CVS caremark®

January 2024

Medical Preferred Drug List

Medicare Part B Step Therapy

The CVS Caremark® Medical Preferred Drug List encourages utilization of clinically appropriate and lower net cost products within the following therapeutic drug classes. The CVS Caremark Medical Preferred Drug List applies to the listed products only and any other product may be available under a plan's medical benefit.

The listed preferred products must be used first. An exception process is in place for specific circumstances that may warrant a need for a non-preferred product. For example, this step therapy requirement does not apply to plan's members who are actively receiving treatment (i.e., members with a paid claim within the past 365 days) with non-preferred product on the CVS Caremark Medical Preferred Drug List.

Drug Class	Non-Preferred Product(s)*	Preferred Product(s)
Alpha-1 Antitrypsin Deficiency	Aralast Glassia Zemaira	Prolastin-C
Autoimmune Infused Infliximab	Avsola Renflexis	Inflectra Infliximab Remicade
Autoimmune Infused/Other	Actemra Cimzia Ilumya Orencia Stelara	Entyvio Simponi Aria

*Non-preferred product(s) are only available if process exception criteria are met.

This list indicates the common uses for which the drug is prescribed. Some medicines are prescribed for more than one condition. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark. Listed products are for informational purposes only and are not intended to replace the clinical judgment of the prescriber. Listed therapeutic classes and specific drug preferred designations are subject to change based on new drug launches, product approvals, drug withdrawals and other market changes.

Your privacy is important to us. Our employees are trained regarding the appropriate way to handle your private health information.

Drug Class	Non-Preferred Product(s)*	Preferred Product(s)
Avastin/Biosimilars (Oncology)	Alymsys Avastin Vegzelma	Mvasi Zirabev
Complement Inhibitors (aHUS, gMG, PNH)		Soliris Ultomiris
Complement Inhibitors (NMOSD)	Uplizna	Soliris
Hematologic, Erythropoiesis – Stimulating Agents (ESA)	Epogen Mircera Retacrit	Aranesp Procrit
Hematologic, Neutropenia Colony Stimulating Factors – Long Acting	Fylnetra Nyvepria Rolvedon Stimufend Udenyca Ziextenzo	Fulphila Neulasta

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Drug Class	Non-Preferred Product()*	Preferred Product(s)
Hematologic, Neutropenia Colony Stimulating Factors – Short Acting	Granix Leukine Neupogen Nivestym Releuko	Zarxio
Hematopoietic Agents- Iron	Feraheme Injectafer Monoferric	Ferrlecit Infed Sodium Ferric Gluconate Venofer
Hemophilia Factor VIII-Recombinant	Advate Afstyla Kogenate Novoeight Nuwiq Recombinate Xyntha Xyntha Solofuse	Kovaltry
Hemophilia Factor IX-Recombinant		Alprolix Idelvion
Lysosomal Storage Disorders – Gaucher Disease	VPRIV	Cerezyme Elelyso

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Drug Class	Non-Preferred Product(s)*	Preferred Product(s)
Multiple Sclerosis (Infused)	Briumvi Lemtrada	Ocrevus Tysabri
Osteoarthritis, Viscosupplements – Multi Injection	Euflexxa Gelsyn-3 GenVisc Hyalgan Hymovis Supartz FX Triluron TriVisc Visco-3	Orthovisc Synvisc
Osteoarthritis, Viscosupplements – Single Injection	Gel-One Monovisc	Durolane Synvisc-One
Prostate Cancer – Luteinizing Hormone Releasing Hormone (LHRH) Antagonists Agents		Firmagon
Rituximab	Riabni Truxima	Rituxan Rituxan Hycela Ruxience
Severe Asthma	Cinqair Nucala Tezspire	Fasenra Xolair

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This list indicates the common uses for which the drug is prescribed. Some medicines are prescribed for more than one condition. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark. Listed products are for informational purposes only and are not intended to replace the clinical judgment of the prescriber. Listed therapeutic classes and specific drug preferred designations are subject to change based on new drug launches, product approvals, drug withdrawals and other market changes.
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Drug Class	Non-Preferred Product(s)*	Preferred Product(s)
Trastuzumab	Herceptin Herceptin Hylecta Herzuma Ogivri Ontruzant	Kanjinti Trazimera

