Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), Pegfilgrastim-bmez (Ziextenzo®), Pegfilgrastim-apgf (Nyvepria™)

Prior Authorization Drug Coverage Policy

Effective Date: 6/1/2021
Revision Date: n/a
Review Date: 9/30/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), and Pegfilgrastim-bmez (Ziextenzo®). Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Pegfilgrastim is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

FDA Indications[1]

Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), Pegfilgrastim-bmez (Ziextenzo®), Pegfilgrastim-apgf (Nyvepria™) are FDA indicated for the following:

- Prevention of chemotherapy-induced neutropenia to decrease the incidence of infection (as manifested by febrile neutropenia) in patients with nonmyeloid malignancies receiving myelosuppressive cancer chemotherapy associated with a clinically significant incidence of febrile neutropenia

Pegfilgrastim (Neulasta®, Neulasta® OnPro) is also FDA indicated for the following:

- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

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Coverage Determinations[1-7]

Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), Pegfilgrastim-bmez (Ziextenzo®), Pegfilgrastim-apgf (Nyvepria™) will require prior authorization. These agents are considered medically necessary for the following oncology-related indications if all criteria below are met:

Prevention of chemotherapy induced febrile neutropenia

- Member has a diagnosis of a solid tumor and a non-myeloid malignancy **AND**
- Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), Pegfilgrastim-bmez (Ziextenzo®) or Pegfilgrastim-apgf (Nyvepria™) will not be administered less than 14 days before (unless on dose-dense chemotherapy) or 24 hours after chemotherapy **AND**
- The member meets at least ONE of the following criteria:
    - Receiving myelosuppressive chemotherapy with a risk of febrile neutropenia of at least 20% **OR**
    - Receiving myelosuppressive chemotherapy with an intermediate risk of febrile neutropenia of 10-20% AND at least one of the following patient-specific risk factors including prior chemotherapy or radiation therapy, persistent neutropenia (Absolute Neutrophil Count < 500/mm^3 or < 1000/mm^3 and expected to decline to less than 500/mm^3 within the next 48 hours), bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction with a total bilirubin > 2 mg/dL, renal dysfunction with a creatinine clearance < 50 mL/min, age > 65 years and receiving full chemotherapy dose intensity **OR**
    - Receiving dose-dense myelosuppressive chemotherapy **OR**
    - The patient experienced a febrile neutropenic event with prior administration of the same chemotherapy regimen

Recommended dosage: 6 mg subcutaneously once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy; Do not administer in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

Hematopoietic Subsyndrome of Acute radiation Syndrome

- Member has a diagnosis of a solid tumor and a non-myeloid malignancy

Recommended dosage: two doses of 6 mg administered subcutaneous injection one week apart.

All indications:

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- Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), and Pegfilgrastim-bmez (Ziextenzo®) will be approved through clinical review for up to a 12-month duration.

Coverage Limitations

Treatment with Pegfilgrastim (Neulasta®, Neulasta® Onpro®), Pegfilgrastim-cbqv (Udenyca®), Pegfilgrastim-jmdb (Fulphila®), Pegfilgrastim-bmez (Ziextenzo®), Pegfilgrastim-apgf (Nyvepria™) is not considered medically necessary for members with the following concomitant conditions:

- For mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplant
- Not routinely supported for patients receiving myelosuppressive chemotherapy with less than a 10% risk of febrile neutropenia.
- For concomitant administration on the same day as myelosuppressive chemotherapy or radiation therapy.
    - Neulasta® Onpro® may be applied to the patient the same day as chemotherapy as this product injects pegfilgrastim approximately 27 hours after application to the body.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary.

Contraindications/Warnings/Precautions[1-7]

- Patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as pegfilgrastim or filgrastim.
- Warnings/precautions:
    - Fatal splenic rupture
    - Acute respiratory distress syndrome
    - Serious allergic reactions
    - The on-body injector for Neulasta® uses acrylic adhesive. For patients who have reactions to acrylic adhesives, use of this product may result in a significant reaction
    - Fatal sickle cell crises
    - Glomerulonephritis
    - Potential device failures

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

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- **Description**: Inj., pegfilgrastim, 6 mg
  - HCPCS: J2505
- **Description**: Inj., pegfilgrastim-cbqv, 6 mg
  - HCPCS: Q5111
- **Description**: Inj., pegfilgrastim-jmdb, 6 mg
  - HCPCS: Q5108
- **Description**: Inj., pegfilgrastim-bmez, 6 mg
  - HCPCS: J5120
- **Description:** Inj., pegfilgrastim-apgf, 6 mg
  - HCPCS: Q5122

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

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2. Pegfilgrastim. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
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