pegfilgrastim

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

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
- Hematopoietic Cell Transplantation (Bone Marrow Transplantation)
- Non-Myeloid Malignancies Receiving Myelosuppressive Anti-Cancer Drugs Associated with a Clinically Significant Incidence of Febrile Neutropenia.

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

For members enrolled in our Blue Shield Select (PPO) and Blue Shield Medicare (PPO) plans:
Fulphila, Fylnetra, Neulasta, Stimufend, and Ziextenzo requires step therapy. Step therapy requires you to try other drugs first before a drug can be covered. The BSC preferred step drugs are Nyvepria and Udenyca. Both of these drugs will need to be tried for members newly initiating Fulphila, Fylnetra, Neulasta, Stimufend, or Ziextenzo therapy.

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:
1. Diagnosis only

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

Coverage Period:
Duration for two doses

ICD-10:
T66.XXXA, T66.XXXD, T66.XXXS

Hematopoietic Cell Transplantation (Bone Marrow Transplantation)
Meets medical necessity if all the following are met:
1. For PPO request for Fulphila, Fylnetra, Neulasta, Stimufend, or Ziextenzo: Intolerance or contraindication with the preferred pegfilgrastim drugs (Nyvepria and Udenyca) that is not expected with requested pegfilgrastim drug

Covered Doses:
6 mg given subcutaneously for one day on Day 1 following transplant

Coverage Period:
One day

CPT:
38240, 38241

ICD-10:
Z48.290, Z52.011, Z94.81, Z94.84

Non-Myeloid Malignancies Receiving Myelosuppressive Anti-Cancer Drugs Associated with a Clinically Significant Incidence of Febrile Neutropenia.
Meets medical necessity if all the following are met:
1. Administered while patient is receiving myelosuppressive chemotherapy medications
2. Administered every 14 days or more

3. Not being used concurrently with long-acting or short-acting granulocyte colony stimulating factors (e.g., filgrastim or pegfilgrastim drugs)
4. For PPO request for Fulphila, Fylnetra, Neulasta, Stimufend, or Ziextenzo: Intolerance or contraindication with the preferred pegfilgrastim drugs (Nyvepria and Udenyca) that is not expected with requested pegfilgrastim drug

Covered Doses:
6 mg given subcutaneously once per chemotherapy cycle

Coverage Period:
Length of chemotherapy

ICD-10:
C00.0-C91.91, D00.00-D49.9

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Fulphila, Fylnetra, Neulasta, Nyvepria, Stimufend, Udenyca and Ziextenzo
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
   c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
   d. Lexi-Drugs – "Use: Off-Label" and rated as "Evidence Level A" (cancer indications only)
   e. Clinical Pharmacology - supportive narrative text (cancer indications only)
3. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections
4. NCCN Guidelines: Hematopoietic Growth Factors; Hematopoietic Stem Cell Transplantation
5. Guideline: American Society of Clinical Oncology (ASCO) Recommendations for the Use of WBC Growth Factors

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Fulphila, Fylnetra, Neulasta, Nyvepria, Stimufend, Udenyca and Ziextenzo are covered in addition to the following:

- Hematopoietic cell transplantation

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Support for using biosimilars as step requirement is found in Noridian Health Care Solutions and supported by the FDA. Noridian will accept a biosimilar drug on the same criteria as the drug to which it is a biosimilar unless an article is published to the contrary. Per the FDA, a biosimilar is highly similar to and has no clinically meaningful difference from an existing FDA approved biologic reference drug.

- Support for using biosimilars in oncology can be found in The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) via the footnote on the reference product (an FDA-approved biosimilar is an appropriate substitute) and in the NCCN Drugs & Biologics Compendium® by the notation that a biosimilar agent may be an appropriate substitute for the reference product.
- NCCN Clinical Practice Guidelines in Oncology for the use of hematopoietic growth factors support use of pegfilgrastim: 1) as prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in patients at risk of febrile neutropenia with solid tumors and non-myeloid malignancies who are receiving treatment in the curative/adjuvant or palliative settings; and 2) for treatment for patients with radiation-induced myelosuppression following a radiologic/nuclear incident (hematopoietic acute radiation syndrome [H-ARS])
- Support for using pegfilgrastim for hematopoietic cell transplant is found in DrugDex and guidelines from American Society of Clinical Oncology (ASCO) and NCCN.
    - DrugDex supports use of pegfilgrastim as effective in peripheral stem cell mobilization in patients undergoing autologous stem cell transplant.
    - Guidelines from the American Society of Clinical Oncology recommend the use of colony-stimulating factors following autologous hematopoietic cell transplantation to reduce the duration of severe neutropenia.
    - NCCN Clinical Practice Guidelines in Oncology for hematopoietic stem cell transplantation support use of pegfilgrastim as treatment for hematopoietic cell mobilization for autologous donors in combination with plerixafor.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. AHFS. Available by subscription at http://www.lexi.com
5. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
6. Fulphila (pegfilgrastim-jmdb) Prescribing Information. Biocon Biologics Inc., Cambridge, MA: 6/2023.
7. Fylnetra (pegfilgrastim-pbbk) Prescribing Information. Amneal Pharmaceuticals LLC., Bridgewater, NJ: 5/2022.
8. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2025). Available at http://www.nccn.org.
   National Comprehensive Cancer Network. Hematopoietic Cell Transplantation, (Version 2.2024). Available at http://www.nccn.org.
9. Neulasta® (pegfilgrastim) [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; 2/2021.
10. Nyvepria (pegfilgrastim-apgf) Prescribing Information. Pfizer Inc., New York, NY: 3/2023.
11. 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.
12. Stimufend (pegfilgrastim-fpgk) Prescribing Information. Fresenius Kabi USA, LLC., Lake Zurich, IL: 9/2023.

13. Udenyca® (pegfilgrastim-cbqv) [Prescribing Information]. Redwood City, CA: Coherus BioSciences, Inc.; 6/2021
14. Ziextenzo (Pegfilgrastim-bmez) Prescribing Information. Princeton, NJ: Sandoz Inc.; 3/2021.

Review History

Date of Last Annual Review: 4Q2024
Changes from previous policy version:

- Update preferred step drugs from Neulasta and Udenyca to Nyvepria and Udenyca for 1/1/2025

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