Reference number(s)
4489-A

JURISDICTION SPECIFIC MEDICARE PART B

GRANIX (tbo-filgrastim)

POLICY

I. 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.

A. Reduce the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive chemotherapy
B. Adjunctive treatment of neutropenia in certain conditions

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. The member's medical record must document the medical necessity of services performed for each date of service submitted on a claim
B. For primary or secondary prophylaxis in conjunction with cancer chemotherapy, the record must document risk factors in members receiving agents/doses uncommonly associated with myelosuppression.
C. For treatment of covered chronic neutropenia, the member's medical record must document appropriate evaluation of the cause of the neutropenia, and where appropriate, a history of recurrent fevers and/or infections. The absolute neutrophil count must be documented but need not be submitted with the claim.
D. For prophylaxis of chemotherapy-associated neutropenia, indicate the chemotherapy drug used in the medical record.
E. The member's medical record must clearly document the time the last dose of the cytotoxic chemotherapy cycle ended and the time the G-CSF drug was administered.
F. If Granix will be administered outside the timeframe specified by the FDA labeling, the reason for the exception should be clearly documented in the medical record.

III. EXCLUSIONS

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

A. Administration of Granix to increase chemotherapy dose intensity except as noted below
B. Continuous use for myelodysplastic syndromes or Felty's syndrome without infections
C. Chemosensitization of myeloid leukemias
D. Continued use if no response is seen within 28-42 days

E. Administration in members with chronic aplastic anemia

IV. CRITERIA FOR APPROVAL

A. Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy
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:

1. Granix will be used for primary prophylaxis in a member whose risk of febrile neutropenia is 20% or greater based on the chemotherapy regimen
2. 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:
   i. Age greater than 65 years
   ii. Poor performance status
   iii. Previous episodes of febrile neutropenia
   iv. History of previous chemotherapy or radiation therapy
   v. After completion of combined chemoradiotherapy
   vi. Bone marrow involvement by tumor producing cytopenias
   vii. Preexisting neutropenia
   viii. Poor nutritional status
   ix. Poor renal function
   x. Liver dysfunction (i.e., elevated bilirubin)
   xi. Presence of open wounds or active infections
   xii. Recent surgery (within the past 12 weeks)
   xiii. Advanced cancer
   xiv. Other serious comorbidities
3. Granix will be used as secondary prophylaxis when both of the following conditions are met:
   i. The member has documented febrile neutropenia from a prior chemotherapy cycle (for which primary prophylaxis was not received)
   ii. A reduction in dosage of the chemotherapeutic agent or delay in treatment may compromise disease-free or overall survival or treatment outcome

B. Adjunctive Treatment of Neutropenia
Authorization of 6 months may be granted for adjunctive treatment of neutropenia when any of the conditions below are present:

1. Expected prolonged (greater than 10 days) and profound (less than 0.1 x 10^9/L) neutropenia
2. Age greater than 65 years
3. Uncontrolled primary disease
4. Pneumonia
5. Hypotension and multiorgan dysfunction (sepsis syndrome)
6. Invasive fungal infection
7. Hospitalization at the time of the development of fever

V. 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.

VI. REFERENCES

1. White Cell Colony Stimulating Factors LCD (L37176) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 1, 2022.
2. Billing and Coding: White Cell Colony Stimulating Factors (A56748) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 1, 2022.
3. Granix [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; November 2019.