

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.

- A. Prevention of febrile neutropenia in cancer patients receiving myelosuppressive chemotherapy and/or immunotherapy
- B. Hematopoietic subsyndrome of acute radiation syndrome (H-ARS)
- C. Acute lymphocytic leukemia after initial induction chemotherapy or first post-remission course of chemotherapy
- D. Myelodysplastic syndromes with severe neutropenia or recurrent infection
- E. Dose-dense myelosuppressive chemotherapy
- F. Promote myeloid reconstitution after hematopoietic progenitor stem cell transplant
- G. Delayed or failed engraftment after hematopoietic progenitor stem cell transplant
- H. Adjunctive treatment of neutropenia in certain conditions

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. The member's medical record must document the medical necessity of services performed for each date of service submitted on a claim
- B. For primary or secondary prophylaxis in conjunction with cancer chemotherapy, the record must document risk factors in members receiving agents/doses uncommonly associated with myelosuppression.
- C. For dose dense chemotherapy, the medical record clearly indicates the member is on a 14-day dose dense chemotherapy cycle regimen.

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- D. For treatment of covered chronic neutropenia, the member's medical record must document appropriate evaluation of the cause of the neutropenia, and where appropriate, a history of recurrent fevers and/or infections. The absolute neutrophil count must be documented but need not be submitted with the claim.
- E. For prophylaxis of chemotherapy-associated neutropenia, indicate the chemotherapy drug used in the medical record.
- F. The member's medical record must clearly document the time the last dose of the cytotoxic chemotherapy cycle ended and the time the G-CSF drug was administered.
- G. If pegfilgrastim will be administered outside the timeframe specified by the FDA labeling for dose dense chemotherapy, the reason for the exception should be clearly documented in the medical record.

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

- A. Administration of pegfilgrastim to increase chemotherapy dose intensity except as noted below
- B. Continuous use of pegfilgrastim for myelodysplastic syndromes or Felty's syndrome without infections
- C. Chemosensitization of myeloid leukemias
- D. Continued use if no response is seen within 28-42 days
- E. Administration in members with chronic aplastic anemia

IV. CRITERIA FOR APPROVAL

A. Prevention of Febrile Neutropenia in Cancer Patients Receiving Myelosuppressive Chemotherapy and/or Immunotherapy

Authorization of 6 months may be granted for prevention of febrile neutropenia when the chemotherapeutic agents are covered by Medicare and any of the following criteria are met:

1. Pegfilgrastim will be used for primary prophylaxis in a member whose risk of febrile neutropenia is 20% or greater based on the chemotherapy regimen
2. Pegfilgrastim will be used for primary prophylaxis in a member whose risk of febrile neutropenia is greater than or equal to 10% and less than 20% based on the chemotherapy regimen and at least one of the following risk factors for febrile neutropenia are present:
 - i. Age greater than 65 years
 - ii. Poor performance status
 - iii. Previous episodes of febrile neutropenia
 - iv. History of previous chemotherapy or radiation therapy
 - v. After completion of combined chemoradiotherapy
 - vi. Bone marrow involvement by tumor producing cytopenias
 - vii. Preexisting neutropenia
 - viii. Poor nutritional status
 - ix. Poor renal function
 - x. Liver dysfunction (i.e., elevated bilirubin)
 - xi. Presence of open wounds or active infections
 - xii. Recent surgery (within the past 12 weeks)
 - xiii. Advanced cancer
 - xiv. Other serious comorbidities
3. Pegfilgrastim will be used as secondary prophylaxis when both of the following conditions are met:

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- i. The member has documented febrile neutropenia from a prior chemotherapy cycle (for which primary prophylaxis was not received)
- ii. A reduction in dosage of the chemotherapeutic agent or delay in treatment may compromise disease-free or overall survival or treatment outcome

B. Adjunctive Treatment of Neutropenia

Authorization of 6 months may be granted for adjunctive treatment of neutropenia when any of the conditions below are present:

1. Expected prolonged (greater than 10 days) and profound (less than $0.1 \times 10^9/L$) neutropenia
2. Age greater than 65 years
3. Uncontrolled primary disease
4. Pneumonia
5. Hypotension and multiorgan dysfunction (sepsis syndrome)
6. Invasive fungal infection
7. Hospitalization at the time of the development of fever

C. Other Indications

Authorization of 6 months may be granted for treatment of any of the following conditions:

1. Acute exposure to myelosuppressive doses of radiation
2. After completion of the first few days of initial induction chemotherapy or for first post-remission course of chemotherapy for the treatment of acute lymphocytic leukemia (ALL)
3. Myelodysplastic syndrome when either of the following criteria is met:
 - i. Absolute neutrophil count (ANC) less than or equal to $500/mm^3$
 - ii. Member is experiencing recurrent infection
4. Dose dense chemotherapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant breast cancer or other malignancies for which dose dense chemotherapy is an accepted treatment option
5. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for any of the following conditions:
 - i. To promote myeloid reconstitution
 - ii. When engraftment is delayed or has failed

V. DOSAGE AND ADMINISTRATION

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation. If the member is on a dose dense 14-day chemotherapy cycle, it would be acceptable to administer pegfilgrastim outside of the 14-day before and 24-hour after rule for chemotherapy. Pegfilgrastim will be covered when administered under direct supervision in the office setting. When administered by the member or caregiver, the drug will be considered self-administered and not payable.

VI. REFERENCES

1. White Cell Colony Stimulating Factors LCD (L37176) Version R15. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed January 26, 2023.

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2. Billing and Coding: White Cell Colony Stimulating Factors (A56748) Version R8. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed May 23, 2022.
3. Neulasta [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2021.
4. Fulphila [package insert]. Morgantown, WV: Mylan Pharmaceuticals, Inc.; October 2021.
5. Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; October 2021.
6. Ziextenzo [package insert]. Princeton, NJ: Sandoz, Inc.; March 2021.
7. Udenyca [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; June 2021

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