Reference number(s)
3932-A

JURISDICTION SPECIFIC MEDICARE PART B

FILGRASTIM PRODUCTS
NEUPOGEN (filgrastim)
NIVESTYM (filgrastim-aafi)
ZARXIO (filgrastim-sndz)

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.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Neutropenia due to myelosuppressive chemotherapy
B. Following induction or consolidation chemotherapy treatment in adults with acute myeloid leukemia
C. Patients with cancer receiving bone marrow transplant
D. Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
E. Severe chronic neutropenia
F. Hematopoietic syndrome of acute radiation syndrome
G. Mobilization of donor hematopoietic progenitor cells or for granulocyte transfusion in the allogenic setting
H. Hematopoietic stem cell mobilization for collection and subsequent autologous transplantation in patients with non-Hodgkin lymphoma or multiple myeloma
I. Supportive care following hematopoietic stem cell transplant
J. Neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy
K. Febrile neutropenia
L. Myelodysplastic syndrome
M. Aplastic anemia
N. Drug-induced or congenital agranulocytosis
O. Acute myeloid leukemia
P. Drug-induced neutropenia
Q. Treatment of mucositis following chemotherapy
R. Neutropenia associated with pre-eclampsia

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.

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II. DOCUMENTATION

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

A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

A. Prevention of Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy
Authorization of 6 months may be granted for prevention of febrile neutropenia in cancer patients receiving myelosuppressive chemotherapy.

B. Induction or Consolidation Chemotherapy in Acute Myeloid Leukemia
Authorization of 6 months may be granted for reducing the time to neutrophil recovery and duration of fever following induction or consolidation chemotherapy treatment of members with acute myeloid leukemia.

C. Bone Marrow Transplantation in Non-Myeloid Malignancies
Authorization of 6 months may be granted to reduce the duration of neutropenia and neutropenia-related sequelae in members with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

D. Mobilization of Hematopoietic Progenitor Cells in the Autologous Setting
Authorization of 6 months may be granted for mobilization of hematopoietic progenitor cells in the autologous setting.

E. Severe Chronic Neutropenia
Authorization of 6 months may be granted for the treatment of severe chronic neutropenia.

F. Acute Exposure to Myelosuppressive Doses of Radiation
Authorization of 6 months may be granted for acute exposure to myelosuppressive doses of radiation.

G. Other Indications
Authorization of 6 months may be granted for treatment of any of the following conditions:

1. Mobilization of donor hematopoietic progenitor cells for granulocyte transfusion in the allogenic setting
2. Hematopoietic stem cell mobilization for collection and subsequent autologous transplantation in patients with non-Hodgkin lymphoma or multiple myeloma
3. Supportive care following hematopoietic stem cell transplant
4. Neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy
5. Febrile neutropenia
6. Myelodysplastic syndrome
7. Aplastic anemia
8. Drug-induced or congenital agranulocytosis
9. Acute myeloid leukemia
10. Drug-induced neutropenia
11. Treatment of mucositis following chemotherapy

12. Neutropenia associated with pre-eclampsia

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 16, 2021.
2. Billing and Coding: Filgrastim, Pegfilgrastim, Tbo-filgrastim and biosimilars (A52408) Version R19. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 16, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed June 16, 2021.
4. Neupogen [package insert]. Thousand Oaks, CA: Amgen, Inc.; June 2018.
5. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed June 16, 2021.
6. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com (cited: June 16, 2021).