

# Medicare Part B Step Therapy Programs

**Policy Number:** IAP.001.19  
**Effective Date:** June 1, 2024

[➔ Instructions for Use](#)

<b>Table of Contents</b>	<b>Page</b>
<a href="#">Application</a> .....	1
<a href="#">Coverage Rationale</a> .....	2
<a href="#">Applicable Codes</a> .....	9
<a href="#">Background/Description of Services</a> .....	15
<a href="#">Benefit Considerations</a> .....	15
<a href="#">References</a> .....	15
<a href="#">Policy History/Revision Information</a> .....	15
<a href="#">Instructions for Use</a> .....	16

<b>Medicare Advantage Coverage Summary</b>
<ul style="list-style-type: none"> <li><a href="#">Medications/Drugs (Outpatient/Part B)</a></li> </ul>

## Application

This Medical Benefit Injectable Policy is applicable to most UnitedHealthcare Medicare Advantage plans offered by UnitedHealthcare and its affiliates. Refer to the **Plan Exceptions** below:

Plan Type	Excluded Plans
Non-Employer Group Medicare Advantage	<ul style="list-style-type: none"> <li>Erickson Advantage® plans: H5652-001 through H5652-008</li> <li>UnitedHealthcare Medicare Direct (Private Fee-For-Service, PFFS): H5435-001, H5435-024</li> <li>Certain UnitedHealthcare Dual Complete and Dual Choice plans:               <ul style="list-style-type: none"> <li>Arizona: H0321-004</li> <li>District of Columbia: H2228-045, H2406-053, H2406-099, H7464-010</li> <li>Florida: H2509-001</li> <li>Minnesota: H0845-001, H7778-001, H7778-002</li> <li>New Jersey: H3113-005</li> <li>New York: H3387-013</li> <li>Tennessee: H0251-004</li> <li>Virginia: H7464-005, H7464-007</li> </ul> </li> <li>UnitedHealthcare Connected plans (Medicare-Medicaid)               <ul style="list-style-type: none"> <li>Massachusetts: H9239-001</li> <li>Ohio: H2531-001</li> <li>Texas: H7833-001</li> </ul> </li> <li>UnitedHealthcare Senior Care Options in Massachusetts: H2226-001, H2226-003</li> </ul>
Employer Group Medicare Advantage	<ul style="list-style-type: none"> <li>All Group HMO plans</li> <li>Select Group PPO plans:               <ul style="list-style-type: none"> <li>Bristol-Myers Squibb: H2001-869</li> <li>Johnson &amp; Johnson: H2001-869</li> <li>United Auto Workers (UAW) Trust: H2001-870</li> <li>U.S. Government of the Virgin Islands (USGVI): H2001-859, H2001-868</li> <li>Verizon: H2001-869</li> </ul> </li> </ul>

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.

# Coverage Rationale

➔ See [Benefit Considerations](#)

This policy supplements Medicare NCDs, LCDs, and manuals for the purpose of determining coverage under Medicare Part B medical benefits. A member cannot be required under this policy to change a current drug/product. For the purposes of this policy, a current drug/product means the member has a paid claim for the drug/product within the past 365 days. For example, a new plan member currently using a particular drug/product will not be required to switch to the preferred drug/ product upon enrollment. Similarly, an existing member currently using a particular drug/product will not be required to change drugs/products in the event this policy is updated.

This policy applies to step therapy for the following drugs/products:

