Medicare Part B Step Therapy Programs

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Instructions for Use

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Medicare Advantage Coverage Summary

- 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	• 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:
	  ○ Arizona: H0321-004
	  ○ District of Columbia: H2228-045, H2406-053, H2406-099, H7464-010
	  ○ Florida: H2509-001
	  ○ Minnesota: H0845-001, H7778-001, H7778-002
	  ○ New Jersey: H3113-005
	  ○ New York: H3387-013
	  ○ Tennessee: H0251-004
	  ○ Virginia: H7464-005, H7464-007
	• 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: H2001-870
	  ○ U.S. Government of the Virgin Islands (USGVI): 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 following drugs/products:

Classes of Medical Benefit Injectables		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, Sustol
Bevacizumab		Mvasi, Zirabev	Alymsys, Avastin, Vegzelma
Bone Density Agents – 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 Factors	Short Acting	Zarxio	Granix, Neupogen, Nivestym, Releuko
	Long Acting	Neulasta, Udenyca,	Fulphila, Fylnetra, Nyvepria, Rolvedon, Stimufend, Ziextenzo
Gemcitabine		Gemcitabine	Infugem
Gonadotropin Releasing Hormone Analogs for Oncology		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
Infliximab		Avsola, Inflectra, Renflexis	Infliximab, Remicade, Zymfentra
Intravenous Iron Replacement Therapy		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)
Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Neovascular (Wet) Age-Related Macular Degeneration		Compounded Avastin, then Eylea	Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo
Intravitreal Vascular Endothelial Growth Factor (VEGF) Inhibitors – Retinal Conditions Other Than Neovascular (Wet) Age-Related Macular Degeneration		Eylea	Beovu, Byooviz, Cimerli, Eylea HD, Lucentis, Susvimo, Vabysmo
Leucovorin/Levoleucovorin		Leucovorin	Fusilev, Khapzory, Levoleucovorin
Lipid Modifying Agents	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
Rituximab		Ruxience, Truxima	Riabni, Rituxan, Rituxan Hycela
Systemic Lupus Erythematosus Agents		Benlysta	Saphnelo
Trastuzumab		Kanjinti, Ogivri,Trazimera	Herceptin, Herceptin Hylecta, Herzuma, 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 (5HT3 RA), NK1 RA/5HT3 RA Combination] (Akynzeo, Aloxi [palonosetron], Cinvanti, Emend [fosaprepitant], Granisetron, Ondansetron, Sustol)

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
Aloxi (palonosetron), Emend (fosaprepitant), 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 (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.

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:[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, Releuko, Zarxio)

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

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

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

Preferred Drug(s)/Product(s)	Non-Preferred Drug(s)/Product(s)
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 (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, Zymfentra)

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

Non-Preferred Product Step Therapy Criteria

Infliximab, Remicade, or Zymfentra 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 (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, Ogivri, Trazimera	Herceptin, Herceptin Hylecta, Herzuma, Ontruzant

Non-Preferred Product Step Therapy Criteria

Herceptin, Herceptin Hylecta, 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.

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], Granisetron, Ondansetron, Sustol)

HCPCS Code	Description
Preferred	
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

HCPCS Code	Description
Preferred	
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
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
Preferred	
Q5107	Injection, bevacizumab-awwb, biosimilar, (Mvasi), 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg
Non-Preferred	
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
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, 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

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

HCPCS Code	Description
Preferred	
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg

HCPCS Code	Description
Non-Preferred	
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
Preferred	
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	
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

HCPCS Code	Description
Non-Preferred	
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
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
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
J1748	Injection, infliximab-dyyb (Zymfentra), 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

HCPCS Code	Description
Preferred	
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 (Compounded Avastin, Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Susvimo, Vabysmo)

HCPCS Code	Description
Preferred	
C9257	Injection, bevacizumab (Avastin), 0.25mg
J0178	Injection, aflibercept, 1 mg
J7999	Compounded drug, not otherwise classified
J9035	Injection, bevacizumab (Avastin), 10mg
Non-Preferred	
J0177	Injection, aflibercept HD, 1 mg
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)

HCPCS 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)

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

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

Trastuzumab (Herceptin, Herceptin Hylecta, 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

HCPCS Code	Description
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

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.

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Policy History/Revision Information

Date	Summary of Changes
07/08/2024	• Changed policy type classification from “Medical Benefit Injectable/Drug Policy” to “Drug Policy” (no change to guidelines)
07/01/2024	**Coverage Rationale** • Revised list of applicable drug products for: ***Immune Globulins*** ○ Added Alyglo (non-preferred) ***Infliximab*** ○ Added Zymfentra (non-preferred) ○ Changed Renflexis from non-preferred to preferred ***Trastuzumab*** ○ Changed Ogivri from non-preferred to preferred **Applicable Codes** ***Immune Globulins*** • Changed HCPCS codes J1599 from preferred to non-preferred ***Infliximab*** • Added HCPCS code J1748 (non-preferred) • Changed HCPCS code Q5104 from non-preferred to preferred ***Trastuzumab*** • Changed HCPCS code Q5114 from non-preferred to preferred **Supporting Information** • Archived previous policy version IAP.001.19

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.