


# 2026 Part B Drugs and Biologics Step Therapy List

Drug Class	Non-Preferred Product(s)*	Preferred Product(s)	Note
<b>Acromegaly-Long Acting</b>	Lanreotide Acetate Sandostatin LAR Depot Signifor LAR	Somatuline Depot	
<b>Alpha-1 Antitrypsin Deficiency</b>	Aralast Glassia	Prolastin-C Zemaira	
<b>Autoimmune Infused Infliximab</b>	Avsola Infliximab Remicade	Inflectra Renflexis	
<b>Avastin/Biosimilars (Oncology)</b>	Alymsys Avastin Avzivi Vegzelma	Mvasi Zirabev	
<b>Botulinum Toxins</b>	Botox Myobloc	Dysport Xeomin	
<b>Complement Inhibitors (aHUS, gMG, PNH)</b>	Soliris  Ultomiris	Bkemv  Vyvgart (gMG)  Vyvgart Hytrulo (gMG)	
<b>Complement Inhibitors (NMOSD)</b>	Soliris	Bkemv	
<b>Hematologic, Erythropoiesis Stimulating Agents (ESA)</b>	Epogen  Mircera  Procrit	Aranesp  Retacrit	
<b>Hematologic, Neutropenia Colony Stimulating Factors Long Acting</b>	Fylintra	Fulphila	

Drug Class	Non-Preferred Product(s)*	Preferred Product(s)	Note
	Nyvepria Rolvedon Stimufend Udenyca Ziextenzo	Neulasta	
<b>Hematologic, Neutropenia Colony Stimulating Factors Short Acting</b>	Granix Leukine Neupogen Nivestym Releuko	Zarxio	
<b>Hereditary Transthyretin Amyloidosis</b>		Amvuttra Onpattro	
<b>Immune Globulin-IV</b>	Asceniv Bivigam Gammagard Liquid Gammaplex Panzyga	Flebogamma Gammaked Gamunex-C Octagam Privigen	
<b>Immune Globulin-SQ</b>	Cutaquig Cuvitru Gammagard Liquid HyQvia Xembify	Hizentra Gammaked Gamunex-C	
<b>Lysosomal Storage Disorders-Gaucher Disease</b>	VPRIV	Cerezyme Elelyso	
<b>Multiple Sclerosis (Infused)</b>	Briumvi	Ocrevus	

Drug Class	Non-Preferred Product(s)*	Preferred Product(s)	Note
	Lemtrada Ocrevus Zunovo Tysabri	Tyruko	
<b>Ophthalmic Geographic Atrophy</b>		Izervay	
<b>Osteoarthritis, Viscosupplements Multi Injection</b>	Gelsyn-3 GenVisc 850 Hyalgan Hymovis Orthovisc Supartz FX Triluron TriVisc Visco-3	Euflexxa Synvisc	
<b>Osteoarthritis, Viscosupplements Single Injection</b>	Gel-One Monovisc	Durolane Synvisc-One	
<b>Osteoporosis-Bone Density</b>	Evenity	Jubbonti Prolia Zoledronic Acid	
<b>Osteoporosis-Hypercalcemia of Malignancy</b>	Xgeva	Pamidronate Wyost Zoledronic Acid	
<b>PD1/L1 Immune Checkpoint Inhibitors-Basal Cell &amp; Squamous Cell</b>	Keytruda	Libtayo	
<b>PD1/L1 Immune Checkpoint Inhibitors-NSCLC</b>	Imfinzi Keytruda Opdivo	Libtayo	

Drug Class	Non-Preferred Product(s)*	Preferred Product(s)	Note
	Tecentriq		
	Yervoy (ipilimumab) + Opdivo (nivolumab) +/- chemotherapy		
<b>Prostate Cancer-Luteinizing Hormone Releasing Hormone (LHRH) Antagonist Agents</b>		Firmagon	
<b>Retinal Disorders Agents-(ARMD) Age- Related Macular Degeneration</b>	Beovu	Avastin (1)	
	Byooviz	Eylea (2)	
	Cimerli	Eylea HD (2)	
	Susvimo	Lucentis (2)	
	Vabysmo	Pavblu (2)	
<b>Rituximab</b>	Riabni Rituxan Rituxan Hycela	Ruxience Truxima	
<b>Severe Asthma</b>	Cinqair Nucala	Fasenra Tezspire Xolair	
<b>Trastuzumab</b>	Herceptin Herceptin Hylecta Herzuma Hercessi Ogivri Trazimera	Kanjinti Ontruzant	

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Acromegaly Long Acting Products	<b>Policy Number (if applicable):</b> ST-GA-Acromegaly Long Acting Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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.

