Medicare Advantage Plans Part B Drugs Prior Authorization Criteria 2025

This prior authorization document was updated on 05/07/2025. 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 05/07/2025. 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

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

Part B Drug Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-101-M-V-3	
GlobalHealth	TITLE Oncology Drug Treatment Prior Authorization Approval Criteria	EFFECTIVE DATE 2/16/2024	LAST REVISED 5/7/2025

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

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

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-103-M-V-1	
GlobalHealth	TITLE Leqvio Prior Authorization Approval Criteria	EFFECTIVE DATE 10/1/2024	LAST REVISED

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 primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

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; July 2023.

UM Committee review dates: 9/12/2024

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-104-M-V-1	
GlobalHealth	TITLE Syfovre Prior Authorization Approval Criteria	EFFECTIVE DATE 10/1/2024	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 2019

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; February 2023.
2. Age-Related Macular Degeneration PPP 2019. American Academy of Ophthalmology. Published October 2019. Accessed August 20, 2024. https://www.aao.org/preferredpractice-pattern/age-related-maculardegeneration-ppp

UM Committee review dates: 9/12/2024

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-105-M-V-1	
GlobalHealth	TITLE Qutenza Prior Authorization Approval Criteria	EFFECTIVE DATE 10/1/2024	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

Pharmacy Utilization Management Policy

GlobalHealth	**ENTITY** GlobalHealth Holdings, LLC	**NUMBER** GH-PT-106-M-V-1	
	TITLE Ozurdex Prior Authorization Approval Criteria	EFFECTIVE DATE 10/1/2024	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

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-107-M-V-1	
GlobalHealth	TITLE Iluvien Prior Authorization Approval Criteria	EFFECTIVE DATE 10/1/2024	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.; November 2016.

UM Committee review dates: 9/12/2024

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

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

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

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

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

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4255-D

EXCEPTIONS CRITERIA

ACROMEGALY LONG ACTING PRODUCTS

PREFERRED PRODUCT: SOMATULINE DEPOT

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the acromegaly long acting products specified in this policy. Coverage for a targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Acromegaly Products

	Product(s)
Preferred*	• **Somatuline Depot** (lanreotide acetate)
Targeted	• **Lanreotide Injection** (lanreotide acetate) • **Sandostatin LAR Depot** (octreotide acetate for injectable suspension) • **Signifor LAR** (pasireotide)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

A. Lanreotide Injection

Coverage for the targeted product is provided when either of the following criteria is met:

1. Member has received treatment with the requested targeted product in the past 365 days.
2. 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.

B. Sandostatin LAR Depot, Signifor LAR

Coverage for a targeted product is provided when either of the following criteria is met:

1. Member has received treatment with the requested targeted product in the past 365 days.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4255-D

2. 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.; February 2023.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; August 2023.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; September 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
3445-D

EXCEPTIONS CRITERIA

ALPHA1-PROTEINASE INHIBITORS

PREFERRED PRODUCTS: PROLASTIN-C, ZEMAIRA

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the alpha$_1$-proteinase inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Alpha1-Proteinase Inhibitor Products

	Product(s)
Preferred*	• **Prolastin-C** (alpha$_1$-proteinase inhibitor [human]) • **Zemaira** (alpha$_1$-proteinase inhibitor [human])
Targeted	• **Aralast NP** (alpha$_1$-proteinase inhibitor [human]) • **Glassia** (alpha$_1$-proteinase inhibitor [human])

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when either of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.
B. 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.; March 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
3445-D

2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2023.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2022.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; September 2022.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5892-D

EXCEPTIONS CRITERIA
ANTIMETABOLITES

PREFERRED PRODUCT: PEMETREXED

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the antimetabolite products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Antimetabolites

	Product(s)
Preferred*	• **pemetrexed** (generic)
Targeted	• **Alimta** (pemetrexed) • **Pemfexy** (pemetrexed)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when any of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. 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.; June 2022.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5892-D

3. Pemfexy [package insert]. Woodcliff Lake, NJ: Eagle Pharmaceuticals, Inc.; December 2022.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4659-D

EXCEPTIONS CRITERIA
ASTHMA

PREFERRED PRODUCTS: FASENRA AND XOLAIR

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the asthma products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Asthma Products

	Product(s)
Preferred*	• **Fasenra** (benralizumab) • **Xolair** (omalizumab)
Targeted	• **Cinqair** (reslizumab) • **Nucala** (mepolizumab) • **Tezspire** (tezepelumab-ekko)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

A. Cinqair
Coverage for Cinqair is provided when either of the following criteria is met:
1. Member has received treatment with Cinqair in the past 365 days.
2. Member has both of the following:
   a. Member has a documented inadequate response or intolerable adverse event with the preferred product Fasenra.
   b. Member has either of the following:

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4659-D

i. 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.
ii. A pretreatment serum IgE level of less than 30 IU/mL.

