SUBJECT: Pegfilgrastim (Neulasta®)
INDEX TITLE: Clinical Pharmacy Services
ORIGINAL DATE: 10/12/05

This policy applies to the following lines of business: (Check those that apply.)

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I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Pegfilgrastim (Neulasta) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization Process for Pegfilgrastim (Neulasta).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. PROCEDURE

Pegfilgrastim (Neulasta) is indicated to decrease the incidence of infection manifested as febrile neutropenia in members with non-myeloid malignancies receiving myelosuppressive chemotherapy associated with a clinically significant incidence of febrile neutropenia.

Criteria for Pegfilgrastim
Pegfilgrastim will be covered for members who meet ALL of the following criteria:

- Members with a diagnosis of cancer with non-myeloid malignancies receiving myelosuppressive chemotherapy, associated with high incidence of febrile neutropenia,
- Member does not have any contraindications to Pegfilgrastim including history of hypersensitivity to E. coli-derived proteins, Pegfilgrastim, Filgrastim, or any component of the product,
- Prescribed dose must be within the recommended dosing guidelines described below:
  a. 6mg as a single SC injection per chemotherapy cycle
  b. The 6mg fixed dose should not be used in infants, children, and smaller adolescents weighing less than 45kg
  c. Should not be administered in the period between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

Initial Authorization:
If above criteria is met, UPMC Health Plan will initially approve for 3 months.

Reauthorization criteria:
Therapy continuation will be authorized for up to 3 months with documentation of improvement or ANC stabilization to maintain ANC > 1500 cells/mm³.

Limitations:
If a member does not meet the above approval criteria, the request will be sent to a UPMC Health Plan Medical Director for review.

VI. BIBLIOGRAPHY