### Acromegaly Products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Somatuline Depot (lanreotide acetate)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Lanreotide Injection (lanreotide acetate)</li> <li>Sandostatin LAR Depot (octreotide acetate for injectable suspension)</li> <li>Signifor LAR (pasireotide)</li> </ul>

**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 with either of the following criteria is met:

- Member has received treatment with the requested non-preferred product in the past 365 days.
- The member has had a documented intolerable adverse event to Somatuline Depot, and the adverse even 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:

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

**REFERENCES:**

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

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Alpha1-Proteinase Inhibitors	<b>Policy Number (if applicable):</b> ST-GA-Alpha1-Proteinase Inhibitors
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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 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.

#### Alpha1-Proteinase Inhibitor Products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• <b>Prolastin-C</b> (alpha1-proteinase inhibitor [human])</li> <li>• <b>Zemaira</b> (alpha1-proteinase inhibitor [human])</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• <b>Aralast NP</b> (alpha1-proteinase inhibitor [human])</li> <li>• <b>Glassia</b> (alpha1-proteinase inhibitor [human])</li> </ul>


#### CRITERIA:

Coverage for a non-preferred product 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 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

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Infliximab	<b>Policy Number (if applicable):</b> ST-GA-Infliximab
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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 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.

#### Inflizimab

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Inflectra (infliximab-dyyb)</li> <li>• Renflexis (infliximab-abda)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Avsola (infliximab-axxq)</li> <li>• Infliximab</li> <li>• Remicade (infliximab)</li> </ul>

#### CRITERIA:

Coverage for a non-preferred product 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 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





	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Bevacizumab-Oncology Products	<b>Policy Number (if applicable):</b> ST-GA-Bevacizumab-Oncology Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the bevacizumab-oncology 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.

#### Bevacizumab-oncology products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Mvasi (bevacizumab-awwb)</li> <li>• Zirabev (bevacizumab-bvzr)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Alymsys (bevacizumab-maly)</li> <li>• Avastin (bevacizumab)</li> <li>• Avzivi (bevacizumab-tnjin)</li> <li>• Vegzelma (bevacizumab-adcd)</li> </ul>

#### 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

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3. Avzivi [package insert] Guangzhou, Guangdong Province, China: Bio-Thera Solutions, Ltd.; December 2023
4. Mvasi [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023
5. Vegzelma [package insert]. Incheon, Republic of Korea: Celltrion, Inc.; February 2023
6. Zirabev [package insert]. New York, NY: Pfizer, Inc.; August 2024

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Botulinum Toxins	<b>Policy Number (if applicable):</b> ST-GA-Botulinum Toxins
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the botulinum toxins 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 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.

### Botulinum Toxins

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Dysport (abobotulinumtoxinA)</li> <li>Xeomin (incobotulinumtoxinA)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Botox (onabotulinumtoxinA)</li> <li>Myobloc (rimabotulinumtoxinB)</li> </ul>

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

Coverage for a non-preferred product is provided when ANY 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 to both of the preferred products.
- Member is requesting Botox for the treatment of blepharospasm, and either of the following criteria is met:
  - Member is 18 years of age and older and the member has a documented inadequate response or intolerable adverse event with Xeomin.
  - Member is 12 years of age or older but less than 18 years of age.
- Member is requesting Botox for the treatment of lower limb spasticity and has had a documented inadequate response or adverse event to Dysport.

