Commercial Plans Medical Drugs Prior Authorization Criteria 2025

This prior authorization document was updated on 12/05/2024. 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 1-877-280-5600 toll free (TTY users should call 711), from 9 am to 5 pm, Monday – Friday.

Este documento de autorización previa fue actualizado el 12/05/2024. 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 1-877-280-5600, 9 am a 5 pm, lunes a viernes.

Pharmacy Utilization Management Policy

GlobalHealth	**ENTITY** GlobalHealth Holdings, LLC	**NUMBER** GH-PT-001-C-V-2	
	TITLE Oncology Drug Commercial Prior Authorization Approval Criteria	**EFFECTIVE DATE** 4/14/2016	**LAST REVISED** 8/1/2023

Criteria for initial approval:

1. Conforms to guideline recommendations from National Comprehensive Cancer Network (NCCN)
2. For advanced metastatic cancer and associated conditions: no step therapy requirements apply when the requested treatment is consistent with best practices, supported by peer-reviewed, evidence-based literature; and the drug is approved by the United States Food and Drug Administration

Criteria for renewal:

1. Conforms to guideline recommendations from National Comprehensive Cancer Network (NCCN)

P&T Committee review dates: 4/14/16, 8/1/2018, 7/31/2019, 7/22/2020, 7/28/2021, 8/3/2022, 8/1/2023, 11/26/2024

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-002-C-V-2	
GlobalHealth	TITLE Zilretta Commercial Prior Authorization Approval Criteria	EFFECTIVE DATE 7/31/2019	LAST REVISED 5/27/2020

HCPCS code: J3304 Inj triamcinolone ace xr 1mg

Therapeutic class: Intra-articular Corticosteroid

Available dosage forms: Triamcinolone acetonide extended-release injectable suspension single-dose kit

Criteria for initial approval (3 months: one injection per knee):

1. FDA-approved diagnosis: Osteoarthritis of the Knee
2. Age 18 years or older
3. Member has had treatment failure with or had clinically significant adverse effects to one of the following treatments.
   - 3.1. Oral nonsteroidal antiinflammatory drug (NSAID) at continuous therapeutic dosing (prescription strength); OR
   - 3.2. Topical NSAID if member an oral NSAID is contraindicated;
4. History of a positive but inadequate response to at least one other intraarticular glucocorticoid injection for the knee (e.g., inadequate pain relief, frequent need of rescue medications such as NSAIDs or opioids, need to decrease or inability to increase activity levels, adequate pain relief but with steroid-induced hyperglycemia);

Renewal: Zilretta is not eligible for renewal as the efficacy and safety of repeat administration of Zilretta have not been established.

References:

1. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically
2. Zilretta Prescribing Information. Burlington, MA: Flexion Therapeutics, Inc.; May 2024.
3. Bodick N, Lufkin J, Willwerth C, et al. An intra-articular, extended-release formulation of triamcinolone acetonide prolongs and amplifies analgesic effect in patients with osteoarthritis of the knee: A randomized clinical trial. J Bone Joint Surg Am. 2015; 97: 877-88. http://dx.doi.org/10.2106/JBJS.N.00918
4. Krause VB, Conaghan PG, Aazami HA, et al. Synovial and systemic pharmacokinetics (PK) of triamcinolone acetonide (TA) following intra-articular (IA) injection of an extended release microsphere-based formulation (FX006) or standard crystalline suspension in patients with knee osteoarthritis (OA). Osteoarthritis and Cartilage. 2018; 26: 34-42.
5. Russell SJ, Sala R, Conaghan PG, et al. In type 2 diabetes mellitus patients with knee osteoarthritis intra-articular injection of FX006 (Extended Release Triamcinolone) is associated with reduced blood glucose elevation vs. standard triamcinolone; a randomized, blinded, parallel group study. Diabetes 2017; 66(Suppl 1): A289.
6. Conaghan PG, Hunter DJ, Cohen SB, et al. Effects of a single intra-articular injection of a microsphere formulation of triamcinolone acetonide on knee osteoarthritis pain. A double-blind, randomized, placebo controlled, multinational study. J Bone Joint Surg Am. April 18, 2018; 100(8): 666-677.

