HAP Medicare Part B

Prior Authorization and Step Therapy Criteria

April 2025

Health Alliance Plan (HAP) has HMO, HMO-POS, PPO plans with Medicare contracts. Enrollment depends on contract renewal.

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HAP
Medicare Part B
Prior Authorization and Step Therapy Criteria

This document contains information regarding HAP Medicare Part B (medical) drugs requiring prior authorization and/or step therapy.

HAP 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, HAP 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 HAP 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).

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. The preferred step drugs must be tried and failed with failure defined as an inadequate response or intolerance to treatment, which must be indicated by your provider or medical records. Step therapy for Part B drugs applies to members who are enrolled in a Medicare Advantage Prescription Drug (MAPD) plan and are not currently receiving the Part B drug.

What is a medically accepted indication (MAI)?

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

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

For Part B: If no NCD, LCD, LCA or other coverage policies exist, Part B drugs will be reviewed for a medically accepted indication. An unlabeled use of a drug may be covered if a HAP 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 HAP determine criteria for a Part B drug? HAP 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, HAP 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 HAP'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.

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

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 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.

For new-to-market drugs not yet reviewed by the HAPs 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

Your doctor can submit a prior authorization for a drug on this list using the HAP Provider Portal on www.hap.org.

Drug	PA/ST Criteria	Criteria Details
Actemra *(tocilizumab)*	**Exclusion Criteria**	Must not be used in combination with other biologic drugs or Otezla.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Up to 1 year. 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 cellarteritis, and treatment of COVID-19): Must first try Inflectra OR Renflexis.and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Alhemo *(Concizumab)*	**Exclusion Criteria**	Must not be used in combination with other drugs indicated for prophylaxis for hemophilia A or B
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. Member must have a documentation of either hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescription must be written by a hematologist.
	Coverage Duration	1. Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. 2. Initial dosing will be Loading dose: 300 mg (two 150 mg injections) by subcutaneous injection followed by: Maintenance dose: One week after the loading dose, initiate maintenance dosing of 150 mg every week. 3. Dose adjustments to 300 mg weekly will require medical records documenting medical necessity, such as increase in spontaneous bleeding.
	Other Criteria	For hemophilia A, must have a trial of two drugs for prophylaxis with one being Hemlibra. For hemophilia B, must has have a trial of two drugs for prophylaxis such as Alprolix, BeneFIX or Idelvion
	Indications	All Medically-Accepted Indications

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

Drug	PA/ST Criteria	Criteria Details
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

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 1 year. 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

Drug	PA/ST Criteria	Criteria Details
Avtozma *(tocilizumab-anoh)*	**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 1 year. 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 cellarteritis, and treatment of COVID-19): Must first try Inflectra OR Renflexis.and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Beovu *(Brolucizumab)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Avastin (bevacizumab).
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Bkemv *(eculizumab-aeeb)*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Epysqli (eculizumab-aagh). Criteria applies
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Byooviz *(Ranibizumab-nuna)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Avastin (bevacizumab).
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Cimreli *(Ranibizumab-eqrn)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Avastin (bevacizumab).
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Cosentyx *(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	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 Inflectra **OR** Renflexis and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Durysta *(bimatoprost) intraocular implant*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation or prior therapies and response to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must try two of the following: latanoprost, bimatoprost, travoprost.
	Indications	All Medically-Accepted Indications

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	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 Inflectra **OR** Renflexis and Hadlima. 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 FDA-Approved Indications

Drug	PA/ST Criteria	Criteria Details
Epysqli *(eculizumab-aagh)*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	For NMSOD and myasthenia gravis: Must be prescribed by or in consultation with a neurologist.
	Coverage Duration	Up to 1 year. In accordance with the FDA-approved labeling or accepted standards of medical practice.
	Other Criteria	**For neuromyelitis optica spectrum disorder (NMOSD):** 1. Patient has anti-aquaporin-4 (AQP4) antibody positive disease - **AND** - 2. Patient is exhibiting one of the following core clinical characteristics: optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions - **AND** - 3. Patient has tried and failed (defined as an inadequate response or intolerance) Uplizna. **AND** - 4. Patient has tried and failed (defined above) Enspryng - **AND** - 5. Must have an Expanded Disability Status Scale (EDSS) score of ≤7

