KelseyCare Advantage

2026

PART B STEP THERAPY CRITERIA

1-866-535-8343 (TTY: 711)

KelseyCareAdvantage.com

Effective 1/1/2026

H0332_PTBST26_C

Contents

Drug List & HCPCS Codes

Drug Class	Non-Preferred Product(s)	Preferred Product(s)
Acromegaly Long Acting	Lanreotide Acetate (J1930, J1932) Sandostatin LAR Depot (J2353) Signifor LAR (J2502)	Somatuline Depot (J1930)
Alpha1-Proteinase Inhibitors	Aralast (J0256) Glassia (J0257)	Prolastin-C (J0256) Zemaira (J0256)
Autoimmune Infused/Infliximab	Avsola (Q5121) Infliximab (J1745) Remicade (J1745)	Inflectra (Q5103) Renflexis (Q5104)
Autoimmune Infused/Other	Actemra IV (J3262) Cimzia (J0717) Orencia IV (J0129) Stelara IV (J3357, J3358)	Entyvio IV (J3380, J3490) Ilumya (J3245) Simponi Aria (J1602) Tremfya IV (J1628)
Bevacizumab – Oncology Products	Alymsys (Q5126) Avastin (J9035) Vegzelma (Q5129)	Mvasi (Q5107) Zirabev (Q5118)
Erythropoiesis Stimulating Agents (ESA)	Epogen (J0885, Q4081) Mircera (J0887, J0888) Retacrit (Q5105, Q5106)	Aranesp (J0881, J0882) Procrit (J0885, Q4081)
Hematologic, Neutropenia Colony Stimulating Factors – Long Acting	Fylnetra (Q5130) Nyvepria (Q5122) Rolvedon (J1449) Stimufend (Q5127) Udenyca (Q5111) Ziextenzo (Q5120)	Fulphila (Q5108) Neulasta (J2506)
Hematologic, Neutropenia Colony Stimulating Factors – Short Acting	Granix (J1447) Leukine (J2820) Neupogen (J1442) Nivestym (Q5110) Releuko (Q5125)	Zarxio (Q5101)
Hematopoietic Agents-Intravenous Iron	Feraheme (Q0138, Q0139) Injectafer (J1439) Monoferric (J1437)	Ferrlecit (J2916) Infed (J1750) Sodium Ferric Gluconate (J2916) Venofer (J1756)
Hemophilia Factor VIII Products	Advate (J7192) Kogenate (J7192) Novoeight (J7182) Recombinate (J7192) Xyntha (J7185) Xyntha Solofuse (J7185)	Afstyla (J7210) Kovaltry (J7211) Nuwiq (J7209)

Drug Class	Non-Preferred Product(s)	Preferred Product(s)
Gaucher Disease Agents	VPRIV (J3385)	Cerezyme (J1786) Elelyso (J3060)
Multiple Sclerosis (Infused)	Briumvi (J2329) Lemtrada (J0202) Ocrevus Zunovo (J2351) Tyruko (Q5134)	Ocrevus (J2350) Tysabri (J2323)
Osteoarthritis, Viscosupplements – Single Injection – Hyaluronates	Gel-One (J7326) Monovisc (J7327)	Durolane (J7318) Synvisc-One (J7325)
Osteoporosis-Bone Density	Evenity (J3111)	Jubbonti (Q5136) Prolia (J0897) Zoledronic Acid (J3489)
Rituximab Products	Riabni (Q5123) Rituxan (J9312) Rituxan Hycela (J9311)	Ruxience (Q5119) Truxima (Q5115)
Severe Asthma	Cinqair (J2786) Nucala (J2182)	Fasenra (J0517) Tezspire (J2356) Xolair (J2357)
Trastuzumab	Herceptin (J9355) Herceptin Hylecta (J9356) Herzuma (Q5113) Hercessi (Q5146) Ogivri (Q5114) Trazimera (Q5116)	Kanjinti (Q5117) Ontruzant (Q5112)

EXCEPTIONS CRITERIA

Acromegaly Long Acting Products

PREFERRED PRODUCTS: SOMATULINE DEPOT

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with Medicare Part B and Medicare Part B Advanced Biosimilars First.