7. Brown GA. American Academy of Orthopaedic Surgeons clinical practice guidelines: Treatment of osteoarthritis of the knee: Evidence-based guideline, 2nd edition. J Am Acad Orthop Surg. September 2013;21(9):577-9. doi: 10.5435/JAAOS-21-09-577.
8. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care & Research. April 2012; 64(4): 465-474.
9. Rannou F, Peletier JP, Martel-Pelletier J. Efficacy and safety of topical NSAIDs in the management of osteoarthritis: Evidence from real-life setting trials and surveys. Semin Arthritis Rheum. 2016; 45:S18-S21.
10. McAlindon TE, Bannuru RR, Sullivan MC, at al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis Cartilage. 2014; 22:363-388.
11. Nelson AE, Allen KD, Golightly YM, et al. A systematic review of recommendations and guidelines for the management of osteoarthritis: The chronic osteoarthritis management initiative of the U.S. Bone and Joint Initiative. Semin Arthritis Rheum. 2014; 43:701-712.

P&T Committee review dates: 7/31/2019, 5/27/2020, 4/28/2021, 8/3/2022, 8/1/2023, 11/26/2024

Pharmacy Utilization Management Policy

	ENTITY GlobalHealth Holdings, LLC	NUMBER GH-PT-003-C-V-1	
GlobalHealth	TITLE Qutenza Commercial Prior Authorization Approval Criteria	EFFECTIVE DATE 11/26/2024	LAST REVISED

HCPCS Code: J7336 Capsaicin 8% patch

Therapeutic class: Analgesic | Central Nervous System Agent

Available dosage forms: Single-use 8% topical system

Criteria for initial approval:

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

Criteria for renewal:

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

Summary of evidence:

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

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

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

Explanation of rationale:

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

References:

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

P&T Committee review dates: 11/26/2024

Reference number(s)
4256-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Acromegaly Products

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the acromegaly products specified in this document. 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 all members requesting treatment with a targeted product.

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

Table. Acromegaly Products

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

	Products
Preferred	• Sandostatin LAR (octreotide acetate for injectable suspension) • Somatuline Depot (lanreotide)
Targeted	• Lanreotide Injection • Signifor LAR (pasireotide injectable suspension) • Somavert (pegvisomant)

Exception Criteria

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

Lanreotide Injection

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

- The member has had a documented intolerable adverse event to Somatuline Depot, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- The member has a documented inadequate response or intolerable adverse event to Sandostatin LAR.

Signifor LAR, Somavert

Coverage for a targeted product is provided when the member has had a documented inadequate response or intolerable adverse event to any of the preferred products.

References

1. Somatuline Depot [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2024.
2. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; July 2024.
4. Somavert [package insert]. New York, NY: Pharmacia & Upjohn Co; July 2023.
5. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; May 2024.

Reference number(s)
5876-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☑
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Alpha1-Proteinase Inhibitors

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Medical Benefit, and Managed Medicaid Medical Benefit (MMMB).

Plan Design Summary

This program applies to the alpha1-proteinase inhibitor products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Alpha1-Proteinase Inhibitor Products

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

	Products
Preferred	• Prolastin-C (alpha1-proteinase inhibitor [human]) • Zemaira (alpha1-proteinase inhibitor [human])
Target	• Aralast NP (alpha1-proteinase inhibitor [human]) • Glassia (alpha1-proteinase inhibitor [human])

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 the 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.

References

1. Aralast NP [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
2. Glassia [package insert]. Lexington, MA: Takeda Pharmaceuticals USA Inc; September 2023.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2022.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; January 2024.

Reference number(s)
5597-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Asthma

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

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

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

Table. Asthma Products

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

	Product(s)
Preferred	• Dupixent (dupilumab) • Fasenra (benralizumab) • Nucala (mepolizumab) • Tezspire (tezepelumab-ekko) • Xolair (omalizumab)

	Product(s)
Target	• Cinqair (reslizumab)

Exception Criteria

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

Coverage for Cinqair is provided when the member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

References

1. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
2. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2024.
3. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
4. Nucala [package insert]. Durham, NC: GlaxoSmithKline; March 2023.
5. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2023.
6. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.

Reference number(s)
4957-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Autoimmune Conditions

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the autoimmune drug products specified in this document. 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. For plaque psoriasis, this program applies to all members requesting treatment with a targeted product. For all other indications, 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. Drugs for Autoimmune Conditions

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

Skyrizi intravenous (IV) and Stelara IV are indicated for induction treatment for Crohn's disease (CD) and ulcerative colitis (UC).

	Product(s)
Preferred	• Entyvio IV (vedolizumab) • Ilumya (tildrakizumab-asmn) • Simponi Aria (golimumab) • Skyrizi IV (risankizumab-rzaa) • Stelara IV (ustekinumab)
Target	• Actemra IV (tocilizumab) • Cimzia lyophilized powder (certolizumab pegol) • Orencia IV (abatacept)

Exception Criteria

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

Plaque Psoriasis

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

- Member has a documented inadequate response or intolerable adverse event with the preferred product (Ilumya).
- The requested product is Cimzia lyophilized powder, and the member is currently breastfeeding, pregnant, or planning pregnancy.

