SmartHealth Ascension

Pegfilgrastim

(Neulasta®) J2506

Covered with prior authorization

Pegfilgrastim (Neulasta®) may be authorized when the following criteria are met:

- Diagnosis of non myeloid malignancy; **AND**
- Used for primary prophylaxis of febrile neutropenia (FN); **AND**
- Individual has a risk of FN of 20% or greater based on chemotherapy regimen.

OR

- Diagnosis of non myeloid malignancy; **AND**
- Used for primary prophylaxis of FN; **AND**
- Individual's risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy regimen; **AND**
- Individual has any of the following risk factors for FN:
    - Age greater than 65 years; **OR**
    - Poor performance status or HIV infection but chemotherapy still indicated; **OR**
    - Prior radiation therapy (within previous 1 year); **OR**
    - Bone marrow involvement by tumor producing cytopenias; **OR**
    - Persistent neutropenia (absolute neutrophil count [ANC] less than 1500 mm^3); **OR**
    - Poor renal function (glomerular filtration rate [GFR] less than 60mL/min); **OR**
    - Liver dysfunction (liver function tests at least 2X upper limit of normal or bilirubin > 2.0 mg/dL); **OR**
    - Recent surgery performed as part of cancer management within previous 30 days (not to include a procedure such as port placement, drain placement, IVC filter, etc.); **OR**
    - History of active infection within previous 60 days; **OR**
    - Current open wound and chemotherapy cannot be delayed.

OR

- Diagnosis of non myeloid malignancy; **AND**
- Used for secondary prophylaxis of FN; **AND**
- Individual has experienced a neutropenic complication from a prior cycle of chemotherapy (for which prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome.

OR

- Individual is using as adjunctive treatment for FN; **AND**
- Individual has not received prophylactic therapy with pegfilgrastim; **AND**
- Individual has a high risk for infection-associated complications as demonstrated by any of the following:
    - Expected prolonged (greater than 10 days) and profound (less than 0.1 x 109/L) neutropenia; **OR**
    - Age greater than 65 years; **OR**
    - Pneumonia or other clinically documented infections; **OR**

- Hypotension and multi organ dysfunction (sepsis syndrome); **OR**
- Invasive fungal infection; **OR**
- Prior episode of febrile neutropenia; **OR**
- Hospitalized at the time of the development of fever.

OR

- Individual is receiving dose dense therapy (treatment given more frequently, such as every 2 weeks instead of every 3 weeks) for adjuvant treatment of breast cancer.

OR

- Individual is using after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome).

OR

- Individual is using after a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment is delayed or has failed.

AND

- Dosing for patients with cancer receiving myelosuppressive **chemotherapy** is
  - 6 mg administered subcutaneously once per chemotherapy cycle OR
  - Weight-based for pediatric patients weighing between 10 and 44 kg 45 kg where dose range is from 1.5 mg to 4 mg; **OR**
- Dosing for patients acutely exposed to myelosuppressive **doses of radiation** is
  - Two doses, 6 mg each, administered subcutaneously one week apart.
  - weight-based for pediatric patients weighing between 10 and 44 kg 45 kg where dose range is from 1.5 mg to 4 mg.

AND

- Individual has had a trial and inadequate response or intolerance to biosimilar product (pegfilgrastim-jmdb (Fulphila); pegfilgrastim-cbqv (Udenyca); pegfilgrastim-bmez (Aiextenzo); pegfilgrastim-apgf, (Nyvepria)); **OR**
- Neulasta® is FDA-approved for the prescribed indication while the biosimilar product is not.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Treatment in neutropenia in those who are afebrile, except when criteria above are met;
- Adjunctive therapy in those with uncomplicated febrile neutropenia, defined as: fever less than 10 days duration, no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection; and no uncontrolled malignancies;
- Chemosensitization of myeloid leukemias;
- Prophylaxis for FN during concomitant chemotherapy and radiation therapy;
- Continuing use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders);

- Using to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
pegfilgrastim-jmdb, biosimilar, (Fulphila) [Q5108]	pegfilgrastim (NEULASTA®)
pegfilgrastim-cbqv, biosimilar, (Udenyca), [Q5111]	
pegfilgrastim-bmez, biosimilar, (Ziextenzo) [Q5120]	
pegfilgrastim-apgf, biosimilar, (Nyvepria) [Q5122]	

Initial authorization for approved indications is up to 6 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Neulasta® is a leukocyte growth factor indicated to:
- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome).

References:

National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 26, 2022, from https://www.nccn.org/guidelines/category_1
Neulasta® (pegfilgrastim) Label. (2019, April). Accessdata.fda.gov. Retrieved April 25, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125031s198lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior

Date	Summary of Changes
	Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.