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This list indicates the common uses for which the drug is prescribed. Some medicines are prescribed for more than one condition. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark. Listed products are for informational purposes only and are not intended to replace the clinical judgment of the prescriber. Listed therapeutic classes and specific drug preferred designations are subject to change based on new drug launches, product approvals, drug withdrawals and other market changes.
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Exception Criteria

EXCEPTIONS CRITERIA

Alpha-1 Antitrypsin Deficiency

PREFERRED PRODUCT: PROLASTIN-C

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Alpha1-Proteinase Inhibitor Products

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

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

EXCEPTION CRITERIA

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

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

REFERENCES

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

EXCEPTIONS CRITERIA

Autoimmune Infused Infliximab

PREFERRED PRODUCTS: INFLECTRA, INFLIXIMAB AND REMICADE

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Infliximab products

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

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

EXCEPTION CRITERIA

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

a. Member has received treatment with the targeted product in the past 365 days.
b. Member has had a documented intolerable adverse event to 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. Avsola [package insert]. Thousand Oaks, CA: Amgen; September 2021.
2. Inflectra [package insert]. New York, NY: Pfizer Inc; March 2022.
3. Remicade [package insert]. Horsham, PA: Janssen Biotech, Inc.; October 2021.
4. Renflexis [package insert]. Jersey City, NJ: Organon & Co.; January 2022.

EXCEPTIONS CRITERIA

Autoimmune Infused/Other

PREFERRED PRODUCTS: ENTYVIO AND SIMPONI ARIA

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Drugs for autoimmune conditions

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

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

EXCEPTION CRITERIA

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

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

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

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

III. APPENDIX: Clinical reasons to avoid TNF inhibitors

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome

- History or risk of lymphoma or other malignancy
- History of being a primary non-responder to a TNF inhibitor

REFERENCES

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; December 2022.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; September 2019.
3. Entyvio [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A. Inc.; June 2022.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2020.
5. Orencia [package insert]. Princeton, NJ: Bristol-Meyers Squibb Company; December 2021.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; February 2021.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2022.

EXCEPTIONS CRITERIA

Avastin/Biosimilars (Oncology)

PREFERRED PRODUCTS: MVASI, ZIRABEV

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Bevacizumab-Oncology Products

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

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

EXCEPTION CRITERIA

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

A. Member has received treatment with the requested targeted product in the past 365 days.
B. Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

REFERENCES

5. Alymsys [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2022.
6. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
7. Mvasi [package insert]. Thousand Oaks, CA: Amgen, Inc.; November 2021.
8. Vegzelma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; September 2022.
9. Zirabev [package insert]. New York, NY: Pfizer, Inc.; May 2021.

EXCEPTIONS CRITERIA

Complement Inhibitors (aHUS, gMG, PNH)

PREFERRED PRODUCT: SOLIRIS

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Complement Inhibitor Products

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

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

EXCEPTION CRITERIA

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

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

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

REFERENCES

10. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; November 2020.
11. Uplizna [package insert]. Baithersburg, MD: Viela Bio, Inc.; July 2021.

EXCEPTIONS CRITERIA

Hematologic, Erythropoiesis – Stimulating Agents (ESA)

PREFERRED PRODUCTS: ARANESP AND PROCRIT

POLICY

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

PLAN DESIGN SUMMARY

This program applies to the erythropoiesis stimulating agents specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred 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. Erythropoiesis Stimulating Agents

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

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

EXCEPTION CRITERIA

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

A. Epogen

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets both of the following criteria:
   a. Member has a documented inadequate response or intolerable adverse event with the preferred product, Aranesp, when prescribed for the treatment of anemia due to chronic kidney disease or the treatment of anemia due to myelosuppressive chemotherapy in cancer.
   b. Member has had a documented intolerable adverse event to the preferred product, Procrit, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

B. Mircera

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

C. Member has received treatment with the targeted product in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Procrit.

C. Retacrit

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

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

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

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

EXCEPTIONS CRITERIA

Hematologic, Neutropenia Colony Stimulating Factors – Long Acting

PREFERRED PRODUCTS: FULPHILA, NEULASTA (INCLUDING ONPRO KIT)

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Colony Stimulating Factors – Long Acting

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

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

EXCEPTION CRITERIA

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

A. Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference products and biosimilar products).
B. Member has received treatment with the requested targeted product in the past 365 days.

