



EVH Clinical Guideline 5094.CC for Medical Drug Step Therapy

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the step therapy process for the following drugs:

- 5HT3 Receptor Antagonists – Palonosetron, Posfrea (palonosetron)
- Bevacizumab Products (oncology only) – Alymsys (bevacizumab-maly), Mvasi (bevacizumab-awwb), Vegzelma (bevacizumab-adcd) and Zirabev (bevacizumab-bvzr)
- Calcimimetics – Parsabiv (etelcalcetide)
- Epoetin Products – Aranesp (darbepoetin alfa), Mircera (epoetin beta), and Retacrit (epoetin alfa-epbx)
- Folic Acid Analogs – Khapzory (levoleucovorin, J0642)
- Hypomethylating Agents - Inqovi (decitabine and cedazurudine)
- Intravenous Iron Products – Ferrlecit (sodium ferric gluconate), Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose)
- Leukocyte Growth Factors – Fulphila (pegfilgrastim-jmdb), Fylnetra (pegfilgrastim-pbbk), Neulasta (pegfilgrastim), Nyvepria (pegfilgrastim-apgf), Stimufend (pegfilgrastim-fpgk), Udenyca/Udenyca Onbody (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez)
- mTOR Products – Fyarro (sirolimus protein bound particles, J9331)
- NK1 Receptor Antagonists – Aponvi (aprepitant IV), Cinvanti (aprepitant IV), Focinvez (fosaprepitant IV), and Fosaprepitant IV
- Osteoporosis Products – Evenity (romosozumab) and Prolia (denosumab)
- Pemetrexed Products – Pemfexy (pemetrexed, J9304)
- Siklos (hydroxyurea)
- Trastuzumab Products – Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), Ontruzant (trastuzumab-dttb), Trazimera (trastuzumab-qyyp), Kanjinti (trastuzumab-anns), and Herceptin Hylecta (trastuzumab-hyaluronidase-oysk)

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Requests for the products in the table below are subject to the preferred medical drug list program. This program applies to the products specified in this guideline. The program applies to indications that are FDA-approved for the preferred product and to indications that are off-label, as clinically appropriate. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product. The coverage review process will ascertain situations where a clinical exception can be made.

Preferred Drugs	Non-Preferred Drugs
5-HT3 Receptor Antagonists	
Ondansetron (IV, Oral)	Palonosetron (J2469) Posfrea (palonosetron, J2468)
Bevacizumab Products (ONCOLOGY ONLY)	
Mvasi (bevacizumab-awwb, Q5107) Zirabev (bevacizumab-bvzr, Q5118)	Alymsys (bevacizumab-maly, Q5126) Avastin (bevacizumab, J9035) Vegzelma (bevacizumab-adcd, Q5129)
Calcimimetics	
Cinacalcet (Oral)	Parsabiv (etelcalcetide, J0606)
Epoetin Products	
Epogen (epoetin alfa, J0885, Q4081) Procrit (epoetin alfa, J0885, Q4081)	Aranesp (darbepoetin alfa, J0881, J0882) Mircera (epoetin beta, J0887, J0888) Retacrit (epoetin alfa-epbx, Q5105, Q5106)
Folic Acid Analogs	
Leucovorin (J0640) Levoleucovorin (J0641)	Khapzory (levoleucovorin, J0642)