Crohn's Disease

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

- Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Skyrizi IV, and Stelara IV), unless the member is a documented primary non-responder to an IL-23 inhibitor.
- The requested product is Cimzia lyophilized powder, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.

All Other Indications

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

- Member has a documented inadequate response or intolerable adverse event with the preferred product (Simponi Aria) where the products' indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).

- The requested product is Cimzia lyophilized powder, and the member is currently breastfeeding, pregnant, or planning pregnancy.
- Member is currently receiving treatment with the requested targeted product, excluding when it is obtained as samples or via manufacturer's patient assistance programs.

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.; September 2024.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2024.
3. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; April 2024.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; May 2024.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
7. Skyrizi [package insert]. North Chicago, IL: AbbVie Inc.; June 2024.
8. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2024.

Reference number(s)
6638-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Infliximab

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

These criteria were developed to align with the following: Medical Benefit and Medical Benefit Advanced Biosimilars First.

Plan Design Summary

This program applies to the infliximab products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Infliximab Products

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

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

	Product(s)
Target	• infliximab • Remicade (infliximab)

Exception Criteria

Coverage for a targeted product is provided when the member has had a documented intolerable adverse event to all of the preferred products (Avsola, Inflectra, and Renflexis), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

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

Reference number(s)
3269-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Botulinum Toxins

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the botulinum toxins products specified in this document. 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 all members requesting treatment with the targeted products.

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

Table. Botulinum Toxins

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

	Product(s)
Preferred	• Botox (onabotulinumtoxinA) • Daxxify (daxibotulinumtoxinA-lanm) • Xeomin (incobotulinumtoxinA)
Target	• Dysport (abobotulinumtoxinA) • Myobloc (rimabotulinumtoxinB)

Exception Criteria

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

Dysport

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

- Member has a documented inadequate response or intolerable adverse event to all of the preferred products.
- Member is requesting Dysport for the treatment of lower limb spasticity and has had a documented inadequate response or an intolerable adverse event to Botox.
- Member is 18 years of age and older, is requesting Dysport for the treatment of upper limb spasticity, and has had a documented inadequate response or an intolerable adverse event to Botox and Xeomin.
- Member is 2 years of age to 17 years of age, is requesting Dysport for the treatment of upper limb spasticity caused by cerebral palsy, and has had a documented inadequate response or an intolerable adverse event to Botox.

Myobloc

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

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

References

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; November 2023.
2. Daxxify [package insert]. Newark, CA: Revance Therapeutics, Inc.; November 2023.
3. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; September 2023.
4. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
5. Xeomin [package insert]. Frankfurt, Germany: Merz Pharmaceuticals GmbH; July 2024.

Reference number(s)
5608-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Breast Cancer

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the breast cancer products specified in this document. 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. HER2-targeted antibodies

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

	Products
Preferred	• Enhertu (fam-trastuzumab deruxtecan-nxki) • Kadcyla (ado-trastuzumab emtansine) • Perjeta (pertuzumab) • Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)
Target	• Margenza (margetuximab-cmkb)

Exception Criteria

This program applies to members requesting treatment for breast cancer.

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

- Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

References

1. Enhertu [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; November 2022.
2. Kadcyla [package insert]. South San Francisco, CA: Genentech, Inc.; February 2022.
3. Margenza [package insert]. Rockville, MD: MacroGenics, Inc.; May 2023.
4. Perjeta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2021.
5. Phesgo [package insert]. South San Francisco, CA: Genentech, Inc.; June 2020.

Reference number(s)
3661-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Colony Stimulating Factors – Long Acting

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

These criteria were developed to align with the following: Medical Advanced Biosimilars First.

Plan Design Summary

This program applies to the long-acting colony stimulating factor products specified in this document. 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. Colony Stimulating Factors – Long Acting

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

	Products
Preferred	• Fulphila (pegfilgrastim-jmdb) • Nyvepria (pegfilgrastim-apgf)

	Products
Target	• Fylnetra (pegfilgrastim-pbbk) • Neulasta (including Onpro kit) (pegfilgrastim) • Stimufend (pegfilgrastim-fpgk) • Udenyca (pegfilgrastim-cbqv) • Ziextenzo (pegfilgrastim-bmez)

Exception Criteria

Coverage for the targeted product is provided when the member has had a documented intolerable adverse event to all of the preferred products and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

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

Reference number(s)
5053-D

Reference number(s)
5053-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Colony Stimulating Factors – Short Acting

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

These criteria were developed to align with the following: Medical Benefit Advanced Biosimilars First.

