Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Short-Acting Colony Stimulating Factors

Effective: October 8, 2024

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
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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

Short-acting colony stimulating factors are leukocyte growth factors indicated for:

Patients with cancer receiving myelosuppressive chemotherapy

- **Neupogen, Nivestym, Releuko, Zarxio:** To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- **Granix, Releuko:** To reduce the duration of severe neutropenia in patients 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, Nivestym, 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, Nivestym, Releuko, Zarxio:** To reduce the duration of neutropenia and neutropenia-related clinical sequelae (e.g., febrile neutropenia) in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by BMT

Patients undergoing autologous peripheral blood progenitor cell collection and therapy

- **Neupogen, Nivestym, Zarxio:** For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

Patients with severe chronic neutropenia

- **Neupogen, Nivestym, 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:** To increase survival in patients acutely exposed to myelosuppressive doses of radiation

Note: Zarxio is the preferred Short-Acting Colony Stimulating Factor for the health plan and does not require prior authorization

About Biosimilars: 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 Granix, Neupogen, Nivestym and Releuko for Members when the following criteria are met:

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

Limitations

- Authorizations will be provided for six (6) months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
J1447	Injection, tbo-filgrastim, (granix), 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 mcg
Q5125	Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg

References

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.
2. National Comprehensive Cancer Network. Myeloid Growth Factors. Version 2.201 8-August 3, 2018. URL: https://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf . Available from Internet. Accessed March 31, 2022.
3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; February 2021.
4. Nivestym (filgrastim-aafi) [prescribing information]. Lake Forest, IL: Hospira, Inc.; November 2021.
5. Releuko (filgrastim-ayow) [prescribing information]. Bridgewater, NJ: Amneal Biosciences. February 2022.
6. 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.
7. 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.
8. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ: Sandoz Inc.; February 2017.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2024: Minor wording changes (eff 12/12023).

- November 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- October 8, 2024: No changes (eff 10/8/24).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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