		- **AND** - 6. Epysqli will not be used in combination with Ultomiris, Uplizna, Enspryng, or other medications to treat neuromyelitis optica spectrum disorder (NMOSD) - **AND** - 7. For reauthorization requests: (1) Epysqli will not be used in combination with Ultomiris, Uplizna, Enspryng, or other medications for neuromyelitis optica spectrum disorder (NMOSD); **AND** (2) documentation of a decrease in relapse rate must be provided **For myasthenia gravis:** 1. Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or more - **AND** 2. Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - **AND** - 3. Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - **AND** - 4. Trial of Vyvgart with an intolerance or inadequate response - **AND** - 5. Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq. (Epysqli has not been studied and there is no data to support use in combination with other medications used to treat MG) - **AND** - 6. For reauthorization requests: (1) Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Vyvgart, Ultomiris, Rystiggo, or Zilbrysq; **AND** (2) Must have documentation of improvement in the MG-ADL total score from baseline. **For atypical hemolytic uremic syndrome (aHUS):** 1. Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out - **AND** - 2. For reauthorization, documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine). **For paroxysmal nocturnal hemoglobinuria (PNH):** 1. Must have diagnosis confirmed by flow cytometry – **AND** – 2. Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain) – AND 3. Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli. (Epysqli has not been studied and there is no data to support use in combination with other medications used for PHN) - **AND** – 4. For reauthorization requests: (1) Must not be used in combination with other complement drug therapy including Fabhalta, Ultomiris, Empaveli; **AND** (2) Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - **AND** - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline.
	Indications	All Medically-Accepted Indications

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 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.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Eylea *(Aflibercept)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Avastin (bevacizumab).
	Indications	All Medically-Accepted Indications

Drug	PA/ST	Criteria Details

	Criteria	
Eylea HD *(Aflibercept)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Eylea (Aflibercept).
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Fulphila *(Pegfilgrastim-jmbd)*	**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, Udenyca, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details

Fylnetra *(Pegfilgrastim-pbbk)*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Udenyca, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications

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

Drug	PA/ST Criteria	Criteria Details
Herceptin Hylecta *(trastuzumab/ hyaluronidase-oysk)*	**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

Drug	PA/ST Criteria	Criteria Details
Hercessi *(trastuzumab-strf)*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Trazimera **AND** Kanjinti. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications

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

Drug	PA/ST Criteria	Criteria Details
Hympavzi *(marstacimab hncq inj)*	**Exclusion Criteria**	Must not be used in combination with other drugs indicated for prophylaxis for hemophilia A or B
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment. Member must have a documentation of either hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescription must be written by a hematologist.
	Coverage Duration	4. Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. 5. Initial dosing will be Loading dose: 300 mg (two 150 mg injections) by subcutaneous injection followed by: Maintenance dose: One week after the loading dose, initiate maintenance dosing of 150 mg every week. 6. Dose adjustments to 300 mg weekly will require medical records documenting medical necessity, such as increase in spontaneous bleeding.
	Other Criteria	For hemophilia A, must have a trial of two drugs for prophylaxis with one being Hemlibra. For hemophilia B, must has have a trial of two drugs for prophylaxis such as Alprolix, BeneFIX or Idelvion
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
iDose TR *(travoprost) intracameral implant*	**Exclusion Criteria**	The requested eye for treatment must not have received prior treatment with IDOSE TR.
	Required Medical Information	1. Medical records supporting the request must be provided; AND 2. Patient has open angle glaucoma or ocular hypertension; AND 3. Patient meets one of the following (a or b): a. Patient has tried and failed one generic prostaglandin eye drop such as latanoprost, bimatoprost, or travoprost - and - Durysta; OR b. Patient is not able to use Durysta and has tried and failed two generic topical prostaglandin eye drops Failed is defined as a trial with an inadequate response or intolerance, or a trial with demonstrated compliance issues with glaucoma eye drops.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	One-time administration as indicated per the FDA-approved labeling or within accepted standards of medical practice.
	Other Criteria	N/A
	Indications	All FDA-Approved Indications

Drug	PA/ST Criteria	Criteria Details
Ilumya *(Tildrakizumab)*	**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 1 year. 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 and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Ixifix *(Infliximab-qbtx)*	**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	1 year. 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