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

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B 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	• Somatuline Depot (lanreotide acetate)
Non-preferred	• Lanreotide Injection (lanreotide acetate) • Sandostatin LAR Depot (octreotide acetate for injectable suspension) • Signifor LAR (pasireotide)

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

Lanreotide Injection
Coverage for the non-preferred product is provided when either of the following criteria is met:

1. Member has received treatment with the requested non-preferred product in the past 365 days.
2. The member has had a documented intolerable adverse event to Somatuline Depot, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

Sandostatin LAR Depot, Signifor LAR

Coverage for a non-preferred product is provided when either of the following criteria is met:

1. Member has received treatment with the requested non-preferred product in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with the preferred product.

References

3. Somatuline Depot [package insert]. Cambridge, NJ: Ipsen Biopharmaceuticals, Inc.; July 2024.
4. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
5. Signifor LAR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Company; July 2024.
6. Lanreotide Injection [package insert]. Warren, NJ: Cipla USA, Inc.; May 2024.

EXCEPTIONS CRITERIA

Alpha1-Proteinase Inhibitors

PREFERRED PRODUCTS: PROLASTIN-C AND ZEMAIRA

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

These criteria were developed to align with the following: Medicare Part B and Medicare Part B: Advanced Biosimilars First.

Plan Design Summary

This program applies to the alpha1-proteinase inhibitor products specified in this document. Coverage for non-preferred 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 non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Alpha1-Proteinase Inhibitor Products

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

	Product(s)
Preferred	**Prolastin-C** (alpha1-proteinase inhibitor [human]) **Zemaira** (alpha1-proteinase inhibitor [human])
Non-preferred	**Aralast NP** (alpha1-proteinase inhibitor [human]) **Glassia** (alpha1-proteinase inhibitor [human])

Step Therapy Criteria

Coverage for a non-preferred product is provided when either of the following criteria are met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has had a documented intolerable adverse event to both of the preferred products (Prolastin-C and Zemaira), and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References

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

EXCEPTIONS CRITERIA

Autoimmune Infused/Infliximab

PREFERRED PRODUCTS: INFLECTRA AND RENFLEXIS

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the infliximab products specified in this document. Coverage for non-preferred 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 non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Infliximab Products
Medications considered preferred on your plan may still require a clinical prior authorization review.

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

Step Therapy Criteria
Coverage for a non-preferred product is provided when either of the following criteria is met:
1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has had a documented intolerable adverse event to both of the preferred infliximab products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

References

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

EXCEPTIONS CRITERIA

Autoimmune Infused/Other

PREFERRED PRODUCTS: ENTYVIO, ILUMYA, SIMPONI ARIA, AND TREMFYA

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B

Plan Design Summary
This program applies to the autoimmune drug products specified in this document. Coverage for non-preferred 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 non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Drugs for Autoimmune Conditions
Medications considered preferred on your plan may still require a clinical prior authorization review.
Abbreviation: IV = intravenous

	Product(s)
Preferred	• Entyvio (IV) (vedolizumab) • Ilumya (tildrakizumab-asmn) • Simponi Aria (golimumab) • Tremfya (IV) (guselkumab)
Non-preferred	• Actemra (IV) (tocilizumab) • Cimzia lyophilized powder (certolizumab pegol) • Orencia (IV) (abatacept) • Stelara (IV) (ustekinumab)

Step Therapy Criteria

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

Cimzia lyophilized powder

Coverage for Cimzia lyophilized powder is provided when any of the following criteria is met:

- Member has received treatment with Cimzia lyophilized powder in the past 365 days.

- Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Ilumya, Simponi Aria, and Tremfya IV), where the products' indications overlap. If the member is a documented primary non-responder to an interleukin-23 (IL-23) inhibitor, then the member would not need to use the corresponding preferred product(s) from the respective class.
- Member is currently breastfeeding, pregnant, or planning pregnancy.

All Other Non-Preferred Products

Coverage for all other non-preferred products is provided when either of the following criteria is met:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member has a documented inadequate response or intolerable adverse event with all of the preferred products (Entyvio IV, Ilumya, Simponi Aria, and Tremfya IV) where the products' indications overlap, unless there is a documented clinical reason to avoid tumor necrosis factor (TNF) inhibitors (see Appendix).

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]. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; May 2024.
4. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2024.
5. Orencia [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; May 2024.
6. Simponi Aria [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
7. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; November 2024.
8. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.

EXCEPTIONS CRITERIA

Bevacizumab-Oncology Products

PREFERRED PRODUCTS: MVASI, ZIRABEV

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the bevacizumab-oncology products specified in this document. Coverage for the non-preferred 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Bevacizumab-Oncology Products
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	Mvasi (bevacizumab-awwb) Zirabev (bevacizumab-bvzr)
Non-preferred	Alymsys (bevacizumab-maly) Avastin (bevacizumab) Vegzelma (bevacizumab-adcd)

Step Therapy Criteria
Coverage for a non-preferred product is provided when either of the following criteria is met:

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

References

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

EXCEPTIONS CRITERIA

Erythropoiesis Stimulating Agents (ESA)

PREFERRED PRODUCTS: ARANESP AND PROCRIT

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B.

Plan Design Summary
This program applies to the erythropoiesis stimulating agents specified in this document. Coverage for non-preferred 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 requesting treatment with a non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Erythropoiesis Stimulating Agents
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Aranesp (darbepoetin alfa) • Procrit (epoetin alfa)
Non-preferred	• Epogen (epoetin alfa) • Mircera (methoxy polyethylene glycol-epoetin beta) • Retacrit (epoetin alfa-epbx)

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

Anemia Due to Chronic Kidney Disease (CKD)
Epogen or Retacrit
Coverage for Epogen or Retacrit is provided when either of the following criteria is met:
1. Member has received treatment with Epogen or Retacrit in the past 365 days.
2. Member meets both of the following criteria:
    - Member has had a documented intolerable adverse event with 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 product).

- Member has a documented inadequate response or intolerable adverse event with the preferred product Aranesp.

Mircera
Coverage for Mircera is provided when either of the following criteria is met:
1. Member has received treatment with Mircera in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Procrit.

Anemia Due to Myelosuppressive Chemotherapy in Cancer

Epogen or Retacrit
Coverage for Epogen or Retacrit is provided when either of the following criteria is met:
1. Member has received treatment with Epogen or Retacrit in the past 365 days.
2. Member meets both of the following criteria:
   - Member has had a documented intolerable adverse event with 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 product).
   - Member has a documented inadequate response or intolerable adverse event with the preferred product Aranesp.

Anemia Due to Zidovudine in Patients with Human Immunodeficiency Virus (HIV) Infection and To Reduce Need for Allogeneic Red Blood Cell (RBC) Transfusions

Epogen or Retacrit
Coverage for Epogen or Retacrit is provided when either of the following criteria is met:
1. Member has received treatment with Epogen or Retacrit in the past 365 days.
2. Member has had a documented intolerable adverse event with 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 product).

References

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

EXCEPTIONS CRITERIA

Hematologic, Neutropenia Colony Stimulating Factors – Long Acting

PREFERRED PRODUCTS: FULPHILA, NEULASTA (INCLUDING ONPRO KIT)

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

These criteria were developed to align with the following: Medicare Part B.

Plan Design Summary

This program applies to the colony stimulating factor-long acting products specified in this document. Coverage for the non-preferred 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Long Acting
Medications considered preferred on your plan may still require a clinical prior authorization review.

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

Step Therapy Criteria

Coverage for the non-preferred products is provided when the member meets one of the following criteria:

- 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).
- Member has received treatment with the requested non-preferred product in the past 365 days.

References

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

EXCEPTIONS CRITERIA

Hematologic, Neutropenia Colony Stimulating Factors – Short Acting

PREFERRED PRODUCT: ZARXIO

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the colony stimulating factors – short acting products specified in this document. Coverage for the non-preferred 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 the non-preferred product.
Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Colony Stimulating Factors – Short Acting
Medications considered preferred on your plan may still require a clinical prior authorization review.

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

Step Therapy Criteria
Coverage for the non-preferred 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 is requesting Granix, Neupogen vials or Nivestym and has a documented latex allergy that the prescriber states the member must use latex-free products. Neupogen pre-filled syringes contain latex and are not covered under this criterion.
3. Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.