REFERENCES

17. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
18. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; October 2021.
19. Fylnetra [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
20. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; March 2023.
21. Rolvedon [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; September 2022.
22. Stimufend [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2022.
23. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; March 2023.
24. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; March 2021.

EXCEPTIONS CRITERIA

Hematologic, Neutropenia Colony Stimulating Factors – Short Acting

PREFERRED PRODUCT: ZARXIO

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Colony Stimulating Factors – Short Acting

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

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

EXCEPTION CRITERIA

A. Coverage for the targeted products, Granix, Neupogen, Nivestym or Releuko, is provided when the member meets one of the following criteria:
   1. Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).
   2. Member has a documented latex allergy and the prescriber states that the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion.
   3. Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.
   4. Member has received treatment with the requested targeted product in the past 365 days.

B. Coverage for the targeted product, Leukine, is provided when the member meets one of the following criteria:
   1. Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
   2. Leukine is being requested for an indication that is not FDA-approved for the preferred product.
   3. Member has received treatment with the requested targeted product in the past 365 days.

REFERENCES

25. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
26. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2022.
27. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2021.
28. Nivestym [package insert]. Lake Forest, IL: Hospira, Inc., a Pfizer Company: March 2023.
29. Releuko [package insert]. Piscataway, NJ: Kashiv BioSciences, LLC; April 2022.
30. Zarxio [package insert]. Princeton, NJ: Sandoz, Inc.; September 2022.

EXCEPTIONS CRITERIA

Hematopoietic Agents- Iron

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

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Complement Inhibitor Products

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

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

EXCEPTION CRITERIA

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

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

A. Member has received treatment with the targeted product in the past 365 days.
B. The requested product is Feraheme and the member meets any of the following:
   1. Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
   2. Member has a diagnosis of hemodialysis-dependent chronic kidney disease and is receiving supplemental epoetin therapy and has had a documented inadequate response or intolerable adverse event with both Ferrlecit and sodium ferric gluconate.
   3. Member has a diagnosis of chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
C. The requested product is Injectafer and the member meets any of the following:
   1. Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.
   2. Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
D. The requested product is Monoferric and the member meets any of the following:
   1. Member has a diagnosis of iron deficiency anemia with intolerance or unsatisfactory response to oral iron and has had documented inadequate response or intolerable adverse event with Infed.

4. 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

31. Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; March 2022.
32. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; September 2021.
33. Sodium Ferric Gluconate [package insert]. Berkley Heights, NJ: Hikma Pharmaceuticals USA, Inc.; January 2021
34. Venofer [package insert]. Shirley, NY: American Regent, Inc.; July 2020.
35. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
36. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; February 2022.
37. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022.

EXCEPTIONS CRITERIA

Hemophilia Factor VIII- Recombinant

PREFERRED PRODUCTS: KOVALTRY

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Factor VIII Products

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

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

EXCEPTION CRITERIA

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

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

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

REFERENCES

1. Advate [package insert]. Lexington, MA: Baxalta US Inc.; December 2018.
2. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; April 2021.
3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
4. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
5. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; October 2021.
7. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
8. Recombinate [package insert]. Lexington, MA: Baxalta US Inc.; June 2018.
9. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.

EXCEPTIONS CRITERIA

Lysosomal Storage Disorders – Gaucher Disease

PREFERRED PRODUCTS: CEREZYME AND ELELYSO

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Gaucher Disease Agents

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

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

EXCEPTION CRITERIA

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

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

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

REFERENCES

38. Elelyso [package insert]. New York, NY: Pfizer, Inc; August 2022.
39. Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation; December 2022.
40. VPRIV [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2021.

EXCEPTIONS CRITERIA

Multiple Sclerosis (Infused)

PREFERRED PRODUCTS: OCREVUS AND TYSABRI

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

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

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

Table. Multiple sclerosis (MS) products

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

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

EXCEPTION CRITERIA

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

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

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

REFERENCES

41. Briumvi [package insert]. Morrisville, NC: TG Therapeutics, Inc; December 2022.
42. Lemtrada [package insert]. Cambridge, MA: Genzyme Corporation; January 2023.
43. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc; August 2022.
44. Tysabri [package insert]. Cambridge, MA: Biogen Inc; December 2021.