Plan Design Summary

This program applies to the short-acting colony stimulating factor products specified in this document. 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 Granix or Neupogen and for members who are new to treatment with Leukine 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

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

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

Exception Criteria

Coverage for the targeted products, Neupogen or Granix, is provided when one of the following criteria is met:

- 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 products and biosimilar products).
- Member has a documented latex allergy and the prescriber states that the member must use latex-free products (Neupogen vial, Granix pre-filled syringe, or Granix vial) and the member has had an intolerable adverse effect to Nivestym and Releuko 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).
- Neupogen or Granix are requested for doses less than 180 mcg and the member has had an intolerable adverse effect to Nivestym 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).

Coverage for the targeted product, Leukine, is provided when one of the following criteria is met:

- Member has had a documented inadequate response or an intolerable adverse event to one of the preferred products.
- Leukine is being requested for an indication that is not FDA-approved for the preferred product.
- Member is currently receiving treatment with Leukine, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.

References

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

Reference number(s)
6656-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Fabry Disease

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the Fabry disease products specified in this document. Coverage for the targeted product 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. Fabry Disease

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

	Product(s)
Preferred	• Elfabrio (pegunigalsidase alfa-iwxj)
Target	• Fabrazyme (agalsidase beta)

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:

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member is 2 to 17 years of age.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

1. Elfabrio [package insert]. Cary, NC: Chiesi USA, Inc.; May 2024.
2. Fabrazyme [package insert]. Cambridge, MA: Genzyme Corporation; July 2024.

Reference number(s)
5654-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Factor IX Products

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the Factor IX products specified in this document. Coverage for 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 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 IX Products

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

	Products
Preferred	• Alprolix (coagulation factor IX [recombinant], Fc fusion protein) • Idelvion (coagulation factor IX [recombinant], albumin fusion protein) • Rebinyn (coagulation factor IX [recombinant], glycoPEGylated)
Target	• Benefix (coagulation factor IX [recombinant]) • Ixinity (coagulation factor IX [recombinant]) • Rixubis (coagulation factor IX [recombinant])

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 the member has a documented inadequate response or intolerable adverse event with all of the preferred products.

References

1. Alprolix [package insert]. Cambridge, MA: Biogen Idec Inc.; May 2023.
2. Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceutical LLC; November 2022.
3. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
4. Ixinity [package insert]. Seattle, WA: Aptevo BioTherapeutics LLC; February 2021.
5. Rixubis [package insert]. Lexington, MA. Baxalta US Inc.; March 2023.
6. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; August 2022.

Reference number(s)
2699-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Factor VIII Products

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the Factor VIII products specified in this document. 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. Factor VIII Products

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

	Products
Preferred	• Advate (antihemophilic factor [recombinant]) • Afstyla (antihemophilic factor [recombinant]) • Kogenate FS (antihemophilic factor [recombinant]) • Kovaltry (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant]) • Nuwiq (antihemophilic factor [recombinant]) • Xyntha (antihemophilic factor [recombinant])
Target	• Recombinate (antihemophilic factor [recombinant])

Exception Criteria

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

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

- Member is currently receiving treatment with the targeted product, excluding when the targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

References

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

Reference number(s)
4218-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Gaucher Disease Agents

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the Gaucher disease products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Gaucher Disease Agents

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

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

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 the member has had a documented inadequate response or an intolerable adverse event with the preferred product.

References

1. Elelyso [package insert]. New York, NY: Pfizer, Inc; JULY 2024.
2. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; July 2024.
3. VPRIV [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc., a Takeda company; July 2024.

Reference number(s)
6648-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Geographic Atrophy Products

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the ophthalmic geographic atrophy products specified in this document. 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. Ophthalmic Geographic Atrophy Products

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

	Products
Preferred	• Syfovre (pegcetacoplan)
Target	• Izervay (avacincaptad pegol)

Reference number(s)
6648-D

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 are met:

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

1. Izervay [package insert]. Parsippany, NJ: Iveric Bio Inc; February 2024.
2. Syfovre [package insert]. Waltham, MA: Apellis Pharmaceuticals Inc; November 2023.

Reference number(s)
4258-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Gonadotropin Releasing Hormone Agonists

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the gonadotropin releasing hormone agonist products specified in this document. 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 requesting treatment with Camcevi and Lupron Depot. This program also applies to members who are new to treatment with Firmagon, Trelstar, or Zoladex for the first time.

