Medicare Advantage Plans Part B Drugs Prior Authorization Criteria 2026

This prior authorization document was updated on 6/16/2026. To determine if your drug has a prior authorization requirement, or for information on how to request an authorization for any of these drugs, please contact Customer Care at 1-844-280-5555 toll free (TTY users should call 711), from 8 am to 8 pm, 7 days a week (October 1 – March 31) and 8 am to 8 pm, Monday – Friday (April 1 – September 30).

Este documento de autorización previa fue actualizado el 6/16/2026. Para determinar si su medicamento tiene un requisito de autorización previa, o para obtener información sobre cómo solicitar una autorización para cualquiera de estos medicamentos, comuníquese con Atención al Cliente al 1-844-280-5555 sin costo (los usuarios de TTY deben llamar al 711), de 8 a.m. a 8 p.m., los 7 días de la semana (del 1 de octubre al 31 de marzo) y de 8 a.m. a 8 p.m., de lunes a viernes (del 1 de abril al 30 de septiembre).

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-096-CM-V-3	
GlobalHealth	TITLE Givlaari Prior Authorization Approval Criteria	EFFECTIVE DATE 1/27/2021	LAST REVISED 4/11/2024

Therapeutic class: Gastrointestinal Agent

Available dosage forms: Subcutaneous Solution: 189 MG/1 ML

Criteria for initial approval (3 months):

1. FDA-approved diagnosis: Acute Hepatic Porphyria (Acute Intermittent Porphyria, Hereditary Corproporhyria, Variegate Porphyria, ALA dehydratase deficient porphyria)
2. Prescribed dose is no more than 2.5mg/kg once monthly
3. Diagnosis is confirmed by genetic testing (applies to Medicare Advantage patients only)
4. Prescribed by or in consultation with a physician who specializes in treatment of Acute Hepatic Porphyria (hepatologist, gastroenterologist, hematologist)
5. Member is 18 years of age or older
6. No anticipated liver transplantation
7. No active HIV, hepatitis C virus, or hepatitis B virus infection(s)
8. No history of recurrent pancreatitis
9. All of the following:
   - 9.1. Member has elevated urinary or plasma PBG (urinary porphobilinogen) or ALA (urinary aminolevulinic acid) values within the past year; AND
   - 9.2. Member has active disease, with at least 2 documented porphyria attacks (requiring hospitalization, urgent healthcare visit, or intravenous hemin administration) within the last 6 months; AND
   - 9.3. Member is not prophylactically using hemin while on the requested treatment (this does NOT include hemin treatment for acute attacks)

Criteria for renewal:

1. Member continues to meet initial approval criteria; AND
2. Member has a positive response, defined as ≥ 70% reduction from baseline in fewer porphyria attacks that required hospitalizations, urgent healthcare visits or intravenous hemin administration; AND
3. No unacceptable toxicity, such as anaphylactic reactions, hepatic toxicity (severe or clinically significant transaminase elevations), renal toxicity, etc.

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Givlaari
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Givlaari covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information and the clinical trial ENVISION cited in the prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Givosiran (Givlaari) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically
2. Givlaari [Prescribing Information]. Alnylam Pharmaceuticals, Inc., Cambridge, MA. January 2022. Available at: https://www.alnylam.com/sites/default/files/pdfs/GIVLAARI-Prescribing-Information.pdf
3. ENVISION: A Study to Evaluate the Efficacy and Safety of Givosiran (ALN-AS1) in Patients With Acute Hepatic Porphyrias (AHP). Available at: https://clinicaltrials.gov/ct2/show/NCT03338816

P&T Committee review dates: 1/27/2021, 4/27/2022, 4/26/2023
UM Committee review dates: 12/29/2023, 4/11/2024, 2/3/2025, 3/17/2026

Part B Drug Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-101-M-V-4	
GlobalHealth	TITLE Oncology Drug Treatment Prior Authorization Approval Criteria	EFFECTIVE DATE 2/16/2024	LAST REVISED 3/17/2026

List of applicable medications:

- Injection, doxorubicin hydrochloride, 10 mg
- Injection, aldesleukin, per single use vial
- Injection, arsenic trioxide, 1 mg
- Injection, asparaginase (Erwinaze), 1, 000 IU
- Injection, asparaginase, not otherwise specified, 10, 000 units
- Injection, asparaginase, recombinant, (rylaze), 0.1 mg
- Injection, atezolizumab, 10 mg
- Injection, avelumab, 10 mg
- Injection, azacitidine, 1 mg
- Injection, clofarabine, 1 mg
- Injection, nadofaragene firadenovec-vncg, per therapeutic dose
- BCG live intravesical instillation, 1 mg
- Injection, belinostat, 10 mg
- Injection, bendamustine HCL (treanda), 1 mg
- Injection, bendamustine HCL (bendeka), 1 mg
- Injection, bevacizumab, 10 mg
- Injection, bendamustine hydrochloride, (Belrapzo), 1 mg
- Injection, belantamab mafodontin-blmf, 0.5 mg
- Injection, blinatumomab, 1 microgram
- Injection, bleomycin sulfate, 15 units
- Injection, bortezomib, 0.1 mg
- Injection, brentuximab vedotin, 1 mg
- Injection, cabazitaxel, 1 mg
- Injection, carboplatin, 50 mg
- Injection, bortezomib, (dr. reddy's), not therapeutically equivalent to j9041, 0.1 mg
- Injection, carfilzomib, 1 mg
- Injection, bortezomib (fresenius kabi), not therapeutically equivalent to j9041, 0.1 mg
- Injection, bortezomib (hospira), not therapeutically equivalent to j9041, 0.1 mg
- Injection, carmustine, 100 mg
- Injection, bortezomib (maia), not therapeutically equivalent to j9041, 0.1 mg
- Injection, cetuximab, 10 mg
- Injection, bendamustine hydrochloride (vivimusta), 1 mg
- Injection, copanlisib, 1 mg
- Injection, bendamustine hydrochloride (apotex), 1 mg
- Injection, bendamustine hydrochloride (baxter), 1 mg
- Injection, cisplatin, powder or solution, 10 mg
- Injection, amivantamab-vmjw, 2 mg
- Injection, mirvetuximab soravtansine-gynx, 1 mg
- Injection, cabazitaxel (sandoz), not therapeutically equivalent to j9043, 1 mg
- Injection, cladribine, per 1 mg
- Cyclophosphamide, 100 mg
- Injection, cyclophosphamide, (auromedics), 5 mg

- Injection, cytarabine liposome, 10 mg
- Injection, cytarabine, 100 mg
- Injection, calaspargase pegol-mknl, 10 units
- Injection, cemiplimab-rwlc, 1 mg
- Injection, dactinomycin, 0.5 mg
- Dacarbazine, 100 mg
- Injection, daratumumab, 10 mg and hyaluronidase-fihj
- Injection, daratumumab, 10 mg
- Injection, daunorubicin, 10 mg
- Injection, daunorubicin Citrate, liposomal formulation, 10 mg
- Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine
- Injection, degarelix, 1 mg
- Injection, denileukin diftitox, 300 micrograms
- Injection, diethylstilbestrol diphosphate, 250 mg
- Injection, docetaxel, 1 mg
- Injection, durvalumab, 10 mg
- Injection, Elliotts' B solution, 1 ml
- Injection, elotuzumab, 1 mg
- Injection, enfortumab vedotin-ejfv, 0.25 mg
- Injection, epirubicin HCl, 2 mg
- Injection, eribulin mesylate, 0.1 mg
- Injection, etoposide, 10 mg
- Injection, fludarabine phosphate, 50 mg
- Injection, fluorouracil, 500 mg
- Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg
- Injection, gemcitabine hydrochloride, (infugem), 100 mg
- Injection, floxuridine, 500 mg
- Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg
- Goserelin acetate implant, per 3.6 mg
- Injection, gemtuzumab ozogamicin, 0.1 mg
- Injection, mogamulizumab-kpkc, 1 mg
- Injection, irinotecan liposome, 1 mg
- Injection, irinotecan, 20 mg
- Injection, ixabepilone, 1 mg
- Injection, ifosfamide, 1 gram
- Injection, mesna, 200 mg
- Injection, emapalumab-lzsg, 1 mg
- Injection, idarubicin hydrochloride, 5 mg
- Injection, interferon alfacon-1, recombinant, 1 microgram
- Injection, interferon, alfa-2a, recombinant, 3 million units
- Injection, interferon, alfa-2b, recombinant, 1 million units
- Injection, interferon, alfa-N3, (human leukocyte derived), 250, 000 IU
- Injection, interferon, gamma 1-b, 3 million units
- Leuprolide acetate (for depot suspension), 7.5 mg
- Leuprolide acetate, per 1 mg
- Leuprolide acetate implant, 65 mg
- Injection, lurbinectedin, 0.1 mg
- Histrelin implant (Vantas), 50 mg
- Histrelin implant (Supprelin LA), 50 mg
- Injection, isatuximab-irfc, 10 mg
- Injection, ipilimumab, 1 mg
- Injection, inotuzumab ozogamicin, 0.1 mg
- Injection, mechlorethamine hydrochloride, (nitrogen mustard), 10 mg

