

Medicare Part B Step Therapy Programs

Policy Number: IAP.001.26
Effective Date: October 1, 2025

[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	2
Applicable Codes	10
Background/Description of Services	17
Benefit Considerations	17
References	17
Policy History/Revision Information	18
Instructions for Use	19

Medicare Advantage Medical Policy

- [Medications/Drugs \(Outpatient/Part B\)](#)

Application

This 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"> Erickson Advantage® plans: H5652-001 through H5652-008 UnitedHealthcare Medicare Direct (Private Fee-For-Service, PFFS): H5435-001, H5435-024 Certain UnitedHealthcare Dual Complete and Dual Choice plans: <ul style="list-style-type: none"> Alabama: H2802-064 Arizona: H0321-004 District of Columbia: H2406-053, H7464-010 Florida: H1045-063, H1045-065, H1889-026, H2509-001, H2509-003, H5420-016 Hawaii: H2406-132 New Jersey: H3113-005 New Mexico: H0294-049 New York: H3387-013 Tennessee: H0251-004 Virginia: H0421-001, H2445-001, H2445-003, H2445-005 UnitedHealthcare Connected plans (Medicare-Medicaid) <ul style="list-style-type: none"> Massachusetts: H9239-001 Ohio: H2531-001 Texas: H7833-001 UnitedHealthcare Senior Care Options in Massachusetts: H2226-001, H2226-003
Employer Group Medicare Advantage	<ul style="list-style-type: none"> All Group HMO plans Select Group PPO plans: <ul style="list-style-type: none"> Bristol-Myers Squibb: H2001-869 Johnson & Johnson: H2001-869 United Auto Workers (UAW) Trust: H1537-869, H2001-870 U.S. Government of the Virgin Islands (USGVI): H1537-868, H2001-859, H2001-868 Verizon: H2001-869

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 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 UnitedHealthcare plan member with claim history of a particular drug/product will not be required to switch to the preferred drug/product upon enrollment. Similarly, an existing UnitedHealthcare plan member with paid claims for 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 drugs/products in the tables below. Drugs/products must satisfy the step therapy criteria in this policy 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.