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- Member is requesting Botox for the treatment of upper limb spasticity, and both of the following criteria are met:
  - Member is a pediatric patient 2 years of age to 17 years of age and the upper limb spasticity is caused by cerebral palsy.
  - Member has had a documented inadequate response or adverse event with Dysport.
- Member is requesting Myobloc for the treatment of chronic sialorrhea and has had a documented inadequate response or an intolerable adverse event with Xeomin.

**REFERENCES:**

1. Botox [package insert]. North Chicago, IL: Allergan, Inc., an AbbVie company; November 2023
2. Dysport [package insert]. Cambridge, MA: Ipsen Biopharmaceuticals, LLC; September 2023
3. Myobloc [package insert]. Rockville, MD: Solstice Neurosciences, Inc.; March 2021
4. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; July 2024

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Complement Inhibitor Products	<b>Policy Number (if applicable):</b> ST-GA-Complement Inhibitor Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the complement 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 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.

#### **Atypical Hemolytic Uremic Syndrome (aHUS), Paroxysmal Nocturnal Hemoglobinuria (PNH) Products**

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Bkemv (eculizumab-aeeb)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Soliris (eculizumab)</li> <li>Ultomiris (ravulizumab-cwvz)</li> </ul>

#### **Myasthenia Gravis Products**

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Bkemv (eculizumab-aeeb)</li> <li>Vyvgart (efgartigimod alfa)</li> <li>Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Soliris (eculizumab)</li> <li>Ultomiris (ravulizumab-cwvz)</li> </ul>

#### **Neuromyelitis Optica Spectrum Disorder (NMOSD) Products**

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

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	<b>Products</b>
Preferred	<ul style="list-style-type: none"> <li>Bkemv (eculizumab-aeeb)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Soliris (eculizumab)</li> </ul>

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

#### **Atypical Hemolytic Uremic Syndrome (aHUS), Paroxysmal Nocturnal Hemoglobinuria (PNH) Products**

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

- Member has received treatment with the non-preferred product in the past 365 days.
- The request is for Soliris and the member has a documented intolerable adverse event to Bkemv, 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).
- The request is for Ultomiris and the member has a documented inadequate response or intolerable adverse event with the preferred product.

#### **Myasthenia Gravis Products**

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

- Member has received treatment with the non-preferred product in the past 365 days.
- Request is for Soliris and both of the following are met:
  - Member has a documented intolerable adverse event to Bkemv, 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).
  - Member has a documented inadequate response or intolerable adverse event with either Vyvgart or Vyvgart Hytrulo.
- The request is for Ultomiris and the member has a documented inadequate response or intolerable adverse event with Bkemv, and either Vyvgart or Vyvgart Hytrulo.

#### **Neuromyelitis Optica Spectrum Disorder (NMOSD) Products**

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


- Member has received treatment with the non-preferred product in the past 365 days.
- Member has a documented intolerable adverse event to Bkemv, 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:**

- Bkemv [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024
- Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; March 2025
- Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; September 2025
- Vyvgart [package insert]. Boston, MA: Argenx US Inc.; August 2024
- Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US. Inc.; August 2024

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	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Erythropoiesis Stimulating Agents	<b>Policy Number (if applicable):</b> ST-GA- Erythropoiesis Stimulating Agents
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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.

#### Erythropoiesis Stimulating Agents

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Aranesp (darbepoetin alfa)</li> <li>• Retacrit (epoetin alfa-epbx)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Epogen (epoetin alfa)</li> <li>• Mircera (methoxy polyethylene glycol-epoetin beta)</li> <li>• Procrit (epoetin alfa)</li> </ul>

#### 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 Procrit

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

- Member has received treatment with Epogen or Procrit in the past 365 days.
- Member meets both of the following criteria:
  - Member has had a documented intolerable adverse event with Retacrit, 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:

- Member has received treatment with Mircera in the past 365 days.
- Member has a documented inadequate response or intolerable adverse event with both of the preferred products, Aranesp and Retacrit.