Classes of Medical Benefit Injectables		Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
<a href="#">Antiemetics for Oncology</a> [Neurokinin 1 Receptor Antagonist (NK1 RA), 5-hydroxytryptamine Receptor Antagonist (5HT3 RA), NK1 RA/5HT3 RA combination]		Aloxi, Emend, Granisetron, Ondansetron	Akynzeo, Cinvanti, Sustol
<a href="#">Bevacizumab</a>		Mvasi, Zirabev	Alymsys, Avastin, Vegzelma
<a href="#">Bone Density Agents – Oncology</a>		Alendronate, Ibandronate, Pamidronate, Risedronate, Zoledronic Acid	Prolia, Xgeva
<a href="#">Bone Density Agents – Osteoporosis</a>	Non-Employer Group MAPD Plans	Alendronate, Ibandronate, Pamidronate, Risedronate, Zoledronic Acid	Evenity, Prolia
	MA and Employer Group MAPD Plans	Ibandronate, Pamidronate, Zoledronic Acid	Evenity, Prolia
<a href="#">Colony Stimulating Factors</a>	<a href="#">Short Acting</a>	Zarxio	Granix, Neupogen, Nivestym, Releuko
	<a href="#">Long Acting</a>	Neulasta, Udenyca,	Fulphila, Fynetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo
<a href="#">Gemcitabine</a>		Gemcitabine	Infugem
<a href="#">Gonadotropin Releasing Hormone Analogs for Oncology</a>		J9217 (leuprolide acetate, 7.5mg)	J1950 (leuprolide acetate, 3.75mg)
<a href="#">Gout Agents</a>	Non-Employer Group MAPD Plans only	Allopurinol, Febuxostat	Krystexxa
<a href="#">Hyaluronic Acid Polymers</a>		Durolane, Gelsyn-3, Synvisc, Synvisc-One	Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synjoynt, Triluron, TriVisc, Visco-3
<a href="#">Immune Globulins</a>		Bivigam, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammplex, Gamunex-C, Hizentra, HyQvia, Octagam, Privigen, Xembify	Asceniv, Cutaquig, Panzyga
<a href="#">Infliximab</a>		Avsola, Inflectra	Infliximab, Remicade, Renflexis
<a href="#">Intravenous Iron Replacement Therapy</a>		Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFed, Venofer	Injectafer, Monoferric

Classes of Medical Benefit Injectables		Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
<a href="#">Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Neovascular (Wet) Age-Related Macular Degeneration</a>		Compounded Avastin, then Eylea	Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo
<a href="#">Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Retinal Conditions Other Than Neovascular (Wet) Age-Related Macular Degeneration</a>		Eylea	Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo
<a href="#">Leucovorin/Levoleucovorin</a>		Leucovorin	Fusilev, Khapzory, Levoleucovorin
<a href="#">Lipid Modifying Agents</a>	Non-Employer Group MAPD plans only	Praluent, Repatha	Leqvio
<a href="#">Migraine Prophylaxis – Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists</a>	Non-Employer Group MAPD plans only	Aimovig, Ajovy, Emgality	Vyepti
<a href="#">Rituximab</a>		Ruxience, Truxima	Riabni, Rituxan, Rituxan Hycela
<a href="#">Systemic Lupus Erythematosus Agents</a>		Benlysta	Saphnelo
<a href="#">Trastuzumab</a>		Kanjinti, Trazimera	Herceptin, Herceptin Hylecta, Herzuma, Ogivri, Ontruzant

Drugs/products must satisfy the following step therapy criteria, and if approved, authorization will be provided for 12 months.

If a provider administers a non-preferred drug/product without obtaining prior authorization, UnitedHealthcare may deny claims for the non-preferred drug/product.

### **Antiemetics for Oncology [Neurokinin 1 Receptor Antagonist (NK1 RA), 5-Hydroxytryptamine Receptor Antagonist (5HT<sub>3</sub> RA), NK1 RA/5HT<sub>3</sub> RA Combination] (Akynzeo, Aloxi, Cinvanti, Emend, Granisetron, Ondansetron, Sustol)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Aloxi, Emend, Granisetron, Ondansetron	Akynzeo, Cinvanti, Sustol

#### ***Non-Preferred Product Step Therapy Criteria***

**Akynzeo, Cinvanti, or Sustol, may be covered when any of the criteria listed below are satisfied:**

- History of use of Aloxi, Emend, Granisetron, or Ondansetron resulting in minimal clinical response to therapy; **or**
- History of intolerance or adverse event(s) to Aloxi, Emend, Granisetron, or Ondansetron; **or**
- Continuation of prior therapy within the past 365 days.

