Pharmacy Medical Necessity Guidelines: Pegfilgrastim Products

Effective: November 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Neulasta (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.

COVERAGE GUIDELINES

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

Hematopoietic Subsyndrome of Acute Radiation Syndrome

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

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

Armlupeg (pegfilgrastim-unne), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf), Stimufend (pegfilgrastim-fpgk), Udenyca (pegfilgrastim-cbqv), or Ziextenzo (pegfilgrastim-bmez)

In addition to the coverage criteria above for Hematopoietic Subsyndrome of Acute Radiation Syndrome or Prophylaxis of Chemotherapy-induced Neutropenia:

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

LIMITATIONS

- Authorizations of all pegfilgrastim products will be provided for six (6) months.

CODES

None

REFERENCES

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3. Fulphila (pegfilgrastim-jmdb) [prescribing information]. Zurich, Switzerland: Mylan GmbH; June 2018.
4. Fylnetra (pegfilgrastim-pbbk) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2022.
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10. Pegfilgrastim. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. 2010. Available from Wolters Kluwer Health, Inc. Accessed May 1, 2017.
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16. Stimufend (pegfilgrastim-fpgk) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; Sep 2022.
17. Udenyca (pegfilgrastim-cbqv) [prescribing information]. Redwood City, CA: Coherus Biosciences: November 2018.
18. 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.
19. Ziextenzo (pegfilgrastim-bmez) [prescribing information]. Princeton, NJ: Sandoz Inc.; November 2019.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.
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. January 13, 2026: No changes.
5. October 13, 2026: Added Armlupeg to the Medical Necessity Guideline (effective November 1, 2026).

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.

Provider Services