**Anemia Due to Myelosuppressive Chemotherapy in Cancer**

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

- Member has received treatment with Epogen or Procrit in the past 365 days.
- Member meets both of the following criteria:
  - Member has had a documented intolerable adverse event with Retacrit, 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**


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

- Member has received treatment with Epogen or Procrit in the past 365 days.
- Member has had a documented intolerable adverse event with Retacrit, 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



	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Colony Stimulating Factors-Long Acting	<b>Policy Number (if applicable):</b> ST-GA-Colony Stimulating Factors-Long Acting
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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

**SCOPE:** This program applies to the colony stimulating factors-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 (NCO). Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client

#### Colony Stimulating Factors- Long Acting

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Fulphila (pegfilgrastim-jmdb)</li> <li>Neulasta (including Onpro kit) (pegfilgrastim)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Fylnetra (pegfilgrastim-pbbk)</li> <li>Nyvepria (pegfilgrastim-apgf)</li> <li>Rolvedon (eflapeggrastim-xnst)</li> <li>Stimufend (pegfilgrastim-fpgk)</li> <li>Udenyca (pegfilgrastim-cbqv)</li> <li>Ziextenzo (pegfilgrastim-bmez)</li> </ul>

#### 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:

*Printed copies are for reference only. Please refer to the electronic copy for the latest version.*

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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.

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Colony Stimulating Factors-Short Acting	<b>Policy Number (if applicable):</b> ST-GA-Colony Stimulating Factors-Short Acting
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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.

#### Colony Stimulating Factors - Short Acting

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Zarxio (filgrastim-sndz)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Granix (TBO-filgrastim)</li> <li>• Leukine (sargramostim)</li> <li>• Neupogen (filgrastim)</li> <li>• Nivestym (filgrastim-aafi)</li> <li>• Releuko (filgrastim-ayow)</li> </ul>

#### CRITERIA:

Coverage for the non-preferred products, Granix, Neupogen, Nivestym or Releuko, is provided when the member meets one of the following criteria:

- 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).
- 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.
- Neupogen, Nivestym, or Granix are requested for doses less than 180 mcg.
- Member has received treatment with the requested non-preferred product in the past 365 days.

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

- Member has had a documented inadequate response or an intolerable adverse event to the preferred product.
- Leukine is being requested for an indication that is not FDA-approved for the preferred product.
- 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.

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Immune Globulin Products	<b>Policy Number (if applicable):</b> ST-GA- Immune Globulin Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the immune globulin 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.

#### Immune Globulin Products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Flebogamma (intravenous)</li> <li>• Gammaked (subcutaneous/intravenous)</li> <li>• Gamunex-C (subcutaneous/intravenous)</li> <li>• Hizentra (subcutaneous)</li> <li>• Octagam (intravenous)</li> <li>• Privigen (intravenous)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Asceniv (intravenous)</li> <li>• Bivigam (intravenous)</li> <li>• Cutaquig (subcutaneous)</li> <li>• Cuvitru (subcutaneous)</li> <li>• Gammagard Liquid (subcutaneous/intravenous)</li> <li>• Gammaplex (intravenous)</li> <li>• HyQvia (subcutaneous)</li> <li>• Panzyga (intravenous)</li> <li>• Xembify (subcutaneous)</li> </ul>

#### CRITERIA:

Coverage for a non-preferred product 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 intolerable adverse event with at least 3 of the preferred products.



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## REFERENCES:

1. Asceniv [package insert]. Boca Raton, FL: ADMA Biologics; April 2019.
2. Bivigam [package insert]. Boca Raton, FL: ADMA Biologics; December 2023.
3. Cutaquig [package insert]. Paramus, NJ: Octaphanna USA, Inc.; November 2021.
4. Flebogamma Dif [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.: September 2019.
5. Gammagard Liquid [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.
6. Gammagard Liquid [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC: January 2020.
7. Gammaplex 5% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
8. Gammaplex 10% [package insert]. Hertfordshire, United Kingdom: Bio Products Laboratory; November 2021.
9. Gamunex-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2020.
10. Octagam 10% [package insert]. Paramus, NJ: Octaphanna USA, Inc.; April 2022.
11. Octagam 5% [package insert]. Paramus, NJ: Octaphanna USA, Inc.; April 2022.
12. Panzyga [package insert]. New York, NY: pfizer; February 2021.
13. Privigen [package insert]. Kankakee, IL: CSL Behring LLC; March 2022.
14. Cuvitru [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
15. Hizentra [package insert]. Kankakee, IL: CSL Behring LLC; April 2023.
16. HyQvia [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; January 2024.

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Gaucher Disease Agents	<b>Policy Number (if applicable):</b> ST-GA-Gaucher Disease Agents
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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

**SCOPE:** 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.

#### Gaucher Disease Agents

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Cerezyme (imiglucerase)</li> <li>Elelyso (taliglucerase alfa)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>VPRIV (velaglucerase alfa)</li> </ul>

**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:

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

#### REFERENCES:

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



	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Multiple Sclerosis Products	<b>Policy Number (if applicable):</b> ST-GA- Multiple Sclerosis Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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.

### Multiple Sclerosis

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Ocrevus (ocrelizumab)</li> <li>Tyruko (natalizumab-sztn)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Briumvi (ublituximab-xiiy)</li> <li>Lemtrada (alemtuzumab)</li> <li>Ocrevus Zunovo (ocrelizumab and hyaluronidase-ocsq)</li> <li>Tysabri (natalizumab)</li> </ul>

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

### Briumvi and Lemtrada

Coverage for either of the 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, 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:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member meets both of the following criteria:
  - 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.

- Member has a documented inadequate response, intolerable adverse event, or contraindication to therapy with the preferred product, Tyruko, or any of its components.


### **Tysabri**

Coverage for Tysabri 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 meets both of the following criteria:
  - Member has had a documented intolerable adverse event to the preferred product, Tyruko, 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).
  - 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.

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Hyaluronate Products	<b>Policy Number (if applicable):</b> ST-GA- Hyaluronate Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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

#### **Hyaluronate Products (Osteoarthritis-Multi)**

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Euflexxa (1% sodium hyaluronate)</li> <li>• Synvisc (hylan G-F 20)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Gelsyn-3 (sodium hyaluronate)</li> <li>• GenVisc 850 (sodium hyaluronate)</li> <li>• Hyalgan (sodium hyaluronate)</li> <li>• Hymovis (high molecular weight viscoelastic hyaluronan)</li> <li>• Orthovisc (high molecular weight hyaluronan)</li> <li>• Supartz FX (sodium hyaluronate)</li> <li>• Triluron (sodium hyaluronate)</li> <li>• Trivisc (sodium hyaluronate)</li> <li>• Visco-3 (sodium hyaluronate)</li> </ul>

#### **Hyaluronate Products (Osteoarthritis-Single)**

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

	Products
Preferred	<ul style="list-style-type: none"> <li>• Durolane (hyaluronic acid)</li> <li>• Synvisc-One (hylan G-F 20)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Gel-One (cross-linked hyaluronate)</li> <li>• Monovisc (high molecular weight hyaluronan)</li> </ul>

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

#### **Osteoarthritis-Multi**

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 a documented intolerable adverse event to both of the preferred products, Euflexxa and Synvisc.

#### **Osteoarthritis-Single**

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 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; May 2023.
12. Synvisc One [package insert]. Ridgefield, NJ: Genzyme Biosurgery; May 2023.
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.





	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Osteoporosis-Oncology Indications	<b>Policy Number (if applicable):</b> ST-GA-Osteoporosis-Oncology Indications
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the osteoporosis products specified in the 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 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.

