

# STANDARD MEDICARE PART B MANAGEMENT

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

## 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 Indication

1. Patients with Cancer Receiving Myelosuppressive Chemotherapy  
Neulasta 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 clinically significant incidence of febrile neutropenia.
2. Hematopoietic Syndrome of Acute Radiation Syndrome  
Neulasta is indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).

#### B. Compendial Use

1. Stem cell transplantation-related indications
2. Prophylaxis for chemotherapy-induced febrile neutropenia in patients with solid tumors
3. Hematopoietic Syndrome of Acute Radiation Syndrome
4. Hairy cell leukemia
5. Chronic Myeloid Leukemia (CML), treatment of persistent neutropenia due to tyrosine kinases inhibitor therapy

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:

**Primary Prophylaxis of Febrile Neutropenia**

Member's diagnosis and chemotherapeutic regimen.

### III. CRITERIA FOR INITIAL APPROVAL

|                            |
|----------------------------|
| <b>Reference number(s)</b> |
| 4237-A                     |

**A. Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy**

Authorization of 6 months may be granted for prevention of febrile neutropenia for members with solid tumors or non-myeloid malignancies when the member will not be receiving concurrent chemotherapy and radiation therapy.

**B. Other indications**

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

1. Stem cell transplantation-related indications
2. Hematopoietic Syndrome of Acute Radiation Syndrome
3. Hairy cell leukemia with neutropenic fever following chemotherapy
4. Chronic Myeloid Leukemia for treatment of persistent neutropenia due to tyrosine kinase inhibitor therapy

**IV. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 6 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Neulasta.
- B. Neulasta is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy.

**V. REFERENCES**

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc.; January 2020.
2. Fulphila [package insert]. Zurich, Switzerland: Mylan; June 2018.
3. Udenyca [package insert]. Redwood City, California: Coherus BioSciences, Inc: September 2019.
4. Ziextenzo [package insert]. Princeton, NJ: Sandoz Inc.; November 2019.
5. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc., June 2020.
6. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org> Accessed June 10, 2020.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors. Version 2.2020. [https://www.nccn.org/professionals/physician\\_gls/pdf/growthfactors.pdf](https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf) Accessed June 02, 2020.
8. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at <https://www.micromedexsolutions.com> (Accessed: 06/10/2020).