4. Member has received treatment with the requested non-preferred product in the past 365 days.

Coverage for the non-preferred 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 non-preferred product in the past 365 days.

References

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

EXCEPTIONS CRITERIA

Hematopoietic Agents – Intravenous Iron

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

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the intravenous iron products specified in this document. Coverage for non-preferred 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 non-preferred 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.

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

Step Therapy Criteria
This program applies to members requesting treatment for an indication that is FDA-approved for any of the preferred products.
Coverage for a non-preferred product is provided when any of the following criteria is met:
1. Member has received treatment with the non-preferred product in the past 365 days.
2. The requested product is **Feraheme** and the member meets any of the following:

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

3. The requested product is **Injectafer** and the member meets any of the following:
    a. 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.
    b. Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.
    c. Member has a diagnosis of iron deficiency with heart failure categorized as New York Heart Association class II/III.
4. The requested product is **Monoferric** and the member meets any of the following:
    a. 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.
    b. Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.

References

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

EXCEPTIONS CRITERIA

Hemophilia Factor VIII Products

PREFERRED PRODUCTS: AFSTYLA, KOVALTRY AND NUWIQ

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the Factor VIII products specified in this document. Coverage for non-preferred 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 non-preferred product for the first time.

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

	Products
Preferred	• Afstyla (antihemophilic factor [recombinant]) • Kovaltry (antihemophilic factor [recombinant]) • Nuwiq (antihemophilic factor [recombinant])
Non-preferred	• Advate (antihemophilic factor [recombinant]) • Kogenate FS (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant]) • Recombinate (antihemophilic factor [recombinant]) • Xyntha (antihemophilic factor [recombinant]) • Xyntha Solofuse (antihemophilic factor [recombinant])

Step Therapy Criteria
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.
Coverage for the non-preferred product is provided when either of the following criteria is met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member has a documented inadequate response or intolerable adverse event with all of the preferred products.

References

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

EXCEPTIONS CRITERIA

Gaucher Disease Agents

PREFERRED PRODUCTS: CEREZYME AND ELELYSO

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the Gaucher disease products specified in this document. Coverage for non-preferred 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 non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Gaucher Disease Agents
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Cerezyme (imiglucerase) • Elelyso (taliglucerase alfa)
Non-preferred	• VPRIV (velaglucerase alfa)

Step Therapy Criteria
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.
Coverage for a non-preferred product is provided when ANY of the following criteria is met:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. The member has had a documented inadequate response or an intolerable adverse event with Cerezyme AND is between 2 and 4 years of age.
3. Member has had a documented inadequate response or an intolerable adverse event with both of the preferred products, Cerezyme and Elelyso.

References

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

EXCEPTIONS CRITERIA

Multiple Sclerosis (Infused)

PREFERRED PRODUCTS: OCREVUS AND TYSABRI

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B.

Plan Design Summary
This program applies to the multiple sclerosis products specified in this document. Coverage for the non-preferred 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Multiple Sclerosis
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Ocrevus (ocrelizumab) • Tysabri (natalizumab)
Non-preferred	• Briumvi (ublituximab-xiiy) • Lemtrada (alemtuzumab) • Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq) • Tyruko (natalizumab-sztn)

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

Briumvi or Lemtrada
Coverage for either of the non-preferred products is provided when either of the following criteria is met:

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

Ocrevus Zunovo

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

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member meets both of the following criteria:
    a. Member has had a documented intolerable adverse event with the preferred product, Ocrevus, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
    b. Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Tysarbi, or any of its components.

Tyruko

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

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member meets both of the following criteria:
    a) Member has had a documented intolerable adverse event to the preferred product, 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 products).
    b) Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Ocrevus, or any of its components.

References

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

EXCEPTIONS CRITERIA

Osteoarthritis, Viscosupplements – Single Injection – Hyaluronates

PREFERRED PRODUCTS: DUROLANE AND SYNVISC-ONE

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

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

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Hyaluronate Products (Osteoarthritis-Single)
Medications considered preferred on your plan may still require a clinical prior authorization review.

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

Step Therapy Criteria
This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.
Coverage for a non-preferred product is provided when either of the following criteria is met:

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

References

1. Durolane [package insert]. Durham, NC: Bioventus, LLC; September 2017.
2. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
3. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
4. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.