Classes of Medical Benefit Injectables		Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
<u>Antiemetics for Oncology</u> [Neurokinin 1 Receptor Antagonist (NK1 RA), 5-hydroxytryptamine Receptor Antagonist (5HT3 RA), NK1 RA/5HT3 RA combination]		Aloxi (palonosetron), Emend (fosaprepitant), Granisetron, Ondansetron	Akynzeo, Cinvanti, Focinvez, Posfrea, Sustol
<u>Asthma Immunomodulators – Respiratory Interleukins</u>		Fasenra, Nucala	Cinqair
<u>Bevacizumab</u>		Alymsys, Mvasi, Zirabev	Avastin, Avzivi, Vegzelma
<u>Bone Density Agents – Oncology</u>		Jubbonti, Osenvelt, Stoboclo, Wyost	Prolia, Xgeva
<u>Bone Density Agents – Osteoporosis</u>		Jubbonti, Stoboclo	Evenity, Prolia
<u>Colony Stimulating Factors</u>	<u>Short Acting</u>	Zarxio	Granix, Neupogen, Nivestym, Nypozi, Releuko
	<u>Long Acting</u>	Neulasta, Fulphila, Udenyca,	Fylnetra, Nyvepria, Rolvedon, Ryzneuta, Stimufend, Ziextenzo
<u>Gemcitabine</u>		Gemcitabine (HCPCS codes J9196 and J9201)	Infugem
<u>Gonadotropin Releasing Hormone Analogs for Oncology</u>		HCPCS codes J1954 and J9217 (leuprolide acetate, 7.5mg)	HCPCS code J1950 (leuprolide acetate, 3.75mg)
<u>Gout Agents</u> Non-Employer Group MAPD Plans only		Allopurinol, Febuxostat	Krystexxa
<u>Hyaluronic Acid Polymers</u>		Durolane, Gelsyn-3, Synvisc, Synvisc-One	Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Triluron, TriVisc, Visco-3
<u>Immune Globulins</u>		Bivigam, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, HyQvia, Octagam, Privigen, Xembify	Alyglo, Asceniv, Cutaquig, Panzyga
<u>Infliximab</u>		Avsola, Inflectra, Renflexis	Infliximab, Remicade
<u>Intravenous Iron Replacement Therapy</u>		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)
<u>Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Neovascular (Wet) Age-Related Macular Degeneration</u>	Re-packaged Avastin, then Eylea or Eylea HD or Pavblu	Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo
<u>Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Retinal Conditions Other Than Neovascular (Wet) Age-Related Macular Degeneration</u>	Eylea, Eylea HD, Pavblu	Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo
<u>Leucovorin/Levoleucovorin</u>	Leucovorin	Fusilev, Khapzory, Levoleucovorin
<u>Lipid Modifying Agents</u> Non-Employer Group MAPD plans only	Praluent, Repatha	Leqvio
<u>Migraine Prophylaxis – Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists</u> Non-Employer Group MAPD plans only	Aimovig, Ajovy, Emgality	Vyepti
<u>Pemetrexed</u>	Alimta, generic Pemetrexed products (HCPs codes J9294, J9296, J9297, J9305, and J9314)	Axtle, Pemfexy, Pemrydi RTU
<u>Rituximab</u>	Ruxience, Truxima	Riabni, Rituxan, Rituxan Hycela
<u>Systemic Lupus Erythematosus Agents</u>	Benlysta	Saphnelo
<u>Tocilizumab</u>	Tofidence, Tyenne	Actemra
<u>Trastuzumab</u>	Kanjinti, Ogivri, Trazimera	Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Ontruzant

Classes of Medical Benefit Injectables	Indication(s)	Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Antineoplastic Monoclonal Antibodies	<u>Head and Neck Cancers: Cancer of the Nasopharynx, Recurrent, Unresectable, Oligometastatic, or Metastatic Disease</u>	Loqtorzi	Keytruda, Opdivo, Opdivo Qvantig, Tevimbra
	<u>Non-Small Cell Lung Cancer: Advanced or Metastatic, Monotherapy, PD-L1 expression positive ≥ 50%</u>	Keytruda, Libtayo, Tecentriq, Tecentriq Hybreza	Opdivo plus Yervoy

Antiemetics for Oncology [Neurokinin 1 Receptor Antagonist (NK1 RA), 5-Hydroxytryptamine Receptor Antagonist (5HT₃ RA), NK1 RA/5HT₃ RA Combination] (Akynzeo, Aloxi [palonosetron], Cinvanti, Emend [fosaprepitant], Focinvez, Granisetron, Ondansetron, Posfrea, Sustol)

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

Non-Preferred Product Step Therapy Criteria

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

- History of use of Aloxi (palonosetron), Emend (fosaprepitant), Granisetron, or Ondansetron resulting in minimal clinical response to therapy; **or**

- History of intolerance or adverse event(s) to Aloxi (palonosetron), Emend (fosaprepitant), Granisetron, or Ondansetron; **or**
- Continuation of prior therapy within the past 365 days.

Asthma Immunomodulators – Respiratory Interleukins (Cinqair, Fasenra, Nucala)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Fasenra, Nucala	Cinqair

Non-Preferred Product Step Therapy Criteria

Cinqair, when used for the treatment of severe asthma, may be covered when any of the criteria listed below are satisfied:

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

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

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

Non-Preferred Product Step Therapy Criteria

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

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

Bone Density Agents – Oncology (Jubbonti, Osenvelt, Prolia, Stoboclo, Wyost, Xgeva)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Jubbonti, Osenvelt, Stoboclo, Wyost	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 Osenvelt or Wyost resulting in minimal clinical response to therapy; **or**
 - History of contraindication, intolerance or adverse event(s) to Osenvelt or Wyost; **or**
 - Continuation of prior therapy within the past 365 days.