B. Nucala

Coverage for Nucala is provided when either of the following criteria is met:

1. Member has received treatment with Nucala in the past 365 days.
2. Member meets either of the following:
   a. Member has a comorbidity of nasal polyps and meets either of the following:
      i. 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.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   b. Member meets both of the following:
      i. Member has a documented inadequate response or an intolerable adverse event with the preferred product Fasenra.
      ii. Member has either of the following:
         aa. 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.
         bb. A pretreatment serum IgE level of less than 30 IU/mL.

C. Tezspire

Coverage for Tezspire is provided when either of the following criteria is met:

1. Member has received treatment with Tezspire in the past 365 days.
2. Member meets both of the following:
   a. Member has either of the following:
      i. Blood eosinophil count of at least 150 cells per microliter and has had a documented inadequate response or an intolerable adverse event with the preferred product Fasenra.
      ii. Blood eosinophil count of less than 150 cells per microliter.
   b. Member has either of the following:
      i. 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.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

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.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4659-D

4. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
5. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4649-D

EXCEPTIONS CRITERIA
AUTOIMMUNE CONDITIONS

PREFERRED PRODUCTS: ENTYVIO AND SIMPONI ARIA

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the autoimmune drug products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Drugs for autoimmune conditions

	Products	
Preferred*	• **Entyvio** (vedolizumab)	• **Simponi Aria** (golimumab, intravenous)
Targeted	• **Actemra** (tocilizumab) • **Cimzia** (certolizumab pegol) • **Ilumya** (tildrakizumab-asmn)	• **Orencia** (abatacept) • **Stelara IV** (ustekinumab)

Abbreviations: IV = intravenous
*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. For Cimzia, when any of the following criteria is met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. Member has a documented inadequate response or intolerable adverse event with both Entyvio and Simponi Aria where the product's indications overlap.
   3. Member is currently breastfeeding, pregnant, or planning pregnancy.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4649-D

B. For all other targeted products, when either of the following criteria is met:
   1. Member has received treatment with the targeted product in the past 365 days.
   2. Member has a documented inadequate response or intolerable adverse event with both Entyvio and Simponi Aria where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).

III. APPENDIX: Clinical reasons to avoid 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.; December 2022.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; December 2022.
3. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A. Inc.; April 2024.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2022.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; October 2023.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2023.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2024.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5290-D

EXCEPTIONS CRITERIA
INFLIXIMAB

PREFERRED PRODUCTS: INFLECTRA AND RENFLEXIS

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the infliximab products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Infliximab products

	Product(s)
Preferred*	• **Inflectra** (infliximab-dyyb) • **Renflexis** (infliximab-abda)
Targeted	• **Avsola** (infliximab-axxq) • **infliximab** • **Remicade** (infliximab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when any of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. 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

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
5290-D

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

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5295-D

EXCEPTIONS CRITERIA
BEVACIZUMAB-ONCOLOGY PRODUCTS

PREFERRED PRODUCTS: MVASI, ZIRABEV

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the bevacizumab products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Bevacizumab-Oncology Products

	Product(s)
Preferred*	• **Mvasi** (bevacizumab-awwb) • **Zirabev** (bevacizumab-bvzr)
Targeted	• **Alymsys** (bevacizumab-maly) • **Avastin** (bevacizumab) • **Vegzelma** (bevacizumab-adcd)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the requested targeted product in the past 365 days.
B. 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.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5295-D

4. Vegzelma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; February 2023.
5. Zirabev [package insert]. New York, NY: Pfizer, Inc.; February 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
3792-D

EXCEPTIONS CRITERIA
BONE METASTASES

PREFERRED PRODUCTS: PAMIDRONATE AND ZOLEDRONIC ACID

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the bone metastases products specified in this policy. Coverage for the targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Bone Metastases Products

	Product(s)
Preferred*	• pamidronate • zoledronic acid
Targeted	• **Xgeva** (denosumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for any of the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response with either of the preferred products.
C. Member has a documented intolerable adverse event or documented contraindication to therapy with both the preferred products (i.e., severe renal impairment [creatinine clearance less than 35 mL/min]).