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

Table. Gonadotropin Releasing Hormone Agonists

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

	Product(s)
Preferred	• Eligard (leuprolide acetate)

	Product(s)
Target	• Camcevi (leuprolide mesylate) • Firmagon (degarelix) • Lupron Depot (leuprolide acetate for depot suspension) • Trelstar (triptorelin) • Zoladex (goserelin acetate)

Exception Criteria

This program applies to members requesting treatment for prostate cancer.

Firmagon, Trelstar, and Zoladex

Coverage for Firmagon, Trelstar, and Zoladex is provided when any of the following criteria is met:

- Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented hypersensitivity to the preferred product.
- The request is for Firmagon and the member has metastatic, castration-naïve disease.

Camcevi and Lupron Depot

Coverage for Camcevi and Lupron Depot is provided when the member has a documented hypersensitivity to the preferred product.

References

1. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; May 2024.
2. Camcevi [package insert]. Durham, NC: Accord BioPharma Inc.; May 2021.
3. Firmagon [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; February 2020.
4. Lupron Depot [package insert]. North Chicago, IL: AbbVie Inc.; March 2024.
5. Trelstar [package insert]. Ewing, NJ: Verity Pharmaceuticals Inc.; April 2024.
6. Zoladex [package insert]. Deerfield, IL: TerSera Therapeutics LLC; December 2020.

Reference number(s)
3304-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☑
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☑
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☑
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Hereditary Angioedema

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

These criteria were developed to align with the following: Managed Medicaid Template (MMT), Standard Control Formulary Chart (SFC), Advanced Control Specialty Formulary Chart (ACSFC), Medical Benefit, and Managed Medicaid Medical Benefit (MMMB).

Plan Design Summary

This program applies to the hereditary angioedema products specified in this document. Coverage for targeted product 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 requesting treatment with a targeted product.

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

Table. C1 Esterase Inhibitors for the Treatment of Acute Attacks of Hereditary Angioedema

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

	Product(s)
Preferred	• Ruconest (C1 esterase inhibitor [recombinant])

	Product(s)
Target	• Berinert (C1 esterase inhibitor [human])

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:

- Member is using the targeted product for short-term preprocedural prophylaxis (i.e., prior to surgical or major dental procedures).
- Member has a documented inadequate response to the preferred product.
- Member has a documented intolerable adverse event with the preferred product.
- Member has a documented contraindication to the preferred product (i.e., known or suspected allergy to rabbits or rabbit-derived products).
- Member is less than 13 years of age.
- Targeted product is being requested for treatment of laryngeal attacks.

References

1. Ruconest [package insert]. Warren, NJ: Pharming Healthcare, Inc.; April 2020.
2. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September 2021.

Reference number(s)
3025-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
hATTR Disorders

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the products for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis specified in this document. Coverage for the targeted product 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. Polyneuropathy of Hereditary Transthyretin-Mediated (hATTR) Amyloidosis Products

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

	Product(s)
Preferred	• Onpattro (patisiran) injection
Targeted	• Amvuttra (vutrisiran) injection • Tegsedi (inotersen) injection

Exception Criteria

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

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

- Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

1. Onpattro [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; January 2023.
2. Tegsedi [package insert]. Waltham, MA: Sobi Inc; January 2024.
3. Amvuttra [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; February 2023.

Reference number(s)
1762-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Hyaluronates

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the hyaluronate products specified in this document. 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 initiating a new treatment course with a targeted product.

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

Table. Hyaluronate Products

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

	Products
Preferred	• Monovisc (high molecular weight hyaluronan) • Orthovisc (high molecular weight hyaluronan) • Synvisc One (hylan G-F 20)

	Products
Targeted	• Durolane (hyaluronic acid) • Euflexxa (1% sodium hyaluronate) • Gel-One (cross-linked hyaluronate) • Gelsyn-3 (sodium hyaluronate) • GenVisc 850 (sodium hyaluronate) • Hyalgan (sodium hyaluronate) • Hymovis (high molecular weight viscoelastic hyaluronan) • Supartz FX (sodium hyaluronate) • Synojoynt (1% sodium hyaluronate) • Synvisc (hylan G-F 20) • Triluron (sodium hyaluronate) • TriVisc (sodium hyaluronate) • Visco-3 (sodium hyaluronate)

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:

