Pharmacy Medical Necessity Guidelines: Short-acting Colony Stimulating Agents (Granix®, Neupogen®, Nivestym™)

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED/ RX	Department to Review	RxUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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

OVERVIEW

FOOD AND DRUG ADMISTRATION (FDA)-APPROVED INDICATIONS

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

- **Patients with cancer receiving myelosuppressive chemotherapy**
  - Neupogen®, Nivestym™, 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 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™, 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™, 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™, Zarxio®)**
  For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- **Patients with severe chronic neutropenia (Neupogen®, Nivestym™, 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.

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 Granix (tbo-filgrastim), Neupogen (filgrastim), Nivestym (filgrastim-aafi) for Members, when the following criteria are met:

1. Documented previous failure, contraindication, or clinical inappropriateness with Zarxio (filgrastim-sndz)

LIMITATIONS

None

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
J1447	Injection, tbo-filgrastim, 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg

REFERENCES

1. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; June 2017.
2. National Comprehensive Cancer Network. Myeloid Growth Factors. Version 2.2018-August 3, 2018. URL: nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf. Available from Internet. Accessed 2018 December 18.
3. Neupogen (filgrastim) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2016.
4. Nivestym (filgrastim-aafi) [prescribing information]. Lake Forest, IL: Hospira, Inc.; July 2018.
5. 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.
6. 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.
7. Zarxio (filgrastim-sndz) [prescribing information]. Princeton, NJ:Sandoz Inc.; February 2017.

APPROVAL HISTORY

September 12, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 9, 2018: Administrative update, the HCPCS/CPT codes were updated.
2. December 19, 2018: Added Nivestym to the Medical Necessity Guideline.
3. September 10, 2019: No changes.
4. February 11, 2020: No changes.
5. December 8, 2020: Effective January 1, 2021, Tufts Health Together removed from the Medical Necessity Guideline.

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.