### **Bevacizumab (Alymsys, Avastin, Mvasi, Vegzelma, Zirabev) – Oncology Uses Only**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Mvasi, Zirabev	Alymsys, Avastin, Vegzelma

#### ***Non-Preferred Product Step Therapy Criteria***

**Alymsys, Avastin, or Vegzelma, when prescribed for a cancer condition, may be covered when any of the criteria listed below are satisfied:**

- History of use of Mvasi or Zirabev resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Mvasi or Zirabev; **or**
- Continuation of prior therapy within the past 365 days.

## Bone Density Agents – Oncology (Alendronate, Ibandronate, Pamidronate, Prolia, Risedronate, Xgeva, Zoledronic Acid)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Alendronate, Ibandronate, Pamidronate, Risedronate, Zoledronic Acid	Prolia, Xgeva

### ***Xgeva Non-Preferred Product Step Therapy Criteria***

Xgeva, when used for treatment of the following conditions, may be covered when any of the criteria listed below are satisfied.

#### **Conditions**

- Prevention of skeletal related events in patients with multiple myeloma
- Prevention of skeletal related events in patients with bone metastases from solid tumors
- Hypercalcemia of malignancy
- Osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain

#### **Criteria**

- History of use of an injectable bisphosphonate resulting in minimal clinical response to therapy; or
- History of contraindication, intolerance or adverse event(s) to an injectable bisphosphonate; or
- Continuation of prior therapy within the past 365 days.

### ***Prolia Non-Preferred Product Step Therapy Criteria (for Non-Employer Group MAPD Plans)***

Prolia may be covered when any of the criteria listed below are satisfied:<sup>9</sup>

- History of use of both an oral bisphosphonate (e.g., Alendronate, Risedronate) **and** an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid) resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to an oral bisphosphonate (e.g., Alendronate, Risedronate) **and** an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid); **or**
- Continuation of prior therapy within the past 365 days.

### ***Prolia Non-Preferred Product Step Therapy Criteria (for MA and Employer Group MAPD Plans)***

Prolia may be covered when any of the criteria listed below are satisfied:<sup>9</sup>

- History of use of an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid) resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid); **or**
- Continuation of prior therapy within the past 365 days.

## Bone Density Agents – Osteoporosis (Alendronate, Evenity, Ibandronate, Pamidronate, Prolia, Risedronate, Zoledronic Acid)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Alendronate, Ibandronate, Pamidronate, Risedronate, Zoledronic Acid	Evenity, Prolia

### ***Non-Preferred Product Step Therapy Criteria (for Non-Employer Group MAPD Plans)***

Evenity or Prolia may be covered when any of the criteria listed below are satisfied:

- History of use of both an oral bisphosphonate (e.g., Alendronate, Risedronate) **and** an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid) resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to an oral bisphosphonate (e.g., Alendronate, Risedronate) **and** an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid); **or**
- Continuation of prior therapy within the past 365 days.

## ***Non-Preferred Product Step Therapy Criteria (for MA and Employer Group MAPD Plans)***

**Evenity or Prolia may be covered when any of the criteria listed below are satisfied:**

- History of use of an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid) resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to an injectable bisphosphonate (e.g., Pamidronate, Zoledronic Acid); **or**
- Continuation of prior therapy within the past 365 days.

## **Colony Stimulating Factors**

### ***Short-Acting (Granix, Neupogen, Nivestym, Releuko, Zarxio)***

<b>Preferred Drug(s)/Product(s)</b>	<b>Non-Preferred Drug(s)/Product(s)</b>
Zarxio	Granix, Neupogen, Nivestym, Releuko

## **Non-Preferred Product Step Therapy Criteria**

**Granix, Neupogen, Nivestym, or Releuko may be covered when any of the criteria listed below are satisfied:**

- History of use of Zarxio resulting in minimal clinical response to therapy; **or**
- History of intolerance or adverse event(s) to Zarxio; **or**
- Continuation of prior therapy within the past 365 days.