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
3792-D

REFERENCES

1. Pamidronate [package insert]. Morgantown, WV: Mylan Institutional LLC.; July 2023.
2. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020.
3. Zoledronic acid [package insert]. Memphis, TN: Northstar Rx LLC; April 2019.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4248-D

EXCEPTIONS CRITERIA
BOTULINUM TOXINS

PREFERRED PRODUCTS: DYSPORT AND XEOMIN

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the botulinum toxins products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Botulinum Toxins

	Product(s)
Preferred*	• **Dysport** (abobotulinumtoxinA) • **Xeomin** (incobotulinumtoxinA)
Targeted	• **Botox** (onabotulinumtoxinA) • **Myobloc** (rimabotulinumtoxinB)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when ANY of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event with both of the preferred products.
C. Member is requesting Botox for the treatment of blepharospasm and either of the following criteria is met:
   1. Member is 18 years of age and older and the member has a documented inadequate response or intolerable adverse event with Xeomin.
   2. Member is 12 years of age or older but less than 18 years of age.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
4248-D

D. Member is requesting Botox for the treatment of lower limb spasticity and has a documented inadequate response or intolerable adverse event with Dysport.
E. Member is requesting Botox for the treatment of upper limb spasticity and both of the following criteria are met:
   1. Member is a pediatric patient 2 years of age to 17 years of age and the upper limb spasticity is caused by cerebral palsy.
   2. Member has a documented inadequate response or intolerable adverse event with Dysport.
F. Member is requesting Myobloc for the treatment of chronic sialorrhea and has a documented inadequate response or 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; September 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5890-D

EXCEPTIONS CRITERIA
BREAST CANCER

PREFERRED PRODUCT: PHESGO

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the breast cancer products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. HER2-targeted antibodies

	Product(s)
Preferred*	• **Phesgo** (pertuzumab, trastuzumab, and hyaluronidase-zzxf)
Targeted	• **Perjeta** (pertuzumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for breast cancer.

Coverage for the targeted product is provided when any of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. 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.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5890-D

2. Phesgo [package insert]. South San Francisco, CA: Genentech, Inc.; June 2020.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
3801-D

EXCEPTIONS CRITERIA
COMPLEMENT INHIBITORS

PREFERRED PRODUCT: SOLIRIS

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the complement inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Complement Inhibitor Products

	Product(s)
Preferred*	• **Soliris** (eculizumab)
Targeted	• **Uplizna** (inebilizumab-cdon)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment of neuromyelitis optica spectrum disorder (NMOSD).

Coverage for a targeted product is provided when either of the following criteria is met:
A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event with the preferred product.

REFERENCES

1. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2024.
2. Uplizna [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; July 2021.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5280-D

EXCEPTIONS CRITERIA

Colony Stimulating Factors – Long Acting

PREFERRED PRODUCTS: FULPHILA, ZIEXTENZO

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the long acting colony stimulating factor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Long Acting

	Product(s)
Preferred*	• **Fulphila** (pegfilgrastim-jmdb) • **Ziextenzo** (pegfilgrastim-bmez)
Targeted	• **Fylnetra** (pegfilgrastim-pbbk) • **Neulasta (including Onpro kit)** (pegfilgrastim) • **Nyvepria** (pegfilgrastim-apgf) • **Rolvedon** (eflapegrastim-xnst) • **Stimufend** (pegfilgrastim-fpgk) • **Udenyca** (pegfilgrastim-cbqv)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for the targeted products is provided when the member meets one of the following criteria:

A. 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).

B. Member has received treatment with the requested targeted product in the past 365 days.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**		**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5280-D

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]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; June 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.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4282-D

EXCEPTIONS CRITERIA

Colony Stimulating Factors – Short Acting

PREFERRED PRODUCT: ZARXIO

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the short acting colony stimulating factor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Short Acting

	Product(s)
Preferred*	• **Zarxio** (filgrastim-sndz)
Targeted	• **Granix** (TBO-filgrastim) • **Leukine** (sargramostim) • **Neupogen** (filgrastim) • **Nivestym** (filgrastim-aafi) • **Releuko** (filgrastim-ayow)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