Drug	PA/ST Criteria	Criteria Details
Izervay *(Avacincaptad pegol)*	**Exclusion Criteria**	GA (geographic atrophy) secondary to a condition other than AMD (age-related macular degeneration) is not covered. Izervay must not be used in combination with Syfovre or any other medication for GA (Izervay has not been studied and there is no data to support use in combination with other medications used to treat GA).
	Required Medical Information	Medical records supporting the request must be provided. For initial requests, must also have documentation confirming the diagnosis.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by or in consultation with an ophthalmologist.
	Coverage Duration	1 year. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.
	Other Criteria	Must try Syfovre. 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

Drug	PA/ST Criteria	Criteria Details
Kisunla *(donanemab-azbt)*	**Exclusion Criteria**	1. Bleeding disorder that is not under adequate control (including a platelet count less than 50,000 or international normalized ratio [INR] greater than 1.5); 2. Combination therapy with any other amyloid beta-directed antibodies (e.g., aducanumab).
	Required Medical Information	1. Member has a signed consent form and is enrolled in a CMS-approved registry. 2. Diagnosis of mild cognitive impairment (MCI) or early dementia caused by Alzheimer's disease 3. Members must have one of the following scores at baseline on any of the following assessment tools: • Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1; or • Mini-Mental Status Examination (MMSE) score of 20 – 30; or • Montreal Cognitive Assessment (MoCA) score of greater than or equal to 16 4. Confirmed presence of amyloid beta pathology prior to initiating treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescribed by a board-certified neurologist, geriatric psychiatrist, or geriatrician participating in a registry.
	Coverage Duration	1. Up to 1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. 2. Initial dosing will be 700 mg IV infusion over 30 minutes every 4 weeks for 3 doses and then increase to 1400 mg IV infusion every 4 weeks thereafter.
	Other Criteria	1. Member meets one of the following regarding apolipoprotein E ε4 (ApoE ε4) status: • Genotype testing for ApoE ε4 status has been performed prior to initiation of treatment to inform member of the risk of developing ARIA. Member is ApoE ε4 heterozygote or non-carrier; OR • Genotype testing has not been performed and the prescriber has informed the member that it cannot be determined if they are ApoE ε4 homozygous and may be at higher risk for ARIA [applies to Medicare members only].
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Leqembi *(lecanemab-irmb)*	**Exclusion Criteria**	1. Bleeding disorder that is not under adequate control (including a platelet count less than 50,000 or international normalized ratio [INR] greater than 1.5); 2. Combination therapy with any other amyloid beta-directed antibodies (e.g., aducanumab).
	Required Medical Information	1. Member has a signed consent form and is enrolled in a CMS-approved registry. 2. Diagnosis of mild cognitive impairment (MCI) or early dementia caused by Alzheimer's disease 3. Members must have one of the following scores at baseline on any of the following assessment tools: • Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1; or • Mini-Mental Status Examination (MMSE) score of 20 – 30; or • Montreal Cognitive Assessment (MoCA) score of greater than or equal to 16 4. Confirmed presence of amyloid beta pathology prior to initiating treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescribed by a board-certified neurologist, geriatric psychiatrist, or geriatrician participating in a registry.
	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	1. Member meets one of the following regarding apolipoprotein E ε4 (ApoE ε4) status: • Genotype testing for ApoE ε4 status has been performed prior to initiation of treatment to inform member of the risk of developing ARIA. Member is ApoE ε4 heterozygote or non-carrier; OR • Genotype testing has not been performed and the prescriber has informed the member that it cannot be determined if they are ApoE ε4 homozygous and may be at higher risk for ARIA [applies to Medicare members only].
	Indications	All Medically-Accepted Indications

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	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Patient has tried Repatha and LDL-C remains greater than or equal to 70mg/dL. For reauthorization, documentation confirming patient has improved and maintained an improved LDL compared to baseline must be provided.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Lucentis *(Ranibizumab)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Avastin (bevacizumab).
	Indications	All Medically-Accepted Indications

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	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

