Reference number(s)
3916-A

JURISDICTION SPECIFIC MEDICARE PART B

PEGFILGRASTIM PRODUCTS
NEULASTA (pegfilgrastim)
FULPHILA (pegfilgrastim-jmdb)
NYVEPRIA (pegfilgrastim-apgf)
UDENYCA (pegfilgrastim-cbqv)
ZIEXTENZO (pegfilgrastim-bmez)

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. Patients with cancer receiving myelosuppressive chemotherapy
B. Patients with hematopoietic subsyndrome of acute radiation syndrome
C. Harvesting of peripheral blood stem cells prior to autologous stem cell transplantation
D. Supportive care post autologous hematopoietic cell transplant

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.

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.

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B. Acute Radiation Syndrome
Authorization of 6 months may be granted for treatment of hematopoietic subsyndrome of acute radiation syndrome.

C. Harvesting of Peripheral Blood Stem Cells Prior to Autologous Stem Cell Transplantation
Authorization of 6 months may be granted for harvesting of peripheral blood stem cells prior to autologous stem cell transplantation.

D. Supportive Care Post Autologous Hematopoietic Cell Transplant
Authorization of 6 months may be granted for supportive care post-autologous hematopoietic cell transplant.

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. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; January 2020.
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).