- Injection, melphalan hydrochloride, not otherwise specified, 50 mg
- Injection, melphalan (evomela), 1 mg
- Injection, melphalan flufenamide, 1mg
- Methotrexate sodium, 5 mg
- Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
- Methotrexate sodium, 50 mg
- Injection, nelarabine, 50 mg
- Injection, omacetaxine mepesuccinate, 0.01 mg
- Injection, oxaliplatin, 0.5 mg
- Injection, paclitaxel protein-bound particles, 1 mg
- Injection, pegaspargase, per single dose vial
- Injection, paclitaxel, 1 mg
- Injection, pentostatin, 10 mg
- Injection, tagraxofusp-erzs, 10 micrograms
- Injection, plicamycin, 2.5 mg
- Injection, pembrolizumab, 1 mg
- Injection, dostarlimab-gxly, 10 mg
- Injection, tisotumab vedotin-tftv, 1 mg
- Injection, tebentafusp-tebn, 1 microgram
- Injection, mitomycin, 5 mg
- Mitomycin pyelocalyceal instillation, 1 mg
- Injection, olaratumab, 10 mg
- Injection, mitoxantrone hydrochloride, per 5 mg
- Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
- Injection, necitumumab, 1 mg
- Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
- Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
- Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg
- Injection, nivolumab, 1 mg
- Injection, obinutuzumab, 10 mg
- Injection, ofatumumab, 10 mg
- Injection, panitumumab, 10 mg
- Injection, pemetrexed (pemfexy), 10 mg
- Injection, pemetrexed, not otherwise specified, 10 mg
- Injection, pertuzumab, 1 mg
- Injection, pralatrexate, 1 mg
- Injection, ramucirumab, 5 mg
- Injection, polatuzumab vedotin-piiq, 1 mg
- Injection, rituximab 10 mg and hyaluronidase
- Injection, rituximab, 10 mg
- Injection, moxetumomab pasudotox-tdfk, 0.01 mg
- Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg
- Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg
- Injection, sacituzumab govitecan-hziy, 2.5 mg
- Injection, romidepsin, non-lyophilized, 0.1 mg
- Injection, romidepsin, lyophilized, 0.1 mg
- Injection, streptozocin, 1 gram
- Injection, pemetrexed (bluepoint) not therapeutically equivalent to j9305, 10 mg
- Injection, pemetrexed ditromethamine, 10 mg
- Injection, talimogene laherparepvec, per 1 million plaque forming units
- Injection, temozolomide, 1 mg
- Injection, temsirolimus, 1 mg

- Injection, sirolimus protein-bound particles, 1 mg
- Injection, efgartigimod alfa-fcab, 2mg
- Injection, thiotepa, 15 mg
- Injection, retifanlimab-dlwr, 1 mg
- Injection, tremelimumab-actl, 1 mg
- Injection, naxitamab-gqgk, 1 mg
- Injection, tafasitamab-cxix, 2 mg
- Injection, mosunetuzumab-axgb, 1 mg
- Injection, topotecan, 0.1 mg
- Injection, trabectedin, 0.1 mg
- Injection, margetuximab-cmkb, 5 mg
- Injection, ado-trastuzumab emtansine, 1 mg
- Injection, trastuzumab, excludes biosimilar, 10 mg
- Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
- Injection, valrubicin, intravesical, 200 mg
- Injection, fam-trastuzumab deruxtecan-nxki, 1 mg
- Injection, loncastuximab tesirine-lpyl, 0.075 mg
- Injection, vinblastine sulfate, 1 mg
- Vincristine sulfate, 1 mg
- Injection, vincristine sulfate liposome, 1 mg
- Injection, teclistamab-cqyv, 0.5 mg
- Injection, teplizumab-mzwv, 5 mcg
- Injection, vinorelbine tartrate, 10 mg
- Injection, fulvestrant (teva) not therapeutically equivalent to j9395, 25 mg
- Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to j9395, 25 mg
- Injection, fulvestrant, 25 mg
- Injection, ziv-aflibercept, 1 mg
- Injection, porfimer sodium, 75 mg
- Not otherwise classified, antineoplastic drugs
- Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram
- Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
- Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
- Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
- Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
- Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
- Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
- Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg
- Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg
- Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
- Injection, pegfilgrastim-bmez (ziextenzo), biosimilar, 0.5 mg
- Injection, rituximab-arrx, biosimilar, (riabni), 10 mg
- Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg
- Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
- Injection, glofitamab gxbm, 2.5 mg
- Injection, epcoritamab-bysp 0.16 mg
- Inj, nogapendekin pmln, 1mcg
- Inj, cyclophosphamd, Sandoz
- Docetaxel (docivyx), 1 mg
- Inj melphalan (hepzato) 1 mg
- Inj, pemrydi rtu, 10 mg
- Injection, imetelstat, 1 mg
- Inj, decitabine (sun pharma)
- Inj atezolizumb 5mg hya-tqjs

- Inj, tarlatamab-dlle, 1 mg
- Inj cyclophos avyxa 5mg
- Inj pemetrexed (accord) 10mg
- Inj pemetrexed ditromethamin
- Telisotuzumab vedotin-tllv
- Inj thiotepa (tepylute) 1 mg
- Datopotamab deruxtecan, 1 mg
- Inj axatilimab-csfr 0.1 mg
- Inj bortezomib boruzu 0.1 mg
- Inj nivolumab 2 mg hyaluron
- Inj zenocutuzumab-zbco 1 mg
- Inj, cyclophos (baxter) 5mg
- Inj zanidatamab-hrii, 2 mg
- Inj, pemetrexed dipotassium
- Inj romidepsin non-lyo 0.1mg
- Inj, tislelizumab-jsgr
- Inj thiotepa nos 1 mg
- Afamitresgene autoleucel
- Inj, decitabine (sun pharma)
- Inj atezolizumb 5mg hya-tqjs
- Inj, tarlatamab-dlle, 1 mg
- Inj cyclophos avyxa 5mg
- Inj pemetrexed (accord) 10mg
- Inj pemetrexed ditromethamin

Criteria for initial approval:

- Prescribed for an FDA approved and/or medically accepted indication. See below for definition of "medically accepted indication."
- Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information.
- Prescribed by or in consultation with a hematologist and/or oncologist.

Approval timeframe: Approval will be for the duration of the clinical recommendation based on the selected regimen and guidelines for re-evaluation.

Criteria for renewal:

- Initial approval criteria are still met
- Documentation of positive response to treatment
- No unacceptable toxicity is present

Criteria for off-label use in medically accepted indications:

Drugs or regimens may be used off-label (without FDA approval) and considered medically accepted if supported by any of the following compendia below and not listed as unsupported, not indicated, or not recommended within any compendium below.

- NCCN Drugs & Biologics Compendium ®
  - Category 1-2A recommendations are considered medically accepted uses
  - Category 2B recommendations will be considered if identified as medically accepted in an alternative compendium or supported by peer-reviewed scientific literature eligible for coverage (meeting abstracts and case reports are excluded from consideration)
  - Category 3 listings are considered not medically accepted uses
  - OA subscribes to the NCCN Flash UpdatesTM, which informs OA when the NCCN Guidelines® and the NCCN Drugs & Biologics Compendium are updated
- Clinical Pharmacology

    - Medically accepted uses are identified by narrative text that is supportive
    - Not medically accepted uses are identified by narrative text that is “not supportive
- American Hospital Formulary Service-Drug Information (AHFS-DI)
    - Medically accepted uses are identified by narrative text that is supportive
    - Not medically accepted uses are identified by narrative text that is “not supportive”
- Thompson Micromedex DrugDex®
    - Class I, IIA, or IIb recommendations are considered medically accepted uses
    - Class III listings are considered not medically accepted uses
- Wolters Kluwer Lexi-Drugs®
    - Medically accepted uses are identified by an indication listed as “Use: Off-Label” and rated as “Evidence Level A”
    - Not medically accepted uses are those indications listed as “Use: Unsupported”
- American Society for Radiation Oncology (ASTRO)
- Clinical Practice Guidelines and Model Policies; American Radium Society Appropriate Use Criteria; American Brachytherapy Consensus Statement
- American Brachytherapy Consensus Statements
- Pediatric Hematology and Oncology
- Pediatric Blood and Cancer
- Journal of Adolescent and Young Adult Oncology

Off-label use of drugs or regimens may also be considered medically accepted if supported as safe and effective according to peer-reviewed articles eligible for coverage from one of the following journals:

- American Journal of Medicine;
- Annals of Internal Medicine;
- Annals of Oncology;
- Annals of Surgical Oncology;
- Biology of Blood and Marrow Transplantation;
- Blood;
- Bone Marrow Transplantation;
- British Journal of Cancer
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Clinical Cancer Research;
- Drugs;
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Journal of the National Cancer Institute;
- Journal of the National Comprehensive Cancer Network (NCCN);
- Journal of Urology;
- Lancet;
- Lancet Oncology;
- Leukemia;
- The New England Journal of Medicine;
- Radiation Oncology
    - Meeting abstracts and case reports are excluded from consideration

References:

1. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically
2. L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses
3. CMS Medicare Benefit Policy Manual. Chapter 15, Section 50.4.5, 2015.