Drug	PA/ST Criteria	Criteria Details
Ohtuvayre *ensifentrine) inhalation suspension*	**Exclusion Criteria**	Must not be used in combination with roflumilast.
	Required Medical Information	Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. For initial requests, medical records supporting the request must be provided and include the following: 1. Diagnosis of moderate-to-severe COPD defined as an FEV1 between 30-70% - AND - 2. Within the past year, the patient has had two or more COPD exacerbations that required the use of oral steroids - OR - 1 COPD exacerbation that required hospitalization or an emergency room visit – AND – 3. Trial and failure of dual or triple therapy in the past 6 months that included a LABA/LAMA therapy (e.g., Trelegy Ellipta, Anoro Ellipta, Stiolto Respimat). Failure is defined as no improvement, worsening of the condition, or an intolerance after trying the required therapy at the maximum dosages for at least 4 weeks consistently.
	Age Restrictions	Patient is at least 18 years of age.
	Prescriber Restrictions	Prescriber is or has consulted a pulmonologist.
	Coverage Duration	1 year. Dose will be approved according to the FDA- approved labeling or within accepted standards of medical practice.
	Other Criteria	For reauthorization, documentation supporting a decrease in symptoms, improvement in lung function, and/or reduced COPD exacerbations with Ohtuvayre compared to baseline must be provided.
	Indications	All FDA-Approved Indications

Drug	PA/ST Criteria	Criteria Details
Omvoh *(Mirikizumab-mrkz)*	**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	Up to 1 year. 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	Must first try Inflectra **OR** Renflexis and Hadlima.
	Indications	All FDA-Approved Indications

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

Drug	PA/ST Criteria	Criteria Details
Opdivo Qvantig *(nivolumab hyaluronidase nvhy)*	**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 Opdivo IV infusion. Criteria will be applied consistent with LCD L37205: Chemotherapy Drugs and their Adjuncts.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Phesgo *(Pertuzumab/ trastuzumabhyaluronidase-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.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Remicade *(Infliximab)*	**Exclusion Criteria**	Must not be used in combination with other biological drugs or Otezla.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	1 year. 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	Must not be used in combination with other biological drugs or Otezla.

Drug	PA/ST Criteria	Criteria Details
Riabni *(Rituximab-arrx)*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1year. 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

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	1 year. 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

Drug	PA/ST Criteria	Criteria Details
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	1 year. 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

Drug	PA/ST Criteria	Criteria Details
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, Udenyca, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Simponi Aria *(Golimumab)*	**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	1 year. 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 and Hadlima. For reauthorization: Must have a positive clinical response to Simponi Aria (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 FDA-Approved Indications

Drug	PA/ST Criteria	Criteria Details
Skyrizi *(Risankizumab)*	**Exclusion Criteria**	Must not be used in combination with other biological drugs or Otezla.
	Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.
	Age Restrictions	N/A
	Prescriber Restrictions	Prescriber is, or has consulted with, a specialist for the condition being treated.
	Coverage Duration	Three IV induction doses will be approved. Subsequent maintenance doses must be approved under the pharmacy benefit.
	Other Criteria	Must first try Inflectra **OR** Renflexis and Hadlima.
	Indications	All Medically-Accepted Indications

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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Epysqli (eculizumab-aagh). Criteria applies
	Indications	All Medically-Accepted Indications

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	**For GPP requests:** (1) Medical records supporting the request must be provided; **AND** (2) Patient has a diagnosis of generalized pustular psoriasis (GPP) confirmed by a skin biopsy, presence of systemic symptoms such as fever and fatigue, **AND** relapsing episodes (history of GPP flares); **AND** (3) Patient is experiencing a GPP flare of moderate-to-severe intensity defined by all the following (a, b, c, and d): (a) a Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 3 or more; (b) New or worsening pustules; (c) a GPPPGA pustulation sub-score of 2 or more; and (d) 5% of more of body surface area (BSA) with erythema and pustules; **AND** (4) Must first try and fail (defined as an inability to improve flares) one traditional non- biologic immunomodulator drug or a generic retinoid (ex: cyclosporine, acitretin, isotretinoin); **AND** must try and fail (defined above) a biologic DMARD with evidence for use in GPP (ex: infliximab).
	Age Restrictions	Must be age 12 or older
	Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	Coverage Duration	Up to 2 infusions total as indicated per the FDA approved labeling and accepted standards of medical practice. Reauth: N/A.
	Other Criteria	N/A
	Indications	FDA-Approved Indications