A. Coverage for the targeted products, Granix, Neupogen, Nivestym or Releuko, is provided when the member meets one of the following criteria:
   1. 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).
   2. Member has a documented latex allergy and the prescriber states that the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion.
   3. Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4282-D

4. Member has received treatment with the requested targeted product in the past 365 days.

B. Coverage for the targeted product, Leukine, is provided when the member meets one of the following criteria:
   1. Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
   2. Leukine is being requested for an indication that is not FDA-approved for the preferred product.
   3. Member has received treatment with the requested targeted 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.; January 2024.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5278-D

EXCEPTIONS CRITERIA

ERYTHROPOIESIS STIMULATING AGENTS

PREFERRED PRODUCTS: ARANESP AND RETACRIT

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the erythropoiesis stimulating agents specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Erythropoiesis Stimulating Agents

	Product(s)
Preferred*	• **Aranesp** (darbepoetin alfa) • **Retacrit** (epoetin alfa-epbx)
Targeted	• **Epogen** (epoetin alfa) • **Mircera** (methoxy polyethylene glycol-epoetin beta) • **Procrit** (epoetin alfa)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

A. Mircera

Coverage for Mircera is provided when either of the following criteria is met:

1. Member has received treatment with Mircera in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Retacrit.

B. Epogen or Procrit

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5278-D

Coverage for Epogen or Procrit is provided when either of the following criteria is met:

1. Member has received treatment with Epogen or Procrit in the past 365 days.
2. Member meets both of the following criteria:
   a. Member has a documented inadequate response or intolerable adverse event with the preferred product, Aranesp, when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.
   b. Member has had a documented intolerable adverse event to the preferred product, 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 products).

REFERENCES

1. Aranesp [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2019.
2. Epogen [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2018.
3. Procrit [package insert]. Horsham, PA: Janssen Products, LP; July 2018.
4. Mircera [package insert]. St. Gallen, Switzerland: Vifor (International) Inc.; March 2023.
5. Retacrit [package insert]. Lake Forest, IL: Hospira Inc.; April 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5894-D

EXCEPTIONS CRITERIA
FACTOR VIII PRODUCTS

PREFERRED PRODUCTS: AFSTYLA AND KOVALTRY

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the Factor VIII products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Factor VIII Products

	Product(s)
Preferred*	• **Afstyla** (antihemophilic factor [recombinant]) • **Kovaltry** (antihemophilic factor [recombinant])
Targeted	• **Advate** (antihemophilic factor [recombinant]) • **Kogenate FS** (antihemophilic factor [recombinant]) • **Novoeight** (antihemophilic factor [recombinant]) • **Nuwiq** (antihemophilic factor [recombinant]) • **Recombinate** (antihemophilic factor [recombinant]) • **Xyntha** (antihemophilic factor [recombinant]) • **Xyntha Solofuse** (antihemophilic factor [recombinant])

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5894-D

B. Member has a documented inadequate response, intolerable adverse event or contraindication to both 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.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4219-D

EXCEPTIONS CRITERIA
GAUCHER DISEASE AGENTS

PREFERRED PRODUCTS: CEREZYME AND ELELYSO

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the Gaucher disease products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Gaucher Disease Agents

	Product(s)
Preferred*	• **Cerezyme** (imiglucerase) • **Elelyso** (taliglucerase alfa)
Targeted	• **VPRIV** (velaglucerase alfa)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has had a documented inadequate response or an intolerable adverse event with both of the preferred products, Cerezyme and Elelyso.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
4219-D

REFERENCES

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; May 2023.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.
3. VPRIV [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2021.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
6433-D

EXCEPTIONS CRITERIA

GEOGRAPHIC ATROPHY PRODUCTS

PREFERRED PRODUCT: SYFOVRE

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the geographic atrophy products specified in this policy. Coverage for a targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with the targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Acromegaly Products

	Product(s)
Preferred*	• **Syfovre** (pegcetacoplan injection)
Targeted	• **Izervay** (avacincaptad pegol intravitreal solution)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the requested targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event with the preferred product.

REFERENCES

1. Izervay [package insert]. Parsippany, NJ: Iveric Bio Inc; August 2023.
2. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; November 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4257-D

EXCEPTIONS CRITERIA

GONADOTROPIN RELEASING HORMONE AGONISTS

PREFERRED PRODUCT: ELIGARD

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the gonadotropin releasing hormone agonist products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Gonadotropin releasing hormone agonists

	Product(s)
Preferred*	• **Eligard** (leuprolide acetate)
Targeted	• **Camcevi** (leuprolide mesylate) • **Lupron Depot** (leuprolide acetate for depot suspension) • **Trelstar** (triptorelin) • **Zoladex** (goserelin acetate)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for prostate cancer.

