blue california
Promise Health Plan

pegfilgrastim

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

pegfilgrastim (Neulasta)
pegfilgrastim-apgf (Nyvepria)
pegfilgrastim-bmez (Ziextenzo)
pegfilgrastim-cbqv (Udenyca)
pegfilgrastim-fpgk (Stimufend)
pegfilgrastim-jmdb (Fulphila)
pegfilgrastim-pbbk (Fylnetra)

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration
Self-Administration

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: colony stimulating factor
HCPCS:
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
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
How Supplied:
Neulasta

- 6 mg per 0.6 mL single-dose prefilled syringe
- 6 mg/0.6 mL solution in a single-dose prefilled syringe with On-body Injector.

Udenyca

- 6 mg per 0.6 mL single-dose prefilled syringe or autoinjector.
- 6 mg/0.6 mL solution in a single-dose prefilled syringe with On-body Injector.

Fulphila, Fylnetra, Nyvepria, Stimufend, Ziextenzo

- 6 mg/0.6 mL single-dose prefilled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Acute Exposure to Myelosuppressive Doses of Radiation
- Bone Marrow Transplantation (BMT)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca and Ziextenzo are the preferred pegfilgrastim products. Request for Neulasta for members newly initiating pegfilgrastim therapy will require treatment failure or intolerance to all the preferred drugs or contraindication to all the preferred drugs for certain indications.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Acute Exposure to Myelosuppressive Doses of Radiation
Meets medical necessity if all the following are met:

Covered Doses:
Up to 6 mg given subcutaneously for two doses, given one week apart

Coverage Period:
1 month

ICD-10:
T66.X (X = any number)

Bone Marrow Transplantation (BMT)
Meets medical necessity if all the following are met:

1. For Neulasta: Intolerance or contraindication with the preferred pegfilgrastim products (Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca and Ziextenzo) that is not expected with Neulasta

Covered Doses:
Up to 6 mg given subcutaneously for one dose on Day 1 following transplant

Coverage Period:
One dose

ICD-10:
Z48.290, Z52.011, Z94.81, Z94.84, or CPT codes: 38240, 38241

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Fulphila (pegfilgrastim-jmdb) Prescribing Information. Biocon Biologics Inc., Cambridge, MA: 6/2023.
4. Fylnetra (pegfilgrastim-pbbk) Prescribing Information. Amneal Pharmaceuticals LLC., Bridgewater, NJ: 5/2022.
5. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation, (Version 2.2025). Available at http://www.nccn.org.
6. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2025). Available at http://www.nccn.org.
7. Neulasta (pegfilgrastim) Prescribing Information. Amgen, Inc., Thousand Oaks, CA: 2/2021.
8. Nyvepria (pegfilgrastim-apgf) Prescribing Information. Pfizer Inc., New York, NY: 3/2023.
9. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the Use of WBC Growth Factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015;33(28):3199-3212.
10. Stimufend (pegfilgrastim-fpgk) Prescribing Information. Fresenius Kabi USA, LLC., Lake Zurich, IL: 9/2023.
11. Udenyca (pegfilgrastim-cbqv) Prescribing Information. Coherus BioSciences, Inc., Redwood City, CA: 12/2023.
12. Ziextenzo (Pegfilgrastim-bmez) Prescribing Information. Princeton, NJ: Sandoz Inc.; 3/2021.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee