



Medicare Part B Step Therapy Programs

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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:

	an Exceptions below.
Plan Type	Excluded Plans
Non-Employer Group Medicare Advantage	 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: 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) Massachusetts: H9239-001 Ohio: H2531-001 Texas: H7833-001 UnitedHealthcare Senior Care Options in Massachusetts: H2226-001, H2226-003
Employer Group Medicare Advantage	 All Group HMO plans Select Group PPO plans: 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.

Olassis	Madiaal		
Classes of Benefit Inje		Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Antiemetics for Oncology [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
Asthma Immunoi Respiratory In		Fasenra	Cinqair, Nucala
Bevacizu	<u>ımab</u>	Alymsys, Mvasi, Zirabev	Avastin, Avzivi, Vegzelma
Bone Density Ager	nts – Oncology	Alendronate, Ibandronate, Pamidronate, Risedronate, Zoledronic Acid	Prolia, Xgeva
Bone Density Agents – Osteoporosis	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
Colony Stimulating <u>Factors</u>	Short Acting	Zarxio	Granix, Neupogen, Nivestym, Nypozi, Releuko
	Long Acting	Neulasta, Fulphila, Udenyca,	Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo
Gemcita	<u>bine</u>	Gemcitabine (J9196, J9201)	Infugem
Gonadotropin Rele Analogs for 0		J1954, J9217 (leuprolide acetate, 7.5mg)	J1950 (leuprolide acetate, 3.75mg)
Gout Agents	Non-Employer Group MAPD Plans only	Allopurinol, Febuxostat	Krystexxa
Hyaluronic Acid Polymers		Durolane, Gelsyn-3, Synvisc, Synvisc-One	Euflexxa, Gel-One, Genvisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Supartz Fx, Synojoynt, Triluron, TriVisc, Visco-3
Immune Globulins		Bivigam, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex- C, Hizentra, HyQvia, Octagam, Privigen, Xembify	Alyglo, Asceniv, Cutaquig, Panzyga

Classes o Benefit In		Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
<u>Infliximab</u>		Avsola, Inflectra, Renflexis	Infliximab, Remicade
Intravenous Iron Replacement Therapy		Feraheme (ferumoxytol), Ferrlecit (sodium ferric gluconate complex), INFeD, Venofer	Injectafer, Monoferric
Intravitreal Vasc Growth Factor (V Neovascular (W Macular De	EGF) Inhibitors – et) Age-Related	Re-packaged Avastin, then Eylea or Eylea HD or Pavblu	Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo
Intravitreal Vasc Growth Factor (V Retinal Condition Neovascular (W Macular De	EGF) Inhibitors – ons Other Than et) Age-Related	Eylea, Eylea HD, Pavblu	Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo
Leucovorin/Le	evoleucovorin evoleucovorin evoleucovorin evoleucovorin evoleucovorin evoleucovorin evoleucovorin evoleucovorin	Leucovorin	Fusilev, Khapzory, Levoleucovorin
<u>Lipid Modifying</u> <u>Agents</u>	Non-Employer Group MAPD plans only	Praluent, Repatha	Leqvio
Migraine Prophylaxis – Calcitonin Gene- Related Peptide (CGRP) Receptor Antagonists	Non-Employer Group MAPD plans only	Aimovig, Ajovy, Emgality	Vyepti
Pemetrexed		Alimta, generic Pemetrexed products (J9294, J9296, J9297, J9305, J9314)	Axtle, Pemfexy, Pemrydi RTU
<u>Rituximab</u>		Ruxience, Truxima	Riabni, Rituxan, Rituxan Hycela
Systemic Lupus Erythematosus Agents		Benlysta	Saphnelo
<u>Tocilizumab</u>		Tofidence, Tyenne	Actemra
Trastuzumab		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	Head and Neck Cancers: Recurrent, Unresectable, Oligometastatic, or Metastatic Disease, Nasopharyngeal	Loqtorzi	Keytruda, Opdivo
	Non-Small Cell Lung Cancer: Advanced or Metastatic, Monotherapy, PD-L1 expression positive ≥ 50%	Keytruda, Libtayo, Tecentriq	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,	Akynzeo, Cinvanti, Focinvez, Posfrea, Sustol
Ondansetron	•

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	Cinqair, Nucala

Non-Preferred Product Step Therapy Criteria

Cinqair or Nucala, 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 resulting in minimal clinical response to therapy; or
- History of intolerance or adverse event(s) to Fasenra; 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 (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:9

- 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:9

- 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, 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, Stimufend, Udenyca, Ziextenzo)

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

Non-Preferred Product Step Therapy Criteria

Fylnetra, Nyvepria, Rolvedon, 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 (J9196, 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 (J9196, J9201) resulting in minimal clinical response to therapy and residual disease activity; or
- History of intolerance or adverse event(s) to Gemcitabine (J9196, J9201); or
- Continuation of prior therapy within the past 365 days.

Gonadotropin Releasing Hormone Analogs for Oncology (Leuprolide Acetate)

-	_	_		-	
Preferred	Drug(s)/Product(s	s)	Non-Pref	ferred Drug(s)/Product(s)	
· ·	e acetate (cipla), per olide acetate, per 7.5	• ,	J1950 (leu	prolide acetate, per 3.75mg)	

Non-Preferred Product Step Therapy Criteria

J1950 (leuprolide acetate, per 3.75mq) 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 (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, Cutaguig, 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, 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 (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	Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo
Eylea or Eylea HD or Pavblu	

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:
 - o Eylea
 - o Eylea HD
 - o 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 <u>other than</u> 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

Fusiley, 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 (J9294, J9296, J9297, J9305, 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)/P	roduct(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: Recurrent, Unresectable, Oligometastatic, or Metastatic Disease, Nasopharyngeal

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

Non-Preferred Product Step Therapy Criteria

Keytruda or Opdivo, 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 ≥ 50%

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Keytruda, Libtayo, Tecentriq	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, or Tecentriq resulting in minimal clinical response to therapy and residual disease activity; **or**
- History of intolerance or adverse event(s) to Keytruda, Libtayo, or Tecentriq; 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)

HCPCS 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
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 (avyxa), not therapeutically equivalent to j2469, 25 micrograms

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

HCPCS Code	Description
Preferred	
J0517	Injection, benralizumab, 1 mg
Non-Preferred	
J2182	Injection, mepolizumab, 1 mg
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, Ibandronate, Pamidronate, Prolia, Xgeva, Zoledronic Acid)

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HCPCS Code	Description	
Preferred		
J1740	Injection, ibandronate sodium, 1 mg	
J2430	Injection, pamidronate disodium, per 30 mg	
J3489	Injection, zoledronic acid, 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, Stimufend, Udenyca, Ziextenzo)

Zicktenzo)	
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
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

HCPCS Code	Description
Non-Preferred	
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg

Gemcitabine (Gemcitabine, Infugem)

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

HCPCS Code	Description
Preferred	
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SClg), 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)

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

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

HCPCS Code	Description
Non-Preferred	
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-dbll, 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)

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HCPCS Code		Description	
Preferred			
J0640	Injection, leucovorin calcium, per 50 mg		

HCPCS Code	Description
Non-Preferred	
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (Khapzory), 0.5 mg

Lipid Modifying Agents (Leqvio)

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

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

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

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

HCPCS 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 (avyxa), not therapeutically equivalent to j9305, 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

HCPCS Code	Description
Non-Preferred	
J0491	Injection, anifrolumab-fnia, 1 mg

Tocilizumab (Actemra, Tofidence, Tyenne)

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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: Recurrent, Unresectable, Oligometastatic, or Metastatic Disease, Nasopharyngeal)

HCPCS Code	Description
Preferred	
J3263	Injection, toripalimab-tpzi, 1 mg
Non-Preferred	
J9271	Injection, pembrolizumab, 1 mg
J9299	Injection, nivolumab, 1 mg

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

HCPCS Code	Description	
Preferred		
J9022	Injection, atezolizumab, 10 mg	
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 <u>Plan Exceptions</u> table.

Seven classes of medications (Bevacizumab, Colony Stimulating Factors, 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.

<u>References</u>

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- 7. https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses.
- 8. For CMS Memorandum titled *Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage*, dated August 7, 2018; see: https://www.cms.gov/Medicare/Health-Plans/Health-PlansGenInfo/Downloads/MA Step Therapy HPMS Memo 8 7 2018.pdf.
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Policy History/Revision Information

Date	Summary of Changes
04/01/2025	Applicable Codes
	 Updated list of applicable HCPCS codes to reflect quarterly edits for:
	Colony Stimulating Factors: Short-Acting
	 Replaced C9173, J3490, and J3590 with Q5148
	Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors
	o Replaced J3490 and J3590 with Q5147

Date	Summary of Changes
	Supporting Information
	 Archived previous policy version IAP.001.22

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.