#### **Osteoporosis-Hypercalcemia of Malignancy**

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

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>• Pamidronate</li> <li>• Wyost (denosumab-bbdz)</li> <li>• Zoledronic acid</li> </ul>
Non-preferred	<ul style="list-style-type: none"> <li>• Xgeva (denosumab)</li> </ul>

**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 wither of the following criteria:

- Member has received treatment with the non-preferred product in the past 365 days.
- Member meets both of the following criteria:
  - Member meets either of the following criteria:
    - Member has a documented inadequate response to pamidronate or zoledronic acid.
    - Member has had a documented intolerable adverse event or contraindication to therapy with both pamidronate and zoledronic acid (i.e., severe renal impairment [creatinine clearance less than 35mL/min])
  - Member has had a documented intolerable adverse event to Wyost, 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. Pamidronate [package insert]. Morgantown, WV: Mylan Institutional LLC; July 2022
2. Wyost [package insert]. Princeton, NJ: Sandoz Inc.; March 2024
3. Xgeva [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2020
4. Zoledronic acid [package insert]. Raleigh, NC: Accord Healthcare, Inc.; September 2023

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy PD1/PDL1 Products- Non-Small Cell Lung Cancer	<b>Policy Number (if applicable):</b> ST-GA- PD1 PDL1 Non-Small Cell Lung Cancer
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the PD1/PDL1 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.

#### PD1/PDL1 Products

**Non-Small Cell Lung Cancer: advanced or metastatic**

		Product(s)
Preferred	•	• Libtayo (cemiplimab) +/- chemotherapy
Non-Preferred	•	• Imfinzi (durvalumab) +/- chemotherapy • Keytruda (pembrolizumab) +/- chemotherapy • Opdivo (nivolumab) +/- chemotherapy • Tecentriq (atezolizumab) +/- chemotherapy • Yervoy (ipilimumab) + Opdivo (nivolumab) +/- chemotherapy


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

- Member has received treatment with the non-preferred product in the past 365 days.
- Member has had a documented intolerable adverse event to the preferred product.
- Keytruda, Imfinzi or Tecentriq is being used for the adjuvant treatment of NSCLC.
- Imfinzi is being used following concurrent chemoradiation for NSCLC.
- Keytruda, Imfinzi, or Opdivo is being used for the neoadjuvant treatment of NSCLC.

#### REFERENCES:

*Printed copies are for reference only. Please refer to the electronic copy for the latest version.*

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2025
2. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; March 2024
3. Keytruda [package insert]. Rathway, NJ: Merck & Co., Inc.; March 2025
4. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2024
5. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; April 2024
6. National Comprehensive Cancer Network Drugs & Biologics Compendium – Non Small Cell Lung Cancer Guidelines December 2025

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Retinal Disorders Products	<b>Policy Number (if applicable):</b> ST-GA- Retinal Disorders Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the retinal disorders 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.

#### Retinal Disorders Products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Avastin (bevacizumab)</li> </ul>
Secondary Preferred	<ul style="list-style-type: none"> <li>Eylea (aflibercept) or Eylea HD (aflibercept)</li> <li>Lucentis (ranibizumab)</li> <li>Pavblu (aflibercept-ayyh)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Beovu (brolucizumab-dblI)</li> <li>Byooviz (ranibizumab-nuna)</li> <li>Cimerli (ranibizumab-eqrm)</li> <li>Susvimo (ranibizumab injection)</li> <li>Vabysmo (faricimab-svoa)</li> </ul>

#### CRITERIA:

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

- Member has received treatment with the non-preferred product in the past 365 days.
- The requested product is Eylea or Pavblu and either of the following criteria are met:
  - Member has a diagnosis of retinopathy of prematurity.
  - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
  - The requested product is Eylea HD or Lucentis and member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.


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- The requested product is Beovu or Vabysmo and both of the following criteria are met:
  - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
  - Member has had a documented inadequate response or intolerable adverse event with any of the secondary preferred products: Eylea, Eylea HD, Lucentis, or Pavblu.
- The requested product is Byooviz or Cimerli and either of the following criteria are met:
  - Member has a diagnosis of myopic choroidal neovascularization (mCNV) and both of the following criteria are met:
    - Member has a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
    - Member has had a documented intolerable adverse event to the secondary preferred product, Lucentis, 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 diagnosis other than myopic choroidal neovascularization (mCNV) and both of the following criteria are met:
    - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
    - Member has had a documented intolerable adverse event to the secondary preferred product, Lucentis, 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) OR member has had a documented inadequate response or intolerable adverse event with any of the secondary preferred products: Eylea, Eylea HD, or Pavblu.
- The requested product is Susvimo and both of the following criteria are met:
  - Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin.
  - Member has had a documented intolerable adverse event to the secondary preferred products, Lucentis 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) OR member has had a documented inadequate response or intolerable adverse event with any of the secondary preferred products: Eylea, Eylea HD, Pavblu.

