tbo-filgrastim (Granix)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

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
- Hematopoietic Stem Cell Transplantation (Bone Marrow Transplantation)
- Myelodysplastic Syndromes
- Peripheral Blood Stem Cell Mobilization
- Prevention of Febrile Neutropenia in Cancer Patients Receiving Myelosuppressive Anticancer Agents

Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

For members enrolled in our Blue Shield Select (PPO) and Blue Shield Medicare (PPO) plans:
Granix requires step therapy. Step therapy requires you to try other drugs first before another drug can be covered. The BSC preferred step drugs are Zarxio and Nivestym. These drugs will need to be tried for members newly initiating Granix therapy.

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: (X = any number)
T66.X

Hematopoietic Stem Cell Transplantation (Bone Marrow Transplantation)

Meets medical necessity if all the following are met:

1. For PPO requests: Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses:
10 mcg/kg given subcutaneously daily starting Day 5 following transplant until ANC recovery

Coverage Period:
6 months

CPT:
38240, 38241

ICD-10:
C94.81

Myelodysplastic Syndromes

Meets medical necessity if all the following are met:

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
   b. Being used in combination with an erythropoiesis-stimulating agent [ESA] (e.g. Procrit, Aranesp) to improve symptoms of anemia AND both of the following:
      i. Hgb < 10 gm/dl
      ii. EPO level ≤ 500 mU/mL
2. For PPO requests: Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses:
10 mcg/kg given subcutaneously once daily

Coverage Period:
yearly

ICD-10:
D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

Peripheral Blood Stem Cell Mobilization
Meets medical necessity if all the following are met:
1. For PPO requests: Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses:
12 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

Prevention of Febrile Neutropenia in Cancer Patients Receiving Myelosuppressive Anticancer Agents
Meets medical necessity if all the following are met:
1. Drug is not being used concurrently with long-acting or short-acting granulocyte colony stimulating factors (e.g. filgrastim or pegfilgrastim drugs)
2. For PPO requests: Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with requested filgrastim product

Covered Doses:
10 mcg/kg given subcutaneously once daily

Coverage Period:
Up to the length of the chemotherapy treatment

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

Additional Information

Summary of Evidence
The contents of this policy were created after examining the following resources:
1. The prescribing information for Granix
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
   a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
   b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
   c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
   d. Lexi-Drugs – "Use: Off-Label" and rated as "Evidence Level A" (cancer indications only)

e. Clinical Pharmacology - supportive narrative text (cancer indications only)
3. Noridian Healthcare Solutions Medicare: Drugs, Biologics and Injections
4. NCCN Guideline: Hematopoietic Growth Factors; Acute Myeloid Leukemia; Hemapoietic Stem Cell Transplantation; Myelodysplastic Syndromes

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Granix are covered in addition to the following:

- Acute exposure to myelosuppressive radiation
- Bone marrow transplantation
- Myelodysplastic syndromes
- Peripheral blood stem cell mobilization

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Beginning January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) provided Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs to lower costs and improve the quality of care for Medicare beneficiaries.
- NCCN Clinical Practice Guidelines in Oncology for the use of hematopoietic growth factors support use of short-acting granulocyte colony-stimulating factors (G-CSFs): 1) as prophylaxis of chemotherapy-induced febrile neutropenia or other dose-limiting neutropenic events in patients at risk of febrile neutropenia with solid tumors and non-myeloid malignancies who are receiving treatment in the curative/adjuvant or palliative settings; 2) as treatment of chemotherapy-induced febrile neutropenia: in patients who have been receiving prophylactic tbo-filgrastim or in patients who have not received prophylactic granulocyte colony-stimulating factors but who have risk factors for an infection-associated complication; and 3) for treatment for patients with radiation-induced myelosuppression following a radiologic/nuclear incident (hematopoietic acute radiation syndrome [H-ARS])
- NCCN Clinical Practice Guidelines in Oncology for myelodysplastic syndromes (MDS) support use of short-acting granulocyte colony-stimulating factors (G-CSFs) for use in MDS patients with neutropenia with recurrent or resistant infections, and for treatment of lower risk MDS associated with symptomatic anemia, in combination with an erythropoiesis-stimulating agent.
- NCCN Clinical Practice Guidelines in Oncology for hematopoietic stem cell transplantation support use of short-acting granulocyte colony-stimulating factors (G-CSFs) for hematopoietic cell mobilization.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. Granix (tbo-filgrastim) Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 11/2023.

5. National Comprehensive Cancer Network. Hematopoietic Stem Cell Transplantation (Version 2.2024). Available at: www.nccn.org.
6. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 3.2024). Available at: www.nccn.org.
7. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Version 3.2024). Available at: www.nccn.org.

Review History

Date of Last Annual Review: 3Q2024
Changes from previous policy version:

- New Part B policy

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