Preferred Drugs	Non-Preferred Drugs
Hypomethylating Agents	
Vidaza (azacitidine, J9025) Dacogen (decitabine, J0894)	Inqovi (decitabine and cedazurudine)
Hydroxyurea Products	
Generic hydroxyurea Droxia (adults ONLY)	Siklos (hydroxyurea, S0176)
Iron Products	
Infed (iron dextran, J1750)* Venofer (iron sucrose, J1756)*	Ferrlecit (sodium ferric gluconate, J2916) Feraheme (ferumoxytol, Q0138) Injectafer (ferric carboxymaltose, J1439) Monoferric (ferric derisomaltose, J1437)
Leukocyte Growth Factors	
Fulphila (pegfilgrastim-jmdb, Q5108) Udenyca (pegfilgrastim-cbqv, Q5111) Udenyca Onbody (pegfilgrastim-cbqv, Q5111)	Fylnetra (pegfilgrastim-pbbk, Q5130) Neulasta (pegfilgrastim, J2506) Neulasta Onpro (pegfilgrastim, J2506) Nyvepria (pegfilgrastim-apgf, Q5122) Stimufend (pegfilgrastim-fpgk, Q5127) Ziextenzo (pegfilgrastim-bmez, Q5120)
mTOR Inhibitors	
Generic sirolimus (oral)	Fyarro (sirolimus protein bound particles, J9331)
NK1 Receptor Antagonists	
Aprepitant (Oral)	Aponvi (aprepitant IV, C9145) Cinvanti (aprepitant IV, J0185) Focinvez (fosaprepitant IV, J1434) Fosaprepitant (IV, J1453, J1456)
Osteoporosis Products	

Preferred Drugs	Non-Preferred Drugs
Zoledronic Acid (J3489)*	Prolia (denosumab, J0897) Jubbonti (denosumab-bbdz, Q5136) Evenity (romosozumab, J3111)
Pemetrexed Products	
Pemetrexed disodium (J9292, J9294, J9296, J9297, J9305, J9314, J9322) Pemetrexed ditromethamine (J9323)	Pemfexy (pemetrexed, J9304)
Trastuzumab Products	
Ogivri (trastuzumab-dkst, Q5114) Trazimera (trastuzumab-qyyp, Q5116)	Herceptin (trastuzumab, J9355) Herceptin Hylecta (trastuzumab-hyaluronidase-oysk, J9356) Herzuma (trastuzumab-pkrb, Q5113) Kanjinti (trastuzumab-anns, Q5117) Ontruzant (trastuzumab-dttb, Q5112)

*No PA required when OOS for Evolent Specialty Services (formerly NCH)

INITIAL REVIEW CRITERIA

Must meet all the criteria listed below:

- Must be used for an FDA-approved or compendia supported use
- *FDA-approved indications ONLY*: Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA-approved labeling
- Must be used consistently with the manufacturer’s prescribing information (e.g., contraindications, limitations, recommended labs prior to initiation)
- Must have failed, is intolerant to, OR have a contraindication to at least TWO preferred products within the same category as the requested drug in the **Preferred Product Table** above

REAUTHORIZATION REVIEW CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based on the following:

- Must have chart documentation from the prescriber that the member's condition has improved based on the prescriber's assessment while on therapy
- *FDA-approved indications ONLY*: Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA-approved labeling
- *For non-preferred products with preferred biosimilars ONLY*: Must have failed, is intolerant to, OR have a contraindication to at least TWO preferred products within the same category as the requested drug in the **Preferred Product Table** above

APPROVAL DURATIONS

If the above criteria are met, the request will be approved for up to the duration of time specified below:

Initial Authorization	Up to 1 year
Reauthorization	Up to 1 year <ul style="list-style-type: none"> • Evenity (romosozumab) is not eligible for authorization beyond 12 months of therapy

CODING AND STANDARDS

Codes

Code	Brand	Description
C9145	Aponvi	Injection, aprepitant, (aponvie), 1 mg
J0185	Cinvanti	Injection, aprepitant, 1 mg
J0606	Parsabiv	Injection, etelcalcetide, 0.1 mg
J0642	Khapzory	Injection, levoleucovorin (khapsory), 0.5 mg
J0881	Aranesp	Injection, darbepoetin alfa, 1 microgram (non-esrd use)
J0882	Aranesp	Injection, darbepoetin alfa, 1 microgram (for esrd on dialysis)

Code	Brand	Description
J0887	Mircera	Injection, epoetin beta, 1 microgram, (for esrd on dialysis)
J0888	Mircera	Injection, epoetin beta, 1 microgram, (for non esrd use)
J1434	Focinvez	Injection, fosaprepitant (focinvez), 1 mg
J1437	Monoferric	Injection, ferric derisomaltose, 10mg
J1439	Injectafer	Injection, ferric carboxymaltose, 1 mg
J1453	Emend	Injection, fosaprepitant, 1 mg
J1456	Emend	Injection, fosaprepitant (teva), not therapeutically equivalent to J1453, 1 mg
J2506	Neulasta	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
J2916	Ferrlecit	Injection, sodium ferric gluconate complex in sucrose injection, 12.5mg
J3490	Inqovi	decitabine and cedazurudine
J9304	Pemfexy	Injection, pemetrexed (pemfexy), 10 mg
J9331	Fyarro	Injection, sirolimus protein-bound particles, 1 mg
J9356	Herceptin Hylecta	Injection, trastuzumab, 10 mg and hyaluronidase-oysk
Q0138	Feraheme	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-esrd use)
Q5105	Retacrit	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for esrd on dialysis), 100 units
Q5106	Retacrit	Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for non-esrd use), 1000 units
Q5107	Mvasi	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
Q5108	Fulphila	Injection, pegfilgrastim-jmdb, biosimilar, 0.5 mg
Q5111	Udenyca Udenyca Onbody	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar, 0.5 mg

Code	Brand	Description
Q5112	Ontruzant	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg
Q5113	Herzuma	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg
Q5114	Ogivri	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg
Q5116	Trazimera	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Q5117	Kanjinti	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg
Q5118	Zirabev	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg
Q5120	Ziextenzo	Injection, pegfilgrastim-bmez (Ziextenzo), biosimilar, 0.5 mg
Q5122	Nyvepria	Injection, pegfilgrastim-apgf (Nyvepria), biosimilar, 0.5 mg
Q5126	Alymys	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg
Q5127	Stimufend	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5129	Vegzelma	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
Q5130	Fylnetra	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg
S0176	Siklos	Hydroxyurea, oral, 500 mg

APPLICABLE LINES OF BUSINESS

<input type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input type="checkbox"/>	Commercial
<input type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input type="checkbox"/>	Medicare Advantage

POLICY HISTORY

Date	Summary
March 2026	<ul style="list-style-type: none"> • Added preferred/non-preferred product category of leukocyte growth factors • Updated the preferred/non-preferred products for bevacizumab and trastuzumab products
March 2025	<ul style="list-style-type: none"> • Added preferred/non-preferred product categories for the following: 5HT3 receptor antagonists, bevacizumab products (oncology only), calcimimetics, epoetin products, folic acid analogs, hypomethylating agents, mTOR inhibitors, NK1 receptor antagonists, pemetrexed products, and trastuzumab products
October 2024	<ul style="list-style-type: none"> • Addition of Evenity and Prolia
April 2024	<ul style="list-style-type: none"> • New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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16. Khapzory (levoleucovorin) [prescribing information]. East Windsor, NJ: Acrotech Biopharma Inc; June 2023.
17. Inqovi (decitabine and cedazuridine) [prescribing information]. Princeton, NJ: Taiho Oncology Inc; July 2020.
18. Fyarro (sirolimus [protein bound]) [prescribing information]. Pacific Palisades, CA: Aadi Bioscience Inc; October 2024.
19. Cinvanti (aprepitant) injection [prescribing information]. San Diego, CA: Heron Therapeutics Inc; March 2024.
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26. Herzuma (trastuzumab-pkrb) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; December 2024
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29. Kanjinti (trastuzumab-anns) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2024.
30. Herceptin Hylecta (trastuzumab and hyaluronidase) [prescribing information]. South San Francisco, CA: Genentech, Inc; June 2024.
31. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Cambridge, MA: Biocon Biologics Inc; June 2023.
32. Fylnetra (pegfilgrastim-pbbk) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals Inc; April 2025.
33. Neulasta (pegfilgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc; August 2025.
34. Nyvepria (pegfilgrastim) [prescribing information]. Lake Forest, IL: Hospira Inc; March 2023.
35. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA LLC; October 2025.
36. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Raleigh, NC: Accord BioPharma Inc; July 2025.
37. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc; February 2024.