Priority Health Medicare Part B

Prior Authorization and Step Therapy Criteria

May 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 PartB drugs applies to members who are enrolled in a Medicare Advantage Prescription Drug (MAPD) plan and are not currently receiving the Part B drug.

What is a medically accepted indication (MAI)?

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

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

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

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

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

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

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

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

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

How do I use this criteria document?

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

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

coverage for chemotherapeutic (cancer) medications requiring PA and/or ST under Part B. Includes required information necessary for billing purposes.)

- Medicare Coverage Database Search (website to search for National and Local Coverage Determinations and Coverage Articles [NCD, NCA, LCD, and LCAs]: https://www.cms.gov/medicare-coverage-database/search.aspx

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

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

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

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

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

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

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

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Abecma (idecabtagene vicleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References	1. Abecma [Package Insert]. Summit, NJ; Bristol-Myers Squibb: 2021 2. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy.
Actemra IV (tocilizumab) *solution vial*	**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	1. Actemra [Package Insert]. South San Francisco, CA: Genentech USA, Inc.; 2013. 2. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 Jul; 73 (7):924-939. 3. Ringold et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of JIA. Arthritis Care and Research. Vol 71 No 6 Jun 2019

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	1. Adavkveo [Package Insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2019. 2. National Heart, Lung, and Blood Institute. Evidence-based management of sickle cell disease: expert panel report, 2014.
Aduhelm (aducanumab-avwa)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	N/A
	Other Criteria	Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of ALZHEIMER's Disease (AD).
	Indications	In accordance with NCD 200.3.
	References	1. Aduhelm [Package Insert]. Cambridge, MA; Biogen Inc.: 2021 2. Centers for Medicare & Medicaid Services Medicare Coverage Database. National Coverage Determination (NCD) 200.3: Monoclonal Antibodies Directed Against Amyloid for the Treatment of ALZHEIMER's Disease (AD).

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Adzynma (ADAMTS13, recombinant-krhn)	**Exclusion Criteria**	N/A
	Required Medical Information	**For initial and reauthorization requests:** Medical records supporting the request must be provided, including the patient's current weight for dosing purposes. **For initial requests:** Must also have (1) genetic testing confirming the diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP); and (2) ADAMTS13 activity less than 10%.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a specialist for the disease state.
	Coverage Duration	Initial: 12 months. Reauthorization: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For initial requests:** The initial dosing frequency for prophylactic use must be every 2 weeks. The frequency may be adjusted to once weekly based on prior prophylactic dosing regimen or clinical response and supporting documentation is required. **For reauthorization requests:** Must demonstrate a beneficial response to therapy (e.g. decrease in acute and subacute TTP events, improvement in platelet count from baseline, decrease in microangiopathic hemolytic anemia episodes).
	Indications	All FDA-Approved Indications
	References	1. Adzynma [prescribing information]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; 2023 2. Clinicaltrials.gov. A Study of BAX 930 in Children, Teenagers, and Adults Born With Thrombotic Thrombocytopenic Purpura (TTP). (NCT 03393975) Available at: https://clinicaltrials.gov/study/NCT03393975 3. National Organization of Rare Diseases. Thrombotic thrombocytopenic purpura. 2023. https://rarediseases.org/rarediseases/thrombotic-thrombocytopenic-purpura/

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Alymsys (bevacizumab-maly) *injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Mvasi **AND** Zirabev. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Alymsys [Package Insert]. Bridgewater, NJ; Amneal Pharmaceuticals LLC.: 2022 2. Centers for Medicare & Medicaid Services Medicare Coverage Database. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Amvuttra (vutrisiran) *injection*	**Exclusion Criteria**	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., 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	1. Amvuttra (prescribing information). Cambridge, MA: Alnylam Pharmaceuticals, Inc.; 2022. 2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013;8:31. Doi: 10.1186/1750-1172-8-31.
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	1. Anzemet [Package Insert]. Bridgewater, NJ; sanofi-aventis U.S. LLC: 2013

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Asceniv (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** (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	1. Asceniv [Package Insert]. Boca Raton, FL; ADMA Biologics 2. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L34771: Immune Globulins
Avastin (bevacizumab) *Chemotherapy (J9035) only*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Mvasi **AND** Zirabev. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Avastin [Package Insert]. South San Francisco, CA; Genentech, Inc.: 2019 2. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts.

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.
	Indications	All Medically-Accepted Indications
	References	1. Aveed [Package Insert]. Malvern, PA; Endo Pharmaceuticals Inc.: 2020 2. Bhasin et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, May 2018, 103(5):1715–1744. 3. Qaseem, A et al. Testosterone Treatment in Adult Men with Age-Related Low Testosterone: A Clinical Guideline from the American College of Physicians. Ann Intern Med 2020; 172(2): 126-133. 4. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; 200:423.

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	1. Avsola [Package Insert]. Thousand Oaks, CA; Amgen, Inc.: 2021

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Benlysta IV (belimumab) *vial*	**Exclusion Criteria**	Must not be used with another biologic drug or Lupkynis.
	Required Medical Information	**For all medically-accepted indications:** Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. **For SLE Initial Coverage:** Must also have a SELENA-SLEDAI score of 6 or more before starting Benlysta - **AND** - either an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80. **For Lupus Nephritis Initial Coverage:** Must also have a confirmed diagnosis of SLE - **AND** - a kidney biopsy confirming class 3, 4, and/or 5 disease.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be a specialist in treating the condition or have consulted with a specialist.
	Coverage Duration	1 year initial coverage; 2 years reauthorization. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For SLE Initial Coverage:** Must be taking standard of care that includes TWO of the following drugs together for at least 12 weeks each: a steroid, immunosuppressant, hydroxychloroquine. **For SLE Reauthorization:** Must have evidence of clinical improvement since starting Benlysta. **For Lupus Nephritis Initial Coverage:** Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid). **For Lupus Nephritis Reauthorization:** Must have evidence of clinical improvement including improved or stable eGFR.
	Indications	All Medically-Accepted Indications
	References	1. Benlysta [Package Insert]. Rockville, MD; Human Genome Sciences, Inc.: 2018 2. Fanouriakis A, Kostopoulou M , Cheema K, et al. 2019 update of the Joint European League Against Rheumatism and European Renal Association– European Dialysis and Transplant Association (EULAR/ ERA–EDTA) recommendations for the management of lupus nephritis. Ann Rheum Dis. 2020; 79: 713 –23.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Bivigam (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** (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	1. Bivigam [Package Insert]. Boca Raton, FL; ADMA Biologics 2. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L34771: Immune Globulins
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	1. Boniva [Package Insert]. South San Francisco, CA; Genentec USA, Inc.: 2011

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

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
botulinum toxins type A and type B *(continued)* **Botox** (onabotulinumtoxin A) **Daxxify** (daxibotulinumtoxinA-lanm) **Dysport** (abobotulinumtoxin A) **Myobloc** (rimabotulinumtoxin B) **Xeomin** (incobotulinumtoxin A)	**Other Criteria** *(continued)*	**- 3 - Detrusor over activity associated with a neurologic condition:** (1) Must have documentation of the underlying neurological condition that is the cause of detrusor activity (e.g., spinal cord injury or multiple sclerosis) - **AND** - (2) Must try and fail (defined as an inadequate response or intolerance) one urinary anticholinergic (e.g., oxybutynin, trospium). **- 4 - Hyperhidrosis:** (1) Must have hyperhidrosis that significantly affect patient's quality of life – **AND** – (2) Your condition cannot be controlled adequately on topical agents such as aluminum chloride (Drysol). **- 5 - For sialorrhea (excessive salivation):** Must try and fail (defined as an inadequate response or intolerance) one anticholinergic drug (e.g., glycopyrrolate, scopolamine patch, benztropine). **- 6- Urge incontinence/overactive bladder:** Must try and fail (defined as an inadequate response or intolerance) one urinary anticholinergic (e.g., oxybutynin, trospium) – **AND** - Myrbetriq.
	Indications	Coverage is limited to the spastic conditions listed under "Codes that Support Medical Necessity" of the Billing and Coding: Botulinum Toxin Type A & Type B (A57474) article.
	References	1. Botox [Package Insert]. Irvine, CA; Allergen, Inc.: 2017 2. Daxxify [Package Insert]. Newark, CA; Revance Theraputics, Inc.: 2022 3. Dysport [Package Insert]. Wrexham, UK; Ipsen Biopharm Ltd.: 2016 4. Myobloc [Package Insert]. Rockville, MD; Solstice Neurosciences.: 2020 5. Silberstein, S. D., Holland, S., Freitag, F., Dodick, D. W., Argoff, C., Ashman, E., & Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society (2012). Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology, 78(17), 1337–1345. https://doi.org/10.1212/WNL.0b013e3182535d20 6. Silberstein S. D. (2015). Preventive Migraine Treatment. Continuum (Minneapolis, Minn.), 21(4 Headache), 973–989. https://doi.org/10.1212/CON.0000000000000199 7. Xeomin [Package Insert]. Frankfurt, Germany; Merz Pharmaceuticals: 2018

