Tbo-filgrastim (Granix®)	Place of Service Office Administration Home Infusion Administration/ specialty pharmacy Outpatient Facility Administration Infusion Center Administration Self-Administration - *May be covered under the pharmacy benefit* HCPCS: **J1447** per 1 mcg

Condition(s) listed in policy (*see criteria for details*)

- Acute exposure to myelosuppressive radiation
- Bone marrow transplantation
- Myelodysplastic syndromes
- Peripheral blood stem cell mobilization
- Prevention of febrile neutropenia in cancer patients receiving myelosuppressive anticancer agents

AHFS therapeutic class: Hematopoietic agents

Mechanism of action: Granulocyte colony-stimulating factor (G-CSF)

(1) Special Instructions and Pertinent Information

To submit under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Granix® (tbo-filgrastim) for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute exposure to myelosuppressive doses of radiation

Covered Doses
Up to 10 mcg/kg/day SC

ICD-10: (X = any number)
T66.X

Bone marrow transplantation

Covered Doses
Up to 10 mcg/kg SC per day starting Day 5 following transplant until ANC recovery

Coverage Period
6 months

ICD-10:

Z94.81
CPT:
38240, 38241

Myelodysplastic syndromes

1. Either of the following:
    a. Initial absolute neutrophil count ANC ≤800/mm^3 or ANC ≤ 1000/mm^3 with expected neutropenia of > 5 days, or
    b. Being used in combination with an erythropoiesis-stimulating agent [ESA] (e.g. Procrit or Aranesp) to improve symptoms of anemia

    AND
2. Hgb < 10 gm/dl, **AND**
3. EPO level ≤ 500 mU/mL

Covered Doses
Up to 10 mcg/kg SC per day

Coverage Period
Indefinite

ICD-10:
D46.0, D46.1, D46.2-D46.22, D46.4, D46.9, D46.A-D46.C, D46.Z

Peripheral blood stem cell mobilization

1. Drug will be administered at home by the patient or the patient's caregiver

Covered Doses
Up to 12 mcg/kg SC per day

Coverage Period
Up to 3 months
Reauthorization requires continued response to therapy

ICD-10:
Z48.290, Z52.001, Z52.011, Z52.091, Z94.81, Z94.84

CPT:
38205, 38206

Prevention of febrile neutropenia in cancer patients receiving myelosuppressive anticancer agents
(J9000 series codes)

1. Drug is not being used concurrently with long-acting or short-acting granulocyte colony stimulating factors (e.g. filgrastim or pegfilgrastim drugs)

Covered Doses
Up to 10 mcg/kg SC per day

Coverage Period
Up to the length of the chemotherapy treatment that or up to one year (whichever is less).

ICD-10:
C00.0-C91.91, D00.00-D49.9, D70.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Granix® (tbo-filgrastim) for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Combination use of granulocyte-colony stimulating factor (G-CSF) drugs (e.g., Leukine, Neupogen, Nivestym, Zarxio, Neulasta, Fulphila, Udenyca) or using more than one G-CSF drug during a single chemotherapy cycle for neutropenia prophylaxis due to myelosuppressive chemotherapy

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information

(5) Additional Information

How supplied:

Prefilled Syringes (UltraSafe Passive® Needle Guard)

- 300 mcg/0.5 mL: Each prefilled syringe contains 300 mcg of tbo-filgrastim in 0.5 mL solution with a blue plunger in:
  - Pack of 1 with a safety needle guard in blister
  - Packs of 10 with a safety needle guard in blisters
- 480 mcg/0.8 mL: Each prefilled syringe contains 480 mcg of tbo-filgrastim in 0.8 mL solution with a clear plunger in:
  - Pack of 1 with a safety needle guard in blister
  - Packs of 10 with a safety needle guard in blisters

Prefilled Syringes

- 300 mcg/0.5 mL: Each prefilled syringe contains 300 mcg of tbo-filgrastim in 0.5 mL solution with a blue plunger in:
  - Pack of 1 without a safety needle guard (for patients and caregivers)
  - Packs of 5 without a safety needle guard (for patients and caregivers)
- 480 mcg/0.8 mL: Each prefilled syringe contains 480 mcg of tbo-filgrastim in 0.8 mL solution with a clear plunger in:
  - Pack of 1 without a safety needle guard (for patients and caregivers)
  - Packs of 5 without a safety needle guard (for patients and caregivers)

Vials

- 300 mcg/1 mL: Each vial contains 300 mcg of tbo-filgrastim in 1 mL solution. Packs of 10 single-dose vials.

- 480 mcg/1.6 mL: Each vial contains 480 mcg of tbo-filgrastim in 1.6 mL solution. Packs of 10 single-dose vials.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Granix® (tbo-filgrastim) [Prescribing Information]. North Wales, PA: Teva Pharmaceutical Industries Ltd.; 11/2019.
- National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2023). Available at: www.nccn.org.
- National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 1.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 3Q2022
Date of next review: 3Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee