Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Pegfilgrastim Products**

Effective: October 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Pegfilgrastim is indicated to decrease the incidence of infection, as manifested by FN, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of FN. Neulasta (pegfilgrastim) is also indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation. Neulasta (pegfilgrastim) is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Armlupeg (pegfilgrastim-unne), Fulphila (pegfilgrastim-jmdb), Fylnetra (pegfilgrastim-pbbk), Udenyca (pegfilgrastim-cbqv), Nyvepria (pegfilgrastim-apgf), Ziextenzo (pegfilgrastim-bmez), and Stimufend (pegfilgrastim-fpgk) are biosimilars to Neulasta (pegfilgrastim) indicated to decrease the incidence of infection, as manifested by FN, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of FN. These agents are not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. A biosimilar is a biological product (developed from living cells) developed to be similar to an already FDA-approved biologic (or reference product). A biosimilar may have different indications than the reference product. A biosimilar is not an exact duplicate of the reference product; therefore, not considered a generic product. However, there are no clinically meaningful differences between a biosimilar and reference product in terms of safety and efficacy.

Neulasta and Fulphila are the preferred Pegfilgrastim Products and are covered without prior authorization

Clinical Guideline Coverage Criteria

The plan may authorize coverage of a Pegfilgrastim Product for Members when **ALL** of the following criteria are met:

Hematopoietic Subsyndrome of Acute Radiation Syndrome

1. Documentation the requested use is for hematopoietic subsyndrome of acute radiation syndrome

AND

2. Documented previous failure, contraindication, or clinical inappropriateness with Neulasta and Fulphila

Prophylaxis of Chemotherapy-induced Neutropenia

1. Documented diagnosis of solid tumor or non-myeloid malignancy in a patient receiving myelosuppressive chemotherapy

AND

2. Documentation of **one (1)** of the following:
    a. The patient will be receiving a chemotherapy regimen associated with a high risk (>20%) of febrile neutropenia based on National Comprehensive Cancer Network clinical guidelines for myeloid growth factors
    b. The patient will be receiving a chemotherapy regimen associated with an intermediate risk (10 to 20%) of febrile neutropenia based on National Comprehensive Cancer Network clinical guidelines for myeloid growth factors AND the patient has at least one of the following risk factors:
        i. Age ≥65 years
        ii. Active infections, open wounds, or recent surgery
        iii. Advanced disease (stage 2 or higher or bone marrow involvement)

iv. Prior chemotherapy or radiation therapy
v. Pre-existing neutropenia
vi. Poor performance status (Eastern Cooperative Oncology Group [ECOG] score of 2 to 5) or poor nutritional status
vii. Comorbidities (cardiovascular disease, renal dysfunction [creatinine clearance <50], liver dysfunction [bilirubin >2.0], human immunodeficiency virus [HIV] virus)
viii. Concern with Member's comprehension of the severity of fever development or concern with Member's access to a hospital if fever developed
ix. Chronic immunosuppression in the post-transplant setting

c. The patient is receiving dose-dense myelosuppressive chemotherapy
d. The patient has experienced a neutropenic complication (e.g., febrile neutropenia, dose-limiting neutropenic event) from a prior cycle of the same chemotherapy

AND

3. Documented previous failure, contraindication, or clinical inappropriateness with Neulasta and Fulphila

Limitations

1. Authorizations of all Pegfilgrastim Products will be provided for six (6) months.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Armlupeg (pegfilgrastim-unne) injection [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc.; July 2026. Accessed September 29, 2026. DailyMed.
2. Barnes G, Pathak A, Schwartzberg L. G-CSF utilization rate and prescribing patterns in United States: associations between physician and patient factors and GCSF use. Cancer Medicine. 2014;3(6):1477-84.
3. Fylnetra (pegfilgrastim-pbbk) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2022.
4. Goodman LM, Moeller MB, Azzouqa AG, et al. Reduction of inappropriate prophylactic pegylated granulocyte colony-stimulating factor use for patients with non-small-cell lung cancer who receive chemotherapy: An ASCO quality training program project of the Cleveland Clinic Taussig Cancer Institute. American Society of Clinical Oncology. 2016 Jan;12(1):e101-7.
5. Lyman GH, Abella E, Pettengell R. Risk factors for febrile neutropenia among patients with cancer receiving chemotherapy: a systematic review. Crit Rev Oncol Hematol. 2014;90:190-9.
6. National Comprehensive Cancer Network. Myeloid Growth Factors. Version 1.2020-November 15, 2019. URL: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Available from Internet. Accessed 2019 December 27.
7. Nyvepria (pegfilgrastim-apgf) [prescribing information]. Lake Forest, IL: Hospira, Inc.; June 2020.
8. Pegfilgrastim. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. 2010. Available from Wolters Kluwer Health, Inc. Accessed May 1, 2017.
9. Pettengell R, Bosly A, Szucs TD, et al. Multivariate analysis of febrile neutropenia occurrence in patients with non-Hodgkin lymphoma: data from the INC-EU prospective observational European neutropenia study. British Journal of Haematology. 2008;144:677-85.
10. Potosky AL, Malin JL, Kim B, et al. Use of colony stimulating factors with chemotherapy: opportunities for cost savings and improved outcomes. J Natl Cancer Inst. 2011;103:979-82.
11. Ramsey SD, McCune JS, Blough DK, et al. Colony-stimulating factor prescribing patterns in patients receiving chemotherapy for cancer. Am J Manag Care. 2010;16:678-86.
12. 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;33:3199-212.
13. Smith TJ, Khatcheressain J, Lyman GH, et al. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. J Clin Oncol. 2006;24:3187-205.
14. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; Sep 2022.
15. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, CA: Coherus Biosciences: November 2018.
16. Waters GE, Corrigan P, Gatesman M, et al. Comparison of pegfilgrastim prescribing practice to national guidelines at a university hospital outpatient oncology clinic. Journal of Oncology Practice. 2013 Jul;9(4):203-6.
17. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc.; November 2019.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 14, 2023: Added Stimufend to the Medical Necessity Guideline (effective March 1, 2023).
2. February 13, 2024: No changes
3. January 14, 2025: No changes (eff 1/14/25)
4. July 8, 2025: Removed Neulasta and Fulphila from the Medical Necessity Guideline as prior authorization is no longer required. Administrative update to remove Tufts Health Plan Commercial products (including CareLink) from the Medical Necessity Guideline template. (eff 8/1/25).
5. August 2026 E-Vote: No changes
6. September 2026 E-Vote: Effective 10/1/26, Simplified name of MNG to “Pegfilgrstim Products” and added Armlupeg to the list of non-preferred products requiring PA.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.