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Breyanzi (lisocabtagene maraleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD, LCD, and/or LCA criteria. Refer to NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). All NCDs and LCDs can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx
	Indications	All Medically-Accepted Indications
	References	1. Breyanzi [Package Insert]. Bothell, WA; Bristol-Myers Squibb: 2022 2. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy.
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	1. Carvykti [Package Insert]. Horsham, PA; Janssen Biotech, Inc.: 2023 2. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy.

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	**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: Humira, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.
	Indications	All Medically-Accepted Indications
	References	1. Cimzia [Package Insert]. Smyrna, GA; UCB, Inc.: 2016
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	1. Cinqair [Package Insert]. West Chester, PA; Teva Respiratory, LLC: 2020 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023 3. Global Initiative for Asthma. Difficult-To-Treat & Severe Asthma in adolescents and adult patients, 2023.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Busse, P. J., Christiansen, S. C., Riedl, M. A., Banerji, A., Bernstein, J. A., Castaldo, A. J., Craig, T., Davis-Lorton, M., Frank, M. M., Li, H. H., Lumry, W. R., & Zuraw, B. L. (2021). US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. The journal of allergy and clinical immunology. In practice, 9(1), 132–150.e3. https://doi.org/10.1016/j.jaip.2020.08.046 2. Cinryze [Package Insert]. Lexington, MA; ViroPharm Biologics, LLC.: 2022

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	1. COSENTYX [prescribing information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; October 2023. 2. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613. 3. Singh JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019 Jan; 71 (1): 5-32. 4. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50. 5. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64. 6. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
cyclophosphamide inj. (J9071, Auromedics brand)	**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 cyclophosphamide injection (J9073 / J9075)
	Indications	All Medically-Accepted Indications
	References	1. Cyclophosphamide [Package Insert]. Orlando, FL; Ingenus Pharmaceuticals, LLC: 2020
Dalvance (dalbavancin)	**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	1. Dalvance [Package Insert]. Irvine, CA; Allergan USA, INC.: 2018

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Durysta (bimatoprost) *intraocular implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	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	1. Durysta [Package Insert]. Madison, NJ; Allergan USA, INC.: 2020

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	1. Enjaymo [Package Insert]. Waltham, MA; Bioverative USA Inc.: 2022 2. Jäger, U., Barcellini, W., et al. (2020). "Diagnosis and treatment of autoimmune hemolytic anemia in adults: Recommendations from the First International Consensus Meeting." Blood Rev 41: 100648

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	1. Entyvio [Package Insert]. Lexington, MA; Takeda Pharmacetuicals U.S.A. Inc: 2022
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	1. Epogen [Package Insert]. Thousand Oaks, CA; Amgen Inc.: 2017 2. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L34633 Erythropoiesis Stimulating Agents.

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	1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 Update. Endocrine practice : official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists. 2020;26:1-46. 2. Evenity [Package Insert]. Thousand Oaks, CA; Amgen Inc.: 2019

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Evkeeza [Package Insert]. Tarrytown, NY; Regeneron Pharmaceuticals, Inc.: 2021 2. Grundy SM, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. JACC Vol. 73, No. 24. 2019: e285-e350.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Eylea HD (aflibercept)	**Exclusion Criteria**	N/A
	Required Medical Information	(1) Medical records supporting the request must be provided; and (2) the treatment frequency of Eylea HD will be no less than 12 weeks between doses (after initial titration) – OR – (3) if the maintenance treatment frequency of Eylea HD is 8 weeks, documentation that treatment with Eylea has been effective at a minimum of 4 weeks between doses but without successful dosing interval extension beyond 4 weeks.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice
	Other Criteria	N/A
	Indications	All Medically-Accepted Indications
	References	1. Eylea HD [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2023. 2. Clinicaltrials.gov. Study of a high-dose aflibercept in participants with diabetic eye disease (PHOTON) (NCT04429503). 3. Clinicaltrials.gov. Randomized, double-masked, active-controlled, phase 3 study of the efficacy and safety of high dose aflibercept in patients with neovascular age-related macular degeneration (NCT04423718).

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Fasenra (benralizumab)	**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) 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	1. Fasenra [Package Insert]. Sodertalje, Sweden; AstraZeneca AB 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023 3. Global Initiative for Asthma. Difficult-To-Treat & Severe Asthma in adolescents and adult patients, 2023.
Fylnetra (pegfilgrastim-pbbk)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References	1. Fylnetra [Package Insert]. Piscataway, NJ; Kashiv Biosciences, LLC: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Gel-One (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Gel-One [Package Insert]. Warsaw, IN; Zimmer Biomet. 2011
GenVisc 850 (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. GenVisc 850 [Package Insert]. Madrid, Spain; Tedec Meiji Farma

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	1. Granix [Package Insert] Vilnius, Lithuania; Sicor Biotech UAB: 2014
Hemgenix (etranacogene dezaparvovec-drlb)	**Exclusion Criteria**	Hemgenix is not covered for patients with an active hepatitis C infection, uncontrolled HIV infection, or evidence of advanced cirrhosis.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	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 (the safety and effectiveness of repeat administration have not been evaluated).
	Other Criteria	For approval, ONE of the following must be met: • Current use of factor nine (FIX) prophylaxis therapy (have received therapy for at least 2 months with at least 150 previous exposure days with the FIX protein) • Patient has current or historical life-threatening hemorrhage • Patient has had repeated, serious spontaneous bleeding episodes (must include documentation of the number of bleeds in the past year)
	Indications	All FDA-Approved Indications
	References	1. Hemgenix [Package Insert]. Lexington, MA; uniQure, Inc.: 2022

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** Kanjinti. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Herceptin [Package Insert]. South San Francisco, CA; Genentech, Inc.: 2010 3. National Comprehensive Cancer Network. Breast Cancer (Version 5.2023)
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** Kanjinti. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Herceptin Hylecta [Package Insert]. South San Francisco, CA; Genentech, Inc.: 2019 3. National Comprehensive Cancer Network. Breast Cancer (Version 5.2023)

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** Kanjinti. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Herzuma [Package Insert]. Yeonsu-gu, Incheon; Celltrion, Inc.: 2019 3. National Comprehensive Cancer Network. Breast Cancer (Version 5.2023)
Hyalgen (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX FX.
	Indications	All Medically-Accepted Indications
	References	1. Hyalgen [Package Insert]. Abano Terme, Padua; Fidia Farmaceutici S.p.A.: 1997

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Hymovis (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Hymovis [Package Insert]. Abano Terme, Padua; Fidia Farmaceutici S.p.A.
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	1. Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Iheezo [Package Insert]. Coutances, France; Laboratoire Unither: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	**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: Humira, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.
	Indications	All Medically-Accepted Indications
	References	1. Ilumya [Package Insert]. Whitehouse Station, NJ; Merck & CO., Inc.: 2018
Iluvien (fluocinolone acetonide) *intravitreal implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	For reauthorization: Must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References	1. Iluvien [Package Insert]. Alpharetta, GA; Alimera Science, Inc.: 2014

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Inflectra (infliximab-dyyb)	**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	**For ankylosing spondylitis:** Must first try one non-steroidal anti-inflammatory drug (NSAID). **For hidradenitis suppurativa:** Must first try systemic or topical antibiotic therapy. **For all other indications:** Must first try one traditional disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, cyclosporine, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine).
	Indications	All Medically-Accepted Indications
	References	1. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part I: Diagnosis, evaluation, and the use of complementary and procedural management. J Am Acad Dermatol. 2019;81(1):76-90. doi:10.1016/j.jaad.2019.02.067 2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158: 1450 – 6 3. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 Jul; 73 (7):924-939. 4. Inflectra [Package Insert]. Yeonsu-gu, Incheon; Celltrion, Inc.: 2016 5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of crohn's disease in adults. AJG. 2018 April; 113 (4): 481-517 6. Singh JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019 Jan; 71 (1): 5-32. 7. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Infliximab [Package Insert]. Horsham, PA; Janssen Biotech, Inc.: 2021
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	N/A
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Infugem [Package Insert]. Gujarat, India; Sun Pharmaceutical Ind. Ltd.: 2018

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Izervay (avacincaptad pegol sodium/PF)	**Exclusion Criteria**	GA (geographic atrophy) secondary to a condition other than AMD (age-related macular degeneration) is not covered. Izervay must not be used in combination with Syfovre or any other medication for GA (Izervay has not been studied and there is no data to support
	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	1. Clinicaltrials.gov. A Phase 3 Safety and Efficacy Study of Intravitreal Administration of Zimura (Complement C5 Inhibitor). NCT04435366 (GATHER2). 2. Clinicaltrials.gov. Zimura in Participants with Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration NCT02686658) (GATHER1). 3. Izervay [Package Insert]. Parsippany, NJ: IVERIC bio, Inc.; August 2023 4. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020 Jan (updated March 2022); 127 (1): 1 - 65.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Kimyrsa (oritavancin)	**Exclusion Criteria**	N/A
	Required Medical Information	Must provide culture and sensitivity results, or If not available, must specify the suspected organism(s) being treated.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist.
	Coverage Duration	N/A
	Other Criteria	Must try all other susceptible antibiotics (e.g., vancomycin) as determined by culture and sensitivity or as indicated for empiric therapy (e.g., beta-lactam, macrolide, fluoroquinolone).
	Indications	All Medically-Accepted Indications
	References	1. Kimyrsa [Package Insert]. Lincolnshire, IL; Melinta Therapeutics, LLC.: 2021
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	1. Krystexxa [Package Insert]. East Brunswick, NJ; Savient Pharmaceuticals, Inc.: 2012

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy. 2. Kymriah [Package Insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lamzede (velmanase alfa-tycv)	**Exclusion Criteria**	Lamzede is not covered for patients with CNS disease manifestations or rapidly progressive disease, patients who cannot walk without support, and/or patients with a history of a HSCT or bone marrow transplant.
	Required Medical Information	Medical records supporting the request must be provided. For alpha-mannosidosis, documentation of the diagnosis confirmed by one of the following must also be provided: • biallelic pathogenic variants in MAN2B1 gene **OR** • enzyme assay demonstrating alpha-mannosidase activity <10% of normal activity.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a physician who specializes in the management of patients with alphamannosidosis, or in the administration of other enzyme replacement therapies for lysosomal storage disorders.
	Coverage Duration	Initial coverage and reauthorization: 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must have documentation that the patient is using Lamzede for the treatment of non-central nervous system disease manifestations (e.g. has mild to moderate disease, able to ambulate independently). For reauthorization: Must have documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease (e.g. motor function, FVC, rate of infections, serum oligosaccharides, etc.) compared to the predicted natural history trajectory of disease; **AND** the patient continues to have an absence of exclusion criteria.
	Indications	All FDA-approved indications
	References	1. Guffon N, Tylki-Szymanska A, Borgwardt L, et al. Recognition of alpha-mannosidosis in pediatric and adult patients: presentation of a diagnostic algorithm from an international working group. Mole Gen & Metab. 2019; 126: 470 – 4. 2. Lamzede [Package Insert]. Parma, Italy; Chiesi Farmaceutici S.p.A.: 2023

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lantidra (donislecel-jujn solution)	**Exclusion Criteria**	N/A
	Required Medical Information	The following are required for approval: (1) Medical records supporting the request - AND - (2) Diagnosis of type 1 diabetes - AND - (3) Patient has had intensive insulin management that includes the appropriate use of a CGM (i.e., with insulin pump or with an automated insulin delivery system) - AND - (4) Patient has been unable to reach target HbA1c despite intensive diabetes education and insulin management due to current, repeated episodes of severe hypoglycemia defined by the ADA as Level 3 hypoglycemia (a severe event characterized by altered mental and/or physical functioning that requires assistance from another person for recovery, regardless of glucose level) - AND - (5) Lantidra must be taken with concomitant immunosuppressants - AND - (6) Approval of the patient's islet cell transplant must be on file prior to determination of Lantidra's use in any patient.
	Age Restrictions	Patient is at least 18 years of age.
	Prescriber Restrictions	N/A
	Coverage Duration	Initial: 1 infusion. Reauthorization: up to 2 additional infusions.
	Other Criteria	For reauthorization: Patient has not achieved independence from exogenous insulin within one year of infusion - or - within one year after losing independence from exogenous insulin after a previous infusion. A third infusion may be performed using the same criteria as for the second infusion. There are no data regarding the effectiveness or safety for patients receiving more than three infusions.
	Indications	All FDA-approved indications
	References	1. Lantidra [Package Insert]. Chicago, Illinois; CellTrans Inc.: 2023 2. American Diabetes Association. Standards of Care in Diabetes—2024. January 2024. Available at: https://diabetesjournals.org/care/issue/47/Supplement_1 3. Clinicaltrials.gov. Islet Transplantation in Type I Diabetic Patients Using the University of Illinois at Chicago (UIC) Protocol. NCT03791567 and NCT00679042

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 requires the following: 1. Patient is enrolled in Medicare; **AND** 2. Patient is diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia; **AND** 3. Patient's physician is participating in a registry with an appropriate clinical team and follow-up care (attestation required).
	Indications	All FDA-approved indications
	References	1. Centers for Medicare & Medicaid Services Medicare Coverage Database. National Coverage Determination (NCD) 200.3: Monoclonal Antibodies Directed Against Amyloid for the Treatment of ALZHEIMER's Disease (AD). April 7, 2022. 2. Leqembi [Package Insert]. Nutley, NJ; Eisai Inc.: 2023

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Leqvio (inclisiran)	**Exclusion Criteria**	Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet.
	Required Medical Information	Must submit most recent LDL-C level. Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist.
	Coverage Duration	Initial Coverage: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	(1) Patient has tried Repatha and LDL-C remains greater than or equal to 70mg/dL – **AND** – (2) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70mg/dL – **OR** – (3) Patient is statin intolerant demonstrated by experiencing statin associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin - **AND** - (4) For reauthorization, documentation confirming patient has improved and maintained an improved LDL compared to baseline must be provided.
	Indications	All Medically-Accepted Indications
	References	1. Leqvio [Package Insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: 2023 2. McGowan MP, et al. Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia. Journal of the American Heart Association. 2019; 8:e013225

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Lumizyme (alglucosidase alfa)	**Exclusion Criteria**	Must not be used in combination with another ERT (e.g., Nexviazyme, Pombiliti)
	Required Medical Information	Medical records supporting the request must be provided, including the following: · Patient's current weight - **AND** - · 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	1. Lumizyme [Package Insert]. Cambridge, MA; Genzyme Corporation: 2010 2. American College of Medical Genetics – Pompe Disease Diagnosis and Management Guideline, 2006

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Margenza (margetuximab-cmkb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Kanjinti – **AND** – Must follow NCD, LCD, and/or LCA criteria. Refer to the Medicare Part B Oncology PA form and LCD L37205: Chemotherapy Drugs and their Adjuncts. All NCDs and LCDs can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Margenza [Package Insert]. Rockville, MD; MacroGenics, Inc.: 2020 3. National Comprehensive Cancer Network. Breast Cancer (Version 5.2023)
Monovisc (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Monovisc [Package Inesrt]. Bedfored, MA; Anika Therapeutics, Inc.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Neupogen (filgrastim)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Nivestym **AND** Zarxio.
	Indications	All Medically-Accepted Indications
	References	1. Neupogen [Package Insert]. Thousand Oaks, CA; Amgen Inc.: 2013
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: · Patient's current weight - **AND** - · 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	1. Nexviazyme [Package Insert]. Cambrdige, MA; Genzyme Corporation 2. American College of Medical Genetics – Pompe Disease Diagnosis and Management Guideline, 2006

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Nucala (mepolizumab)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs.
	Required Medical Information	**For all medically-accepted indications:** Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. **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. **For initial coverage of Hypereosinophilic Syndrome (HES):** Must also have blood eosinophil count at least 1,000 cells/mcL.
	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). **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). **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). **For chronic rhinosinusitis with nasal polyps:** (1) Must try and fail (defined as an inability to improve symptoms for least 8 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). *(continued on next page)*

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Nucala (mepolizumab) *continued*	**Indications**	All Medically-Accepted Indications
	References	1. Nucala [Package Insert]. Philadelphia, PA; GlaxoSmithKline LLC: 2019 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023 3. Global Initiative for Asthma. Difficult-To-Treat & Severe Asthma in adolescents and adult patients, 2023.
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	Quantity limited to 30-day supply. 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	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L33824: Immunosuppressive Drugs. 2. Nelson, J., Alvey, N., Bowman, L., Schulte, J., Segovia, M. C., McDermott, J., Te, H. S., Kapila, N., Levine, D. J., Gottlieb, R. L., Oberholzer, J., & Campara, M. (2022). Consensus recommendations for use of maintenance immunosuppression in solid organ transplantation: Endorsed by the American College of Clinical Pharmacy, American Society of Transplantation, and International Society for Heart and Lung Transplantation: An executive summary. Pharmacotherapy, 42(8), 594–598. https://doi.org/10.1002/phar.2718 3. Nulojix [Package Insert]. Princeton, NJ; Bristol-Myers Squibb Company: 2014

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ogivri (trastuzumab-dkst)	**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 Trazimera **AND** Kanjinti. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Ogivri [Package Insert]. Steinhausen, Switzerland; Mylan GmbH: 2018
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	1. Omvoh™ intravenous infusion and subcutaneousinjection [prescribing information]. Indianapolis, IN: EliLilly; October 2023. 2. D'Haens G, Dubinsky M, Kobayashi T, et al, for the LUCENTstudy group. Mirikizumab as induction and maintenancetherapy for ulcerative colitis. N Engl J Med.2023;388(26):2444-2455. https://classic.clinicaltrials.gov/ct2/show/NCT03518086

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Onpattro (patisiran)	**Exclusion Criteria**	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., 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	1. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013;8:31. Doi: 10.1186/1750-1172-8-31. 2. Onpattro [Package Insert]. Cambrdige, MA; Alnylam Pharmaceuticals, Inc.: 2018

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ontruzant (trastuzumab-dttb)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Kanjinti. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Oztruzant [Package Insert]. Incheon, Korea; Samsung Bioepis Co., Ltd.: 2019
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	1. Orbactiv [Package Insert]. Lincolnshire, IL; Melinta Therapeutics, LLC: 2021

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Orencia [Package Insert]. Princeton, NJ; Bristol-Myers Squibb Company: 2021
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.
	Indications	All Medically-Accepted Indications
	References	1. Orthovisc [Package Insert]. Woburn, MA; Anika Therapeutics, Inc.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ozurdex (dexamethasone) *intravitreal implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	For reauthorization, must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References	1. Ozurdex [Package Insert]. Irvine, CA; Allergan, Inc.: 2014
Panzyga (immune globulin) *intravenous*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**Part B vs Part D determination required**. **For all requests determined to be a Part B benefit:** (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	1. Center for Medicare & Medicaid Services. Local Coverage Determination (LCD) L34771: Immune Globulins 2. Panzyga [Package Insert]. Lingolsheim, France; Octapharma SAS: 2021

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Parsabiv [Package Insert]. Thousand Oaks, CA; Amgen, Inc.: 2017
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 pemetrexed.
	Indications	All Medically-Accepted Indications
	References	1. Pemfexy [Package Insert]. Woodcliff Lake, NJ; Eagle Pharmaceuticals, Inc.: 2020

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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** Kanjinti in combination with Perjeta. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Phesgo [Package Insert]. South San Francisco, CA; Genentech, Inc.: 2020
Pluvicto (inclisiran)	**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	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Pluvicto [Package Insert]. Millburn, NJ; Advanced Accelerator Applications USA, Inc.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Pombiliti (cipaglucosidase alfa-atga)	**Exclusion Criteria**	Must not be used in combination with another ERT (such as Lumizyme or Nexviazyme)
	Required Medical Information	Medical records supporting the request must be provided, including the following: · Patient's current weight - **AND** - · 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	1. Pombiliti [package insert]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023. 2. Opfolda [package insert]. Philadelphia, PA: Amicus Therapeutics US, LLC; September 2023. 3. American College of Medical Genetics – Pompe Disease Diagnosis and Management Guideline, 2006

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2020 Update. Endocr Pract. 2020;26(Suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL 2. Chakhtoura M, El-Hajj Fuleihan G. Treatment of Hypercalcemia of Malignancy. Endocrinol Metab Clin North Am. 2021;50(4):781-792. doi:10.1016/j.ecl.2021.08.002 3. National Comprehensive Cancer Network. Breast Cancer (Version 5.2023) 4. National Comprehensive Cancer Network. Bone Cancer (Version 1.2024) 5. National Comprehensive Cancer Network. Multiple Myeloma (Version 2.2024) 6. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2023) 7. Prolia [Package Insert]. Thousand Oaks, CA; Amgen, Inc.: 2010

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 FVC ≥50% For reauthorization: Must have documentation of a decrease in plasma neurofilament light chains from baseline
	Indications	All FDA-Approved Indications
	References	1. Qalsody [Package Insert]. Cambridge, MA; Biogen MA Inc.: 2023

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Qutenza (capsaicin) *8% patch*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	**For diabetic peripheral neuropathy of the feet:** Must try and fail (defined as an inadequate response or intolerance) two of the following generic medications, each from a different class: lidocaine 5% patch, duloxetine, venlafaxine, pregabalin, gabapentin, or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline). **For postherpetic neuralgia:** Must try and fail (defined as an inadequate response or intolerance) two of the following generic medications: lidocaine 5% patch, pregabalin, gabapentin, or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline).
	Indications	All FDA-Approved Indications
	References	1. Qutenza [Package Insert]. Morristown, NJ; Averitas Pharma, Inc.: 2020 2. Price R, Smith D, Franklin G, et al. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline Update Summary: Report of the AAN Guideline Subcommittee. Neurology 2022; 98:31. 3. Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic Neuropathy: A Position Statement by the American Diabetes Association. Diabetes Care 2017; 40:136. 4. Johnson RW, Rice AS. Clinical practice. Postherpetic neuralgia. N Engl J Med 2014; 371:1526.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Quzyttir [Package Insert]. Rocky Mount, NC; Pfizer: 2019
Rebyota (fecal microbiota, live-jslm)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 treatment course per FDA label and/or accepted standards of medical practice.
	Other Criteria	Must have been treated for 2 recurrent CDI episodes – **AND** – Must have tried Dificid (fidaxomicin) **AND** vancomycin.
	Indications	FDA-Approved Indications
	References	1. Rebyota [Package Insert]. Roseville, MN; Reviotix, Inc. 2. Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults, Clinical Infectious Diseases, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, https://doi.org/10.1093/cid/ciab549

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Releuko [Package Insert]. Piscataway, NJ; Kashiv BioSciences, LLC: 2022
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	1. Remicade [Package Insert]. Horsham, PA; Janssen Biotech, Inc.: 2013

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Renflexis (infliximab-abda)	**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	**For ankylosing spondylitis:** Must first try one non-steroidal anti-inflammatory drug (NSAID). **For hidradenitis suppurative:** Must first try systemic or topical antibiotic therapy. **For all other indications:** Must first try one traditional disease-modifying antirheumatic drug (DMARD) such as methotrexate, cyclosporine, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine.
	Indications	All Medically-Accepted Indications
	References	1. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part I: Diagnosis, evaluation, and the use of complementary and procedural management. J Am Acad Dermatol. 2019;81(1):76-90. doi:10.1016/j.jaad.2019.02.067 2. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158: 1450 – 6 3. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 Jul; 73 (7):924-939. 4. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of crohn's disease in adults. AJG. 2018 April; 113 (4): 481-517 5. Singh JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019 Jan; 71 (1): 5-32. 6. Renflexis [Package Insert]. Kenilworth, NJ; Merck & Co., Inc.: 2017 7. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Retisert (fluocinolone acetonide) *intravitreal implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try and fail Ozurdex **AND** Yutiq. For reauthorization, must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References	1. Retisert [Package Insert]. Waterford, Ireland; Bausch & Lomb Incorporated
Revcovi (elapegademase-lvlr injection)	**Exclusion Criteria**	N/A
	Required Medical Information	Must provide the following: (1) Trough plasma ADA activity, (2) trough dAXP levels, (3) patient's current weight, (4) requested dose, and (5) medical records supporting the request.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Initial coverage: 1 year. Reauthorization: 2 years.
	Other Criteria	Provider attestation that treatment will follow FDA-approved labeling with dose adjusted to maintain trough ADA activity over 30 mmol/hr/L, trough dAXP level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient.
	Indications	All FDA-Approved Indications
	References	1. Revcovi [Package Insert]. Gaithersburg, MD; Leadiant Biosciences Inc.: 2018

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rezzayo (rezafungin acetate)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records - and - culture & sensitivities must be provided that support the patient has limited or no alternative options for the treatment of candidemia and invasive candidiasis.
	Age Restrictions	Must be 18 years or older.
	Prescriber Restrictions	N/A
	Coverage Duration	Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications
	References	1. Rezzayo [Package Insert]. Monza, Italy; Patheon Italia S.p.A.: 2023
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	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Riabni [Package Insert]. Thousand Oaks, CA; Amgen, Inc.: 2020

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rituxan (rituximab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Truxima **AND** Ruxience. For chemotherapy requests, criteria will also be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Rituxan [Package Insert]. South San Francisco, CA; Genenteh, Inc.: 2010
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	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Rituxan Hycela [Package Insert]. South San Francisco, CA; Genenteh, Inc.: 2017

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Roctavian (valoctocogene roxaparvovc-rvox)	**Exclusion Criteria**	(1) Patient must not have any detectable antibodies to adeno-associated virus serotype 5 (AAV5) – **AND** (2) Patient must not have any FVIII inhibitors – **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	1. Roctavian [Package Insert]. Novata, CA; BioMarin Pharmaceutical Inc.: 2023
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	1. Rolvedon [Package Insert]. Irvine, CA; Spectrum Pharmaceuticals, Inc.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ryplazim (plasminogen, human-tvmh)	**Exclusion Criteria**	N/A
	Required Medical Information	Must have documentation of a baseline plasminogen activity level ≤45% - **AND** –patient's current weight – **AND** - genetic testing confirming diagnosis of PLGD type 1.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a hematologist.
	Coverage Duration	12 weeks initial; 12 months reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	For initial approval: Must have documented lesions (external and/or internal) – **AND** – symptoms consistent with disease. For reauthorization: Must have documentation of improvement in the number and/or size of lesions.
	Indications	All Medically-Accepted Indications
	References	1. National organization for rare disease NORD. Rare disease database, congenital plasminogen deficiency. https://rarediseases.org/rare-diseases/congenital-plasminogen-deficiency/ accessed July 2024 2. Ryplazim [Package Insert]. Fort Lee, NJ; Prometic Biotherapeutics, Inc.: 2021

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Rystiggo (rozanolixizumab-noli)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Zilbrysq. (Rystiggo has not been studied and there is no data to support use in combination with other medications used to treat MG)
	Required Medical Information	**For initial coverage, must have:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 3 – AND - (2) Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive or anti-muscle-specific tyrosine kinase [MuSK] anti-body positive - AND - (3) Trial of 1 non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - AND - (4) Trial of Vyvgart with an inadequate response or intolerance. Vyvgart trial is not required for patients with MuSK anti-body positive disease.
	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	1. Narayanaswami P, Sanders DB, Wolfe GI, et al. International consensus guidance for management of myasthenia gravis: 2020 update. Neurology. 2021; 96: 114 - 22. 2. Rystiggo [Package Insert]. Smyrna, GA; UCB, Inc.: 2023 3. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. European J Neurol. 2010 Jul; 17 (7): 893 - 902. 4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2016 Jul 26; 87 (4): 419 - 25. 5. Howard JF Jr. Clinical Overview of MG. Myasthenia Gravis Foundation of America (MGFA). Published June 2015. https://myasthenia.org/Professionals/Clinical-Overview-of-MG

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Saphnelo (anifrolumab-fnia)	**Exclusion Criteria**	Must not be used with another biologic drug (e.g., Benlysta) or Lupkynis.
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with a rheumatologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For systemic lupus erythematosus (SLE):** (1) Must have tried and failed (defined as an inability to taper the steroid dose and/or have frequent relapses) two of the following in combination: steroid, immunosuppressant, and/or hydroxychloroquine; (2) Must have tried and failed (defined above) Benlysta; (3) Must have a baseline SELENA-SLEDAI score of 6 or more; and (4) for reauthorization, must have documentation of clinical benefit compared to baseline.
	Indications	All Medically-Accepted Indications
	References	1. Saphnelo [Package Insert]. Sodertalje, Sweden; AstraZeneca: 2021 2. Tunnicliffe DJ, Singh-Grewal D, Kim S, at al. Diagnosis, monitoring, and treatment of systemic lupus erythematosus: a systematic review of clinical practice guidelines. 2015 Oct; 67 (10): 1440 – 52.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Signifor LAR (pasireotide)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For acromegaly**: Must first try Sandostatin LAR. **For Cushing's syndrome**: Must first try ketoconazole.
	Indications	All Medically-Accepted Indications
	References	1. Fleseriu, Maria et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." The lancet. Diabetes & endocrinology vol. 9,12 (2021): 847-875. doi:10.1016/S2213-8587(21)00235-7 2. Signifor LAR [Package Insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: 2014
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	1. Simponi Aria [Package Insert]. Horshman, PA; Janssen Biotech, Inc.: 2020

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Sivextro [Package Insert]. Lexington, MA; Cubist Pharmaceuticals: 2014
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 will be approved. Subsequent maintenance doses must be approved under the pharmacy benefit.
	Other Criteria	**For Crohn's disease**: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone).
	Indications	All Medically-Accepted Indications
	References	1. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of crohn's disease in adults. AJG. 2018 May; 113 (4): 481-517 2. Skyrizi [Package Insert]. North Chicago, IL; AbbVie Inc.; 2019

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Skysona (elivaldogene autotemcel)	**Exclusion Criteria**	Must not have history of hematopoietic stem cell transplant (HSCT) – and – must not have had previous gene therapy for any diagnosis.
	Required Medical Information	For approval, the following documentation must be provided: (1) Medical records supporting the request, including any imaging or tests. (2) Genetic testing confirming ABCD1 mutation (3) Early, active cerebral adrenoleukodystrophy (CALD) confirmed by the following: - Elevated very long chain fatty acids (VLCFA) values - Active, CNS disease established by central radiographic review of brain MRI demonstrating: - Loes score equal to or between 0.5 and 9 on the 34-point scale - 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	1. Skysona [Package Insert]. Somerville, MA; bluebird bio, Inc.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Soliris (eculizumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	For NMSOD and myasthenia gravis: Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For neuromyelitis optica spectrum disorder (NMOSD):** (1) Must have anti-aquaporin-4 (AQP4) antibody positive disease - **AND** - (2) Must have had 1 or more attacks in the last year or two attacks in the last 2 years requiring rescue therapy - **AND** - (3) Must try and fail (defined as an inadequate response or intolerance) rituximab - **AND** - (4) Must try and fail (defined above) Uplizna or Enspryng - **AND** - (5) Must have an Expanded Disability Status Scale (EDSS) score of ≤7 - **AND** - (6) For reauthorization, must have documentation of a decrease in relapse rate. **For myasthenia gravis:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or more - AND - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - AND - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - AND - (4) Trial of Vyvgart with an intolerance or inadequate response - AND **For atypical hemolytic uremic syndrome (aHUS):** (1) Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - **AND** - (2) For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine). *(Continued on next page)*

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Soliris (eculizumab) *continued*	**Other Criteria** *continued*	**For paroxysmal nocturnal hemoglobinuria (PNH):** (1) Must have diagnosis confirmed by flow cytometry – AND – (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – AND – (3) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli. (Soliris has not been studied and there is no data to support use in combination with other medications used for PHN) - AND - (4) For reauthorization, must also have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - AND - sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All FDA-Approved Indications
	References	1. Borowitz MJ, Craig FE, DiGiuseppe JA, et al. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Cytometry Part B (Clinical Cytometry). 2010; 78B: 211 – 30. 2. Kaplan BS, Ruebner RL, Spinale JM, et al. Current treatment of atypical hemolytic uremic syndrome. Intractable Rare Dis Res. 2014 May; 3 (2): 34 – 45 3. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2021 Jan 19; 96 (3): 114 – 22. 4. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. EJN. 2010; 17: 1019 – 32. 5. Soliris [Package Insert]. Cheshire, CT; Alexion Pharmaceuticals, Inc.: 2007 6. Howard JF Jr. Clinical Overview of MG. Myasthenia Gravis Foundation of America (MGFA). Published June 2015. https://myasthenia.org/Professionals/Clinical-Overview-of-MG

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Spevigo (spesolimab-sbzo) 450 MG/7.5 ML VIAL	**Exclusion Criteria**	Must not be used in combination with other biological drugs or Otezla. No more than 2 infusions are covered.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. Diagnosis of generalized pustular psoriasis has been confirmed by the following: (1) skin biopsy; (2) systemic symptoms such as fever and fatigue; and (3) relapsing episodes.
	Age Restrictions	Must be age 18 or older
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	One infusion. 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 an inability to improve flare) one traditional non-biologic immunomodulator drug or a generic retinoid (ex: cyclosporine, acitretin, isotretinoin) – **AND** – must try and fail (defined above) a biologic DMARD (ex: infliximab). For reauthorization of 1 additional infusion: Must have documentation of persistent symptoms and dose must be given 1 week after initial dose.
	Indications	FDA-Approved Indications
	References	1. Fujita H, Terui T, et al. Japanese guidelines for the management and treatment of generalized pustular psoriasis: The new pathogenesis and treatment of GPP. Journal of Dermatology 2018; 45: 1235-1270. 2. Krueger J, Puig L, Thaci D. Treatment Options and goals for Patients with Generalized Pustular Psoriasis. Am J Clin Dermatol 23 (Suppl 1), 51–64 (2022). https://doi.org/10.1007/s40257-021-00658-9. 3. Spevigo [Package Insert]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals, Inc.: 2022.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Spinraza (nusinersen 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 Evrysdi.
	Indications	All Medically-Accepted Indications
	References	1. Spinraza [Package Insert]. Cambridge, MA; Biogen Inc.: 2016 2. Bodamer, Olaf A. UpToDate. Spinal muscular atrophy. December 2023.
Spravato (esketamine)	**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 3 different generic antidepressants, each with a different mechanism of action, for at least 12 weeks each.
	Indications	All Medically-Accepted Indications
	References	1. Spravato [Package Insert]. Lakewood, NJ; Renaissance Lakewood LLC: 2019 2. Voineskos, Daphne et al. "Management of Treatment-Resistant Depression: Challenges and Strategies." Neuropsychiatric disease and treatment vol. 16 221-234. 21 Jan. 2020, doi:10.2147/NDT.S198774

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	**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: Humira, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel.
	Indications	All Medically-Accepted Indications
	References	1. Stelara [Package Insert]. Horsham, PA; Janssen Biotech, Inc.: 2016
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	1. Stimufend [Package Insert]. Lake Zurich, IL; Fresenius Kabi USA, LLC: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Supprelin LA (histrelin acetate) *implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Lupron.
	Indications	All Medically-Accepted Indications
	References	1. Supprelin LA [Package Insert]. Chadds Ford, PA; Endo Pharmaceuticals Solutions Inc.: 2011
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	Must try and fail Avastin (defined as an intolerance or inability to improve baseline visual acuity and/or reduce fluid) for at least 3 months – **AND** – must try and be unable to continue Lucentis – **AND** – for reauthorization, must have disease response indicated by stable or improved BCVA score compared to baseline. A trial with Avastin is not required if the patient has serous pigment epithelial detachment (PED), hemorrhagic PED, subretinal hemorrhage, or posterior uveal bleeding syndrome.
	Indications	All Medically-Accepted Indications
	References	1. Susvimo [Package Insert]. South San Francisco, CA; Genentech, Inc.: 2021

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Syfovre (pegcetacoplan intravitreal injection)	**Exclusion Criteria**	GA (geographic atrophy) secondary to a condition other than AMD (age-related macular degeneration) is not covered. Must not be used in combination with Izervay or any other medication for GA (Syfovre has not been studied and there is no data to support use in combination with other medications used to treat GA).
	Required Medical Information	Medical records supporting the request must be provided. For initial 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. 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	1. Syfovre [Package Insert]. Waltham, MA; Apellis Pharmaceuticals, Inc.: 2023 2. Flaxel CJ, Adelman RA, Bailey ST, et al. Age-related macular degeneration preferred practice pattern. Ophthalmology. 2020 Jan (updated March 2022); 127 (1): 1 - 65. 3. Clinicaltrials.gov. A study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy secondary to age-related macular degeneration (NCT03525613). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT03525613 4. Clinicaltrials.gov. Study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy secondary to age-related macular degeneration (NCT03525600). Available at: https://clinicaltrials.gov/ct2/show/NCT03525600.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Synojoynt (hyaluronan or derivative) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment - AND - Patient's current weight must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Synojoynt [Package Insert]. Gyeonggi-do, Korea; Hanmi Pharm Co., Ltd.
Synvisc/Synvisc One (hyaluronan/ hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Synvisc [Package Insert]. Ridgefiled, NJ; Biomatrix, Incorporated 2. Synvisc One [Package Insert]. Ridgefield, NJ: Biomatrix, Incoorporated

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tecartus (brexucabtagene autoleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy. 2. Tecartus [Package Insert]. Santa Monica, CA; Kite Pharma, Inc.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tepezza (teprotumumab-trbw)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try a systemic corticosteroid for at least 4 weeks.
	Indications	All Medically-Accepted Indications
	References	1. Tepezza [Package Insert]. Dublin, Ireland; Horizon Therapeutics Ireland DAC: 2020

