blue california
Promise Health Plan

## tbo-filgrastim (Granix)

## Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

Place of Service
Home Infusion Administration/ specialty pharmacy
Infusion Center Administration
Office Administration
Outpatient Facility Administration
Self-Administration - *May be covered under the pharmacy benefit*

## Drug Details

**USP Category:** BLOOD PRODUCTS AND MODIFIERS
**Mechanism of Action:** Granulocyte colony-stimulating factor (G-CSF)
**HCPCS:**
J1447:Injection, tbo-filgrastim, 1 microgram
**How Supplied:**

- 300 mcg and 480 mcg (single dose prefilled syringe)
- 300 mcg and 480 mcg (single dose vial)

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

- Acute Exposure to Myelosuppressive Doses of Radiation
- Bone Marrow Transplantation
- Peripheral Blood Stem Cell Mobilization

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

## Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

## Coverage Criteria
**The following condition(s) require Prior Authorization/Preservice.**

**Acute Exposure to Myelosuppressive Doses of Radiation**
**Meets medical necessity if all the following are met:**

**Covered Doses:**
10 mcg/kg given subcutaneously once daily

**Coverage Period:**
Up to the length of the radiation therapy

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

**Bone Marrow Transplantation**
**Meets medical necessity if all the following are met:**

**Covered Doses:**
10 mcg/kg given subcutaneously once daily starting Day 5 following transplant until absolute neutrophil count recovery

**Coverage Period:**
6 months

**ICD-10:**
Z94.81, or CPT: 38240, 38241

**Peripheral Blood Stem Cell Mobilization**
**Meets medical necessity if all the following are met:**

**Covered Doses:**
10 mcg/kg given subcutaneously once daily

**Coverage Period:**
Initial: 3 months
Reauthorization requires continued response to therapy

**ICD-10:**
Z48.290, Z52.001, Z52.011, Z52.091, Z94.81, Z94.84, OR CPT: 38205, 38206

## References

1. Granix (tbo-filgrastim) Prescribing Information. Teva Pharmaceuticals USA, Inc., North Wales, PA: 11/2023.

2. National Comprehensive Cancer Network. Hematopoietic Stem Cell Transplantation (Version 2.2025). Available at: www.nccn.org.
3. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2025). Available at: www.nccn.org.
4. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 2.2025). Available at: www.nccn.org.

**Review History**

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

*Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee*