KelseyCare Advantage

2025

PART B STEP THERAPY CRITERIA

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

KelseyCareAdvantage.com

Effective 1/1/2025

H0332_PTBST25_C

Contents

Drug List & HCPCS Codes

Drug Class	Non-Preferred Product(s)	Preferred Product(s)
Alpha-1 Antitrypsin Deficiency	Aralast (J0256) Glassia (J0257)	Prolastin-C (J0256) Zemaira (J0256)
Autoimmune Infused/Infliximab	Avsola (Q5121) Infliximab (Q5102) Remicade (J1745)	Inflectra (Q5103) Renflexis (Q5104)
Autoimmune Infused/Other	Actemra (J3262) Cimzia (J0717) Ilumya (J3245) Orencia (J0129) Stelara (J3358)	Entyvio (J3380) Simponi Aria (J1602) Tremfya** (J1628)
Avastin/Biosimilars (Oncology)	Alymsys (Q5126) Avastin (J9035) Vegzelma (Q5129)	Mvasi (Q5107) Zirabev (Q5118)
Complement Inhibitors (NMOSD)	Uplizna (J1823)	Soliris (J1300) Bkemv**(Q5152)
Hematologic, Erythropoiesis – Stimulating Agents (ESA)	Epogen (J0885) Mircera (J0887, J0888) Retacrit (Q5105, Q5106)	Aranesp (J0882) Procrit (J0885)
Hematologic, Neutropenia Colony Stimulating Factors – Long Acting	Fylnetra (Q5130) Nyvepria (Q5122) Rolvedon (J3590) Stimufend (Q5127) Udenyca (Q5111) Ziextenzo (Q5120)	Fulphila (Q5108) Neulasta (J2505)
Hematologic, Neutropenia Colony Stimulating Factors – Short Acting	Granix (J1446) Leukine (J2820) Neupogen (J1442) Nivestym (Q5110) Releuko (Q5125)	Zarxio (Q5101)
Hematopoietic Agents-Iron	Feraheme (Q0138) Injectafer (J1439) Monoferric (J14373)	Ferrlecit (J2916) Infed (J1750) Sodium Ferric Gluconate (J2916) Venofer (J1756)
Hemophilia Factor VIII-Recombinant	Advate (J7192) Kogenate (J7192) Novoeight (J7182) Nuwiq (J7209) Recombinate (J7192) Xyntha (J7185) Xyntha Solofuse (J7185)	Afstyla (J7210) Kovaltry (J7192)
Lysosomal Storage Disorders – Gaucher Disease	VPRIV (J3385)	Cerezyme (J1786) Elelyso (J3060)

Multiple Sclerosis (Infused)	Briumvi (J2329) Lemtrada (J0202)	Ocrevus (J2350) Tysabri (J2323)
Osteoarthritis, Viscosupplements – Single Injection	Gel-One (J7326) Monovisc (J7327)	Durolane (J7318) Synvisc-One (J7325)
Rituximab	Riabni (Q5123) Truxima (Q5115)	Rituxan (J9312) Rituxan Hycela (J9311) Ruxience (Q5119)
Severe Asthma	Cinqair (J2786) Nucala (J2182)	Fasenra (J0517) Xolair (J2357) Tezspire** (J2356)
Trastuzumab	Herceptin (J9355) Herceptin Hylecta (J9356) Herzuma (Q5113) Ogivri (Q5114)	Kanjinti (Q5117) Trazimera (Q5116) Ontruzant** (Q5112)

**: Preferred product effective 10/1/2025

EXCEPTIONS CRITERIA

Alpha-1 Antitrypsin Deficiency

PREFERRED PRODUCTS: PROLASTIN-C AND ZEMAIRA

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 alpha1-proteinase inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

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

Table. Alpha1-Proteinase Inhibitor Products

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

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

EXCEPTION CRITERIA

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

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

REFERENCES

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

EXCEPTIONS CRITERIA

Infliximab

PREFERRED PRODUCTS: INFLECTRA AND RENFLEXIS

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Infliximab products

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

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

EXCEPTION CRITERIA

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

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

REFERENCES

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

EXCEPTIONS CRITERIA

Autoimmune Infused/Other

PREFERRED PRODUCTS: ENTYVIO, SIMPONI ARIA AND TREMFYA**

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) • **Tremfya** (guselkumab)**	• **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.

**: Preferred product effective 10/1/2025

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 all of the preferred products (Entyvio IV, Simponi Aria, and Tremfya IV) where the product's 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 from the respective class.
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 all of the preferred products (Entyvio IV, Simponi Aria, and Tremfya IV) where the product's indications overlap, unless there is a documented clinical reason to avoid TNF inhibitors (see Appendix).

III. APPENDIX: Clinical reasons to avoid TNF inhibitors

- History of demyelinating disorder
- History of congestive heart failure
- History of hepatitis B virus infection
- Autoantibody formation/lupus-like syndrome
- History or risk of lymphoma or other malignancy
- History of being a primary non-responder to a TNF inhibitor

REFERENCES

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

EXCEPTIONS CRITERIA

Bevacizumab-Oncology Products

PREFERRED PRODUCTS: MVASI, ZIRABEV

POLICY

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

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:

1. Member has received treatment with the requested targeted 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. 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.; February 2023.