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Testopel (testosterone) *implant*	**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	1. Testopel [Package Insert]. Malvern, PA; Endo Pharmaceuticals Inc.: 2018 2. Bhasin et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, May 2018, 103(5):1715–1744. 3. Qaseem, A et al. Testosterone Treatment in Adult Men with Age-Related Low Testosterone: A Clinical Guideline from the American College of Physicians. Ann Intern Med 2020; 172(2): 126-133. 4. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. J Urol 2018; 200:423.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tezspire (tezepelumab-ekko)	**Exclusion Criteria**	Must not be used in combination with other biologic drugs.
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	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	1. Global Initiative for Asthma. Difficult-To-Treat & Severe Asthma in adolescents and adult patients, 2023. 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023 3. Tezspire [Package Insert]. Sodertalje, Sweden; AstraZeneca: 2023
Triluron (hyaluronan/hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Tiluron [Package Insert]. Padua, Italy; Fidia Farmaceutici S.p.A.: 2019

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Trivisc (hyaluronan/hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Trivisc [Package Insert]. Madrid, Spain; Tedec Meiji Farma

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Tyvaso (treprostinil) 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. **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).
	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	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):** (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** and endothelin receptor antagonist (e.g., ambrisentan or bosentan). **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.
	Indications	All Medically-Accepted Indications
	References	1. 2022 ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension: Developed by the Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Eur Heart J 2022;Aug 26 2. Tyvaso [Package Insert]. Research Triangle Park, NC; United Therapeutics Corp.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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: - 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: - 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	1. Diagnosis and Classification of Diabetes: Standards of Care in Diabetes - 2024. American Diabetes Association, 2023. 2. Tzield [Package Insert]. Red Bank, NJ; Provention Bio, Inc.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Udenyca (pegfilgrastim-cbqv)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Fulphila, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications
	References	1. Udenyca [Package Insert]. Redwood City, CA; Coherus BioSciences, Inc.: 2019

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

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Ultomiris (ravulizumab-cqvz) *continued*	**Other Criteria** *continued*	**For paroxysmal nocturnal hemoglobinuria (PNH):** (1) Must have diagnosis confirmed by flow cytometry – AND – (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – AND – (3) Must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli. (Ultomiris has not been studied and there is no data to support use in combination with other medications used for PHN). (4) For reauthorization, must also have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - AND - sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All FDA-Approved Indications
	References	1. Borowitz MJ, Craig FE, DiGiuseppe JA, et al. Guidelines for the diagnosis and monitoring of paroxysmal nocturnal hemoglobinuria and related disorders by flow cytometry. Cytometry Part B (Clinical Cytometry). 2010; 78B: 211 – 30. 2. Kaplan BS, Ruebner RL, Spinale JM, et al. Current treatment of atypical hemolytic uremic syndrome. Intractable Rare Dis Res. 2014 May; 3 (2): 34 – 45 3. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2021 Jan 19; 96 (3): 114 – 22. 4. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. EJN. 2010; 17: 1019 – 32. 5. Ultomiris [Package Insert]. Boston, MA; Alexion Pharmaceuticals, Inc.: 2018 6. Howard JF Jr. Clinical Overview of MG. Myasthenia Gravis Foundation of America (MGFA). Published June 2015. https://myasthenia.org/Professionals/Clinical-Overview-of-MG.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Uplizna (inebilzumab-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	1. Chan, Koon-Ho, and Chi-Yan Lee. "Treatment of Neuromyelitis Optica Spectrum Disorders." International journal of molecular sciences vol. 22,16 8638. 11 Aug. 2021, doi:10.3390/ijms22168638 2. Sherman, Elena, and May H Han. "Acute and Chronic Management of Neuromyelitis Optica Spectrum Disorder." Current treatment options in neurology vol. 17,11 (2015): 48. doi:10.1007/s11940-015-0378-x 3. Uplinza [Package Insert]. Gaithersburg, MD; Viela Bio, Inc.: 2020
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	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Vegzelma [Package Insert]. Incheon, Korea; Celltrion, Inc.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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** and endothelin receptor antagonist (e.g., ambrisentan or bosentan).
	Indications	All Medically-Accepted Indications
	References	1. 2022 ESC/ERS Guidelines for the Diagnosis and Treatment of Pulmonary Hypertension: Developed by the Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Eur Heart J 2022;Aug 26 2. Ventavis [Package Insert]. South San Francisco, CA; Actelion Pharmaceuticals US, Inc.: 2009

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	1. Clinicaltrials.gov. Open-Label Efficacy and Safety Study of Pozelimab in Patients With CD55-Deficient Protein-Losing Enteropathy (CHAPLE Disease) (NCT04209634). 2. Veopoz [Package Insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; August 2023
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	1. Vibativ [Package Insert]. South San Francisco, CA; Theravance, Inc.: 2009

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Visco-3 (hyaluronan/hyaluronic acid) *for intra-articular injection*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One treatment series every 6 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Euflexxa and one of the following: Durolane, Gelsyn-3, or Supartz FX.
	Indications	All Medically-Accepted Indications
	References	1. Visco-3 [Package Insert]. Tokyo, Japan; Seikagaku Corporation
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	1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. 2. Vivimusta [Package Insert]. Sermoneta, Italy; Corden Pharma Latina S.p.A.: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyepti (eptinezumab-jjmr)	**Exclusion Criteria**	Must not be used in combination with other CGRP antagonist therapy.
	Required Medical Information	**For initial requests:** (1) Medical records supporting the request must be provided; (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, Ajovy, 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	1. Vyepti [Package Insert]. Bothell, WA; Lundbeck Seattle BioPharmaceuticals, Inc.: 2020 2. Sacco S, Amin FM, Ashina M, et al: European Headache Federation guideline on the use of monoclonal antibodies targeting the calcitonin gene related peptide pathway for migraine prevention - 2022 update. J Headache Pain 2022; 23(1):67.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyjuvek Gel topical (beremagene geperpavec-svdt)	**Exclusion Criteria**	Patients with any of the following will not be approved for coverage: (1) Current evidence or a history of squamous cell carcinoma in the area that will undergo treatment; OR, (2) Active infection in the area to be treated; OR, (3) Skin graft in the past 3 months.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of a diagnosis of DEB and documentation of genetic testing confirming mutation(s) in the COL7A1 gene.
	Age Restrictions	Patient is at least 6 months of age.
	Prescriber Restrictions	Prescribed by or in consultation with a dermatologist who specializes in DEB management
	Coverage Duration	6 months initial and reauthorization
	Other Criteria	**Initial**: Must have presence of open DEB skin wounds - **AND** - application is limited to open DEB skin wounds only. **Reauthorization**: Clinical documentation must be provided to confirm that initial criteria are met and that the Vyjuvek is providing clinical benefit (e.g. complete wound closure, decrease in wound size, increase in granulation tissue).
	Indications	All FDA-Approved Indications
	References	1. Vvyjuvek [Package Insert]. Pittsburgh, PA; Krystal Biotech, Inc.: 2023

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyvgart (efgartigimod alfa-fcab)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Rystiggo, or Zilbrysq. (Vyvgart has not been studied and there is no data to support use in combination with other medications used to treat MG)
	Required Medical Information	**For initial coverage, must have:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 5 - AND - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - AND - (3) Trial of two non-steroid, generic immunosuppressants (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months each (onset of action is slow and make take several months) with an inadequate response or intolerance. **For initial and reauthorization:** Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References	1. Narayanaswami P, Sanders DB, Wolfe GI, et al. International consensus guidance for management of myasthenia gravis: 2020 update. Neurology. 2021; 96: 114 - 22. 2. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. European J Neurol. 2010 Jul; 17 (7): 893 - 902. 3. Vyvgart [Package Insert]. Zwijnaarde, Belgium; argenx BV: 2021 4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2016 Jul 26; 87 (4): 419 - 25. 5. Howard JF Jr. Clinical Overview of MG. Myasthenia Gravis Foundation of America (MGFA). Published June 2015. https://myasthenia.org/Professionals/Clinical-Overview-of-MG

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Rystiggo, or Zilbrysq. (Vyvgart Hytrulo 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 two non-steroid, generic immunosuppressants (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months each (onset of action is slow and make take several months) with an inadequate response or intolerance. **For initial and reauthorization:** Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year initial; 2 years reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	**For reauthorization:** Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References	1. Narayanaswami P, Sanders DB, Wolfe GI, et al. International consensus guidance for management of myasthenia gravis: 2020 update. Neurology. 2021; 96: 114 - 22. 2. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. European J Neurol. 2010 Jul; 17 (7): 893 - 902. 3. Vyvgart Hytrulo [Package Insert]. Zwijnaarde, Belgium; argenx BV: 2023 4. Howard JF Jr. Clinical Overview of MG. Myasthenia Gravis Foundation of America (MGFA). Published June 2015. https://myasthenia.org/Professionals/Clinical-Overview-of-MG. 5. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2016 Jul 26; 87 (4): 419 - 25.