UM Committee review dates: 2/16/2024, 9/12/2024, 5/7/2025, 3/17/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-102-M-V-2	
GlobalHealth	TITLE Zilretta Prior Authorization Approval Criteria	EFFECTIVE DATE 9/12/2024	LAST REVISED 2/3/2025

HCPCS codes: J3304 Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg

Therapeutic class: Corticosteroid

Available dosage forms: Injection Powder for Suspension, Extended Release: 32 MG

Criteria for initial approval:

1. FDA-approved diagnosis:
   a) Osteoarthritis of the knee confirmed by imaging (e.g., X-ray or MRI)
   b) The medication must be prescribed by or in consultation with a specialist, such as a rheumatologist, orthopedist, or sports medicine physician.
   c) The patient must be 18 years or older.
   d) Individual has had a therapeutic failure, a contraindication, or is intolerant to all of the following:
      i. Oral NSAIDs at continuous therapeutic doses (prescription strength).
      ii. Topical NSAIDs, if the patient is 75 years or older or unable to take oral NSAIDs.
      iii. Two conventional injectable corticosteroids
   e) Limited to one dose per knee (Approval is granted for 3 months)
      a. *The prolonged use of Zilretta should be determined by medical judgment, as it is approved only for single administration. Repeat use must be assessed based on clinical response and the evaluation of risks versus benefits. Provide progress note with clinical evaluation.*

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Zilretta
2. The available compendium
   a. 2019 American College of Rheumatology/Arthritis Foundation Guideline
   b. 2021 American Academy of Orthopaedic Surgeons (AAOS) Guideline
   c. *Pubmed: Safety and Efficacy of Repeat Administration of Triamcinolone Acetonide Extended-release in Osteoarthritis of the Knee: A Phase 3b, Open-label Study*

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zilretta are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, triamcinolone extended release (Zilretta) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Zilretta [package insert]. Burlington, MA: Flexion Therapeutics, Inc.; May 2024.
2. *McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis Cartilage. 2014;22(3):363-388. doi:10.1016/j.joca.2014.01.003. Accessed January 15, 2025.*
3. *Osteoarthritis Guideline 2019. American College of Rheumatology and Arthritis Foundation. Published 2019. Accessed January 15, 2025.*

UM Committee review dates: 9/12/2024, 2/3/2025, 3/17/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-103-M-V-2	
GlobalHealth	TITLE Leqvio Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 9/12/2024	LAST REVISED 6/16/2026

Therapeutic class: Antihyperlipidemic | Cardiovascular Agent

Available dosage forms: Subcutaneous Solution: 189 MG/1 ML

Criteria for initial approval:

1. FDA-approved diagnosis: adjunct to diet and statin therapy for the treatment of adults with hypercholesterolemia or heterozygous familial hypercholesterolemia (HeFH)

Criteria for renewal:

1. The member is currently receiving therapy with Leqvio.
2. Initial approval criteria are still met.
3. Member will continue to receive concomitant statin therapy if no contraindication or intolerance.
4. The member is receiving benefit from therapy. Benefit is defined as achievement or maintenance of an LDL-C reduction.

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Leqvio
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Leqvio are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, inclisiran (Leqvio) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Leqvio [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2026.

UM Committee review dates: 9/12/2024, 8/6/2025, 6/16/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-104-M-V-1	
GlobalHealth	TITLE Syfovre Prior Authorization Approval Criteria	EFFECTIVE DATE 9/12/2024	LAST REVISED

Therapeutic class: Ophthalmologic Agent

Available dosage forms: Intraocular Solution: 15 MG/0.1 ML

Criteria for initial approval:

1. FDA-approved indication/diagnosis: treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
2. Prescriber submits chart notes or medical records confirming the diagnosis of geographic atrophy secondary to AMD.

Criteria for renewal:

1. The member is currently receiving therapy with Syfovre.
2. Initial approval criteria are still met.
3. The member is receiving benefit from therapy (e.g., a reduction or stabilization in the rate of vision decline or the risk of more severe vision loss, stabilization or normalization or reduction in total area of GA lesions).

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Syfovre.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. Age-Related Macular Degeneration Preferred Practice Pattern 2024

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Syfovre are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and

necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, pegcetacoplan (Syfovre) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; December 2024.
2. Age-Related Macular Degeneration PPP 2024. American Academy of Ophthalmology. Published February 2025. Accessed July 30, 2025. https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp

UM Committee review dates: 9/12/2024, 8/6/2025, 6/16/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-105-M-V-1	
GlobalHealth	TITLE Qutenza Prior Authorization Approval Criteria	EFFECTIVE DATE 9/12/2024	LAST REVISED

Therapeutic class: Analgesic | Central Nervous System Agent

Available dosage forms: Single-use 8% topical system

Criteria for initial approval:

1. FDA-approved indication/diagnosis: treatment of neuropathic pain associated with postherpetic neuralgia (PHN) and neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

Criteria for renewal:

1. The member is currently receiving therapy with Qutenza.
2. Initial approval criteria are still met.
3. The member is receiving benefit from therapy.

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Qutenza.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Qutenza are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, capsaicin 8 % (Qutenza) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:
1. QUTENZA® [package insert]. Ardsley, NY; Acorda Therapeutics, Inc.; July 2024.

UM Committee review dates: 9/12/2024, 8/6/2025, 6/16/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-106-M-V-1	
GlobalHealth	TITLE Ozurdex Prior Authorization Approval Criteria	EFFECTIVE DATE 9/12/2024	LAST REVISED

Therapeutic class: Ophthalmologic Agent | Corticosteroid

Available dosage forms: Intraocular Implant: 0.7 MG

Criteria for initial approval:

1. FDA-approved indication/diagnosis:
   a. The treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
   b. The treatment of non-infectious uveitis affecting the posterior segment of the eye (1.2)
   c. The treatment of diabetic macular edema

Criteria for renewal:

1. The member is currently receiving therapy with Ozurdex.
2. Initial approval criteria are still met.
3. The member is receiving benefit from therapy (e.g., improvement from baseline in best-corrected visual acuity).

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Ozurdex.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Ozurdex are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, dexamethasone intraocular implant (Ozurdex) will be covered for Medicare Advantage

members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Ozurdex® [package insert]. North Chicago, IL; Allergan, Inc.; May 2024.

UM Committee review dates: 9/12/2024, 8/6/2025, 6/16/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-107-M-V-1	
GlobalHealth	TITLE Iluvien Prior Authorization Approval Criteria	EFFECTIVE DATE 9/12/2024	LAST REVISED

Therapeutic class: Ophthalmologic Agent | Corticosteroid

Available dosage forms: Intraocular Implant: 0.19 MG

Criteria for initial approval:

1. FDA-approved indication/diagnosis: treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.

Criteria for renewal:

1. The member is currently receiving therapy with Iluvien.
2. Initial approval criteria are still met.
3. The member is receiving benefit from therapy (e.g., improvement from baseline in best-corrected visual acuity).

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Iluvien.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Iluvien are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, fluocinolone acetonide intraocular implant (Ozurdex) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Iluvien® [package insert]. Alpharetta, GA; Alimera Sciences, Inc.; March 2025.

UM Committee review dates: 9/12/2024, 8/6/2025, 6/16/206

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-108-M-V-1	
GlobalHealth	TITLE Vyvgart/Vyvgart Hytrulo Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 12/2/2024	LAST REVISED

HCPCS codes: J9332 Inj efgartigimod 2mg and J9334 Inj efgart-alfa 2mg hya-qvfc

Therapeutic class: Central Nervous System Agent

Available dosage forms: Vyvgart Intravenous Solution: 20 MG/1 ML and Vyvgart Hytrulo Subcutaneous Solution: (Efgartigimod Alfa - Hyaluronidase-qvfc) 180 MG/1 ML-2000 U/1 ML

Criteria for initial approval (3 months):

1. FDA-approved diagnosis: generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive
2. Positive anti-acetylcholine receptor (AChR) antibody test
3. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
4. MG-Activities of Daily Living (MG-ADL) total score of ≥ 5
5. On stable dose of myasthenia gravis therapy: acetylcholinesterase (AChE) inhibitors, steroids, or non-steroidal immunosuppressive therapies (NSISTs), either in combination or alone

Criteria for renewal:

1. The member is currently receiving therapy with Vyvgart/Vyvgart Hytrulo
2. Therapy is being used to treat generalized myasthenia gravis (gMG) in adult
3. patients who are anti-acetylcholine receptor (AChR) antibody positive
4. The member is receiving benefit from therapy. Benefit is defined as:
    a. No evidence of unacceptable toxicity or disease progression while on the current regimen, AND
    b. The member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Vyvgart/Vyvgart Hytrulo
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vyvgart/Vyvgart Hytrulo are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Vyvgart/Vyvgart Hytrulo will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; April 2022.
2. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US, Inc.: June 2023

UM Committee review dates: 12/2/2024, 11/14/2025

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-109-M-V-1	
GlobalHealth	TITLE Aminolevulinic Acid Hydrochloride Prior Authorization Approval Criteria	EFFECTIVE DATE 12/2/2024	LAST REVISED

HCPCS code: J7308 Aminolevulinic acid hcl top

Therapeutic class: Antineoplastic, Dermatological

Available dosage forms: Ameluz Topical Gel/Jelly: 10 %; Levulan Kerastick Topical Solution: 20 %

Criteria for initial approval:

1. FDA-approved indication/diagnosis: photodynamic therapy (treatment) of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratoses of the upper extremities.

Criteria for renewal:

1. The member has lesions that have not completely resolved after 8 weeks or new lesions are present.

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Levulan Kerastick and Ameluz Topical Gel.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Levulan Kerastick and Ameluz (Aminolevulinic Acid Hydrochloride) are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Levulan Kerastick and Ameluz (Aminolevulinic Acid Hydrochloride will be covered for

Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Levulan Kerastick [package insert]. Billerica, MA: Sun Pharmaceutical Industries Inc; February 2020.
2. Ameluz Topical Gel 10% [package insert]. Wobern, MA: Biofrontera Inc; March 2024.

UM Committee review dates: 12/2/2024, 11/14/2025

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-110-M-V-1	
GlobalHealth	TITLE Zinplava Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 12/2/2024	LAST REVISED

HCPCS Code: J0565 Inj, bezlotoxumab, 10 mg

Therapeutic class: Antitoxin | Immunological Agent

Available dosage forms: Intravenous Solution: 25 MG/1 ML

Criteria for initial approval:

1. FDA-approved indication/diagnosis: reduce recurrence of Clostridioides difficile infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.
2. High risk for CDI recurrence. High risk defined as: age 65 years and older, history of CDI in the past 6 months, immunocompromised state, severe CDI at presentation, or C. difficile ribotype 027.