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with a targeted product in the past 365 days.

B. Member has a documented hypersensitivity to the preferred product.

REFERENCES

1. Camcevi [package insert]. Durham, NC: Accord BioPharma Inc.; May 2021.
2. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; January 2024.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4257-D

3. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; December 2023.
4. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; November 2023.
5. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4664-D

EXCEPTIONS CRITERIA

HYALURONATES

PREFERRED PRODUCTS (Osteoarthritis-Multi): EUFLEXXA AND SYNVISC
PREFERRED PRODUCTS (Osteoarthritis-Single): DUROLANE AND SYNVISC-ONE

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the hyaluronate products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table 1. Hyaluronate products (Osteoarthritis-Multi)

	Product(s)
Preferred*	• **Euflexxa** (1% sodium hyaluronate) • **Synvisc** (hylan G-F 20)
Targeted	• **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)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

Table 2. Hyaluronate products (Osteoarthritis-Single)

	Product(s)
Preferred*	• **Durolane** (hyaluronic acid) • **Synvisc-One** (hylan G-F 20)

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
4664-D

Targeted	• **Gel-One** (cross-linked hyaluronate) • **Monovisc** (high molecular weight hyaluronan)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

A. Osteoarthritis-Multi

Coverage for a targeted product is provided when either of the following criteria is met:

1. Member has received treatment with the requested targeted product in the past 365 days.
2. Member has a documented intolerable adverse event to both of the preferred products, Euflexxa and Synvisc.

B. Osteoarthritis-Single

Coverage for a targeted product is provided when either of the following criteria is met:

1. Member has received treatment with the requested targeted product in the past 365 days.
2. 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; September 2014.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
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.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
3797-D

EXCEPTIONS CRITERIA

IMMUNE GLOBULINS

PREFERRED PRODUCTS:
FLEBOGAMMA DIF, GAMMAKED, GAMUNEX-C, HIZENTRA, OCTAGAM, PRIVIGEN

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the immune globulin products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Immune Globulin Products

	Product(s)
Preferred*	• **Flebogamma** (intravenous) • **Gammaked** (subcutaneous/intravenous) • **Gamunex-C** (subcutaneous/intravenous) • **Hizentra** (subcutaneous) • **Octagam** (intravenous) • **Privigen** (intravenous)
Targeted	• **Asceniv** (intravenous) • **Bivigam** (intravenous) • **Cutaquig** (subcutaneous) • **Cuvitru** (subcutaneous) • **Gammagard Liquid** (subcutaneous/intravenous) • **Gammaplex** (intravenous) • **HyQvia** (subcutaneous) • **Panzyga** (intravenous) • **Xembify** (subcutaneous)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
3797-D

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response or 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.
17. Xembify [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2020.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5895-D

EXCEPTIONS CRITERIA

INTRAVENOUS IRON

PREFERRED PRODUCTS: FERRLECIT, INFED, SODIUM FERRIC GLUCONATE, VENOFER

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the intravenous iron products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Complement Inhibitor Products

	Product(s)
Preferred*	• **Ferrlecit** (sodium ferric gluconate complex) • **Infed** (iron dextran) • **Sodium ferric gluconate** • **Venofer** (iron sucrose)
Targeted	• **Feraheme** (ferumoxytol) • **Injectafer** (ferric carboxymaltose) • **Monoferric** (ferric derisomaltose)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for any of the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.

B. The requested product is Feraheme and the member meets any of the following:

1. 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.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5895-D

2. 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.
3. Member has a diagnosis of chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.

C. The requested product is Injectafer and the member meets any of the following:
1. 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.
2. Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.