EXCEPTIONS CRITERIA

Osteoarthritis

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

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table 1. Hyaluronate products (Osteoarthritis-Multi)

	Product(s)
Preferred*	• **Orthovisc** (high molecular weight hyaluronan) • **Synvisc** (hylan G-F 20)
Targeted	• **Euflexxa** (1% sodium hyaluronate) • **Gelsyn-3** (sodium hyaluronate) • **GenVisc 850** (sodium hyaluronate) • **Hyalgan** (sodium hyaluronate) • **Hymovis** (high molecular weight viscoelastic hyaluronan) • **Supartz FX** (sodium hyaluronate) • **Triluron** (sodium hyaluronate) • **Trivisc** (sodium hyaluronate) • **Visco-3** (sodium hyaluronate)

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

Table 2. Hyaluronate products (Osteoarthritis-Single)

	Product(s)
Preferred*	• **Durolane** (hyaluronic acid) • **Synvisc-One** (hylan G-F 20)
Targeted	• **Gel-One** (cross-linked hyaluronate) • **Monovisc** (high molecular weight hyaluronan)

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

EXCEPTION CRITERIA

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

A. Osteoarthritis-Multi

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

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

B. Osteoarthritis-Single

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

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

REFERENCES

45. Durolane [package insert]. Durham, NC: Bioventus, LLC; September 2017.
46. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
47. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
48. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; December 2017.
49. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
50. Hyalgan [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
51. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; September 2017.
52. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
53. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
54. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
55. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
56. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
57. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
58. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
59. Visco-3 [package insert]. Warsaw, IN: Zimmer Inc.; May 2017.

EXCEPTIONS CRITERIA

Rituximab

PREFERRED PRODUCTS: RITUXAN, RITUXAN HYCELA AND RUXIENCE

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

PLAN DESIGN SUMMARY
This program applies to the rituximab products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred 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 who are new to treatment with a targeted product for the first time.

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

Table. Rituximab Products

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

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

EXCEPTION CRITERIA

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

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

60. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; June 2022.
61. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
62. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
63. Ruxience [package insert]. New York, NY: Pfizer; November 2021.
64. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; February 2022.

EXCEPTIONS CRITERIA

Severe Asthma

PREFERRED PRODUCTS: FASENRA AND XOLAIR

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Asthma products

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

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

EXCEPTION CRITERIA

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

A. Cinqair

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member has both of the following:
   a. Member has a documented inadequate response or intolerable adverse event with Fasenra.
   b. Member has either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

B. Nucala

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

1. Member has received treatment with the targeted product in the past 365 days.
2. Member meets any of the following:
   a. Member has a comorbidity of nasal polyps and meets either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.

b. Member is less than 12 years of age and meets either of the following:
    i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
    ii. A pretreatment serum IgE level of less than 30 IU/mL.
c. Member is 12 years of age or older and meets both of the following:
    i. Member has a documented inadequate response or an intolerable adverse event with Fasenra.
    ii. Member has either of the following:
        aa. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with Xolair.
        bb. A pretreatment serum IgE level of less than 30 IU/mL.

C. Tezspire

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

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

REFERENCES

65. Cinqair [package insert]. West Chester, PA: Teva Respiratory, LLC; June 2020.
66. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
67. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; March 2023.
68. Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.
69. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.

EXCEPTIONS CRITERIA

Trastuzumab

PREFERRED PRODUCTS: KANJINTI AND TRAZIMERA

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Trastuzumab Products

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

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

EXCEPTION CRITERIA

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

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has had a documented intolerable adverse event to both of the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

REFERENCES

70. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc; February 2021.
71. Herceptin Hylecta [package insert]. South San Francisco, CA: Genentech, Inc.; February 2019.
72. Kanjinti [package insert]. Thousand Oaks, CA: Amgen Inc; October 2022.
73. Trazimera [package insert]. New York, NY Pfizer Labs; November 2020.
74. Herzuma [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; May 2019.
75. Ogivri [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; February 2021.
76. Ontruzant [package insert]. Jersey City, NJ: Organon LLC; June 2021.