- There is documentation that the member is currently undergoing treatment and coverage is required to complete the current course of treatment.
  Number of injections per treatment course:
  - Euflexxa: 3 injections (2 mL each; 6 mL total) per course
  - Gelsyn-3: 3 injections (2 mL each, 6 mL total) per course
  - GenVisc 850: 3 to 5 injections (2.5 mL each; 12.5 mL total) per course
  - Hyalgan: 3 to 5 injections (2 mL each; 10 mL total) per course
  - Hymovis: 2 injections (3 mL each; 6 mL total) per course
  - Supartz FX: 3 to 5 injections (2.5 mL each; 12.5 mL total) per course
  - Synojoynt: 3 injections (2 mL each; 6 mL total) per course
  - Synvisc: 3 injections (2 mL each; 6 mL total) per course
  - Triluron: 3 injections (2 mL each; 6 mL total) per course
  - TriVisc: 3 injections (2.5 mL each, 7.5 mL total) per course
  - Visco-3: 3 injections (2.5 mL each, 7.5 mL total) per course
- Member has a documented intolerable adverse event to all of the preferred products.

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.; December 2013.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; June 2005.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synojoynt [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2019.
12. Synvisc [package insert]. Ridgefield, NJ: Genzyme Corporation; May 2023.
13. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Corporation; May 2023.
14. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
15. TriVisc [package insert]. Doylestown, PA: OrthogenRx, Inc.; September 2018.
16. Visco-3 [package insert]. Warsaw, IN: Zimmer Inc.; December 2015.

Reference number(s)
6657-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Immune Globulins

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the immune globulin products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Immune Globulin Products

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

	Product(s)
Preferred	• Gammagard Liquid • Gammagard S/D • Gammaplex • Octagam • Privigen

	Product(s)
Targeted	• Alyglo • Asceniv • Bivigam • Gammaked • Gamunex-C • Panzyga

Exception Criteria

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

Coverage for a targeted product is provided when the member has a documented inadequate response or intolerable adverse event with at least 3 of the preferred products.

References

1. Alyglo [package insert]. Teaneck, NJ: GC Biopharma USA, Inc.; December 2023.
2. Asceniv [package insert]. Boca Raton, FL: ADMA Biologics; April 2019.
3. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics; March 2024.
4. Gammagard Liquid [package insert]. Westlake Village, CA: Baxalta US Inc.; January 2024.
5. Gammagard S/D [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
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]. Hoboken, NJ: Octapharma USA, Inc.; April 2022.
11. Octagam 5% [package insert]. Hoboken, NJ: Octapharma USA, Inc.; April 2022.
12. Panzyga [package insert]. Hoboken, NJ: Octapharma USA.; February 2021.
13. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; March 2022.

Reference number(s)
6655-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Immune Globulins

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the immune globulin products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Immune Globulin Products

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

	Product(s)
Preferred	• Cutaquig • Hizentra
Targeted	• Cuvitru • Hyqvia • Xembify

Reference number(s)
6655-D

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 the member has a documented inadequate response or intolerable adverse event with both of the preferred products.

References

1. Cutaquig [package insert]. Hoboken, NJ: Octapharma USA Inc.; November 2021.
2. Cuvitru [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
3. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; April 2023.
4. HyQvia [package insert]. Lexington, MA: Baxalta US Inc.; January 2024.
5. Xembify [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2020.

Reference number(s)
6652-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Intravenous Iron

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the intravenous iron products specified in this document. 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 initiating a new treatment course with a targeted product for the first time.

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

Table. Intravenous Iron Products

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

	Products
Preferred	• Ferrlecit (sodium ferric gluconate complex) • Infed (iron dextran) • Venofer (iron sucrose)

	Products
Targeted	• Feraheme (ferumoxytol) • Injectafer (ferric carboxymaltose) • Monoferric (ferric derisomaltose)

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:

- There is documentation that the member is currently undergoing treatment and coverage is required to complete the current course of treatment.
  Number of injections per treatment course (if multiple day injections required)
  - Feraheme: 2 injections (17 mL each; 34 mL total) per course
  - Injectafer: 2 injections (15 mL each, 30 mL total) per course
- The requested product is Feraheme and the member meets any of the following:
  - Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
  - 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 Ferrlecit.
  - Member has a diagnosis of chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
- The requested product is Injectafer and the member meets any of the following:
  - Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
  - Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
  - Member has a diagnosis of iron deficiency with heart failure categorized as New York Heart Association class II/III.
- The requested product is Monoferric and the member meets any of the following:
  - Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
  - 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. Venofer [package insert]. Shirley, NY: American Regent, Inc.; June 2022.
4. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
5. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; May 2023.
6. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022.

Reference number(s)
4289-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Multiple Myeloma

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the multiple myeloma products specified in this document. 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 Kyprolis for the first time to all members requesting treatment with Velcade.