Prolia Non-Preferred Product Step Therapy

Prolia may be covered when any of the criteria listed below are satisfied:⁹

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

Bone Density Agents – Osteoporosis (Evenity, Jubbonti, Prolia, Stoboclo)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Jubbonti, Stoboclo	Evenity, Prolia

Non-Preferred Product Step Therapy Criteria

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

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

Colony Stimulating Factors

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

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Zarxio	Granix, Neupogen, Nivestym, Nypozi, Releuko

Non-Preferred Product Step Therapy Criteria

Granix, Neupogen, Nivestym, Nypozi, 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, Ryzneuta, Stimufend, Udenyca, Ziextenzo)

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

Non-Preferred Product Step Therapy Criteria

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

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

Gemcitabine (Gemcitabine, Infugem)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Gemcitabine (HCPCS codes J9196 and J9201)	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 (HCPCS codes J9196 and J9201) resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Gemcitabine (HCPCS codes J9196 and J9201); **or**
- Continuation of prior therapy within the past 365 days.

Gonadotropin Releasing Hormone Analogs for Oncology (Leuprolide Acetate)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
HCPCS code J1954 [leuprolide acetate (lutrate depot), per 7.5mg] HCPCS code J9217 (leuprolide acetate, per 7.5mg)	HCPCS code J1950 (leuprolide acetate, per 3.75mg)

Non-Preferred Product Step Therapy Criteria

HCPCS code 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, Synjoynt, 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, Synjoynt, Triluron, TriVisc, Visco-3

Non-Preferred Product Step Therapy Criteria

Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz FX, Synjoynt, 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 (Alyglo, 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	Alyglo, Asceniv, Cutaquig, Panzyga

Non-Preferred Product Step Therapy Criteria

Alyglo, 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, Renflexis	Infliximab, Remicade

Non-Preferred Product Step Therapy Criteria

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

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

Intravenous Iron Replacement Therapy [Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFeD, Injectafer, Monoferic, Venofer]

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

Non-Preferred Product Step Therapy Criteria

Injectafer or Monoferic 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 (Re-packaged Avastin, Beovu, Byooviz, Eylea, Eylea HD, Lucentis, Pavblu, Susvimo, Vabysmo)

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

Step Therapy Criteria

Eylea, Eylea HD, Pavblu

Eylea, Eylea HD, or Pavblu 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 re-packaged Avastin (bevacizumab); **or**
- History of contraindication or adverse event(s) to re-packaged Avastin (bevacizumab); **or**
- Continuation of prior therapy within the past 365 days.

Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo

Beovu, Byooviz, Cimerli, 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 re-packaged Avastin (bevacizumab); **and**
 - History of use of **one** of the following, resulting in minimal clinical response to therapy:
 - Eylea
 - Eylea HD
 - Pavblu**or**
- History of contraindication, intolerance, or adverse event(s) to re-packaged Avastin (bevacizumab) **and one** of the following: Eylea, Eylea HD, Pavblu; **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, Pavblu, Susvimo, Vabysmo)

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

Non-Preferred Product Step Therapy Criteria

Beovu, Byooviz, Cimerli, 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 **one** of the following, resulting in minimal clinical response to therapy: Eylea, Eylea HD, Pavblu; **or**
- History of contraindication or adverse event(s) to **one** of the following: Eylea, Eylea HD, Pavblu; **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.

Pemetrexed (Alimta, Axtle, Pemetrexed, Pemfexy, Pemrydi RTU)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Alimta, generic Pemetrexed products (HCPCS code J9294, J9296, J9297, J9305, and J9314)	Axtle, Pemfexy, Pemrydi RTU

Non-Preferred Product Step Therapy Criteria

Axtle, Pemfexy or Pemrydi RTU may be covered when any of the criteria listed below are satisfied:

- History of use of Alimta/generic Pemetrexed resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Alimta/generic Pemetrexed; **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.

Tocilizumab (Actemra, Tofidence, Tyenne)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Tofidence, Tyenne	Actemra

Non-Preferred Product Step Therapy Criteria

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

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

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

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

Non-Preferred Product Step Therapy Criteria

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

Antineoplastic Monoclonal Antibodies – Head and Neck Cancers: Cancer of the Nasopharynx, Recurrent, Unresectable, Oligometastatic, or Metastatic Disease

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Loqtorzi	Keytruda, Opdivo, Opdivo Qvantig, Tevimbra

Non-Preferred Product Step Therapy Criteria

Keytruda, Opdivo, Opdivo Qvantig, or Tevimbra when prescribed for nasopharyngeal carcinoma, may be covered when any of the criteria listed below are satisfied:

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

Antineoplastic Monoclonal Antibodies – Non-Small Cell Lung Cancer: Advanced or Metastatic, Monotherapy, PD-L1 Expression Positive $\geq 50\%$

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Keytruda, Libtayo, Tecentriq, Tecentriq Hybreza	Opdivo plus Yervoy

Non-Preferred Product Step Therapy Criteria

Opdivo plus Yervoy, when prescribed for non-small cell lung cancer, may be covered when any of the criteria listed below are satisfied:

- History of use of Keytruda, Libtayo, Tecentriq, or Tecentriq Hybreza resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Keytruda, Libtayo, Tecentriq, or Tecentriq Hybreza; **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 (5HT₃ RA), NK1 RA/5HT₃ RA Combination] (Akynzeo [palonosetron], Aloxi, Cinvanti, Emend [fosaprepitant], Focinvez, Granisetron, Ondansetron, Posfrea, Sustol)

HCPSC Code	Description
Preferred	
J1453	Injection, fosaprepitant, 1 mg
J1456	Injection, fosaprepitant (teva), not therapeutically equivalent to j1453, 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
Non-Preferred	
J0185	Injection, aprepitant, 1 mg

HCPCS Code	Description
Non-Preferred	
J1434	Injection, fosaprepitant (focinvez), 1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
J1627	Injection, granisetron, extended-release, 0.1mg
J2468	Injection, palonosetron hydrochloride (avyya), not therapeutically equivalent to j2469, 25 micrograms

Asthma Immunomodulators – Respiratory Interleukins (Cinqair, Fasenra, Nucala)

HCPCS Code	Description
Preferred	
J0517	Injection, benralizumab, 1 mg
J2182	Injection, mepolizumab, 1 mg
Non-Preferred	
J2786	Injection, reslizumab, 1 mg

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

HCPCS Code	Description
Preferred	
Q5107	Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Non-Preferred	
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg
J9035	Injection, bevacizumab, 10 mg
J9999	Not otherwise classified, antineoplastic drugs

Bone Density Agents – Oncology and Osteoporosis (Evenity, Jubbonti, Osenvelt, Prolia, Stoboclo, Wyost, Xgeva)

HCPCS Code	Description
Preferred	
Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
Q5157	Injection, denosumab-bmwo (Stoboclo/Osenvelt), biosimilar, 1 mg
Non-Preferred	
J0897	Injection, denosumab, 1 mg
J3111	Injection, romosozumab-aqqg, 1 mg

Colony Stimulating Factors

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

HCPCS Code	Description
Preferred	
Q5101	Injection, filgrastim-sndz, biosimilar, (Zarxio) 1 microgram
Non-Preferred	
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
Q5148	Injection, filgrastim-txid (Nypozi), biosimilar, 1 mcg

