Maryland
DEPARTMENT OF HEALTH

Neulasta (pegfilgrastim)

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).

Limitations of Use: Neulasta **IS NOT** indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

I. Criteria for Initial Approval

Neulasta will be considered for coverage when **ALL** of the criteria below are met, and confirmed with supporting medical documentation:

Primary prophylaxis of chemotherapy-induced neutropenia (CIN)

- Appropriate for patients of all age ranges.
- Prescribed by or in consultation with an oncologist.
- Documentation the member will be receiving a chemotherapy regimen associated with a high risk (>20%) of febrile neutropenia (FN) based on the National Comprehensive Cancer Network (NCCN) clinical guidelines for myeloid growth factors.
- Documentation the member will be receiving a chemotherapy regimen associated with an intermediate risk (10 to 20%) of FN based on the NCCN clinical guidelines for myeloid growth factors AND the member has at least one (1) of the following risk factors:
    - Age ≥ 65 years
        - Advanced disease (stage 2 or higher or bone marrow involvement).
        - Prior chemotherapy or radiation therapy.
    - Pre-existing neutropenia.
    - Poor performance status (Eastern Cooperative Oncology Group [ECOG] score of 2 to 5).
    - Poor nutritional status.

    - Recent infection (<60 days prior to the start of chemotherapy).
    - Recent surgery or open wounds.
    - Comorbidities (cardiovascular disease, renal dysfunction [creatinine clearance <50], liver dysfunction [bilirubin >2.0], human immunodeficiency virus [HIV] virus).
    - Concern with patient's comprehension of the severity of fever development or concern with patient's access to a hospital if fever developed.
    - Chronic immunosuppression in the post-transplant setting.
- Monitoring of complete blood count (CBC) including platelet counts, during Neulasta therapy is recommended.
- Myelodysplastic Syndrome (MDS) and Acute Myeloid Leukemia (AML): Monitor patients with breast and lung cancer using Neulasta in conjunction with chemotherapy and/or radiotherapy for signs and symptoms of MDS/AML.
- Do not administer Neulasta between 14 days before and 24 hours after administration of cytotoxic chemotherapy.
- Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Patients with Hematopoietic Subsyndrome of Acute Radiation Syndrome

- Appropriate for patients of all age ranges.
- When the treatment is prescribed by, or in consultation with, an oncologist.
- Monitoring of complete blood count (CBC) during Neulasta therapy is recommended.
- Do not administer Neulasta between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in **Section I**) must be met **AND** the provider attests to both:

- A positive clinical response; AND
- Absence of unacceptable toxicity from the drug.
  NOTE: Examples of unacceptable toxicity include: splenic rupture, acute respiratory distress syndrome (ARDS), serious allergic reactions/anaphylaxis, sickle cell crisis, glomerulonephritis, leukocytosis, capillary leak syndrome, potential for tumor growth stimulation of malignant cells, and aortitis.

III. Dosing/Administration

Neulasta must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

Patients with cancer receiving myelosuppressive chemotherapy

- 6 mg administered subcutaneously once per chemotherapy cycle.
- Use weight-based dosing for pediatric patients weighing less than 45 kg:
    - <10 kg = 0.1 mg/kg
    - 10-20 kg = 1.5 mg
    - 21-30 kg = 2.5 mg
    - 31-44 kg = 4 mg

NOTE: Do not administer between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

Patients acutely exposed to myelosuppressive doses of radiation

- Two doses, 6 mg each, administered subcutaneously one week apart. Administer the first dose as soon as possible after suspected or confirmed exposure to myelosuppressive doses of radiation, and a second dose one week after.
- Use weight-based dosing for pediatric patients weighing less than 45 kg:
    - <10 kg = 0.1 mg/kg
    - 10-20 kg = 1.5 mg
    - 21-30 kg = 2.5 mg
    - 31-44 kg = 4 mg

IV. Length of Authorization for Initial Therapy

Neulasta will be authorized for six months when the criteria for initial approval are met. Continuing therapy with Neulasta will be authorized for 12 months.

V. Billing Code/Information

HCPCS code J2506: Injection, pegfilgrastim, 6 mg.

1 Billable Unit = 0.5 mg.

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or

payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 7/8/2022
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