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

Table. Multiple Myeloma Therapies

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

	Products
Preferred	• bortezomib • Ninlaro (ixazomib)

	Products
Targeted	• Kyprolis (carfilzomib) • Velcade (bortezomib)

Exception Criteria

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

- Coverage for Kyprolis is provided when either of the following criteria are met:
    - Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
    - Member has a documented inadequate response or intolerable adverse event with both of the preferred products.
- Coverage for Velcade is provided when the member has a documented intolerable adverse event to bortezomib, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References

1. Ninlaro [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; July 2024.
2. Velcade [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2022.
3. Kyprolis [package insert]. Thousand Oaks, CA: Onyx Pharmaceuticals, Inc.; June 2022.
4. bortezomib [package insert]. Lake Zurich, IL: Fresenius Kabi; April 2022.

Reference number(s)
6644-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Multiple Sclerosis

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

These criteria were developed to align with the following: Medical Benefit and Medical Benefit Advanced Biosimilars First.

Plan Design Summary

This program applies to the multiple sclerosis products specified in this document. 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 Tyruko. This program also applies to members who are new to treatment with Briumvi or Lemtrada for the first time.

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

Table. Multiple Sclerosis (MS) Products

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

	Product(s)
Preferred	• Ocrevus (ocrelizumab) • Tysabri (natalizumab)

	Product(s)
Target	• Briumvi (ublituximab-xiiy) • Lemtrada (alemtuzumab) • Tyruko (natalizumab-sztn)

Exception Criteria

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

Briumvi

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

- Member is currently receiving treatment with Briumvi, excluding when Briumvi is obtained as samples or via manufacturer's patient assistance programs.
- Member meets both of the following criteria:
  - Member has a documented intolerable adverse event to Ocrevus.
  - Member has a documented inadequate response, intolerable adverse event, or contraindication with Tysabri.

Lemtrada

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

- Member is currently receiving treatment with Lemtrada, excluding when Lemtrada is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response, intolerable adverse event, or contraindication with both of the preferred products (including any of their components).

Tyruko

Coverage for Tyruko is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to Tysabri, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar product).
- Member has a documented inadequate response, intolerable adverse event, or contraindication with Ocrevus.

References

1. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc; December 2022.

2. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; May 2024.
3. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
4. Tysabri [package insert]. Cambridge, MA: Biogen Inc; October 2023.
5. Tyruko [package insert]. Princeton, NJ: Sandoz Inc.; August 2023.

Reference number(s)
6626-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Osteoporosis

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the osteoporosis products specified in this document. Coverage for the targeted product 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 initiating a new treatment regimen with Evenity.

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

Table. Osteoporosis Products

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

	Product(s)
Preferred	• Prolia (denosumab)
Target	• Evenity (romosozumab-aqqg)

Reference number(s)
6626-D

Exception Criteria

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

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

- There is documentation that the member is currently undergoing treatment with the targeted product Evenity, and coverage is required to complete the current course of treatment.
- Member has a documented inadequate response, intolerable adverse event, contraindication, or clinical reason to avoid the preferred product Prolia.

References

1. Evenity [package insert]. Thousand Oaks, CA: Amgen, Inc.; April 2024.
2. Prolia [package insert]. Thousand Oaks, CA: Amgen Inc.; March 2024.

Reference number(s)
4977-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the paroxysmal nocturnal hemoglobinuria (PNH) agents specified in this document. 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. Paroxysmal Nocturnal Hemoglobinuria (PNH) Agents

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

	Products
Preferred	• Ultomiris (ravulizumab-cwvz) • Soliris (eculizumab)

	Products
Target	• Empaveli (pegcetacoplan)

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:

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with one of the preferred products.

References

1. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2024.
2. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2024.
3. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2024.

Reference number(s)
6658-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Pompe Disease

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the Pompe disease products specified in this document. Coverage for a targeted product 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. Pompe Disease

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

	Product(s)
Preferred	• Nexviazyme (avalglucosidase alfa-ngpt)
Target	• Lumizyme (alglucosidase alfa) • Pombiliti (cipaglucosidase alfa-atga)

Reference number(s)
6658-D

Exception Criteria

Lumizyme

Coverage for Lumizyme is provided when the member meets any of the following criteria:

- Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a diagnosis of infantile-onset Pompe disease.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

Pombiliti

Coverage for Pombiliti is provided when the member meets any of the following criteria:

- Member is currently receiving treatment with the requested targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

1. Nexviazyme [package insert]. Cambridge, MA: Genzyme Corporation; September 2023.
2. Lumizyme [package insert]. Cambridge, MA: Genzyme Corporation; March 2024.
3. Pombiliti [package insert]. Philadelphia, PA: Amicus Therapeutics US, LLC; July 2024.

