Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Filgrastim Products: Filkri, Granix, Neupogen, Nivestym, Nypozi, Releuko, Zarxio**

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

☒ Tufts Health Plan 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

Filgrastim products are leukocyte growth factors indicated to:

- **Patients with cancer receiving myelosuppressive chemotherapy**
  - Neupogen, Filkri, Nivestym, Nypozi, Releuko, Zarxio: To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
  - Granix: To reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
- **Patients with acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy (Neupogen, Filkri, Nivestym, Nypozi, Releuko, Zarxio)**
  For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML
- **Patients with cancer undergoing bone marrow transplantation (BMT) (Neupogen, Filkri, Nivestym, Nypozi, Releuko, Zarxio)**
  To reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in patients with nonmyeloid malignancies undergoing myeloblative chemotherapy followed by BMT
- **Patients undergoing autologous peripheral blood progenitor cell collection and therapy (Neupogen, Nivestym, Nypozi, Zarxio, and Releuko)**
  For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- **Patients with severe chronic neutropenia (Neupogen, Filkri, Nivestym, Nypozi, Releuko, Zarxio)**
  For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia
- **Patients acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) (Neupogen, Filkri, Nypozi, Releuko, Zarxio)**
  To increase survival in patients acutely exposed to myelosuppressive doses of radiation

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.

Clinical Guideline Coverage Criteria

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

Prophylaxis of Chemotherapy-induced Neutropenia

1. Documentation of **one (1)** of the following:
    a. Documentation of **BOTH** of the following:
        i. Diagnosis of solid tumor or non-myeloid malignancy in a patient receiving myelosuppressive chemotherapy

AND

        ii. Documentation of **one (1)** of the following:
            1. 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
            2. 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:
                a. Age ≥65 years
                b. Active infections, open wounds, or recent surgery
                c. Advanced disease (stage 2 or higher or bone marrow involvement)
                d. Prior chemotherapy or radiation therapy
                e. Pre-existing neutropenia
                f. Poor performance status (Eastern Cooperative Oncology Group [ECOG] score of 2 to 5) or poor nutritional status
                g. Comorbidities (cardiovascular disease, renal dysfunction [creatinine clearance <50], liver dysfunction [bilirubin >2.0], human immunodeficiency virus [HIV] virus)
                h. Concern with Member's comprehension of the severity of fever development or concern with Member's access to a hospital if fever developed
                i. Chronic immunosuppression in the post-transplant setting
            3. The patient is receiving dose-dense myelosuppressive chemotherapy
            4. The patient has experienced a neutropenic complication (e.g., febrile neutropenia, dose-limiting neutropenic event) from a prior cycle of the same chemotherapy

OR

    b. Diagnosis of acute myeloid leukemia in a patient who is scheduled to receive induction chemotherapy or consolidation chemotherapy

OR

    c. Diagnosis of a non-myeloid malignancy in a patient undergoing myeloablative chemotherapy followed by bone marrow transplantation

Other Requested Uses

1. Documentation the requested use is for one (1) of the following:
    a. Severe chronic neutropenia (congenital, cyclic, or idiopathic)
    b. Agranulocytosis
    c. Aplastic anemia
    d. Neutropenia related to HIV/AIDS
    e. Neutropenia related to renal transplantation
    f. Stem cell transplantation-related indications
    g. Neutropenia related to CAR-T-cell-related toxicities
    h. Glycogen Storage Disease Type 1 with documented low neutrophil count
    i. Febrile neutropenia treatment and the filgrastim product is being used as adjunct with antibiotic therapy
    j. Myelodysplastic syndrome (anemia or neutropenia)
    k. Radiation therapy/injury
    l. Hairy Cell Leukemia with neutropenic fever following chemotherapy
    m. Chronic Myeloid Leukemia for treatment of resistant neutropenia due to tyrosine kinase inhibitor therapy

Filkri (filgrastim-laha), Granix (tbo-filgrastim), Neupogen (filgrastim), Nivestym (filgrastim-aafi), Nypozi (filgrastim-txid), Releuko (filgrastim-ayow)

In addition to the coverage criteria above for Prophylaxis of Chemotherapy-induced Neutropenia and Other Requested Uses

1. Documented previous failure, contraindication, or clinical inappropriateness with Zarxio.

Limitations

1. Authorizations of all Filgrastim Products will be provided for six 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. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.
2. National Comprehensive Cancer Network. Hematopoietic Growth Factors. Version 3.2026. URL: https://www.nccn.org. December 2025.
3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; July 2026.
4. Nivestym (filgrastim-aafi) [prescribing information]. Lake Forest, IL: Hospira, Inc.; August 2025.
5. Nypozi (filgrastim-txid) [prescribing information]. San Diego, CA: Tavnex BioPharma USA, Inc.; May 2025.
6. Releuko (filgrastim-ayow) [prescribing information]. Piscataway, NJ: Kashiv BioSciences, LLC; April 2025.
7. 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.
8. 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.
9. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ: Sandoz Inc.; August 2025.
10. Filkri (filgrastim-laha) [prescribing information]. Raleigh, NC: Accord BioPharma Inc.; July 2026.

Approval And Revision History

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

- August 8, 2023: No changes
- June 11, 2024: No changes (eff 6/11/24)
- December 10, 2024: Added Nypozi to the Medical Necessity Guideline (eff 2/1/25).
- December 9, 2025: Updated the overview section to include expanded indications of Granix, Releuko, Nypozi, and Zarxio.
- September 15, 2026: Updated title of Medical Necessity Guideline. Added Filkri to the Medical Necessity Guideline. Administrative update to remove Carelink from Medical Necessity Guideline template. (eff 10/1/26).

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.