

## SPECIALTY GUIDELINE MANAGEMENT

### NEUPOGEN (filgrastim) GRANIX (tbo-filgrastim) ZARXIO (filgrastim-sndz)

#### POLICY

#### I. INDICATIONS

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

##### A. FDA-Approved Indications

###### **Neupogen**

1. Patients with Cancer Receiving Myelosuppressive Chemotherapy
  - i. Neupogen is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
2. Patients With Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy
  - i. Neupogen is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia.
3. Patients with Cancer Receiving Bone Marrow Transplant
  - i. Neupogen is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, (e.g., febrile neutropenia) in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation.
4. Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy
  - i. Neupogen is indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
5. Patients With Severe Chronic Neutropenia
  - i. Neupogen is indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

###### **Granix**

Granix is indicated to reduce the duration of severe neutropenia in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

###### **Zarxio**

- A. Patients with Cancer Receiving Myelosuppressive Chemotherapy
  - o Zarxio is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.
- B. Patients With Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy
  - o Zarxio is indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia.
- C. Patients with Cancer Undergoing Bone Marrow Transplant

- Zarxio is indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, (e.g., febrile neutropenia) in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation.
- D. Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy
  - Zarxio is indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
- E. Patients With Severe Chronic Neutropenia
  - Zarxio is indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
- B. Compendial Uses (Neupogen/Granix/Zarxio)
  1. Treatment of chemotherapy-induced febrile neutropenia in patients with non-myeloid malignancies
  2. Treatment of symptomatic anemia in patients with myelodysplastic syndromes (MDS), in combination with epoetin or darbepoetin
  3. Treatment of neutropenia in patients with MDS and recurrent or resistant infections
  4. Following chemotherapy for acute lymphocytic leukemia (ALL)
  5. Leukemic relapse following allogeneic stem cell transplantation
  6. Agranulocytosis
  7. Aplastic anemia
  8. Neutropenia related to HIV/AIDS
  9. Neutropenia related to renal transplantation

All other indications are considered experimental/investigational and are not a covered benefit.

## II. CRITERIA FOR INITIAL APPROVAL

### A. Neutropenia in cancer patients receiving myelosuppressive chemotherapy

Authorization of 6 months may be granted for prevention or treatment of febrile neutropenia when both of the following criteria are met:

- a. Member has a non-myeloid malignancy and currently receiving or will be receiving myelosuppressive anti-cancer therapy
- b. Neupogen/Granix/Zarxio will not be administered less than 24 hours before or after chemotherapy or radiotherapy

### B. Other indications

Authorization of 6 months may be granted for members with any of the following indications:

1. Agranulocytosis
2. Aplastic anemia
3. Neutropenia related to HIV/AIDS
4. Neutropenia related to renal transplantation
5. Acute myeloid leukemia
6. Stem cell transplantation-related indications
7. Severe chronic neutropenia (congenital, cyclic, or idiopathic)
8. Myelodysplastic syndrome (anemia or neutropenia)

## III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

#### IV. REFERENCES

1. Neupogen [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2015.
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8. Aapro MS, Bohlius J, Cameron DA, et al. 2010 update of EORTC guidelines for the use of granulocyte-colony stimulating factor to reduce the incidence of chemotherapy-induced febrile neutropenia in adult patients with lymphoproliferative disorders and solid tumors. *Eur J Cancer*. 2011;47(1):8-32.
9. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-3212.
10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 1.2016. [http://www.nccn.org/professionals/physician\\_gls/pdf/mds.pdf](http://www.nccn.org/professionals/physician_gls/pdf/mds.pdf). Accessed July 8, 2016.