#### REFERENCES:

1. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; September 2022.
2. Beovu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2024.
3. Byooviz [package insert]. Cambridge, MA: Biogen, Inc.; October 2023.
4. Cimerli [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2024.
5. Eylea [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
6. Eylea HD [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; December 2023.
7. Lucentis [package insert]. San Francisco, CA: Genentech, Inc.; February 2024.
8. Pavblu [package insert]. Thousand Oaks, CA: Amgen, Inc.; August 2024.
9. Susvimo [package insert]. San Francisco, CA: Genentech, Inc.; February 2025.
10. Vabysmo [package insert]. San Francisco, CA: Genentech, Inc.; July 2024.



	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Rituximab Products	<b>Policy Number (if applicable):</b> ST-GA- Rituximab Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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

**SCOPE:** 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 (NCO), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client

#### Rituximab Products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Ruxience (rituximab-pwr)</li> <li>Truxima (rituximab-abbs)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Riabni (rituximab-arrx)</li> <li>Rituxan (rituxir nab)</li> <li>Rituxan Hycela (rituximab and hyaluronidase human)</li> </ul>

#### CRITERIA:

Coverage for a non-preferred product 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 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:

- Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
- Rituxan [package insert]. South San Francisco, CA: Genentech. Inc.; December 2021.
- Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
- Ruxience [package insert]. New York, NY: pfizer; October 2023.



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5. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; December 2024.

	Clinical Guideline	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Asthma	<b>Policy Number (if applicable):</b> ST-GA-Asthma
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** This program applies to the asthma products specified in this document. Coverage for 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.

#### Asthma Products

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

	Products
Preferred	<ul style="list-style-type: none"> <li>Fasenra (benralizumab)</li> <li>Tezspire (Tezepelumab-ekko)</li> <li>Xolair (omalizumab)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>Cinqair (reslizumab)</li> <li>Nucala (mepolizumab)</li> </ul>

**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:

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

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

### **Nucala**


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

- Member has received treatment with Cinqair in the last 365 days.
- Member meets any of the following:
  - Member has a comorbidity of nasal polyps and meets either of the following:
    - 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.
    - A pretreatment serum IgE level of less than 30 IU/mL.
  - Member meets both of the following:
    - 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.
    - Member is less than 12 years of age and has a documented inadequate response or an intolerable adverse event with the preferred product Fasenra.
    - Member has either of the following
      - 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.
      - A pretreatment serum IgE level of less than 30 IU/mL.
  - 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



 <b>Martin's Point</b>	<b>Clinical Guideline</b>	
	<i>A specific set of instructions for completing a particular task</i>	
	<b>Clinical Guideline Title:</b> Medicare Part B Step Therapy Trastuzumab Products	<b>Policy Number (if applicable):</b> ST-GA- Trastuzumab Products
	<b>Issuing Department:</b> Version	<b>Effective Date:</b> 1/1/2026

**PURPOSE:** 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.

**SCOPE:** 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.

#### **Trastuzumab Products**

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

	<b>Products</b>
Preferred	<ul style="list-style-type: none"> <li>• Kanjinti (trastuzumab-anns)</li> <li>• Ontruzant (trastuzumab-dttb)</li> </ul>
Non-Preferred	<ul style="list-style-type: none"> <li>• Herceptin (trastuzumab)</li> <li>• Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)</li> <li>• Hercessi (trastuzumab-strf)</li> <li>• Herzuma (trastuzumab-pkrb)</li> <li>• Ogivri (trastuzumab-dkst)</li> <li>• Trazimera (trastuzumab-qyyp)</li> </ul>

#### **CRITERIA:**

Coverage for a non-preferred product 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 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:**

*Printed copies are for reference only. Please refer to the electronic copy for the latest version.*

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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.