Criteria for renewal:

1. Not eligible for renewal as the safety and efficacy of repeat administration of Zinplava in patients with CDI have not been studied

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Zinplava.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Zinplava are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers

drugs that are furnished “incident to” a physician’s service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Zinplava will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. ZINPLAVA™ [package insert]. Rahway, NJ; Merck Sharp & Dohme LLC; May 2023.

UM Committee review dates: 12/2/2024, 11/14/2025

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-111-M-V-1	
GlobalHealth	TITLE Izervay Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 12/2/2024	LAST REVISED

HCPCS Code: J2782 Inj avacincapted pegol 0.1mg

Therapeutic class: Ophthalmologic Agent

Available dosage forms: Intraocular Solution: 2 MG/0.1 ML

Criteria for initial approval:

1. FDA-approved indication/diagnosis: treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
2. Prescriber submits chart notes or medical records confirming the diagnosis of geographic atrophy secondary to AMD.

Criteria for renewal:

1. The member is currently receiving therapy with Izervay.
2. Initial approval criteria are still met.
3. The member is receiving benefit from therapy (e.g., a reduction or stabilization in the rate of vision decline or the risk of more severe vision loss, stabilization or normalization or reduction in total area of GA lesions).

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Izervay.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. Age-Related Macular Degeneration Preferred Practice Pattern 2019

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Izervay are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer’s prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Avacincaptad Pegol (Izervay) will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. Izervay [package insert]. Parsippany, NJ: Iveric Bio Inc; August 2023.
2. Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed November 20, 2024. https://www.aao.org/education/preferred-practice-pattern/age-related-macular-degeneration-ppp

UM Committee review dates: 12/2/2024, 11/14/2025

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-112-M-V-1	
GlobalHealth	TITLE Qalsody Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 2/3/2025	LAST REVISED

HCPCS codes: J1304 Tofersen, for Intrathecal use

Therapeutic class: Antisense Oligonucleotide | Central Nervous System Agent

Available dosage forms: Qalsody Intrathecal Solution: 6.7 MG/1 ML

Criteria for initial approval (6 months):

1. Diagnosis of an FDA-approved and/or medically accepted indication.
    a. FDA Indications: Amyotrophic lateral sclerosis (ALS) in adults with a mutation in the superoxide dismutase 1 (SOD1) gene.
2. The member is ≥ 18 years old
3. Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information. Must include the following:
    a. Diagnosis Confirmation of amyotrophic lateral sclerosis (ALS) by Electromyography (EMG) or Magnetic resonance imaging (MRI)
    b. Confirmation of the superoxide dismutase 1 (SOD1) gene mutation
    c. Previous treatment history
4. FDA-approved dosing: Recommended dose: 100 milligrams (15 mL) per administration given as 3 loading doses administered at 14-day intervals. A maintenance dose should be administered once every 28 days thereafter.
5. Prescribed by or consult with a neurologist

Criteria for renewal:

1. The member is receiving benefit from therapy. Benefit is defined as:
    a. No evidence of unacceptable toxicity while on the current regimen, AND
    b. The member demonstrates a positive response to therapy

Note: This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. The prescribing information for Qalsody
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Qalsody are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Qalsody will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. QALSODY(TM) INTRATHECAL INJECTION, TOFERSEN INTRATHECAL INJECTION. BIOGEN MA INC (PER FDA), CAMBRIDGE, MA, 2023. HTTPS://WWW.BIOGENCDN.COM/US/PDFS/QALSODY-PRESCRIBING-INFORMATION.PDF
2. https://www.ninds.nih.gov/health-information/disorders/amyotrophic-lateral-sclerosis-als#toc-how-is-amyotrophic-lateral-sclerosis-als-diagnosed-and-treated-

UM Committee review dates: 2/3/2025, 3/17/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-114-M-V-1	
GlobalHealth	TITLE Orbactiv (Oritavancin) - Prior Authorization Approval Criteria	EFFECTIVE DATE 05/07/2025	LAST REVISED

Therapeutic class: Lipoglycopeptide, antibacterial

Available dosage forms:
Intravenous (IV): 1.2g single dose by intravenous over 3 hours

- 3 of ORBACTIV 400 mg vial needs to be reconstituted and diluted to prepare a single 1,200mg IV dose.

J-code: J2407

Criteria for initial approval:

1. FDA-approved diagnosis:
    a. Treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused or suspected to be caused by susceptible isolates of designated Gram-positive microorganisms.
        a. Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus group (includes S. anginosus, S. intermedius, and S. constellatus), and Enterococcus faecalis (vancomycin-susceptible isolates only)*
    b. Should be the used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
    c. The patient must be 18 years and older
    d. Contraindicated with Intravenous Unfractionated Heparin Sodium and patient with known hypersensitivity to oritavancin products.
        a. Use of intravenous unfractionated heparin sodium is contraindicated for 120 hours (5 days) after ORBACTIV® administration because the activated partial thromboplastin time (aPTT) test results may remain falsely elevated for approximately 120 hours (5 days) after ORBACTIV® administration

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. Package insert from Orbactiv
2. The available compendium
    a. *Lexi-Drugs*

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Orbactiv are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, Orbactiv will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service

References:

1. *ORBACTIV® [package insert]: Melinta Therapeutics, Inc.; 2019.Wu X, Tao M, Zhu L, Zhang T, Zhang M. Pathogenesis and current therapies for non-infectious uveitis. Clin Exp Med. 2022;23(4):1089-1106. doi:10.1007/s10238-022-00954-6*
2. *National Institutes of Health. (2022). DailyMed - orbactiv- oritavancin injection, powder, lyophilized, for solution. U.S. National Library of Medicine. https://www.dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=ff09a726-9f9b-4e30-b509-396781293220*

UM Committee review dates: 5/7/2025, 3/17/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-115-M-V-1	
GlobalHealth	TITLE DEXTENZA (Dexamethasone Ophthalmic Insert) Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 6/16/2026	LAST REVISED

HCPCS codes: J1096

Therapeutic class: Ophthalmic Corticosteroid

Available dosage forms: Ophthalmic intracanalicular insert containing dexamethasone 0.4 mg.

Criteria for initial approval (1 month):

1. Diagnosis of ocular inflammation and pain following ophthalmic surgery or ocular itching associated with allergic conjunctivitis.
2. The member is ≥ 2 years of age.
3. Prescribed and administered by a licensed ophthalmologist or qualified healthcare provider.
4. Administered in a clinical setting and is not self-administered.
5. There is no evidence of active ocular infection, including viral, bacterial, mycobacterial, or fungal infections of the eye.
6. The requested dose does not exceed one insert per affected eye per surgical or treatment episode.

Criteria for renewal (NOT APPLICABLE):

1. Intended for single-use only and releases dexamethasone for up to 30 days; therefore, renewals are not covered.

Summary of evidence:
The contents of this policy were created after examining the following resources:

1. The prescribing information for *DEXTENZA®.*
2. The available compendium
   a. FDA Prescribing Information for DEXTENZA®.
   b. Micromedex DrugDex.
   c. *AHFS Drug Information.*
   d. *Lexi-Drugs.*
   e. *Clinical Pharmacology.*
3. DEXTENZA has demonstrated clinical efficacy in reducing postoperative ocular inflammation and pain and in treating ocular itching associated with allergic conjunctivitis through sustained local delivery of dexamethasone over a 30-day period.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information. DEXTENZA provides a resorbable, sustained-release corticosteroid delivery system that minimizes the burden of post-surgical eye drop administration and improves adherence by eliminating the need for patient self-administration.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug.
Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service, are FDA-approved, medically reasonable and necessary, and are not usually self-administered by the patient.

Therefore, DEXTENZA® is covered for Medicare Advantage members when:

All utilization management criteria are met.
The drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. FDA Prescribing Information DEXTENZA® (dexamethasone ophthalmic insert). Ocular Therapeutix, Inc., Bedford, MA. April 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/208742s013lbl.pdf

2. Ocular Therapeutix, Inc. DEXTENZA® Coding Overview.Ocular Therapeutix, Inc., Bedford, MA. Updated periodically. Available at: https://www.dextenza.com/wp-content/uploads/DEXTENZA-Coding-Overview.pdf

3. Centers for Medicare & Medicaid Services (CMS). Billing and Coding: Dexamethasone Intracanalicular Ophthalmic Insert (DEXTENZA®) (Article A58392). CMS, Baltimore, MD. Revision effective January 1, 2025. Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58392&LCDId=38792

UM Committee review dates: 6/16/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-116-M-V-1	
GlobalHealth	TITLE REBYOTA (Fecal Microbiota, Live-jslm) Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 6/16/2026	LAST REVISED

HCPCS codes: J1440

Therapeutic class: Live Biotherapeutic Product / Fecal Microbiota Product.

Available dosage forms: Rectal suspension, Single dose: 150 mL.

Criteria for initial approval 1 dose (single administration):

1. The member is 18 years of age or older.
2. The member has a documented diagnosis of recurrent Clostridioides difficile infection (CDI).
3. The requested use is for the prevention of recurrence of CDI and NOT for treatment of an active CDI episode.
4. The member has completed standard-of-care antibiotic therapy (e.g., *vancomycin or fidaxomicin (± metronidazole when clinically appropriate) for the most recent CDI episode.*
5. REBYOTA will be administered 24 to 72 hours after the last dose of antibiotics for CDI.
6. REBYOTA is prescribed and administered by a licensed healthcare provider in an appropriate clinical setting.
7. The requested dose does not exceed one single 150 mL rectal dose per treatment course.
8. REBYOTA is not used concurrently with other microbiota-based therapies for recurrent CDI (e.g., fecal microbiota transplant alternatives).

Criteria for renewal (NOT APPLICABLE):

1. REBYOTA is indicated as a single-dose therapy only.
2. Repeat dosing is not recommended per FDA labeling.

Summary of evidence:
The contents of this policy were created after examining the following resources:

1. FDA Prescribing Information for REBYOTA®.
2. The available compendium
   a. Micromedex DrugDex
   b. AHFS Drug Information
   c. *Lexi-Drugs*
   d. *Clinical Pharmacology.*
3. Clinical trials and FDA review data demonstrate that REBYOTA significantly reduces the risk of recurrent CDI compared to placebo following standard antibiotic therapy, primarily by restoration of microbial diversity.

Explanation of rationale:
There is no National Coverage Determination (NCD) specific to REBYOTA.

Per Medicare Part B policy, drugs administered by a provider and furnished "incident to" a physician's service may be covered when they are:

FDA-approved
Medically reasonable and necessary
Not self-administered

REBYOTA is covered for Medicare Advantage members when:
All utilization management criteria are met.
The drug is furnished and administered by a licensed medical provider as part of a physician service.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 Self-Administered Drug Exclusion List, Medicare covers drugs that are furnished "incident to" a physician's service provided that the drugs are medically reasonable and necessary, approved by the Food and Drug Administration (FDA) and are not usually administered by the patients who take them. Therefore, REBYOTA will be covered for Medicare Advantage members when the above utilization management criteria are met AND the drug is furnished and administered by a licensed medical provider as part of a physician service.

References:

1. U.S. Food and Drug Administration. (2022). Rebyota® (fecal microbiota, live-jslm) prescribing information. https://www.fda.gov/media/163587/download
2. Centers for Medicare & Medicaid Services. (2023). Hospital Outpatient Prospective Payment System: July 2023 update (MLN Matters No. MM13210). https://www.cms.gov/files/document/mm13210-hospital-outpatient-prospective-payment-system-july-2023-update.pdf
3. Ferring Pharmaceuticals Inc. (n.d.). Support, reimbursement & coding for Rebyota® (fecal microbiota, live-jslm). https://www.rebyotahcp.com/support-reimbursement/

UM Committee review dates: 6/16/2026

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-117-M-V-1	
GlobalHealth	TITLE DURYSTA (bimatoprost intracameral implant) Medicare Part B Prior Authorization Approval Criteria	EFFECTIVE DATE 6/16/2026	LAST REVISED

HCPCS codes: J7351

Therapeutic class: Ophthalmic agent; prostaglandin analog (intraocular pressure–lowering agent)

Available dosage forms: Intracameral biodegradable implant, containing bimatoprost 10 mcg.

Criteria for initial approval (single administration):

1. The member has a documented diagnosis of:
    a. Open-angle glaucoma (OAG)
    b. Ocular hypertension (OHT)

2. Durysta® is prescribed by, or in consultation with, an:
    a. Ophthalmologist
    b. Licensed eye-care medical provider

3. The member has contraindications, intolerance, poor adherence, or inadequate response to at least one topical intraocular pressure–lowering medication, OR clinical justification is provided for bypassing topical therapy.
4. The member has NOT previously received Durysta® in the same eye, as administration is limited to one implant per eye due to the risk of corneal endothelial cell loss.

5. The member does NOT have any of the following contraindications:
    a. Active or suspected ocular or periocular infection.
    b. Corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy).
    c. History of corneal transplants or endothelial cell transplants.
    d. Absent or ruptured posterior lens capsule.
    e. Know hypersensitivity to bimatoprost or any component of the product.

6. Durysta® will be:
    a. Administered by a licensed medical provider.
    b. Furnished as part of a physician service in accordance with Medicare Part B requirement.

Criteria for renewal (Not Applicable):

1. Durysta® is FDA-approved for single administration per eye only, and repeat treatment is associated with an increased risk of corneal adverse events.

Summary of evidence:

The contents of this policy were created after examining the following resources:

1. Durysta® is an FDA-approved sustained-release intracameral implant containing bimatoprost, indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Clinical studies demonstrate that a single intracameral implant provides meaningful IOP reduction for several months while addressing adherence challenges associated with daily topical therapy. However, due to the risk of corneal endothelial cell loss, its use is limited to one implant per eye without retreatment.

2. The prescribing information for Durysta®
3. The available compendium
   a. Micromedex DrugDex
   b. American Hospital Formulary Service- Drug Information (AHFS-DI)
   c. Lexi-Drugs
   d. Clinical Pharmacology

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information and available drug compendium. The limitation to a single implant per eye is necessary to mitigate safety risks, particularly corneal endothelial cell loss. Prior authorization ensures appropriate patient selection, safe administration, and compliance with Medicare Part B coverage requirements.

Medicare Coverage:

There is no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for jurisdiction JL specifically for this drug. Per Local Coverage Article A53127 – Self-Administered Drug Exclusion List, Medicare covers drugs furnished "incident to" a physician's service when they are medically reasonable and necessary, FDA-approved, and not usually self-administered.

Therefore, Durysta® is covered for Medicare Advantage members when:

Utilization management criteria above are met.
The drug is furnished and administered by a licensed medical provider as part of a physician service under Medicare Part B.

References:

1. AbbVie Inc. (2020). Durysta® (bimatoprost intracameral implant) prescribing information. https://www.rxabbvie.com/pdf/durysta_pi.pdf

2. National Library of Medicine. (2024). Durysta® (bimatoprost intracameral implant) prescribing information. DailyMed. https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=3f59da84-0bcc-4c84-b3e2-e215681ef341

3. *Centers for Medicare & Medicaid Services. (n.d.). HCPCS code J7351: Injection, bimatoprost implant, intracameral, 1 microgram.* J7351 - HCPCS Code for Inj bimatoprost itc imp1mcg

UM Committee review dates: 6/16/2026

Medicare Part B Drug Step Therapy Exception Criteria

January 2026

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Acromegaly Long-Acting Products	• Lanreotide injection	Preferred Product: • Somatuline Depot (lanreotide acetate) Coverage for the non-preferred product is provided when **either** of the following criteria is met: • Member has received treatment with the requested non-preferred product in the past 365 days; OR • The member has had a documented intolerable adverse event to Somatuline Depot, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
Acromegaly Long-Acting Products	• Sandostatin LAR Depot • Signifor LAR	Preferred Product: • Somatuline Depot (lanreotide acetate) Coverage for a non-preferred product is provided when **either** of the following criteria is met: • Member has received treatment with the requested non-preferred product in the past 365 days; OR • Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

1. Somatuline Depot [package insert]. Cambridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2024.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; July 2024.

4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; May 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Alpha1-Proteinase Inhibitors	• Aralast NP (alpha1-proteinase inhibitor [human]) • Glassia (alpha1-proteinase inhibitor [human])	Preferred products: • Prolastin-C (alpha1-proteinase inhibitor [human]) • Zemaira (alpha1-proteinase inhibitor [human]) Coverage for a non-preferred product is provided when **either** of the following criteria are met: • Member has received treatment with the non-preferred product in the past 365 days; OR • Member has had a documented intolerable adverse event to both of the preferred products (Prolastin-C and Zemaira), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References
1. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; October 2024.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; February 2025.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2022.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; January 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Antimetabolites	• Alimta (pemetrexed) • Pemfexy (pemetrexed)	Preferred products: • pemetrexed (generic) Coverage for a non-preferred product is provided when **either** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days; OR

		• Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References

1. Alimta [package insert]. Indianapolis, IN: Lilly USA, LLC; May 2023.
2. Pemetrexed [package insert]. Lake Forest, IL: Hospira, Inc.; February 2023.
3. Pemfexy [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc.; December 2022.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**

Asthma	• Cinqair	Preferred Products:
		• Fasenra (benralizumab)
		• Tezspire (tezepelumab-ekko)
		• Xolair (omalizumab)
		
		Coverage for Cinqair is provided when **either** of the following criteria is met:
		• Member has received treatment with Cinqair in the past 365 days; OR
		• Member has **both** of the following:
		  ○ Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Fasenra and Tezspire; AND
		  ○ Member has either of the following:
		  ▪ A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with

		the preferred product Xolair; OR ▪ A pretreatment serum IgE level of less than 30 IU/mL.
Asthma	• Nucala	Preferred Products: • Fasenra (benralizumab) • Tezspire (tezepelumab-ekko) • Xolair (omalizumab) Coverage for Nucala is provided when **either** of the following criteria is met: • Member has received treatment with Nucala in the past 365 days; OR • Member meets **any** of the following: o Member has a comorbidity of nasal polyps and meets either of the following: ▪ A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair; OR ▪ A pretreatment serum IgE level of less than 30 IU/mL. o Member meets **both** of the following: ▪ Member is 12 years of age and older and has a documented inadequate response or an intolerable adverse event with both of the preferred products, Fasenra and Tezspire; OR Member is less than

		12 years of age and has a documented inadequate response or an intolerable adverse event with the preferred product Fasenra; AND ▪ Member has pretreatment serum IgE level of at least 30 IU/mL and has had adocumented inadequate response or an intolerable adverse event with the preferred product Xolair; OR Member has a pretreatment serum IgE level of less than 30 IU/mL. ○ Member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and has a documented inadequate response or intolerable adverse event with the preferred product Fasenra.

References
1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2024.
3. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
4. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
5. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Autoimmune Conditions	• Cimzia lyophilized powder (certolizumab pegol)	Preferred Products: • Entyvio (IV) (vedolizumab) • Simponi Aria (golimumab) • Tremfya (IV) (guselkumab)

		Coverage for Cimzia lyophilized powder is provided when **any** of the following criteria is met: • Member has received treatment with Cimzia lyophilized powder in the past 365 days; OR • Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Simponi Aria, and Tremfya IV), where the products' indications overlap. If the member is a documented primary non-responder to an interleukin-23 (IL-23) inhibitor, then the member would not need to use the corresponding preferred product(s) from the respective class; OR • Member is currently breastfeeding, pregnant, or planning pregnancy.
Autoimmune Conditions	• Actemra (IV) (tocilizumab) • Ilumya (tildrakizumab-asmn) • Orencia (IV) (abatacept) • Stelara (IV) (ustekinumab)	Preferred Products: • Entyvio (IV) (vedolizumab) • Simponi Aria (golimumab) • Tremfya (IV) (guselkumab) Coverage for all other non-preferred products is provided when **either** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days; OR • Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Simponi Aria, and Tremfya IV) where the products' indications overlap, unless there is a documented clinical reason to avoid tumor necrosis factor (TNF) inhibitors ○ History of demyelinating disorder

		○ History of congestive heart failure ○ History of hepatitis B virus infection ○ Autoantibody formation/lupus-like syndrome ○ History or risk of lymphoma or other malignancy ○ History of being a primary non-responder to a TNF inhibitor

References
1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.
3. Entyvio [package insert]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; May 2024.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
5. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
8. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Infliximab	• Avsola (infliximab-axxq) • infliximab • Remicade (infliximab)	Preferred products: • Inflectra (infliximab-dyyb) • Renflexis (infliximab-abda) Coverage for a non-preferred product is provided when **either** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has had a documented intolerable adverse event to both of the preferred infliximab products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both

		the reference product and biosimilar products).

References
1. Avsola [package insert]. Thousand Oaks, CA: Amgen, Inc.; September 2021.
2. Inflectra [package insert]. New York, NY: Pfizer Inc.; April 2023.
3. infliximab [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
4. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2025.
5. Renflexis [package insert]. Jersey City, NJ: Organon & Co.; December 2023.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Bevacizumab-Oncology Products	• Alymsys (bevacizumab-maly) • Avastin (bevacizumab) • Vegzelma (bevacizumab-adcd)	Preferred products: • Mvasi (bevacizumab-awwb) • Zirabev (bevacizumab-bvzr) Coverage for a non-preferred product is provided when **either** of the following criteria is met: • Member has received treatment with the requested non-preferred product in the past 365 days**; OR** • Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References
1. Alymsys [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
2. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
3. Mvasi [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
4. Vegzelma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; February 2023.
5. Zirabev [package insert]. New York, NY: Pfizer, Inc.; August 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Botulinum Toxins	• Botox (onabotulinumtoxinA) • Myobloc (rimabotulinumtoxinB)	Preferred products: • Dysport (abobotulinumtoxinA) • Xeomin (incobotulinumtoxinA) Coverage for a non-preferred product is provided when **any** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented inadequate response or intolerable adverse event to both of the preferred products**; OR** • Member is requesting Botox for the treatment of blepharospasm and **either** of the following criteria is met: o Member is 18 years of age and older and the member has had a documented inadequate response or intolerable adverse event with Xeomin**; OR** o Member is 12 years of age or older but less than 18 years of age**; OR** • Member is requesting Botox for the treatment of lower limb spasticity and has had a documented inadequate response or adverse event to Dysport**; OR** • Member is requesting Botox for the treatment of upper limb spasticity and both of the following criteria are met: o Member is a pediatric patient 2 years of age to 17 years of age and the

		upper limb spasticity is caused by cerebral palsy**; AND** ○ Member has had a documented inadequate response or adverse event with Dysport**; OR** • Member is requesting Myobloc for the treatment of chronic sialorrhea and has had a documented inadequate response or an intolerable adverse event with Xeomin.

References
1. Botox [package insert]. North Chicago, IL: Allergan, Inc., an AbbVie company; November 2023.
2. Dysport [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, LLC; September 2023.
3. Myobloc [package insert]. Rockville, MD: Solstice Neurosciences, Inc.; March 2021.
4. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; July 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Breast Cancer	• Perjeta (pertuzumab)	Preferred products: • Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)) Coverage for a non-preferred product is provided when **any** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References
1. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.

2. Phesgo [package insert]. South San Francisco, CA: Genentech, Inc.; November 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Complement Inhibitor Products - Atypical Hemolytic Uremic Syndrome (aHUS), Paroxysmal Nocturnal Hemoglobinuria (PNH)	• Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz)	Preferred products: • Bkemv (eculizumab-aeeb) Coverage for a non-preferred product is provided when **any** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • The request is for Soliris and the member has a documented intolerable adverse event to Bkemv, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)**; OR** • The request is for Ultomiris and the member has a documented inadequate response or intolerable adverse event with the preferred product.
Complement Inhibitor Products - Myasthenia Gravis	• Soliris (eculizumab) • Ultomiris (ravulizumab-cwvz)	Preferred products: • Bkemv (eculizumab-aeeb) • Vvygart (efgartigimod alfa) • Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Coverage for a non-preferred product is provided when **any** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR**

		• The request is for Soliris and both of the following are met:
		  ○ Member has a documented intolerable adverse event to Bkemv, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)**; AND**
		  ○ Member has a documented inadequate response or intolerable adverse event with either Vyvgart or Vyvgart Hytrulo**; OR**
		• The request is for Ultomiris and the member has a documented inadequate response or intolerable adverse event with Bkemv, and either Vyvgart or Vyvart Hytrulo.

Complement Inhibitor Products - Neuromyelitis Optica Spectrum Disorder (NMOSD)	• Soliris (eculizumab)	Preferred products: • Bkemv (eculizumab-aeeb) Coverage for a non-preferred product is provided when **any** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented intolerable adverse event to Bkemv, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse

		reaction for both the reference product and biosimilar products).

References
1. Bkemv [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024.
2. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2025.
3. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2024.
4. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; August 2024.
5. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US. Inc.; August 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Colony Stimulating Factors-Long Acting	• Neulasta (including Onpro kit) (pegfilgrastim) • Nyvepria (pegfilgrastim-apgf) • Rolvedon (eflapegrastim-xnst) • Stimufend (pegfilgrastim-fpgk) • Udenyca (pegfilgrastim-cbqv) • Ziextenzo (pegfilgrastim-bmez)	Preferred products: • Fulphila (pegfilgrastim-jmdb) • Fylnetra (pegfilgrastim-pbbk) Coverage for a non-preferred product is provided when **one** of the following criteria is met: • Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference products and biosimilar products)**; OR** • Member has received treatment with the requested non-preferred product in the past 365 days.

References
1. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
2. Fulphila [package insert]. Cambridge, MA: Biocon Biologics Inc.; June 2023.
3. Fylnetra [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
4. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; March 2023.
5. Rolvedon [package insert]. Lake Forest, IL: Spectrum Pharmaceuticals, Inc.; November 2023.
6. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
7. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
8. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; February 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Colony Stimulating Factors – Short Acting	• Granix (TBO-filgrastim) • Neupogen (filgrastim) • Nivestym (filgrastim-aafi) • Releuko (filgrastim-ayow)	Preferred products: • Zarxio (filgrastim-sndz) Coverage for the non-preferred products, Granix, Neupogen, Nivestym or Releuko, is provided when the member meets **one** of the following criteria: • Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)**; OR** • Member is requesting Granix, Neupogen vials or Nivestym and has a documented latex allergy that the prescriber states the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion**; OR** • Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg**; OR** • Member has received treatment with the requested non-preferred product in the past 365 days.
Colony Stimulating Factors – Short Acting	• Leukine (sargramostim)	Preferred Product: • Zarxio (filgrastim-sndz) Coverage for the non-preferred product, Leukine, is provided when the member meets **one** of the following criteria:

		• Member has had a documented inadequate response or an intolerable adverse event to the preferred product**; OR** • Leukine is being requested for an indication that is not FDA-approved for the preferred product**; OR** • Member has received treatment with the requested non-preferred product in the past 365 days.

References
1. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.
2. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
3. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2023.
4. Nivestym [package insert]. Lake Forest, IL: Hospira, Inc., a Pfizer Company: February 2024.
5. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; September 2023.
6. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; October 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Erythropoiesis Stimulating Agents - Anemia Due to Chronic Kidney Disease (CKD)	• Epogen (epoetin alfa) • Mircera (methoxy polyethylene glycol-epoetin beta) • Procrit (epoetin alfa)	Preferred products: • Aranesp (darbepoetin alfa) • Retacrit (epoetin alfa-epbx) Coverage for **Epogen or Procrit** is provided when **either** of the following criteria is met: • Member has received treatment with Epogen or Procrit in the past 365 days**; OR** • Member meets **both** of the following criteria: o Member has had a documented intolerable adverse event with Retacrit, and the adverse event was not an expected adverse event attributed to the active

		ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; AND** ○ Member has a documented inadequate response or intolerable adverse event with the preferred product Aranesp. Coverage for **Mircera** is provided when **either** of the following criteria is met: • Member has received treatment with Mircera in the past 365 days**; OR** • Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Retacrit.
Erythropoiesis Stimulating Agents - Anemia Due to Myelosuppressive Chemotherapy in Cancer	• Epogen (epoetin alfa) • Procrit (epoetin alfa)	Preferred products: • Aranesp (darbepoetin alfa) • Retacrit (epoetin alfa-epbx) Coverage for Epogen or Procrit is provided when **either** of the following criteria is met: • Member has received treatment with Epogen or Procrit in the past 365 days**; OR** • Member meets **both** of the following criteria: ○ Member has had a documented intolerable adverse event with Retacrit, and the adverse event was

		not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; AND** ○ Member has a documented inadequate response or intolerable adverse event with the preferred product Aranesp.
Erythropoiesis Stimulating Agents – Anemia Due to Zidovudine in Patients with Human Immunodeficiency Virus (HIV) Infection and To Reduce Need for Allogeneic Red Blood Cell (RBC) Transfusions	• Epogen (epoetin alfa) • Procrit (epoetin alfa)	Preferred products: • Retacrit (epoetin alfa-epbx) Coverage for Epogen or Procrit is provided when **either** of the following criteria is met: • Member has received treatment with Epogen or Procrit in the past 365 days**; OR** • Member has had a documented intolerable adverse event with Retacrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).

