Medicare Advantage Plans Part B Drugs Prior Authorization Criteria 2024

This prior authorization document was updated on 04/11/2024. 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 04/11/2024. 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

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-099-CM-V-2	
GlobalHealth	TITLE Leqembi Prior Authorization Approval Criteria	EFFECTIVE DATE 8/1/2023	LAST REVISED 4/11/2024

Therapeutic class: Central Nervous System Agent | Monoclonal Antibody

Available dosage forms: Intravenous Solution: 100 MG/1 ML

Criteria for initial approval:

1. FDA-approved diagnosis: treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease
2. Documented evidence of beta-amyloid plaque on the brain demonstrated by recent baseline PET/MRI (within the previous 12 months)
3. Prescribed dose is no more than 10 mg/kg once every two weeks.
4. Member is treated by a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Criteria for renewal:

1. Member continues to meet initial approval criteria
2. Member has a positive response to treatment as documented by repeat PET/MRI (months 12 and 18) and assessment by treating physician
3. No unacceptable toxicity is present

Summary of evidence:

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

1. The prescribing information for Leqembi
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 Leqembi are covered.

Explanation of rationale:

Support for FDA-approved indications can be found in the manufacturer's prescribing information and the clinical trials (Study 1, NCT01767311; Study 2 NCT03887455) 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, lecanemab (Leqembi) 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. Leqembi [Prescribing Information]. Eisai Inc., Nutley, NJ. July 2023. Available at: https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=77aa4a86-b786-457a-b894-01de37199024

P&T Committee review dates: 8/1/2023 UM
Committee review dates: 12/29/2023, 4/11/2024

Part B Drug Utilization Management Policy

GlobalHealth	**ENTITY** GlobalHealth Holdings, LLC	**NUMBER** GH-PT-101-M-V-1	
	TITLE Oncology Drug Treatment Prior Authorization Approval Criteria	EFFECTIVE DATE 2/16/2024	LAST REVISED 2/16/2024

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

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.

P&T Committee review dates:
UM Committee review dates: 2/16/2024

Part B Drug MCG Clinical Guidelines

Name of Policy	Policy No.	Rationale for Approval
C1 Esterase Inhibitor	ACG: A-0740	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Icatibant	ACG: A-0679	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Lanadelumab	ACG: A-1014	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Abatacept	ACG: A-0453	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Belimumab	ACG: A-0666	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Canakinumab	ACG: A-1015	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Certolizumab	ACG: A-0576	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Golimumab	ACG: A-0575	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Infliximab	ACG: A-0308	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Tocilizumab	ACG: A-0622	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Ustekinumab	ACG: A-0621	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Vedolizumab	ACG: A-0731	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Evinacumab	ACG: A-1036	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Aflibercept	ACG: A-0680	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance:

		Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Bevacizumab	ACG: A-0491	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Brolucizumab	ACG: A-1026	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Faricimab-svoa	ACG: A-1051	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Ranibizumab	ACG: A-0450	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Voretigene Neparvovec	ACG: A-1028	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Teduglutide	ACG: A-0703	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Antihemophilic Factor	ACG: A-0451	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Betibeglogene Autotemcel	ACG: A-1057	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Coagulation Factor IX	ACG: A-0714	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Coagulation Factor VIIa	ACG: A-0452	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Crizanlizumab	ACG: A-1027	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Eculizumab	ACG: A-0676	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Emicizumab-kxwh	ACG: A-0987	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Pegcetacoplan	ACG: A-1046	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Ravulizumab	ACG: A-1002	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Romiplostim	ACG: A-0756	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Belatacept	ACG: A-0678	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Agalsidase Beta	ACG: A-0465	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Alglucosidase Alfa	ACG: A-0458	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Imiglucerase	ACG: A-0461	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Taliglucerase Alfa	ACG: A-0697	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Abaloparatide	ACG: A-0963	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Bisphosphonates, Intavenous	ACG: A-0294	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Collagenase, Injectable	ACG: A-0639	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Denosumab	ACG: A-0644	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Pegloticase	ACG: A-0674	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Romosozumab	ACG: A-1008	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Teriparatide	ACG: A-0321	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Alemtuzumab (non-oncology indications only)	ACG: A-0577	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Eptinezumab	ACG: A-1032	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Natalizumab	ACG: A-0469	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Ocrelizumab	ACG: A-0977	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Rituximab (non-oncology indications only)	ACG: A-0448	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Alpha-1 Proteinase Inhibitor	ACG: A-0468	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Benralizumab	ACG: A-0985	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Epoprostenol	ACG: A-0300	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Iloprost	ACG: A-0307	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Mepolizumab	ACG: A-0922	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Omalizumab	ACG: A-0315	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Reslizumab	ACG: A-0942	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Tezepelumab-ekko	ACG: A-1053	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Treprostinil	ACG: A-0322	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Becaplermin	ACG: A-0325	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Buprenorphine Extended-Release Injection	ORG: B-001-Rx (BHG)	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Naltrexone Extended-Release Injection	ORG: B-005-Rx (BHG)	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and

		accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Naltrexone Implant	ORG: B-006-Rx (BHG)	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Brexanolone	ORG: B-008-Rx (BHG)	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.
Esketamine	ORG: B-007-Rx (BHG)	Rationale: Establishes clear, evidence-based guidelines for reviewing medical necessity and appropriateness of Part B medication treatments. Compliance: Develops and periodically updates guidelines based on the latest clinical evidence and standards of care. Ensures transparency and accessibility of criteria to providers and beneficiaries, in line with CMS requirements for utilization management programs.

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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4255-D

EXCEPTIONS CRITERIA

ACROMEGALY PRODUCTS

PREFERRED PRODUCTS: SANDOSTATIN LAR, LANREOTIDE INJECTION

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 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*	• **Sandostatin LAR Depot** (octreotide acetate for injectable suspension) • **Lanreotide Injection** (lanreotide acetate)
Targeted	• **Signifor LAR** (pasireotide) • **Somatuline Depot** (lanreotide 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 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. Member has received treatment with the requested targeted product in the past 365 days.
B. The request is for Signifor LAR and member has a documented inadequate response or intolerable adverse event to any of the preferred products.
C. The request is for Somatuline Depot and both of the following criteria are met:
   1. The member has a documented intolerable adverse event to lanreotide injection, and the adverse event was not an unexpected adverse event attributed to the active ingredient as described in the prescribing information.
   2. The member has a documented inadequate response or intolerable adverse event to Sandostatin LAR Depot.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4255-D

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2019.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2021.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; September 2021.
4. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; December 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
3445-D

EXCEPTIONS CRITERIA

ALPHA1-PROTEINASE INHIBITORS

PREFERRED PRODUCT: PROLASTIN-C

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 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. Alpha1-Proteinase Inhibitor Products

	Product(s)
Preferred*	• **Prolastin-C** (alpha$_1$-proteinase inhibitor [human])
Targeted	• **Aralast NP** (alpha$_1$-proteinase inhibitor [human]) • **Glassia** (alpha$_1$-proteinase inhibitor [human]) • **Zemaira** (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 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. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2022.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; March 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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
3445-D

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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	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; August 2022.
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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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 the targeted product is provided 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 both of the following:
   a. Member has a documented inadequate response or intolerable adverse event with 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**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

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

B. Nucala

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets any 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 Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   b. Member is less than 12 years of age 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 Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   c. Member is 12 years of age or older and meets both of the following:
      i. Member has a documented inadequate response or an intolerable adverse event with 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 Xolair.
         bb. A pretreatment serum IgE level of less than 30 IU/mL.

C. Tezspire

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets both of the following:
   a. The 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 Fasenra.
      ii. Blood eosinophil count of less than 150 cells per microliter.
   b. The 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 Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4659-D

REFERENCES

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
3. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
4. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.
5. Xolair [package insert]. South San Francisco, CA: Genentech, 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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4659-D

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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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** (ustekinumab)

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

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.; September 2019.
3. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A. Inc.; June 2022.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2020.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; December 2021.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5292-D

EXCEPTIONS CRITERIA

INFLIXIMAB

PREFERRED PRODUCTS: AVSOLA AND INFLECTRA

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

*: 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).

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5292-D

REFERENCES

1. Avsola [package insert]. Thousand Oaks, CA: Amgen; September 2021.
2. Inflectra [package insert]. New York, NY: Pfizer Inc; March 2022.
3. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
4. Renflexis [package insert]. Jersey City, NJ: Organon & Co.; January 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5298-D

EXCEPTIONS CRITERIA
BEVACIZUMAB-ONCOLOGY PRODUCTS

PREFERRED PRODUCT: MVASI

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)
Targeted	• **Alymsys** (bevacizumab-maly) • **Avastin** (bevacizumab) • **Vegzelma** (bevacizumab-adcd) • **Zirabev** (bevacizumab-bvzr)

*: 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 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).

REFERENCES
1. Alymsys [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5298-D

2. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
3. Mvasi [package insert]. Thousand Oaks, CA: Amgen, Inc.; November 2021.
4. Vegzelma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; September 2022.
5. Zirabev [package insert]. New York, NY: Pfizer, Inc.; May 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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 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. 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 are 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])

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
3792-D

1. Pamidronate [package insert]. Lake Forest, IL: Akorn-Strides, LLC.; November 2008.
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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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 to 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 had a documented inadequate response or intolerable adverse event to Xeomin
   2. Member is 12 years of age or older but less than 18 years of age
D. Member is requesting Botox for the treatment of lower limb spasticity and has had a documented inadequate response or adverse event to Dysport.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4248-D

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 had a documented inadequate response or adverse event to Dysport.

F. Member is requesting Myobloc for the treatment of chronic sialorrhea and has had a documented inadequate response or an intolerable adverse event to Xeomin.

REFERENCES

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; July 2021.
2. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2020.
3. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
4. Xeomin [package insert]. Frankfurt, Germany: Merz Pharmaceuticals GmbH; August 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	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.
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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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.; November 2020.
2. Uplizna [package insert]. Baithersburg, MD: Viela Bio, 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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
3801-D

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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Managed Medicaid	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)						Medicare Part B: Add-on
			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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**						**Medicare Part B: Add-on**
			IVL						

Reference #
5280-D

REFERENCES

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
2. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; October 2021.
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.; September 2022.
6. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2022.
7. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; March 2023.
8. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; March 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Managed Medicaid	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)						Medicare Part B: Add-on
			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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**						**Medicare Part B: Add-on**
			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 2019.
2. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2022.
3. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
4. Nivestym [package insert]. Lake Forest, IL: Hospira, Inc., a Pfizer Company: March 2023.
5. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; April 2022.
6. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Balanced (BF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
	Value (VF)		IVL						

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 the targeted product is provided 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 of the preferred products, Aranesp and Retacrit.

B. Epogen or Procrit

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets both of the following criteria:

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Balanced (BF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
	Value (VF)		**IVL**						

Reference #
5278-D

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.

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

Reference #
5894-D

EXCEPTIONS CRITERIA
FACTOR VIII PRODUCTS

PREFERRED PRODUCTS: 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 all members requesting treatment with a targeted product.

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

Table. Factor VIII Products

	Product(s)
Preferred*	• **Kovaltry** (antihemophilic factor [recombinant])
Targeted	• **Advate** (antihemophilic factor [recombinant]) • **Afstyla** (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**
	Preferred Drug Plan Design (PDPD)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical Benefit: Biosimilars First**	✓	**Medicare Part B: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5894-D

B. Member has a documented inadequate response, intolerable adverse event or contraindication with the preferred product.

REFERENCES

1. Advate [package insert]. Lexington, MA: Baxalta US Inc.; December 2018.
2. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; April 2021.
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; October 2021.
7. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
8. Recombinate [package insert]. Lexington, MA: Baxalta US Inc.; June 2018.
9. Xyntha [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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4219-D

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; August 2022.
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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	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.; April 2019.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
4257-D

3. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
4. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; March 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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
4664-D

EXCEPTIONS CRITERIA

HYALURONATES

PREFERRED PRODUCTS (Osteoarthritis-Multi): ORTHOVISC 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*	• **Orthovisc** (high molecular weight hyaluronan) • **Synvisc** (hylan G-F 20)
Targeted	• **Euflexxa** (1% sodium hyaluronate) • **Gelsyn-3** (sodium hyaluronate) • **GenVisc 850** (sodium hyaluronate) • **Hyalgan** (sodium hyaluronate) • **Hymovis** (high molecular weight viscoelastic 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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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