### ***Long-Acting (Fulphila, Fylnetra, Neulasta, Nyvepria, Rolvedon, Stimufend, Udenyca, Ziextenzo)***

<b>Preferred Drug(s)/Product(s)</b>	<b>Non-Preferred Drug(s)/Product(s)</b>
Neulasta, Udenyca,	Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo

## **Non-Preferred Product Step Therapy Criteria**

**Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, or Ziextenzo may be covered when any of the criteria listed below are satisfied:**

- History of use of Neulasta and Udenyca, resulting in minimal clinical response to therapy; **or**
- History of intolerance or adverse event(s) to Neulasta and Udenyca ; **or**
- Continuation of prior therapy within the past 365 days.

## **Gemcitabine (Gemcitabine, Infugem)**

<b>Preferred Drug(s)/Product(s)</b>	<b>Non-Preferred Drug(s)/Product(s)</b>
Gemcitabine	Infugem

## ***Non-Preferred Product Step Therapy Criteria***

**Infugem may be covered when any of the criteria listed below are satisfied:**

- History of use of Gemcitabine (J9201) resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Gemcitabine (J9201); **or**
- Continuation of prior therapy within the past 365 days.

## **Gonadotropin Releasing Hormone Analogs for Oncology (Leuprolide Acetate)**

<b>Preferred Drug(s)/Product(s)</b>	<b>Non-Preferred Drug(s)/Product(s)</b>
J9217 (leuprolide acetate, per 7.5mg)	J1950 (leuprolide acetate, per 3.75mg)

## ***Non-Preferred Product Step Therapy Criteria***

**J1950 (leuprolide acetate, per 3.75mg) may be covered when the criteria listed below are satisfied:**

- Continuation of prior therapy within the past 365 days.

## Gout Agents (Allopurinol, Febuxostat, Krystexxa) – Non-Employer Group MAPD Plans Only

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Allopurinol, Febuxostat	Krystexxa

### Non-Preferred Product Step Therapy Criteria

Krystexxa may be covered when any of the criteria listed below are satisfied:

- Both of the following:
  - Trial of at least 3 months of therapy (at the maximally medically appropriate dose) of Allopurinol resulting in minimal clinical response to therapy; **and**
  - Trial of at least 3 months of therapy (at the maximally medically appropriate dose) of Febuxostat resulting in minimal clinical response to therapy
- **or**
- History of contraindication, intolerance or adverse event(s) to Allopurinol **and** Febuxostat; **or**
- Continuation of prior therapy within the past 365 days.

## Hyaluronic Acid Polymers (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Synvisc, Synvisc-One, Visco-3, Triluron, TriVisc)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Durolane, Gelsyn-3, Synvisc, Synvisc-One	Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Triluron, TriVisc, Visco-3

### Non-Preferred Product Step Therapy Criteria

Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz FX, Synojoynt, Triluron, TriVisc, or Visco-3 may be covered when any of the criteria listed below are satisfied:

- Trial and failure of **all** of the following: Durolane, Gelsyn-3, **and** Synvisc/Synvisc-One, resulting in minimal clinical response to therapy; **or**
- History of intolerance or adverse event(s) to **all** of the following: Durolane, Gelsyn-3, **and** Synvisc/Synvisc-One; **or**
- Continuation of prior therapy within the past 365 days.

## Immune Globulins (Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, HyQvia, Octagam, Panzyga, Privigen, Xembify)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Bivigam, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, HyQvia, Octagam, Privigen, Xembify	Asceniv, Cutaquig, Panzyga

### Non-Preferred Product Step Therapy Criteria

Asceniv, Cutaquig, or Panzyga may be covered when any of the criteria listed below are satisfied:

- History of use of at least **two** preferred Immune Globulin products (either IV or SC products), resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to at least **two** preferred Immune Globulin products (either IV or SC products); **or**
- Continuation of prior therapy within the past 365 days.

## Infliximab (Avsola, Inflectra, Infliximab, Remicade, Renflexis)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Avsola, Inflectra	Infliximab, Remicade, Renflexis

### Non-Preferred Product Step Therapy Criteria

Infliximab, Remicade or Renflexis may be covered when any of the criteria listed below are satisfied:



- Trial of at least 14 weeks of Avsola or Inflectra resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Avsola or Inflectra; **or**
- Continuation of prior therapy within the past 365 days.