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

HCPCS Code	Description
Preferred	
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Q5108	Injection, pegfilgrastim-jmdb (Fulphila), biosimilar, 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg
Non-Preferred	
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J9361	Injection, efbemalenograstim alfa-vuxw, 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
Preferred	
J9196	Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to J9201, 200 mg
J9201	Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg
Non-Preferred	
J9198	Injection, gemcitabine hydrochloride, (Infugem), 100 mg

Gonadotropin Releasing Hormone Analogs for Oncology

HCPCS Code	Description
Preferred	
J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
Non-Preferred	
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg

Gout Agents (Krystexxa)

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

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

HCPCS Code	Description
Preferred	
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
Non-Preferred	
J7320	Hyaluronan or derivative, GenVisc 850, for intra-articular injection, 1 mg

HCPSC Code	Description
Non-Preferred	
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, Synjoynt, for intra-articular injection, 1mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1mg

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

HCPSC Code	Description
Preferred	
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIg), human, for use in subcutaneous infusions, 100 mg, each
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
Non-Preferred	
J1551	Injection, immune globulin (cutaquig), 100 mg
J1552	Injection, immune globulin (alyglo), 100 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg

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

HCPSC Code	Description
Preferred	
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10mg

HCPCS Code	Description
Non-Preferred	
J1745	Injection, infliximab, excludes biosimilar, 10 mg

Intravenous Iron Replacement Therapy [Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFeD, Injectafer, Monoferic, Venofer]

HCPCS Code	Description
Preferred	
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)
Non-Preferred	
J1437	Injection, ferric derisomaltose, 10 mg
J1439	Injection, ferric carboxymaltose, 1 mg

Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors (Re-Packaged Avastin, Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Pavblu, Susvimo, Vabysmo)

HCPCS Code	Description
Preferred	
C9257	Injection, bevacizumab (Avastin), 0.25mg
J0177	Injection, aflibercept hd, 1 mg
J0178	Injection, aflibercept, 1 mg
J7999	Compounded drug, not otherwise classified
J9035	Injection, bevacizumab (Avastin), 10mg
Q5147	Injection, aflibercept-ayyh (Pavblu), biosimilar, 1 mg
Non-Preferred	
J0179	Injection, brolucizumab-dbl, 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

Diagnosis Code	Description
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)

HCPSC Code	Description
Preferred	
J0640	Injection, leucovorin calcium, per 50 mg
Non-Preferred	
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (Khapzory), 0.5 mg

Lipid Modifying Agents (Leqvio)

HCPSC Code	Description
Preferred	
N/A	N/A
Non-Preferred	
J1306	Injection, inclisiran, 1 mg

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

HCPSC Code	Description
Preferred	
N/A	N/A
Non-Preferred	
J3032	Injection, eptinezumab-jjmr, 1 mg

Pemetrexed (Alimta, Axtle, Pemetrexed, Pemfexy, Pemrydi RTU)

HCPSC Code	Description
Preferred	
J9294	Injection, pemetrexed (hospira), not therapeutically equivalent to j9305, 10 mg
J9296	Injection, pemetrexed (accord), not therapeutically equivalent to j9305, 10 mg
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
J9305	Injection, pemetrexed, not otherwise specified, 10 mg
J9314	Injection, pemetrexed (teva), not therapeutically equivalent to j9305, 10 mg
Non-Preferred	
J9292	Injection, pemetrexed dipotassium, 10 mg
J9304	Injection, pemetrexed (pemfexy), 10 mg
J9324	Injection, pemetrexed (pemrydi rtu), 10 mg

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

HCPCS Code	Description
Preferred	
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
Non-Preferred	
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
Preferred	
J0490	Injection, belimumab, 10 mg
Non-Preferred	
J0491	Injection, anifrolumab-fnia, 1 mg

Tocilizumab (Actemra, Tofidence, Tyenne)

HCPCS Code	Description
Preferred	
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg
Non-Preferred	
J3262	Injection, tocilizumab, 1 mg