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

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 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: Biotest Pharmaceuticals Corporation; July 2019.
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]. Westlake Village, CA: Baxalta US Inc.; March 2021.
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.; March 2022.
11. Octagam 5% [package insert]. Paramus, NJ: Octapharma USA, Inc.; April 2022.
12. Panzyga [package insert]. New York, NY; Pfizer; January 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 2022.
16. HyQvia [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		Medicare Part B: Add-on
			IVL						

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

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.; July 2020.
5. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
6. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; February 2022.
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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5858-D

REFERENCES

1. Abraxane [package insert]. Summit, NJ: Celgene Corporation; August 2020.
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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	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; July 2022.
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
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First	✓	Medicare Part B: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Balanced (BF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
	Value (VF)		IVL						

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 non-preferred 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 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, 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; January 2023.
3. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc; August 2022.
4. Tysabri [package insert]. Cambridge, MA: Biogen Inc; December 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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 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. 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.
2. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2023.
3. Zoledronic acid [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; February 2017.

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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5888-D

EXCEPTIONS CRITERIA

PD1/PDL1 PRODUCTS

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

Indication(s)	Preferred Product*	Targeted Product(s)
Basal Cell and Squamous Cell Carcinoma	• **Libtayo** (cemiplimab)	• **Keytruda** (pembrolizumab)
Non-Small Cell Lung Cancer (NSCLC)	• **Libtayo** (cemiplimab)	• **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.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5888-D

E. Opdivo is being used for the neoadjuvant treatment of NSCLC.

REFERENCES

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2022.
2. Keytruda [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2023.
3. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; February 2023.
4. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; December 2022.
5. 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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5888-D

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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5328-D

1. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; June 2022.
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; November 2021.
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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

Reference #
5269-D

EXCEPTIONS CRITERIA
TRASTUZUMAB PRODUCTS

PREFERRED PRODUCTS: KANJINTI, OGIVRI, 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) • **Ogivri** (trastuzumab-dkst) • **Trazimera** (trastuzumab-qyyp)
Targeted	• **Herceptin** (trastuzumab) • **Herceptin Hylecta** (trastuzumab and hyaluronidase-oysk) • **Herzuma** (trastuzumab-pkrb) • **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 requested targeted product in the past 365 days
B. Member has had a documented intolerable adverse event to all of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

Reference #
5269-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]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2021.
7. Ontruzant [package insert]. Jersey City, NJ: Organon LLC; June 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: Biosimilars First
	Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on	✓	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
			IVL						

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EXCEPTIONS CRITERIA

VEGF INHIBITORS FOR OCULAR INDICATIONS

PRIMARY PREFERRED PRODUCT: AVASTIN

SECONDARY PREFERRED PRODUCT: BYOOVIZ

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 VEGF inhibitors for ocular indications 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. VEGF inhibitors for ocular indications

	Product(s)
Primary Preferred*	• **Avastin** (bevacizumab)
Secondary Preferred*	• **Byooviz** (ranibizumab-nuna)
Targeted	• **Beovu** (brolucizumab-dbll) • **Cimerli** (ranibizumab-eqrn) • **Eylea** (aflibercept) • **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 the 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.

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: Biosimilars First**
	Advanced Control Specialty (ACSF)		**New to Market (NTM)**		**VF Chart (VFC)**		**Medical Benefit: Add-on**	✓	**Medicare Part B: Advanced Biosimilars First**
	Value (VF)		**Aetna Health Exchange (AHE)**				**Medical Benefit: Managed Medicaid**		
			IVL						

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B. The requested product is Byooviz and member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
C. The requested product is Beovu or Vabysmo and member has had a documented inadequate response or intolerable adverse event with both of the preferred products (Avastin, Byooviz).
D. The requested product is Eylea and member meets either of the following criteria:
   1. Member has a diagnosis of retinopathy or prematurity.
   2. Member has had a documented inadequate response or intolerable adverse event with both of the preferred products (Avastin, Byooviz).
E. The requested product is Cimerli, Lucentis, or Susvimo and member meets both of the following criteria:
   1. Member has had 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 products).

REFERENCES

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; January 2021.
2. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2022.
3. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; June 2022.
4. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; November 2022.
5. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2021.
6. Lucentis [package insert]. South San Francisco, CA: Genentech, Inc.; March 2018.
7. Susvimo [package insert]. San Francisco, CA: Genentech, Inc.; April 2022.
8. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.' January 2023.