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xenleta (lefamulin)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must first try all other susceptible antibiotics as determined by culture and sensitivity (e.g., moxifloxacin, azithromycin, doxycycline, linezolid).
	Indications	All Medically-Accepted Indications
	References	1. Xenleta [Package Insert]. Dublin, Ireland; Nabriva therapeutics Ireland DAC: 2019

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xenpozyme (olipudase-alfa-rpcp) *20 MG VIAL*	**Exclusion Criteria**	Patient must not have ASMD Type A.
	Required Medical Information	Must provide medical records supporting the request and patient's current weight and height. For initial coverage, must also provide the following: • Documentation of a diagnosis of acid sphingomyelinase deficiency (ASMD) Type A/B or Type B • Confirmation of ASMD by enzyme assay demonstrating low ASM enzyme activity (<10% of controls) • Clinical symptoms of ASMD including low diffusion capacity of the lungs for carbon monoxide (DLCO) and splenomegaly • 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	1. National Organization of Rare Disorders. Acid sphingomyelinase deficiency. 2019. 2. McGovern MM, Dionisi-Vici C, Giugliani R, at al. Consensus recommendation for a diagnostic guideline for acid sphingomyelinase deficiency. Genet Med. 2017 Sep; 19 (9): 967 - 74. 3. Xenpozyme [Package Insert]. Cambridge, MA; Genzyme Corporation: 2022

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xgeva (denosumab)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Up to 2 years. Doses will be approved according to the FDA- approved labeling or within accepted standards of medical practice.
	Other Criteria	For all medically-accepted indications except bone metastases from breast, prostate, and lung cancer: Must first try zoledronic acid (generic Zometa)
	Indications	All Medically-Accepted Indications
	References	1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2020 Update. Endocr Pract. 2020;26(Suppl 1):1-46. doi:10.4158/GL-2020-0524SUPPL 2. Chakhtoura M, El-Hajj Fuleihan G. Treatment of Hypercalcemia of Malignancy. Endocrinol Metab Clin North Am. 2021;50(4):781-792. doi:10.1016/j.ecl.2021.08.002 3. National Comprehensive Cancer Network. Breast Cancer (Version 5.2023) 4. National Comprehensive Cancer Network. Bone Cancer (Version 1.2024) 5. National Comprehensive Cancer Network. Multiple Myeloma (Version 2.2024) 6. National Comprehensive Cancer Network. Prostate Cancer (Version 4.2023) 7. Xgeva [Package Insert]. Thousand Oaks, CA; Amgen Inc.: 2013

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
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	1. Xipere [Package Insert]. Alpharetta, GA; Clearside Biomedical, Inc.: 2021

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Xolair (omalizumab) *vial/prefilled syringe*	**Exclusion Criteria**	Must not be used in combination with other biologic drugs (e.g., Dupixent, Nucala, Fasenra).
	Required Medical Information	**For all medically-accepted indications:** Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. **For asthma and nasal polyp indications:** Must provide patient's current weight and baseline IgE level.
	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 asthma:** (1) 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 - (2) For reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). **For chronic urticaria:** (1) 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 - AND - (2) For reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). **For nasal polyps:** (1) Must try and fail (defined as an inability to improve symptoms for least 8 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).
	Indications	All Medically-Accepted Indications
	References	1. Global Initiative for Asthma. Difficult-To-Treat & Severe Asthma in adolescents and adult patients, 2023. 2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023 3. Xolair [Package Insert]. South San Francisco, CA: Genentech, Inc.: 2019

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Yescarta (axicabtagene ciloleucel)	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA approved labeling or accepted standards of medical practice.
	Other Criteria	Must follow NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).
	Indications	All Medically-Accepted Indications
	References	1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy. 2. Yescarta [Package Insert]. Santa Monica, CA; Kite Pharma, Inc.: 2022
Yupelri (revefenacin)	**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 Spiriva **AND** Incruse Ellipta.
	Indications	All Medically-Accepted Indications
	References	1. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2023 Report). Global Initiative for Chronic Obstructive Lung Disease, 2023. 2. Yupelri [Package Insert]. Morgantown, WV; Mylan Specialty L.P.: 2018

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Yutiq (fluocinolone) *implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	For reauthorization, must have disease response indicated by stability or improvement in condition compared to baseline.
	Indications	All Medically-Accepted Indications
	References	1. Yutiq [Package Insert]. Watertown, MA; EyePoint Pharmaceuticals US, Inc.: 2021
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	1. Ziextenzo [Package Insert]. Princeton, NJ; Sandoz Inc.: 2019

DRUG	PA/ST CRITERIA	CRITERIA DETAILS
Zilbrysq (zilucoplan injection, solution)	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Rystiggo. (Zilbrysq has not been studied and there is no data to support use in combination with other medications used to treat MG).
	Required Medical Information	**For initial requests, must have:** (1) Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive – AND – (2) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more – AND – (3) Trial of Vyvgart or Rystiggo with an inadequate response or intolerance – AND – (4) Trial of Ultomiris with an inadequate response or intolerance. **For initial and reauthorization:** Medical records supporting the request must be provided.
	Age Restrictions	Must be at least 18 years old.
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	12 weeks (initial); 1 year (reauthorization). Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	For reauthorization: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline.
	Indications	All FDA-Approved Indications
	References	1. Narayanaswami P, Sanders DB, Wolfe GI, et al. International consensus guidance for management of myasthenia gravis: 2020 update. Neurology. 2021; 96: 114 - 22. 2. Skeie GO, Apostolski S, Evoli A, et al. Guidelines for treatment of autoimmune neuromuscular transmission disorders. European J Neurol. 2010 Jul; 17 (7): 893 - 902. 3. Zilbrysq [Package Insert]. Smyrna, Georgia; UCB, Inc.: 2023 4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2016 Jul 26; 87 (4): 419 - 25. 5. Howard JF Jr. Clinical Overview of MG. Myasthenia Gravis Foundation of America (MGFA). Published June 2015. https://myasthenia.org/Professionals/Clinical-Overview-of-MG 6. Clinicaltrials.gov. Open-Label Extension of Zilucoplan in Subjects With Generalized Myasthenia Gravis (RAISE-XT). Available at: https://clinicaltrials.gov/study/NCT04225871. 7. Clinicaltrials.gov. Safety, Tolerability, and Efficacy of Zilucoplan in Subjects With Generalized Myasthenia Gravis (RAISE). Available at: https://clinicaltrials.gov/study/NCT04115293.

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	1. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) 110.24 Chimeric Antigen Receptor (CAR) T-cell Therapy. 2. Zolgensma [Package Insert]. Bannockburn, IL; Novartis Gene Therapies, Inc. 2023

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	1. Zynteglo [Package Insert]. Somerville, MA; bluebird bio, Inc.: 2022 2. Clinicaltrials.gov. A Study Evaluating the Efficacy and Safety of the LentiGlobin® BB305 Drug Product in Participants With Transfusion-Dependent β-Thalassemia, Who do Not Have a β0/β0 Genotype. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT02906202 3. Clinicaltrials.gov. A Study Evaluating the Efficacy and Safety of the LentiGlobin® BB305 Drug Product in Participants With Transfusion-Dependent β-Thalassemia. Available at: https://clinicaltrials.gov/study/NCT03207009. 4. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassemia. 2021. Available at: https://issuu.com/internationalthalassaemiafederation/docs/final_guideline_4th