | For food allergy requests: (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 food allergy reauthorization requests: (1) Xolair must continue to be used in conjunction with a food allergen-avoidant diet; AND (2) 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 |
| 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 |
|--|---|--|
| 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. (2) 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 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) <i>implant</i> | 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 | <p>For initial requests, must have:</p> (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. <p>For initial and reauthorization: Medical records supporting the request must be provided.</p> |
| | 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, Janus Kinase Inhibitors (JAKis), or Otezla. |
| | 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, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel. Preferred adalimumab products include Humira (made by the manufacturer Abbvie), adalimumab-adaz, adalimumab-fkip, 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 | Up to 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 |