References

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
3. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; June 2024.
4. Procrit [package insert]. Horsham, PA: Janssen Products, LP; April 2024.
5. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; June 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Factor VIII Products	• Advate (antihemophilic factor [recombinant]) • Kogenate FS (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant]) • Recombinate (antihemophilic factor [recombinant]) • Xyntha (antihemophilic factor [recombinant]) • Xyntha Solofuse (antihemophilic factor [recombinant])	Preferred products: • Afstyla (antihemophilic factor [recombinant]) • Kovaltry (antihemophilic factor [recombinant]) • Nuwig (antihemophilic factor [recombinant]) Coverage for the non-preferred product is provided when **either** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented inadequate response or intolerable adverse event with all of the preferred products.

References
1. Advate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
2. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
4. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
5. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
7. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2020.
8. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
9. Recombinate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
10. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.
11. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Gaucher Disease Agents	• VPRIV (velaglucerase alfa)	Preferred products: • Cerezyme (imiglucerase) • Elelyso (taliglucerase alfa) Coverage for the non-preferred product is provided when **ANY** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • The member has had a documented inadequate response or an intolerable adverse event with Cerezyme AND is between 2 and 4 years of age**; OR** • Member has had a documented inadequate response or an intolerable adverse event with both of the preferred products, Cerezyme and Elelyso.

References

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; January 2025.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2024.
3. VPRIV [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Gonadotropin Releasing Hormone Agonists (Prostate Cancer Only)	• Camcevi (leuprolide mesylate) • Lupron Depot (leuprolide acetate for depot suspension) • Trelstar (triptorelin) • Zoladex (goserelin acetate))	Preferred products: • Eligard (leuprolide acetate)) Coverage for the non-preferred product is provided when **EITHER** of the following criteria is met: • Member has received treatment with a non-preferred product in the past 365 days**; OR** • Member has a documented hypersensitivity to the preferred product.

References
1. Camcevi [package insert]. Durham, NC: Accord BioPharma Inc.; February 2025.
2. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; February 2025.
3. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; March 2024.
4. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; March 2025.
5. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Hyaluronates (Osteoarthritis-Multi)	• Gelsyn-3 (sodium hyaluronate) • GenVisc 850 (sodium hyaluronate) • Hyalgan (sodium hyaluronate) • Hymovis (high molecular weight viscoelastic hyaluronan) • Orthovisc (high molecular weight hyaluronan) • Supartz FX (sodium hyaluronate) • Triluron (sodium hyaluronate) • Trivisc (sodium hyaluronate) • Visco-3 (sodium hyaluronate)	Preferred products: • Euflexxa (1% sodium hyaluronate) • Synvisc (hylan G-F 20) Coverage for a non-preferred product is provided when **EITHER** of the following criteria is met: • Member has received treatment with the requested non-preferred product in the past 365 days**; OR** • Member has a documented intolerable adverse event to both of the preferred products, Euflexxa and Synvisc.
Hyaluronates (Osteoarthritis-Single)	• Gel-One (cross-linked hyaluronate) • Monovisc (high molecular weight hyaluronan)	Preferred Product: • Durolane (hyaluronic acid) • Synvisc-One (hylan G-F 20) Coverage for a non-preferred product is provided when **EITHER** of the following criteria is met: • Member has received treatment with the requested non-preferred product in the past 365 days**; OR** • Member has a documented intolerable adverse event to both

		of the preferred products, Durolane and Synvisc-One.

References
1. Durolane [package insert]. Durham, NC: Bioventus, LLC; September 2017.
2. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
3. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
4. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; December 2017.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
6. Hyalgan [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; September 2017.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
13. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
14. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
15. Visco-3 [package insert]. Warsaw, IN: Zimmer Inc.; May 2017.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Immune Globulins	• Asceniv (intravenous) • Bivigam (intravenous) • Cutaquig (subcutaneous) • Cuvitru (subcutaneous) • Gammagard Liquid (subcutaneous/intravenous) • Gammaplex (intravenous) • HyQvia (subcutaneous) • Panzyga (intravenous) • Xembify (subcutaneous)	Preferred products: • Flebogamma (intravenous) • Gammaked (subcutaneous/intravenous) • Gamunex-C (subcutaneous/intravenous) • Hizentra (subcutaneous) • Octagam (intravenous) • Privigen (intravenous) Coverage for the non-preferred product is provided when **EITHER** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented intolerable adverse event with at least 3 of the preferred products.

References
1. Asceniv [package insert]. Boca Raton, FL: ADMA Biologics; April 2019.
2. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics; December 2023.
3. Cutaquig [package insert]. Paramus, NJ: Octapharma USA, Inc.; November 2021.
4. Flebogamma Dif [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; September 2019.
5. Gammagard Liquid [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.
6. Gammaked [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2020.
7. Gammaplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
8. Gammaplex 10% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
9. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
10. Octagam 10% [package insert]. Paramus, NJ: Octapharma USA, Inc.; April 2022.
11. Octagam 5% [package insert]. Paramus, NJ: Octapharma USA, Inc.; April 2022.
12. Panzyga [package insert]. New York, NY; Pfizer; February 2021.
13. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; March 2022.
14. Cuvitru [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
15. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; April 2023.
16. HyQvia [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Intravenous Iron	• Feraheme (ferumoxytol) • Injectafer (ferric carboxymaltose) • Monoferric (ferric derisomaltose)	Preferred products: • Ferrlecit (sodium ferric gluconate complex) • Infed (iron dextran) • Sodium ferric gluconate • Venofer (iron sucrose) Coverage for a non-preferred product is provided when **ANY** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • The requested product is Feraheme and the member meets any of the following: o Member has a diagnosis of iron deficiency anemia

		with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed**; OR** ○ Member has a diagnosis of hemodialysis-dependent chronic kidney disease and is receiving supplemental epoetin therapy and has had a documented inadequate response or intolerable adverse event with both Ferrlecit and sodium ferric gluconate**; OR** ○ Member has a diagnosis of chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer**; OR** • The requested product is Injectafer and the member meets any of the following: ○ Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response

		or intolerable adverse event with Infed**; OR** ○ Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer**; OR** ○ Member has a diagnosis of iron deficiency with heart failure categorized as New York Heart Association class II/III. • The requested product is Monoferric and the member meets any of the following: ○ Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed**; OR** ○ Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.

References
1. Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; March 2022.
2. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; August 2024.
3. Sodium Ferric Gluconate [package insert]. Berkley Heights, NJ: Hikma Pharmaceuticals USA, Inc.; January 2021
4. Venofer [package insert]. Shirley, NY: American Regent, Inc.; June 2022.
5. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
6. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; January 2025.
7. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Mitotic Inhibitors	• Abraxane (paclitaxel, albumin-bound)	Preferred products: • docetaxel (generic) • paclitaxel (generic) Coverage for the non-preferred product is provided when **ANY** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented inadequate response or intolerable adverse event with either of the preferred products, docetaxel or paclitaxel**; OR** • Member has a documented clinical reason to avoid all of the preferred products.

References
1. Abraxane [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.
2. docetaxel [package insert]. Lake Forest, IL: Hospira, Inc.; May 2023.
3. paclitaxel [package insert]. Bedminster, NJ: Alembic Pharmaceutical, Inc.; November 2022.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Multiple Myeloma	• Empliciti (elotuzumab) • Kyprolis (carfilzomib) • Sarclisa (isatuximab)	Preferred products: • bortezomib (generic) J9046, NDC 43598-0865-60 • bortezomib (generic) J9048, NDC 63323-0721-10

	• Velcade (J9041) (bortezomib)	• bortezomib (generic) J9049, NDC 00409-1703-01 Coverage for the non-preferred product is provided when **ANY** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • The request is for Empliciti, Kyprolis or Sarclisa and the member has a documented inadequate response or intolerable adverse event with a preferred product**; OR** • The request is for Velcade and the member has had a documented intolerable adverse event to a preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References
1. bortezomib [package insert]. Lake Zurich, IL: Fresenius Kabi; April 2022.
2. Empliciti [package insert]. Princeton, NJ: Bristol-Myers Squibb; March 2022.
3. Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; June 2022.
4. Sarclisa [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; October 2024.
5. Velcade [package insert]. Lexington, MA: Takeda Pharmaceuticals America; August 2022.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Multiple Sclerosis	• Briumvi (ublituximab-xiiy) • Lemtrada (alemtuzumab) • Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)	Preferred products: • Ocrevus (ocrelizumab) Tyruko (natalizumab-sztn) **Briumvi and Lemtrada:** Coverage for Briumvi or Lemtrada is provided when either of the following criteria is met:

	• Tysabri (natalizumab)	• Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with both of the preferred products or any of their components. **Ocrevus Zunovo:** Coverage for Ocrevus Zunovo is provided when either of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member meets both of the following criteria: ○ Member has had a documented intolerable adverse event with the preferred product, Ocrevus, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information**; AND** ○ Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Tyruko, or any of its components.