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

HCPCS Code	Description
Preferred	
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg
Non-Preferred	
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
Q5146	Injection, trastuzumab-strf (hercessi), biosimilar, 10 mg

Antineoplastic Monoclonal Antibodies (Head and Neck Cancers: Cancer of the Nasopharynx, Recurrent, Unresectable, Oligometastatic, or Metastatic Disease)

HCPCS Code	Description
Preferred	
J3263	Injection, toripalimab-tpzi, 1 mg
Non-Preferred	
J9271	Injection, pembrolizumab, 1 mg
J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy
J9299	Injection, nivolumab, 1 mg

HCPSC Code	Description
Non-Preferred	
J9329	Injection, tislelizumab-jsgr, 1mg

Antineoplastic Monoclonal Antibodies (Non-Small Cell Lung Cancer: Advanced or Metastatic, Monotherapy, PD-L1 expression positive $\geq 50\%$)

HCPSC Code	Description
Preferred	
J9022	Injection, atezolizumab, 10 mg
J9024	Injection, atezolizumab, 5 mg and hyaluronidase-tqjs
J9119	Injection, cemiplimab-rwlc, 1 mg
J9271	Injection, pembrolizumab, 1 mg
Non-Preferred	
J9228	Injection, ipilimumab, 1 mg
J9299	Injection, nivolumab, 1 mg

Background/Description of Services

Certain classes of medications 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.

Eight classes of medications (Bevacizumab, Colony Stimulating Factors, Denosumab, Infliximab, Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors, Rituximab, Tocilizumab, 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.

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Policy History/Revision Information

Date	Summary of Changes
10/01/2025	<p>Notice of Revision: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the amended updates to be applied on Oct. 1, 2025.</p> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of preferred drugs/products for: Bone Density Agents – Oncology <ul style="list-style-type: none"> Added: <ul style="list-style-type: none"> Jubbonti Osenvelt Stoboclo Wyost Removed: <ul style="list-style-type: none"> Alendronate Ibandronate Pamidronate Risedronate Zoledronic Acid Bone Density Agents – Osteoporosis <ul style="list-style-type: none"> Added: <ul style="list-style-type: none"> Jubbonti Stoboclo Removed: <ul style="list-style-type: none"> Alendronate [non-employer group Medicare Advantage Part D (MAPD) plans] Ibandronate [all Medicare Advantage (MA) plans] Pamidronate (all MA plans) Risedronate (non-employer group MADP plans) Zoledronic Acid (all MA plans) Revised list of non-preferred drugs/products for Colony Stimulating Factors: Long Acting; added Ryzneuta Added language to indicate Ryzneuta may be covered when any of the criteria listed below are satisfied: <ul style="list-style-type: none"> History of use of Fulphila, Neulasta, or Udenyca, resulting in minimal clinical response to therapy History of intolerance or adverse event(s) to Fulphila, Neulasta, or Udenyca Continuation of prior therapy within the past 365 days Revised step therapy coverage criteria for: Bone Density Agents – Oncology and Osteoporosis Xgeva Non-Preferred Product Step Therapy Criteria <ul style="list-style-type: none"> Replaced references to “an injectable bisphosphonate” with “Osenvelt or Wyost” Prolia Non-Preferred Product Step Therapy Criteria <ul style="list-style-type: none"> Replaced references to “an oral/injectable bisphosphonate” with “Jubbonti or Stoboclo” <p>Applicable Codes Bone Density Agents – Oncology and Osteoporosis</p> <ul style="list-style-type: none"> Added C9399, J3490, J3590, and Q5136 and Q5157 (preferred) Removed J1740, J2430, and J3489 (preferred)

Date	Summary of Changes
	<p><i>Colony Stimulating Factors: Long-Acting</i></p> <ul style="list-style-type: none"> Added J9361 (non-preferred) <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Background/Description of Services</i> section to reflect the most current information Archived previous policy version IAP.001.25

Instructions for Use

This Drug 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.