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

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	Must first try Must first try Inflectra **OR** Renflexis and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Stimufed *(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, Udenyca, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
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	1 year. 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

Drug	PA/ST Criteria	Criteria Details
Tofidence *(tocilizumab-bavi)*	**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 1 year. 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 cellarteritis, and treatment of COVID-19): Must first try Inflectra OR Renflexis.and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Tremfya *(Guselkumab)*	**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 1 year. 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	Must first try Must first try Inflectra **OR** Renflexis and Hadlima.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Tyenne *(tocilizumab-aazg)*	**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 1 year. 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 cellarteritis, and treatment of COVID-19): Must first try Inflectra OR Renflexis and Hadlima.
	Indications	All Medically-Accepted Indications

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

		Zilbrysq. **For atypical hemolytic uremic syndrome (aHUS):** **1.** Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out; **AND** **2.** Medical records supporting the request must be provided; **AND** 3. For reauthorization, must have documentation of decreased signs of thrombotic microangiopathy (e.g., normalization of platelet counts and LDH levels; reduction in serum creatinine). **For paroxysmal nocturnal hemoglobinuria (PNH):** **1.** Must have diagnosis confirmed by flow cytometry; **AND** **2.** Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain); **AND** **3.** Must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli. (Ultomiris has not been studied and there is no data to support use in combination with other medications used for PHN); **AND** **4.** Medical records supporting the request must be provided; **AND** 5. For reauthorization: Must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) compared to baseline - **AND** - a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline - **AND** - must not be used in combination with other complement drug therapy including Fabhalta, Soliris, Empaveli.
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Vabysmo *(Faricimab-svoa)*	**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	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
	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 try Eylea (Aflibercept).
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Vegzelma *(Bevacizumab-adcd)*	**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

Drug	PA/ST Criteria	Criteria Details
Vyalev *(foscarbidopa and foslevodopa)*	**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	Must be prescribed by, or in consultation with, a neurologist.
	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 carbidopa/levodopa extended-release tablet (Sinemet CR) or carbidopa/ levodopa tablets (Sinemet) with members taking ≥400 mg/day of LD equivalents, and one other agent from a different class (entacapone, ropinirole, amantadine, ect)
	Indications	All Medically-Accepted Indications

Drug	PA/ST Criteria	Criteria Details
Vyepti *(Eptinezumab-jjmr)*	**Exclusion Criteria**	Must not be used in combination with other CGRP antagonist therapy.
	Required Medical Information	**For initial requests:** (1) Medical records supporting the request must be provided; AND (2) Patient must be evaluated for and determined not to have medication overuse headache (MOH); (3) must first try 2 of the following for at least 3 months each and be unable to adequately reduce migraine headaches: Aimovig, Ajovy, and/or Nurtec.
	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 reauthorization: Must provide evidence of clinical improvement including a reduction in monthly migraine days compared to baseline.
	Indications	All FDA-Approved Indications

Drug	PA/ST Criteria	Criteria Details
Vyvgart *(Efgartigimod-fcab)*	**Exclusion Criteria**	Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Rystiggo, or Zilbrysq. (Vyvgart has not been studied and there is no data to support use in combination with other medications used to treat MG)
	Required Medical Information	**For initial coverage, must have:** (1) Baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of at least 5 - **AND** - (2) Confirmed diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - **AND** - (3) Trial of one non-steroid, generic immunosuppressant (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus) for at least 6 months (onset of action is slow and make take several months) with an inadequate response or intolerance - **AND** - (4) Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year. 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

Drug	PA/ST Criteria	Criteria Details
Vyvgart hyrtulo *(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 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 – Vyvgart intravenous. (4) Medical records supporting the request must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	Must be prescribed by, or in consultation with, a neurologist.
	Coverage Duration	1 year. 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

Drug	PA/ST Criteria	Criteria Details
Ziextenzo *(Pegfilgrastim-bmez)*	**Exclusion Criteria**	N/A
	Required Medical Information	Medical records supporting the request, including documentation of prior therapies and responses to treatment, must be provided.
	Age Restrictions	N/A
	Prescriber Restrictions	N/A
	Coverage Duration	1 year. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
	Other Criteria	Must first try Neulasta, Udenyca, **AND** Nyvepria.
	Indications	All Medically-Accepted Indications