D. The requested product is Monoferric and the member meets any of the following:
1. 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.
2. 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.; September 2021.
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.; May 2023.
7. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5858-D

EXCEPTIONS CRITERIA

MITOTIC INHIBITORS

PREFERRED PRODUCTS: DOCETAXEL AND PACLITAXEL

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Mitotic Inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Mitotic Inhibitors

	Product(s)
Preferred*	• **docetaxel** (generic) • **paclitaxel** (generic)
Targeted	• **Abraxane** (paclitaxel, albumin-bound)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when any of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response or intolerable adverse event with either of the preferred products, docetaxel or paclitaxel.
C. Member has a documented clinical reason to avoid all of the preferred products.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5858-D

REFERENCES

1. Abraxane [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2022.
2. docetaxel [package insert]. E. Windsor, NJ: AuroMedics Pharma LLC; February 2021.
3. paclitaxel [package insert]. Piscataway, NJ: Novadoz Pharmaceuticals LLC; August 2020.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5861-D

EXCEPTIONS CRITERIA
MULTIPLE MYELOMA

PREFERRED PRODUCTS: BORTEZOMIB (J9046, J9048 AND J9049)

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the multiple myeloma products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Multiple Myeloma

	Product(s)
Preferred*	• **Bortezomib** (generic) J9046, NDC 43598-0865-60 • **Bortezomib** (generic) J9048, NDC 63323-0721-10 • **Bortezomib** (generic) J9049, NDC 00409-1703-01
Targeted	• **Empliciti** (elotuzumab) • **Kyprolis** (carfilzomib) • **Sarclisa** (isatuximab) • **Velcade (J9041)** (bortezomib)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when any of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.
B. The request is for Empliciti, Kyprolis or Sarclisa and the member has a documented inadequate response or intolerable adverse event with a preferred product.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5861-D

C. 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; November 2023.
5. Velcade [package insert]. Lexington, MA: Takeda Pharmaceuticals America; August 2022.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
3431-D

EXCEPTIONS CRITERIA

MULTIPLE SCLEROSIS PRODUCTS

PREFERRED PRODUCTS: OCREVUS AND TYSABRI

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the multiple sclerosis products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Multiple Sclerosis (MS) Products

	Products
Preferred*	• **Ocrevus** (ocrelizumab) • **Tysabri** (natalizumab)
Targeted	• **Briumvi** (ublituximab-xiiy) • **Lemtrada** (alemtuzumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with both of the preferred products or any of their components.

REFERENCES

1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc; December 2022.
2. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; February 2024.
3. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc; January 2024.
4. Tysabri [package insert]. Cambridge, MA: Biogen Inc; October 2023

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5826-D

EXCEPTIONS CRITERIA
OSTEOPOROSIS

PREFERRED PRODUCTS: PROLIA AND ZOLEDRONIC ACID

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the osteoporosis products specified in this policy. Coverage for the targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Osteoporosis Products

	Products
Preferred*	• **Prolia** (denosumab) • zoledronic acid
Targeted	• **Evenity** (romosozumab-aqqg)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA
This program applies to members requesting treatment for an indication that is FDA-approved for any of the preferred products.

Postmenopausal Osteoporosis

Coverage for a targeted product is provided when any of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented inadequate response to both of the preferred products.
C. Member has a documented intolerable adverse event or contraindication to both of the preferred products. (e.g., creatinine clearance less than 35 mL/min for zoledronic acid).

REFERENCES
1. Evenity [package insert]. Thousand Oaks, CA: Amgen, Inc.; April 2020.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
5826-D

2. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2024.
3. Zoledronic acid [package insert]. Princeton, NJ: Fosun Pharma USA, Inc.; June 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
6304-D

EXCEPTIONS CRITERIA

PD1/PDL1 PRODUCTS: BASAL CELL CARCINOMA AND SQUAMOUS CELL CARCINOMA

PREFERRED PRODUCT: LIBTAYO

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the PD1/PDL1 products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. PD1/PDL1 Products

	Product(s)
Preferred*	• **Libtayo** (cemiplimab)
Targeted	• **Keytruda** (pembrolizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has a documented intolerable adverse event with the preferred product.

REFERENCES

1. Keytruda [package insert]. Rathway, NJ: Merck & Co., Inc.; March 2024.
2. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024.
3. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Oncology Clinical Programs. May 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
6305-D

EXCEPTIONS CRITERIA

PD1/PDL1 PRODUCTS- NON-SMALL CELL LUNG CANCER (NSCLC)

PREFERRED PRODUCT: LIBTAYO

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the PD1/PDL1 products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. PD1/PDL1 Products

	Product(s)
Preferred*	• **Libtayo** (cemiplimab)
Targeted	• **Imfinzi** (durvalumab) • **Keytruda** (pembrolizumab) • **Opdivo** (nivolumab) • **Tecentriq** (atezolizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when the member meets one of the following criteria:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has had a documented intolerable adverse event to the preferred product.
C. 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%.
D. Keytruda, Imfinzi or Tecentriq is being used for the adjuvant treatment of NSCLC.
E. Opdivo is being used for the neoadjuvant treatment of NSCLC.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**	✓	**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
6305-D

REFERENCES

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2023.
2. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024.
3. Keytruda [package insert]. Rathway, NJ: Merck & Co., Inc.; March 2024.
4. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2024.
5. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; May 2023.
6. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Oncology Clinical Programs. May 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5903-D

EXCEPTIONS CRITERIA

RETINAL DISORDERS

PRIMARY PREFERRED PRODUCT: AVASTIN

SECONDARY PREFERRED PRODUCTS: BYOOVIZ, EYLEA, EYLEA HD

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the retinal disorder products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Retinal disorder products

	Product(s)
Primary Preferred*	• **Avastin** (bevacizumab)
Secondary Preferred*	• **Byooviz** (ranibizumab-nuna) • **Eylea** (aflibercept) or **Eylea HD** (aflibercept)
Targeted	• **Beovu** (brolucizumab-dbll) • **Cimerli** (ranibizumab-eqrn) • **Lucentis** (ranibizumab) • **Susvimo** (ranibizumab injection) • **Vabysmo** (faricimab-svoa)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when any of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5903-D

B. The requested product is Byooviz or Eylea HD and member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
C. The requested product is Eylea and either of the following criteria are met:
   1. Member has a diagnosis of retinopathy of prematurity
   2. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
D. The requested product is Beovu or Vabysmo and both of the following criteria are met:
   1. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
   2. Member has had a documented inadequate response or intolerable adverse event with two of the secondary preferred products: Byooviz and either Eylea or Eylea HD.
E. The requested product is Cimerli or Lucentis and either of the following criteria are met:
   1. Member has a diagnosis of myopic choroidal neovascularization (mCNV) and all of the following criteria are met:
      i. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
      ii. 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).
   2. Member has a diagnosis other than myopic choroidal neovascularization (mCNV) and all of the following criteria are met:
      i. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
      ii. 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).
      iii. Member has had a documented inadequate response or intolerable adverse event with either of the secondary preferred products, Eylea or Eylea HD.
F. The requested product is Susvimo and all of the following criteria are met:
   1. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
   2. 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).
   3. Member had had a documented inadequate response or intolerable adverse event with either of the secondary preferred products, Eylea or Eylea HD.

REFERENCES

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5903-D

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
2. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2023.
3. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; October 2023.
4. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022.
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. Susvimo [package insert]. San Francisco, CA: Genentech, Inc.; April 2022.
9. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.; October 2023.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5328-D

EXCEPTIONS CRITERIA
RITUXIMAB PRODUCTS

PREFERRED PRODUCTS: RUXIENCE AND TRUXIMA

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the rituximab products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Rituximab Products

	Product(s)
Preferred*	• **Ruxience** (rituximab-pvvr) • **Truxima** (rituximab-abbs)
Targeted	• **Riabni** (rituximab-arrx) • **Rituxan** (rituximab) • **Rituxan Hycela** (rituximab and hyaluronidase human)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. 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

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**		**Medical Benefit**		**Medicare Part B**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**		
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5328-D

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; February 2022.

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4670-D

EXCEPTIONS CRITERIA
TRASTUZUMAB PRODUCTS

PREFERRED PRODUCTS: KANJINTI AND TRAZIMERA

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the trastuzumab products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Trastuzumab Products

	Product(s)
Preferred*	• **Kanjinti** (trastuzumab-anns) • **Trazimera** (trastuzumab-qyyp)
Targeted	• **Herceptin** (trastuzumab) • **Herceptin Hylecta** (trastuzumab and hyaluronidase-oysk) • **Herzuma** (trastuzumab-pkrb) • **Ogivri** (trastuzumab-dkst) • **Ontruzant** (trastuzumab-dttb)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with the targeted product in the past 365 days.
B. 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).

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit	✓	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4670-D

REFERENCES

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc; February 2021.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
3. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; October 2022.
4. Trazimera [package insert]. New York, NY Pfizer Labs; November 2020.
5. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; May 2019.
6. Ogivri [package insert]. Cambridge, MA: Biocon Biologics Inc., July 2023.
7. Ontruzant [package insert]. Jersey City, NJ: Organon LLC; June 2021.