EXCEPTIONS CRITERIA

Osteoporosis-Bone Density

PREFERRED PRODUCTS: JUBBONTI, PROLIA, zoledronic acid

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B.

Plan Design Summary
This program applies to the osteoporosis products specified in this document. Coverage for the non-preferred 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Osteoporosis Products
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Jubbonti (denosumab-bbdz) • Prolia (denosumab) • zoledronic acid
Non-preferred	• Evenity (romosozumab-aqqg)

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

Coverage for the non-preferred product is provided when the member meets one of the following criteria:

1. Member has received treatment with the non-preferred product in the past 365 days.
2. Member meets both of the following criteria:
    a. Member has had a documented inadequate response, intolerable adverse event, contraindication, or clinical reason to avoid Jubbonti or Prolia.

b. Member has had a documented inadequate response, intolerable adverse event, or contraindication to zoledronic acid (e.g., creatinine clearance less than 35 mL/min).

References

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

EXCEPTIONS CRITERIA

Rituximab Products

PREFERRED PRODUCTS: RITUXAN, RITUXAN HYCELA AND RUXIENCE

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B: Advanced Biosimilars First.

Plan Design Summary
This program applies to the rituximab products specified in this document. Coverage for non-preferred 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Rituximab Products
Medications considered preferred on your plan may still require a clinical prior authorization review.

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

Step Therapy Criteria
Coverage for a non-preferred product is provided when either of the following criteria is met:

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

References

1. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
2. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
3. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
4. Ruxience [package insert]. New York, NY: Pfizer; October 2023.
5. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2024.

EXCEPTIONS CRITERIA

Severe Asthma

PREFERRED PRODUCTS: FASENRA, TEZSPIRE AND XOLAIR

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B and Medicare Part B Advanced Biosimilars First.

Plan Design Summary
This program applies to the asthma products specified in this document. Coverage for the non-preferred products are 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 non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Asthma Products
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Products
Preferred	• Fasenra (benralizumab) • Tezspire (tezepelumab-ekko) • Xolair (omalizumab)
Non-preferred	• Cinqair (reslizumab) • Nucala (mepolizumab)

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

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

1. Member has received treatment with Cinqair in the past 365 days.
2. Member has both of the following:
    a. Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Fasenra and Tezspire.

b. Member has either of the following:
    i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair.
    ii. A pretreatment serum IgE level of less than 30 IU/mL.

Nucala

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

1. Member has received treatment with Nucala in the past 365 days.
2. Member meets 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 the preferred product Xolair.
        ii. A pretreatment serum IgE level of less than 30 IU/mL.
    b. Member meets both of the following:
        i. Member meets either of the following:
            1. Member is 12 years of age and older and has a documented inadequate response or an intolerable adverse event with both of the preferred products, Fasenra and Tezspire.
            2. Member is less than 12 years of age and has a documented inadequate response or an intolerable adverse event with the preferred product Fasenra.
        ii. Member has either of the following:
            1. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair.
            2. A pretreatment serum IgE level of less than 30 IU/mL.
            3. Member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and has a documented inadequate response or intolerable adverse event with the preferred product Fasenra.

References

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

EXCEPTIONS CRITERIA

Trastuzumab Products

PREFERRED PRODUCTS: KANJINTI AND ONTRUZANT

This document informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.
These criteria were developed to align with the following: Medicare Part B.

Plan Design Summary
This program applies to the trastuzumab products specified in this document. Coverage for the non-preferred 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 the non-preferred product.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Trastuzumab Products
Medications considered preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Kanjinti (trastuzumab-anns) • Ontruzant (trastuzumab-dttb)
Non-preferred	• Herceptin (trastuzumab) • Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) • Hercessi (trastuzumab-strf) • Herzuma (trastuzumab-pkrb) • Ogivri (trastuzumab-dkst) • Trazimera (trastuzumab-qyyp)

Step Therapy Criteria
Coverage for a non-preferred product is provided when either of the following criteria is met:

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

References
1. Herceptin [package insert]. South San Francisco, CA: Genentech, Inc; June 2024.

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