### **Intravenous Iron Replacement Therapy (Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFeD, Injectafer, Monoferric, Venofer)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFeD, Venofer	Injectafer, Monoferric

#### ***Non-Preferred Product Step Therapy Criteria***

Injectafer or Monoferric may be covered for iron deficiency anemia without chronic kidney disease and iron deficiency anemia associated with chronic kidney disease (without End Stage Renal Disease) when any of the criteria listed below are satisfied:

- Trial of at least 3 weeks of therapy, to at least **two** of the preferred intravenous iron therapies each, resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to at least **two** of the preferred intravenous iron therapies; **or**
- Continuation of prior therapy within the past 365 days.

### **Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Neovascular (Wet) Age-Related Macular Degeneration (Compounded Avastin, Beovu, Byooviz, Eylea, Eylea HD, Lucentis, Susvimo, Vabysmo)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Compounded Avastin, then Eylea	Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo

#### ***Step Therapy Criteria***

##### **Eylea**

Eylea, when prescribed for Neovascular (Wet) Age-Related Macular Degeneration, may be covered when any of the criteria listed below are satisfied:

- History of a trial of at least 3 consecutive doses given monthly, resulting in minimal clinical response to compounded Avastin (bevacizumab); **or**
- History of contraindication or adverse event(s) to compounded Avastin (bevacizumab); **or**
- Continuation of prior therapy within the past 365 days.

##### **Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo**

Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, or Vabysmo, when prescribed for Neovascular (Wet) Age-Related Macular Degeneration, may be covered when any of the criteria listed below are satisfied:

- Both of the following:
  - Trial of at least 3 consecutive doses given monthly, resulting in minimal clinical response to compounded Avastin (bevacizumab); **and**
  - History of use of Eylea, resulting in minimal clinical response to therapy**or**
- History of contraindication, intolerance, or adverse event(s) to compounded Avastin (bevacizumab) **and** Eylea; **or**
- Continuation of prior therapy within the past 365 days.

### **Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Retinal Conditions Other Than Neovascular (Wet) Age-Related Macular Degeneration (Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Susvimo, Vabysmo)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Eylea	Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo

### ***Non-Preferred Product Step Therapy Criteria***

Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, or Vabysmo, when prescribed for a retinal condition other than Neovascular (Wet) Age-Related Macular Degeneration, may be covered when any of the criteria listed below are satisfied:

- History of use of Eylea, resulting in minimal clinical response to therapy; **or**
- History of contraindication or adverse event(s) to Eylea; **or**
- Continuation of prior therapy within the past 365 days.

### **Leucovorin/Levoleucovorin (Fusilev, Khapzory, Leucovorin, Levoleucovorin)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Leucovorin	Fusilev, Khapzory, Levoleucovorin

### ***Non-Preferred Product Step Therapy Criteria***

Fusilev, Khapzory, or Levoleucovorin may be covered when any of the criteria listed below are satisfied:

- History of use of Leucovorin resulting in minimal clinical response to therapy; **or**
- History of intolerance or adverse event(s) to Leucovorin; **or**
- Continuation of prior therapy within the past 365 days.

### **Lipid Modifying Agents (Leqvio, Praluent, Repatha) (for Non-Employer Group MAPD Plans Only)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Praluent, Repatha	Leqvio

### ***Non-Preferred Product Step Therapy Criteria***

Leqvio may be covered when any of the criteria listed below are satisfied:

- Trial of at least 12 consecutive weeks of either Praluent or Repatha, resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance, or adverse event(s) to Praluent or Repatha; **or**
- Continuation of prior therapy within the past 365 days.

### **Migraine Prophylaxis – Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist (Aimovig, Ajovy, Emgality, Vyepti) (for Non-Employer Group MAPD Plans Only)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Aimovig, Ajovy, Emgality	Vyepti

### ***Non-Preferred Product Step Therapy Criteria***

Vyepti may be covered when any of the criteria listed below are satisfied:

- Trial of at least 3 months of therapy each, to **two** of the preferred drugs (e.g. Aimovig, Emgality), resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance, or adverse event(s) to two of the preferred drugs (e.g. Aimovig, Emgality); **or**
- Continuation of prior therapy within the past 365 days.

