

# Jurisdiction Specific Medicare Part B

## Granix

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Granix	tbo-filgrastim

### Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Reduce the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy and/or immunotherapy
- Adjunctive treatment of neutropenia in certain conditions

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

### Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Administration of Granix to increase chemotherapy dose intensity except as noted below
- Continuous use for myelodysplastic syndromes or Felty's syndrome without infections
- Chemosensitization of myeloid leukemias
- Continued use if no response is seen within 28-42 days
- Administration in members with chronic aplastic anemia

# Coverage Criteria

## Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy and/or Immunotherapy

Authorization of 6 months may be granted for prevention of febrile neutropenia when the chemotherapeutic agents are covered by Medicare and any of the following criteria are met:

- Granix will be used for primary prophylaxis in a member whose risk of febrile neutropenia is 20% or greater based on the chemotherapy regimen
- Granix will be used for primary prophylaxis in a member whose risk of febrile neutropenia is greater than or equal to 10% and less than 20% based on the chemotherapy regimen and at least one of the following risk factors for febrile neutropenia are present:
  - Age greater than 65 years
  - Poor performance status
  - Previous episodes of febrile neutropenia
  - History of previous chemotherapy or radiation therapy
  - After completion of combined chemoradiotherapy
  - Bone marrow involvement by tumor producing cytopenias
  - Preexisting neutropenia
  - Poor nutritional status
  - Poor renal function
  - Liver dysfunction (i.e., elevated bilirubin)
  - Presence of open wounds or active infections
  - Recent surgery (within the past 12 weeks)
  - Advanced cancer
  - Other serious comorbidities
- Granix will be used as secondary prophylaxis when both of the following conditions are met:
  - The member has documented febrile neutropenia from a prior chemotherapy cycle (for which primary prophylaxis was not received)
  - A reduction in dosage of the chemotherapeutic agent or delay in treatment may compromise disease-free or overall survival or treatment outcome

## Adjunctive Treatment of Neutropenia

Authorization of 6 months may be granted for adjunctive treatment of neutropenia when any of the conditions below are present:

- Expected prolonged (greater than 10 days) and profound (less than  $0.1 \times 10^9/L$ ) neutropenia
- Age greater than 65 years
- Uncontrolled primary disease
- Pneumonia

Reference number(s)
4489-A

- Hypotension and multiorgan dysfunction (sepsis syndrome)
- Invasive fungal infection
- Hospitalization at the time of the development of fever

## Dosage and Administration

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation. Granix will be covered when administered under direct supervision in the office setting. When administered by the member or caregiver, the drug will be considered self-administered and not payable.

## References

1. White Cell Colony Stimulating Factors LCD (L37176) Version R15. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed June 19, 2024.
2. Billing and Coding: White Cell Colony Stimulating Factors (A56748) Version R12. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed June 19, 2024.
3. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2023.