

tbo-filgrastim (GRANIX)

Diagnoses Considered for Coverage:

- Acute exposure to myelosuppressive doses of radiation
- Bone marrow transplantation
- Myelodysplastic syndromes
- Peripheral blood stem cell mobilization
- Prevention or reduction of febrile neutropenia in patients receiving myelosuppressive anticancer drugs

Coverage Criteria:

For prevention or reduction of neutropenia in patients receiving myelosuppressive chemotherapy:

- Patient is receiving myelosuppressive chemotherapy, **and**
 - Not being used concurrently with peg-filgrastim (Neulasta, Fulphila, Udenyca, Ziextenzo, or Nyvepria) for prevention of neutropenia, **and**
 - Dose does not exceed FDA label maximum
- AND**
- Intolerance or contraindication to Zarxio and Nivestym not expected with Granix.

Coverage Duration: duration of chemotherapy treatment

For prevention or reduction of acute radiation-induced neutropenia:

- Patient is currently receiving radiation therapy, **and**
- Not being used as part of a radiation regimen in combination with peg-filgrastim (Neulasta, Fulphila, Udenyca, Ziextenzo, or Nyvepria) for prevention of neutropenia, **and**
- Dose does not exceed FDA label maximum, **and**
- Intolerance or contraindication to Zarxio and Nivestym not expected with Granix.

Coverage Duration: duration of radiation therapy

For bone marrow transplantation:

- Dose does not exceed FDA label maximum, **and**
- Intolerance or contraindication to Zarxio and Nivestym not expected with Granix.

Coverage Duration: Day 5 following transplant until ANC recovery

For myelodysplastic syndrome (MDS):

- Hgb less than 10gm/dl, **and**
- EPO level less than or equal to 500 mU/mL, **and**
- Either one of the following:
 - Initial ANC $\leq 800/\text{mm}^3$, **or**
 - ANC $\leq 1000/\text{mm}^3$ with expected neutropenia of > 5 days, **or**
 - Being used in combination with an erythropoiesis-stimulating agent (e.g. Procrit or Aranesp) to improve symptoms of anemia, **and**
- Dose does not exceed FDA label maximum, **and**
- Intolerance or contraindication to Zarxio and Nivestym not expected with Granix.

Coverage Duration: one year

For peripheral blood stem cell mobilization:

- Dose does not exceed FDA label maximum, **and**
- Intolerance or contraindication to Zarxio and Nivestym not expected with Granix.

Coverage Duration: up to 2 months

Coverage Duration: see specific criteria

References:

1. Granix® (tbo-filgrastim) [Prescribing Information]. North Wales, PA: Teva Pharmaceutical Industries Ltd.; 11/2019.
2. National Comprehensive Cancer Network. Myelodysplastic Syndromes (Volume 3.2021). Available at: www.nccn.org.

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