### **Rituximab (Riabni, Rituxan, Rituxan Hycela, Ruxience, Truxima)**

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Ruxience, Truxima	Riabni, Rituxan, Rituxan Hycela

### ***Non-Preferred Product Step Therapy Criteria***

Riabni, Rituxan, or Rituxan Hycela may be covered when any of the criteria listed below are satisfied:

- History of use of Ruxience or Truxima resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Ruxience or Truxima; **or**
- Continuation of prior therapy within the past 365 days.



## Systemic Lupus Erythematosus Agents (Benlysta, Saphnelo)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Benlysta	Saphnelo

### Non-Preferred Product Step Therapy Criteria

Saphnelo may be covered when any of the criteria listed below are satisfied:

- History of use of Benlysta resulting in minimal clinical response to therapy; **or**
- History of contraindication, intolerance or adverse event(s) to Benlysta; **or**
- Continuation of prior therapy within the past 365 days.

## Trastuzumab (Herceptin, Herceptin Hylecta, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Kanjinti, Trazimera	Herceptin, Herceptin Hylecta, Herzuma, Ogivri, Ontruzant

### Non-Preferred Product Step Therapy Criteria

Herceptin, Herceptin Hylecta, Herzuma, Ogivri, or Ontruzant, when prescribed for a cancer condition, may be covered when any of the criteria listed below are satisfied:

- History of use of Kanjinti or Trazimera resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Kanjinti or Trazimera; **or**
- Continuation of prior therapy within the past 365 days.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

## Antiemetics for Oncology [Neurokinin 1 Receptor Antagonist (NK1 RA), 5-Hydroxytryptamine Receptor Antagonist (5HT<sub>3</sub> RA), NK1 RA/5HT<sub>3</sub> RA Combination] (Akynzeo, Aloxi, Cinvanti, Emend, Granisetron, Ondansetron, Sustol)

HCPCS Code	Description
<b>Preferred</b>	
J1453	Injection, fosaprepitant, 1 mg
J1626	Injection, granisetron hydrochloride, 100 mcg
J2405	Injection, ondansetron hydrochloride, per 1 mg
J2469	Injection, palonosetron HCl, 25 mcg
Q0162	Ondansetron 1 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen
Q0166	Granisetron hydrochloride, 1 mg oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen
<b>Non-Preferred</b>	
J0185	Injection, aprepitant, 1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
J1627	Injection, granisetron, extended-release, 0.1mg

## Bevacizumb (Alymsys, Avastin, Mvasi, Vegzelma, Zirabev)

HCPCS Code	Description
<b>Preferred</b>	
Q5107	Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg
<b>Non-Preferred</b>	
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg
J9035	Injection, bevacizumab, 10 mg

## Bone Density Agents – Oncology and Osteoporosis (Evenity, Ibandronate, Pamidronate, Prolia, Xgeva, Zoledronic Acid)

HCPCS Code	Description
<b>Preferred</b>	
J1740	Injection, ibandronate sodium, 1 mg
J2430	Injection, pamidronate disodium, per 30 mg
J3489	Injection, zoledronic acid, 1 mg
<b>Non-Preferred</b>	
J0897	Injection, denosumab, 1 mg
J3111	Injection, romosozumab-aqqg, 1 mg

## Colony Stimulating Factors

### Short-Acting (Granix, Neupogen, Nivestym, Releuko, Zarxio)

HCPCS Code	Description
<b>Preferred</b>	
Q5101	Injection, filgrastim-sndz, biosimilar, (Zarxio) 1 microgram
<b>Non-Preferred</b>	
J1442	Injection, filgrastim (G-CSF), (Neupogen) excludes biosimilars, 1 mcg
J1447	Injection, tbo-filgrastim, (Granix)1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram
Q5125	Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg

