CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Colony Stimulating Factors – Granix Utilization Management Medical Policy
- Granix® (tbo-filgrastim subcutaneous injection – Teva)

REVIEW DATE: 10/22/2025

OVERVIEW

Granix, a granulocyte colony stimulating factor (G-CSF), is indicated to **reduce the duration of severe neutropenia** in adults and pediatric patients ≥ 1 month of age with non-myeloid malignancies receiving myelosuppressive anti-cancer medications associated with a clinically significant incidence of febrile neutropenia.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) addresses the use of Granix in several guidelines. Of note, throughout the recommendations, it is acknowledged that Granix is an appropriate substitute for filgrastim.

- **Acute Lymphoblastic Leukemia (ALL):** Guidelines (version 2.2025 – June 27, 2025) recommend G-CSFs as supportive care for myelosuppressive blocks of therapy or as directed by treatment protocol.[5]
- **Hematopoietic Cell Transplantation:** Guidelines (version 3.2025 – September 24, 2025) recommend filgrastim for hematopoietic cell mobilization for allogeneic or autologous donors as a single agent or in combination with other treatments.[4]
- **Hematopoietic Growth Factors:** Guidelines (version 1.2025 – October 11, 2024) recommend Granix, along with other granulocyte colony stimulating factors (CSFs), for prophylactic use if the patient is receiving anti-cancer medications that are associated with a high (> 20%) incidence of severe neutropenia with fever.[2] Consider CSF therapy for patients with an intermediate (10% to 20%) probability of developing febrile neutropenia based on risk factors. The NCCN guidelines also recommend therapy with CSFs in other scenarios in those given myelosuppressive chemotherapy. Granix is also recommended as an appropriate option for the treatment of patients with radiation-induced myelosuppression following a radiologic/nuclear incident (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).
- **Myelodysplastic Syndromes (MDS):** Guidelines (version 1.2026 – October 9, 2025) recommend Granix for use in certain patients with MDS (e.g., neutropenic patients with recurrent or resistant infections, combination use with epoetin alfa or Aranesp® [darbepoetin alfa injection] in patients with anemia).[3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Granix. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Granix as well as the monitoring required for adverse events and

long-term efficacy, approval requires Granix to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Granix is recommended in those who meet one of the following:

FDA-Approved Indication

---

1. Cancer in a Patient Receiving Myelosuppressive Chemotherapy. Approve for 6 months if the patient meets BOTH of the following (A and B):

A) Patient meets ONE of the following (i, ii, iii, or iv):

i. Patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen); OR

ii. Patient meets BOTH of the following (a and b):

a) Patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia, but the risk is less than 20% based on the chemotherapy regimen; AND

b) Patient has at least one risk factor for febrile neutropenia according to the prescriber; OR
Note: Examples of risk factors include age > 65 year receiving full chemotherapy dose intensity; prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver dysfunction (bilirubin > 2.0 mg/dL); renal dysfunction (creatine clearance < 50 mL/min); poor performance status; patient with human immunodeficiency virus (HIV) infection and low CD4 counts.

iii. Patient meets BOTH of the following (a and b):

a) Patient has had a neutropenic complication from a prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor; AND
Note: Examples of colony stimulating factors include filgrastim products, pegfilgrastim products, Ryzneuta (efbemalenograstim alfa-vuxw subcutaneous injection), Rolvedon (eflapegrastim-xnst subcutaneous injection).

b) A reduced dose or frequency of chemotherapy may compromise treatment outcome; OR

iv. Patient who has received chemotherapy has febrile neutropenia AND has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescriber; AND
Note: Examples of risk factors include sepsis syndrome; age > 65 years; severe neutropenia (absolute neutrophil count [ANC] < 100 cells/mm^3); neutropenia expected to be > 10 days in duration; pneumonia or other clinically documented infections; invasive fungal infection; hospitalization at the time of fever; prior episode of febrile neutropenia.

B) The medication is prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve up to 5 mcg/kg per day by subcutaneous injection given for up to 14 days per month.

Other Uses with Supportive Evidence

2. Acute Lymphoblastic Leukemia (ALL) in a Patient Receiving Chemotherapy. Approve for 1 month if prescribed by or in consultation with an oncologist or a hematologist.

Dosing. Approve up to 5 mcg/kg per day by subcutaneous injection.

3. Myelodysplastic Syndromes (MDS). Approve for 3 months if prescribed by or in consultation with an oncologist or hematologist.

Dosing. Approve up to 5 mcg/kg per day by subcutaneous injection.

4. Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy. Approve for 1 month if prescribed by or in consultation with an oncologist, a hematologist, or a physician who specializes in transplantation.

Dosing. Approve up to 10 mcg/kg per day by subcutaneous injection.

5. Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]). Approve for 1 month if prescribed by or in consultation with a physician who has expertise in treating acute radiation syndrome.

Dosing. Approve up to 10 mcg/kg per day as a subcutaneous injection.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Granix is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; November 2023.
2. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 7, 2025.
3. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 1.2026 – October 9, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 16, 2025.
4. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2025 – September 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 7, 2025.
5. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2025 – June 27, 2025). © 2025 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on October 16, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	09/20/2023
Annual Revision	**Cancer in a Patient Receiving Myelosuppressive Chemotherapy**: The Note providing examples of risk factors for febrile neutropenia was updated from "≥ 65 years" to "> 65 years of age receiving full chemotherapy dose intensity", liver dysfunction was defined as "bilirubin > 2.0 mg/dL", renal dysfunction was defined as "creatine clearance < 50 mL/min", and human immunodeficiency infection patients was clarified by adding "with low CD4 counts." The requirement for a patient to have had a neutropenic complication from "prior chemotherapy" was updated to add "cycle." The Note providing examples of colony stimulating factors was updated to add Ryzneuta and Rolvedon and remove Leukine. The Note providing examples of risk factors associated with poor clinical outcomes for patients who have febrile neutropenia was updated to include pneumonia, hospitalization at the time of fever, and prior episode of febrile neutropenia. **Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy:** The dosing limitation was lowered from 32 mcg/kg to 10 mcg/kg. **Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]):** This Other Use with Supportive Evidence was added to the policy. A new dosing limitation was added.	10/09/2024
Annual Revision	**Cancer in a Patient Receiving Myelosuppressive Chemotherapy**: The Note was updated from "human immunodeficiency virus (HIV) infection patients with low CD4 counts" to "a patient with HIV infection and low CD4 counts." **Acute Lymphoblastic Leukemia in a Patient Receiving Chemotherapy**: This Other Use with Supportive Evidence was added to the policy. A new dosing limitation was added**.**	10/22/2025