		Tysabri: Coverage for Tysabri is provided when either of the following criteria is met: Member has received treatment with the non-preferred product in the past 365 days. • Member meets both of the following criteria: ○ Member has had a documented intolerable adverse event to the preferred product, Tyruko, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)**; AND** ○ Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Ocrevus, or any of its components.

References
1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc.; November 2024.
2. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.
3. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
4. Ocrevus Zunovo [package insert]. South San Francisco, CA: Genentech, Inc.; September 2024.
5. Tyruko [package insert]. Princeton, NJ: Sandoz Inc.; August 2023.
6. Tysabri [package insert]. Cambridge, MA: Biogen Inc.; March 2025.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements

Osteoporosis-Bone Density	• Evenity (romosozumab-aqqg)
	• Prolia (denosumab)
		Preferred products:
		• Jubbonti (denosumab-bbdz)
		• zoledronic acid
		
		Evenity:
		Coverage for Evenity is provided when **ANY** of the following criteria are met:
		• Member has received treatment with the non-preferred product in the past 365 days**; OR**
		• Member meets both of the following criteria:
		  ○ Member has had a documented inadequate response, intolerable adverse event, contraindication, or clinical reason to avoid Jubbonti**; AND**
		  ○ Member has had a documented inadequate response, intolerable adverse event, or contraindication to zoledronic acid (e.g., creatinine clearance less than 35 mL/min).
		
		Prolia:
		Coverage for Prolia is provided when **ANY** of the following criteria are met:
		• Member has received treatment with the non-preferred product in the past 365 days**; OR**
		• Member has both of the following:
		  ○ Member has had a documented intolerable adverse event to the preferred products, and the adverse event was not an expected adverse event

		attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; AND** ○ Member has had a documented inadequate response, intolerable adverse event, or a contraindication to zoledronic acid (e.g., creatinine clearance less than 35 mL/min).

References
1. Evenity [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2024.
2. Jubbonti [package insert]. Princeton, NJ: Sandoz Inc.; October 2024.
3. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2024.
4. Zoledronic acid [package insert]. Princeton, NJ: Fosun Pharma USA Inc.; February 2023.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Osteoporosis–Hypercalcemia of Malignancy	• Xgeva (denosumab)	Preferred products: • pamidronate • Wyost (denosumab-bbdz) • zoledronic acid Coverage for the non-preferred product is provided when the member meets **EITHER** of the following criteria: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member meets both of the following criteria: ○ Member meets either of the following criteria: ▪ Member has a documented inadequate response to

		pamidronate or zoledronic acid**; OR** ▪ Member has had a documented intolerable adverse event or contraindication to therapy with both pamidronate and zoledronic acid (i.e., severe renal impairment [creatinine clearance less than 35 mL/min])**; AND** ○ Member has had a documented intolerable adverse event to Wyost, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).

References
1. Pamidronate [package insert]. Morgantown, WV: Mylan Institutional LLC; July 2022.
2. Wyost [package insert]. Princeton, NJ: Sandoz Inc.; March 2024.
3. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
4. Zoledronic acid [package insert]. Raleigh, NC: Accord Healthcare, Inc.; September 2023.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
PD1/PDL1 Products: Basal Cell Carcinoma and Squamous Cell Carcinoma	• Keytruda (pembrolizumab)	Preferred products: • Libtayo (cemiplimab) Coverage for the non-preferred product is provided when **EITHER** of the following criteria is met:

		• Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has a documented intolerable adverse event with the preferred product.

References
1. Keytruda [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; March 2025.
2. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
PD1/PDL1 Products - Non-Small Cell Lung Cancer (NSCLC)	• Imfinzi (durvalumab) • Keytruda (pembrolizumab) • Opdivo (nivolumab) • Tecentriq (atezolizumab)	Preferred products: • Libtayo (cemiplimab) Coverage for a non-preferred product is provided when the member meets **ONE** of the following criteria: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has had a documented intolerable adverse event to the preferred product**; OR** • Keytruda is being used for advanced or metastatic NSCLC with adenocarcinoma or squamous cell histology and with PD-L1 expression of greater than or equal to 1-49%**; OR** • Keytruda, Imfinzi or Tecentriq is being used for the adjuvant treatment of NSCLC**; OR** • Imfinzi is being used following concurrent chemoradiation for NSCLC**; OR** • Keytruda, Imfinzi, or Opdivo is being used for the neoadjuvant treatment of NSCLC.

References
1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2025.
2. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024.

3. Keytruda [package insert]. Rathway, NJ: Merck & Co., Inc.; March 2025.
4. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2024
5. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; April 2024.
6. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 15, 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**

Retinal Disorders	• Beovu (brolucizumab-dbll)
	• Cimerli (ranibizumab-eqrn)
	• Eylea (aflibercept)
	• Eylea HD (aflibercept)
	• Lucentis (ranibizumab)
	• Susvimo (ranibizumab injection)
	• Vabysmo (faricimab-svoa)
		Primary Preferred product:
		• Avastin (bevacizumab)
		
		Secondary Preferred products:
		• Byooviz (ranibizumab-nuna)
		• Pavblu (aflibercept-ayyh)
		
		Coverage for a non-preferred product is provided when **ANY** of the following criteria are met:
		• Member has received treatment with the non-preferred product in the past 365 days**; OR**
		• The requested product is Byooviz or Pavblu and member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin**; OR**
		• The requested product is Eylea and either of the following criteria are met:
		  ○ Member meets both of the following:
		  ▪ Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin, and the secondary preferred product, Byooviz**; AND**

		▪ Member has a documented intolerable adverse event to the secondary preferred product, Pavblu, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; OR** ○ Member has a diagnosis of retinopathy of prematurity and has a documented intolerable adverse event to the secondary preferred product, Pavblu, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; OR** • The requested product is Eylea HD and both of the following criteria are met: ○ Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin, and the secondary preferred product, Byooviz**; AND**

		○ Member has a documented intolerable adverse event to the secondary preferred product, Pavblu, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; OR** • The requested product is Beovu or Vabysmo and both of the following criteria are met: ○ Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin**; AND** ○ Member has had a documented inadequate response or intolerable adverse event with both of the secondary preferred products: Byooviz and Pavblu**; OR** • The requested product is Cimerli or Lucentis and either of the following criteria are met: ○ Member has a diagnosis of myopic choroidal neovascularization (mCNV) and all of the following criteria are met: ▪ Member has a documented inadequate response or intolerable adverse event with the primary preferred

		product, Avastin**; AND** ▪ Member has had a documented intolerable adverse event to the secondary preferred product, Byooviz, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; OR** ○ Member has a diagnosis other than myopic choroidal neovascularization (mCNV) and all of the following criteria are met: ▪ Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin**; AND** ▪ Member has had a documented intolerable adverse event to the secondary preferred product, Byooviz, and the adverse event was not an

		expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; AND** ▪ Member has had a documented inadequate response or intolerable adverse event with the secondary preferred product, Pavblu**; OR** • The requested product is Susvimo and all of the following criteria are met: ○ Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin**; AND** ○ Member has had a documented intolerable adverse event to the secondary preferred product, Byooviz and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product)**; AND** ○ Member has had a documented inadequate

		response or intolerable adverse event with the secondary preferred product, Pavblu.

References
1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
2. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; October 2023.
4. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2024.
5. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
6. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
7. Lucentis [package insert]. San Francisco, CA: Genentech, Inc.; February 2024.
8. Pavblu [package insert]. Thousand Oaks, CA: Amgen, Inc.; August 2024.
9. Susvimo [package insert]. San Francisco, CA: Genentech, Inc.; February 2025.
10. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.; July 2024.

Category/Criteria Name	**Non-Preferred Product(s)**	**Step Therapy Requirements**
Rituximab Products	• Riabni (rituximab-arrx) • Rituxan (rituximab) • Rituxan Hycela (rituximab and hyaluronidase human)	Preferred products: • Ruxience (rituximab-pvvr) • Truxima (rituximab-abbs) Coverage for a non-preferred product is provided when **EITHER** of the following criteria is met: • Member has received treatment with the non-preferred product in the past 365 days**; OR** • Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References
1. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
2. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
3. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.

4. Ruxience [package insert]. New York, NY: Pfizer; October 2023.
5. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2024.

Category/Criteria Name	Non-Preferred Product(s)	Step Therapy Requirements
Trastuzumab Products	• Herceptin (trastuzumab) • Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) • Hercessi (trastuzumab-strf) • Herzuma (trastuzumab-pkrb) • Trazimera (trastuzumab-qyyp)	Preferred products: • Kanjinti (trastuzumab-anns) • Ogivri (trastuzumab-dkst) • Ontruzant (trastuzumab-dttb) Coverage for a non-preferred product is provided when **EITHER** of the following criteria is met: • Member has received treatment with the requested non-preferred product in the past 365 days**; OR** • Member has had a documented intolerable adverse event to all of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc; June 2024.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
3. Hercessi [package insert]. Raleigh, NC: Accord BioPharma Inc.; September 2024.
4. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; December 2024.
5. Trazimera [package insert]. New York, NY Pfizer Labs; November 2020.
6. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2024.
7. Ogivri [package insert]. Cambridge, MA: Biocon Biologics Inc., November 2024.
8. Ontruzant [package insert]. Jersey City, NJ: Organon LLC; February 2025.