### Long-Acting (Fulphila, Fylnetra, Neulasta, Nyvepria, Rolvedon, Stimufend, Udenyca, Ziextenzo)

HCPCS Code	Description
<b>Preferred</b>	
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg
<b>Non-Preferred</b>	
J1449	Injection, eflapegrastim-xnst, 0.1 mg
Q5108	Injection, pegfilgrastim-jmdb (Fulphila), biosimilar, 0.5 mg
Q5120	Injection, pegfilgrastim-bmez, (Ziextenzo), biosimilar, 0.5 mg
Q5122	Injection, pegfilgrastim-apgf (Nyvepria), biosimilar, 0.5 mg
Q5127	Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg

## Gemcitabine (Gemcitabine, Infugem)

HCPCS Code	Description
<b>Preferred</b>	
J9201	Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg
<b>Non-Preferred</b>	
J9198	Injection, gemcitabine hydrochloride, (Infugem), 100 mg

## Gonadotropin Releasing Hormone Analogs for Oncology

HCPCS Code	Description
<b>Preferred</b>	
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
<b>Non-Preferred</b>	
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg

## Gout Agents (Krystexxa)

HCPCS Code	Description
<b>Preferred</b>	
N/A	N/A
<b>Non-Preferred</b>	
J2507	Injection, pegloticase, 1 mg

## Hyaluronic Acid Polymers (Durolane, Euflexxa, Gel-One, Gelsyn-3, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Synvisc, Synvisc-One, Visco-3, Triluron, TriVisc)

HCPCS Code	Description
<b>Preferred</b>	
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7328	Hyaluronan or derivative, Gelsyn-3, for intra-articular injection, 0.1 mg
<b>Non-Preferred</b>	
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan, Supartz or Visco-3, for intra-articular injection, per dose
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
J7323	Hyaluronan or derivative, Euflexxa, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
J7329	Hyaluronan or derivative, TriVisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, Synojoynt, for intra-articular injection, 1mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1mg

## Immune Globulins (Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, HyQvia, Octagam, Panzyga, Privigen, Xembify)

HCPCS Code	Description
<b>Preferred</b>	
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCLg), human, for use in subcutaneous infusions, 100 mg, each

HCPCS Code	Description
<b>Preferred</b>	
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), intravenous, nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immune globulin
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
<b>Non-Preferred</b>	
J1551	Injection, immune globulin (cutaquist), 100 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg

### **Infliximab (Avsola, Inflectra, Infliximab, Remicade, Renflexis)**

HCPCS Code	Description
<b>Preferred</b>	
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10mg
<b>Non-Preferred</b>	
J1745	Injection, infliximab, excludes biosimilar, 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg

### **Intravenous Iron Replacement Therapy (Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFeD, Injectafer, Monoferric, Venofer)**

HCPCS Code	Description
<b>Preferred</b>	
J1750	Injection, iron dextran, 50 mg
J1756	Injection, iron sucrose, 1 mg
J2916	Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
<b>Non-Preferred</b>	
J1437	Injection, ferric derisomaltose, 10 mg
J1439	Injection, ferric carboxymaltose, 1 mg

## Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors (Compounded Avastin, Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Susvimo, Vabysmo)

HCPCS Code	Description
<b>Preferred</b>	
C9257	Injection, bevacizumab (Avastin), 0.25mg
J0178	Injection, aflibercept, 1 mg
J7999	Compounded drug, not otherwise classified
J9035	Injection, bevacizumab (Avastin), 10mg
<b>Non-Preferred</b>	
J0177	Injection, aflibercept HD, 1 mg
J0179	Injection, brolocizumab-dbli, 1 mg
J2777	Injection, faricimab-svoa, 0.1 mg
J2778	Injection, ranibizumab, 0.1 mg
J2779	Injection, ranibizumab, via intravitreal implant (Susvimo), 0.1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (Byooviz), 0.1 mg
Q5128	Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg

Diagnosis Code	Description
H35.3210	Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211	Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212	Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213	Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220	Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221	Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222	Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223	Exudative age-related macular degeneration, left eye, with inactive scar
H35.3230	Exudative age-related macular degeneration, bilateral, stage unspecified
H35.3231	Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization
H35.3232	Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization
H35.3233	Exudative age-related macular degeneration, bilateral, with inactive scar
H35.3290	Exudative age-related macular degeneration, unspecified eye, stage unspecified
H35.3291	Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization
H35.3292	Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization
H35.3293	Exudative age-related macular degeneration, unspecified eye, with inactive scar

## Leucovorin/Levoleucovorin (Fusilev, Khapzory, Leucovorin, Levoleucovorin)

HCPCS Code	Description
<b>Preferred</b>	
J0640	Injection, leucovorin calcium, per 50 mg
<b>Non-Preferred</b>	
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (Khapzory), 0.5 mg

## Lipid Modifying Agents (Leqvio)

HCPCS Code	Description
<b>Preferred</b>	
N/A	N/A
<b>Non-Preferred</b>	
J1306	Injection, inclisiran, 1 mg

## Migraine Prophylaxis – Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist (Vyepti)

HCPCS Code	Description
<b>Preferred</b>	
N/A	N/A
<b>Non-Preferred</b>	
J3032	Injection, eptinezumab-jjmr, 1 mg

## Rituximab (Riabni, Rituxan, Rituxan Hycela, Ruxience, Truxima)

HCPCS Code	Description
<b>Preferred</b>	
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
<b>Non-Preferred</b>	
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg

## Systemic Lupus Erythematosus Agents (Benlysta, Saphnelo)

HCPCS Code	Description
<b>Preferred</b>	
J0490	Injection, belimumab, 10 mg
<b>Non-Preferred</b>	
J0491	Injection, anifrolumab-fnia, 1 mg

## Trastuzumab (Herceptin, Herceptin Hylecta, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera)

HCPCS Code	Description
<b>Preferred</b>	
Q5116	Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg
<b>Non-Preferred</b>	
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg



## Background/Description of Services

Certain classes of medical benefit injectables covered under Medicare Part B will include non-preferred therapies. A non-preferred therapy will generally require history of use of a preferred therapy within the same class, among other criteria. This step therapy requirement will apply to some, but not all, Medicare Advantage Plans. Refer to the [Plan Exceptions](#) table.

Six classes of medical benefit injectables (Bevacizumab, Colony Stimulating Factors, Infliximab, Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors, Rituximab, and Trastuzumab) covered under Medicare Part B that will include preferred and non-preferred drugs/products are biosimilar products.

A biosimilar product is a biologic product that is approved based on demonstrating that it is highly similar to an FDA-approved biologic product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.

## Benefit Considerations

Before using this policy, check the member's EOC/SB and any federal or state mandates, if applicable.

Experimental and investigational procedures, items and medications are not covered. Investigational Device Exemption Studies (IDE) are only covered when Medicare requirements are met. For coverage requirements, refer to [www.cms.gov](http://www.cms.gov).

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## Policy History/Revision Information

Date	Summary of Changes
06/01/2024	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"><li>● Removed language pertaining to prior authorization requirements</li><li>● Revised list of drugs/products which require step therapy; removed erythropoietic agents (Retacrit, Epogen, and Procrit)</li></ul> <p><b>Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors</b></p> <ul style="list-style-type: none"><li>● Revised step therapy criteria; replaced criterion requiring “trial of at least 3 doses, resulting in minimal clinical response to compounded Avastin (bevacizumab)” with “trial of at least 3</li></ul>

Date	Summary of Changes
	<p><i>consecutive doses given monthly, resulting in minimal clinical response to compounded Avastin (bevacizumab)</i></p> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed HCPCS codes J0885 and Q5106</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Background/Description of Services</i> section to reflect the most current information</li> <li>Archived previous policy version IAP.001.18</li> </ul>

## Instructions for Use

This Medical Benefit Injectable Policy is provided for informational purposes only and does not constitute medical advice. Treating physicians and health care providers are solely responsible for making any decisions about medical care.

Each benefit plan contains its own provisions for coverage, limitations and exclusions as stated in the member's Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member's EOC/SB, the member's EOC/SB provision(s) will govern.

In the event of a conflict between this policy and Medicare National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and Medicare manuals, the Medicare NCD/LCD/manual will apply.