

Granix® (tbo-filgrastim) Injection J1446



When requesting Granix® (tbo-filgrastim), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- For reduction in the duration of severe neutropenia in individuals with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia¹

Approved Off-label Compendial uses³

- For treatment of chemotherapy-induced febrile neutropenia
- To mobilize hematopoietic progenitor cells
- Myelodysplastic syndrome

Coverage Guidelines

For all indications:

The individual does **not** have a history of serious allergic reactions to filgrastim or pegfilgrastim ¹

The individual must have **one** of the following diagnoses for approval:

For prophylaxis of chemotherapy-induced febrile neutropenia^{1,3,4}

- Eligible diagnoses (must have one of the following):
 - Solid tumor or non-myeloid malignancy² **OR**
 - Acute Myeloid Leukemia (AML) receiving post-remission treatment. ⁵
- Increased risk for febrile neutropenia (at least one of the following):
 - The individual has experienced hospitalization due to febrile neutropenia or a dose-limiting neutropenic event while on the current regimen³ **OR**
 - The individual is receiving chemotherapy with high risk (≥20%) for febrile neutropenia:^{3,4} **OR**
 - The individual is receiving chemotherapy with intermediate risk (10-19%) for febrile neutropenia and has one or more of the following risk factors for developing febrile neutropenia:⁴
 - Prior chemotherapy or radiation therapy
 - Persistent neutropenia
 - Bone marrow involvement by tumor
 - Recent surgery and/or open wounds
 - Liver dysfunction (bilirubin >2.0)
 - Renal dysfunction (creatinine clearance <50)
 - Age >65 years receiving full chemotherapy dose intensity
 - Poor performance status
 - HIV infection (in particular, individuals with low CD4 counts)

- Chronic immunosuppression in the post-transplant setting, including organ transplant

For treatment of chemotherapy-induced febrile neutropenia:^{3,4}

- The individual has received Granix[®] (tbo-filgrastim) as prophylaxis OR has presence of risk factors for an infection associated complication as referenced by NCCN below⁴:
 - Sepsis syndrome
 - Age >65 years
 - Severe neutropenia [absolute neutrophil count <100/mcL]
 - Neutropenia expected to be more than 10 days in duration
 - Pneumonia or other clinically documented infections
 - Invasive fungal infection
 - Hospitalization at the time of fever
 - Prior episode of febrile neutropenia

For myelodysplastic syndrome:³

- The individual has symptomatic anemia with low risk disease AND
- The individual has serum erythropoietin level less than or equal to 500 mU/mL AND
- Granix[®] (tbo-filgrastim) will be used in combination with epoetin alfa or darbepoetin alfa³

For mobilization of hematopoietic progenitor cells as an allogeneic donor³

Approval duration (initial and renewal): 180 days

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Contraindicated in an individual with a history of a serious allergic reaction to filgrastim or pegfilgrastim
- Do not administer Granix[®] (tbo-filgrastim) within 24 hours prior to chemotherapy
- Administer Granix[®] (tbo-filgrastim) at least 24 hours after chemotherapy
- Evaluate individuals who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture

References

1. Granix prescribing information. North Wales, PA: Teva pharmaceuticals USA, Inc.; February 2017. Accessed April 7, 2017. <http://www.granixhcp.com/Pdf/prescribing-information.pdf>
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed February 27, 2017. <http://www.micromedexsolutions.com>
3. National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN Compendium®) Accessed February 27, 2017. http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=158 Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™). ©2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to [NCCN.org](http://www.nccn.org).
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors. Version 2.2016. Accessed February 27, 2017. http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 1.2017. Accessed March 10, 2017. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

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