SPECIALTY GUIDELINE MANAGEMENT

NEULASTA (pegfilgrastim)

POLICY

A. 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.

FDA-Approved Indication
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.

Compendial Use
• Mobilization of peripheral blood progenitor cells prior to autologous transplantation

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION
The following documentation is required to initiate a prior authorization review:

Neutropenia in cancer patients receiving myelosuppressive chemotherapy: Length of chemotherapy cycle, the days of the cycle on which chemotherapy will be administered, and the day of the cycle on which the Neulasta will be administered (e.g., 21 day cycle, chemotherapy on days 1 and 2, Neulasta administered day 3)

C. CRITERIA FOR APPROVAL
1. Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy
   a. Authorization of 6 months may be granted for members who are prescribed Neulasta for prevention of febrile neutropenia when all of the following criteria are met:
      i. Member has a non-myeloid malignancy
      ii. Member is currently receiving or will be receiving myelosuppressive chemotherapy or radiotherapy
      iii. Neulasta will not be administered with chemotherapy regimens of less than 14 days
      iv. Neulasta will be administered at least 24 hours after chemotherapy or radiotherapy
      v. The member will not receive chemotherapy and radiotherapy concurrently

2. Mobilization of peripheral blood progenitor cells (PBPCs)
   a. Authorization of 6 months may be granted for members who are prescribed Neulasta for mobilization of PBPCs prior to autologous transplantation.

D. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. Dosing Limits
   The following dosing limits apply:
   • Prevention of neutropenia associated with myelosuppressive chemotherapy: 6 mg per cycle
   • PBPC mobilization/collection: One 6mg dose
REFERENCES