Reference number(s)
5057-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Retinal Disorders

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

These criteria were developed to align with the following: Medical Benefit and Medical Benefit Advanced Biosmiliars First.

Plan Design Summary

This program applies to the retinal disorder products specified in this document. 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 Lucentis who have not tried a secondary preferred product. This program applies to members who are new to treatment with Byooviz, Cimerli, Eylea, and Vabysmo for the first time.

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

Table. Retinal Disorder Products

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

	Products
Primary Preferred	• Avastin (bevacizumab)

	Products
Secondary Preferred	1. Byooviz (ranibizumab-nuna) 2. Cimerli (ranibizumab-eqrn)
Targeted	1. Eylea (aflibercept) 2. Lucentis (ranibizumab) 3. Vabysmo (faricimab-svoa)

Exception Criteria

Byooviz, Cimerli

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

1. Member is currently receiving treatment with a targeted product, Byooviz or Cimerli, excluding when the requested targeted product is obtained via samples or via manufacturer's patient assistance programs.
2. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.

Eylea

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

1. Member is currently receiving treatment with the targeted product, Eylea, excluding when the requested targeted product is obtained via samples or via manufacturer's patient assistance programs.
2. Member has a diagnosis of retinopathy of prematurity.
3. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin, and at least one of the secondary preferred products, Byooviz or Cimerli.

Lucentis

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

1. Member meets either of the following criteria:
    1. Member is currently receiving treatment with the targeted product, Lucentis, excluding when the requested targeted product is obtained via samples or via manufacturer's patient assistance programs.
    2. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
2. Member has a documented intolerable adverse event to both of the secondary preferred products, Byooviz and Cimerli, 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).

Vabysmo

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

1. Member is currently receiving treatment with the targeted product, Vabysmo, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
2. Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin, and at least one of the secondary preferred products, Byooviz or Cimerli.

References

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
2. Byooviz (ranibizumab) [package insert]. Cambridge, MA: Biogen Inc; October 2023.
3. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2024.
4. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
5. Lucentis [package insert]. San Francisco, CA: Genentech, Inc.; February 2024.
6. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.; July 2024.

Reference number(s)
3665-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☑
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Rituximab Products

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

These criteria were developed to align with the following: Medical Benefit Advanced Biosimilars First.

Plan Design Summary

This program applies to the rituximab products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Rituximab Products

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

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

Exception Criteria

Coverage for a targeted product is provided when the member has had a documented intolerable adverse event to all of the preferred products. The adverse event must not be an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

1. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
2. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
3. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
4. Ruxience [package insert]. New York, NY: Pfizer; October 2023.
5. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; February 2022.

Reference number(s)
6632-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☐
Standard Control – Choice (SCCF)	☐
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☐
Advanced Control Specialty – Choice (ACSCF)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Systemic Lupus Erythematosus (SLE)

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

These criteria were developed to align with the following: Medical Benefit.

Plan Design Summary

This program applies to the systemic lupus erythematosus (SLE) products specified in this document. Coverage for the targeted product 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. Systemic Lupus Erythematosus (SLE) Products

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

	Product(s)
Preferred	• Benlysta (belimumab)
Target	• Saphnelo (anifrolumab-fnia)

Reference number(s)
6632-D

Exception Criteria

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

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

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

1. Benlysta [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; June 2024.
2. Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2024.

Reference number(s)
4668-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☑
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☑
Medical Benefit	☑
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Trastuzumab Products

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

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Advanced Control Specialty Formulary Chart (ACSFC), Standard Control Formulary Chart (SFC), Value Formulary Chart (VFC), and Medical Benefit.

Plan Design Summary

This program applies to the trastuzumab products specified in this document. 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 requesting treatment with a targeted product.

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

Table. Trastuzumab Products

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

	Products
Preferred	• Kanjinti (trastuzumab-anns) • Trazimera (trastuzumab-qyyp)
Target	• Herceptin (trastuzumab) • Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) • Herzuma (trastuzumab-pkrb) • Ogivri (trastuzumab-dkst) • Ontruzant (trastuzumab-dttb)

Exception Criteria

Coverage for a targeted product is provided when the member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
2. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; June 2024.
3. Herzuma [package insert]. Incheon, Republic of Korea: Celltrion, Inc; May 2019.
4. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2022.
5. Trazimera [package insert]. Cork, Ireland: Pfizer Ireland Pharmaceuticals; November 2020.
6. Ogivri [package insert]. Steinhausen, Switzerland: Mylan GmbH; July 2023.
7. Ontruzant [package insert]. Whitehouse Station, NJ: Merk Sharp & Dohme Corp.; June 2021.