EXCEPTIONS CRITERIA
COMPLEMENT INHIBITORS

PREFERRED PRODUCT: SOLIRIS AND BKEMV

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*	• **Bkemv** (eculizumab-aeeb)** • **Soliris** (eculizumab)
Targeted	• **Uplizna** (inebilizumab-cdon)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.
**: Preferred product effective 10/1/2025

EXCEPTION CRITERIA

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

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

REFERENCES

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

EXCEPTIONS CRITERIA

Erythropoiesis Stimulating Agents

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.

II. EXCEPTION CRITERIA

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

A. Epogen

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

1. Member has received treatment with Epogen 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 Mircera is provided when either of the following criteria is met:

A. 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.

C. Retacrit

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

1. Member has received treatment with Retacrit 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

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

EXCEPTIONS CRITERIA

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

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

EXCEPTIONS CRITERIA

Colony Stimulating Factors – Short Acting

PREFERRED PRODUCT: ZARXIO

POLICY

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

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:
   i. 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).
   ii. 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.
   iii. Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.

iv. 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:
   i. Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
   ii. Leukine is being requested for an indication that is not FDA-approved for the preferred product.
   iii. Member has received treatment with the requested targeted product in the past 365 days.

REFERENCES

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

EXCEPTIONS CRITERIA

Intravenous Iron

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

POLICY

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

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:
    i. 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.

ii. 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.
iii. 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:
i. 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.
ii. 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:
i. 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.
ii. Member has a diagnosis of non-hemodialysis dependent chronic kidney disease and has had a documented inadequate response or intolerable adverse event with Venofer.

REFERENCES

1. Ferrlecit [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; March 2022.
2. Infed [package insert]. Madison, NJ: Allergan USA, Inc.; September 2021.
3. Sodium Ferric Gluconate [package insert]. Berkley Heights, NJ: Hikma Pharmaceuticals USA, Inc.; January 2021
4. Venofer [package insert]. Shirley, NY: American Regent, Inc.; June 2022.
5. Feraheme [package insert]. Waltham, MA: AMAG Pharmaceuticals, Inc.; June 2022.
6. Injectafer [package insert]. Shirley, NY: American Regent, Inc.; May 2023.
7. Monoferric [package insert]. Morristown, NJ: Pharmacosmos Therapeutics, Inc.; February 2022.

EXCEPTIONS CRITERIA

Factor VIII Products

PREFERRED PRODUCTS: AFSTYLA AND KOVALTRY

POLICY

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

PLAN DESIGN SUMMARY

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

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

Table. Factor VIII Products

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

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

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 to both of the preferred products.

REFERENCES

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

EXCEPTIONS CRITERIA

Gaucher Disease Agents

PREFERRED PRODUCTS: CEREZYME AND ELELYSO

POLICY

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

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

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

EXCEPTIONS CRITERIA

Multiple Sclerosis Products

PREFERRED PRODUCTS: OCREVUS AND TYSABRI

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

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 either of the following criteria is met:

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

REFERENCES

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

EXCEPTIONS CRITERIA

Hyaluronates

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

POLICY

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

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-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.

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

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

REFERENCES

1. Durolane [package insert]. Durham, NC: Bioventus, LLC; September 2017.
2. Euflexxa [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
3. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.
4. Gelsyn-3 [package insert]. Durham, NC: Bioventus LLC; December 2017.
5. GenVisc 850 [package insert]. Doylestown, PA: OrthogenRx, Inc.; November 2019.
6. Hyalgan [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; August 2017.
7. Hymovis [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; September 2017.
8. Monovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; July 2020.
9. Orthovisc [package insert]. Bedford, MA: Anika Therapeutics, Inc.; November 2021.
10. Supartz FX [package insert]. Durham, NC: Bioventus LLC; April 2015.
11. Synvisc [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
13. Triluron [package insert]. Florham Park, NJ: Fidia Pharma USA Inc.; July 2019.
14. Trivisc [package insert]. Doylestown, PA: OrthogenRX; September 2018.
15. Visco-3 [package insert]. Warsaw, IN: Zimmer Inc.; May 2017.

EXCEPTIONS CRITERIA

Rituximab Products

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

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

EXCEPTIONS CRITERIA

Severe Asthma

PREFERRED PRODUCTS: FASENRA, XOLAIR AND TEZSPIRE**

POLICY

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

III. 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) • **Tezspire** (tezepelumab-ekko)** • **Xolair** (omalizumab)
Targeted	• **Cinqair** (reslizumab) • **Nucala** (mepolizumab)

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

**: Preferred product effective 10/1/2025

IV. EXCEPTION CRITERIA

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

A. Cinqair

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

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

B. Nucala

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

1. Member has received treatment with Nucala in the past 365 days.
2. Member meets either of the following:
   a. Member has a comorbidity of nasal polyps and meets either of the following:
      i. A pretreatment serum IgE level of at least 30 IU/mL and has had a documented inadequate response or an intolerable adverse event with the preferred product Xolair.
      ii. A pretreatment serum IgE level of less than 30 IU/mL.
   b. Member meets both of the following:
      i. Member is 12 years of age and older has a documented inadequate response or an intolerable adverse event with both of the preferred products, Fasenra and Tezspire.
      ii. Member is less than 12 years of age and has a documented inadequate response or an intolerable adverse event with the preferred product, Fasenra.
   c. 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.
   d. 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, TRAZIMERA AND ONTRUZANT**

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) • **Ontruzant** (trastuzumab-dttb)**
Targeted	• **Herceptin** (trastuzumab) • **Herceptin Hylecta** (trastuzumab and hyaluronidase-oysk) • **Herzuma** (trastuzumab-pkrb) • **Ogivri** (trastuzumab-dkst)

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

**: Preferred product effective 10/1/2025

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

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