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, Filgrastim (Neupogen) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization for Filgrastim (Neupogen).

IV. SCOPE

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

Filgrastim is indicated for the following:

a. To decrease the incidence of infection manifested as febrile neutropenia in oncology members receiving myelosuppressive chemotherapy.

b. To reduce the neutrophil recovery and the duration of fever following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia.

c. To reduce the duration of neutropenia and neutropenia-related clinical sequelae in members undergoing myeloablative chemotherapy followed by marrow transplantation.

d. To reduce the incidence and duration of sequelae of neutropenia with chronic administration in severe chronic neutropenic members.

e. For the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Criteria

Filgrastim will be covered for members who meet the following criteria:

i. For cancer members receiving conventional chemotherapy:
   a. Primary prophylactic filgrastim administration is medically necessary for members receiving chemotherapy which has a significant risk of severe neutropenia (refer to Table 1).

ii. Secondary prophylactic filgrastim administration is medically necessary when the following criteria are met:
   a. Member is receiving a chemotherapy regimen which has a significant risk of severe neutropenia (See Table 1) AND
   b. Member has a disease for which clinical data supports maintenance of chemotherapy dose-intensity (refer to Table 2).

iii. For cancer members receiving high-dose chemotherapy (the administration of cytotoxic agents at doses several times greater than the standard therapeutic dose): Neupogen® is medically necessary as primary prophylactic administration for cases in which the physician anticipates a life-threatening drop in the member’s neutrophil count.

iv. Bone Marrow Transplant (BMT): To reduce the duration of neutropenia and neutropenia-related clinical sequelae in members undergoing myeloablative chemotherapy followed by marrow transplantation.

v. For members undergoing solid organ transplant: Neupogen® will be considered medically necessary.

vi. Members undergoing peripheral blood progenitor cell (PBPC) collection and therapy: For the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

vii. Myeloid malignancies: Neupogen® is medically necessary as primary prophylactic administration for members after induction chemotherapy for treatment of adults with acute myeloid leukemia (AML).

viii. Congenital neutropenia: Neupogen® is medically necessary for members with a neutrophil count less that 1000 cells/mm³.

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ix. Drug-induced agranulocytosis: Neupogen® is medically necessary for members with a neutrophil count less than 1000 cells/mm³ associated with fever or other evidence of serious infection

x. AIDS: Neupogen® is medically necessary for members being treated with ganciclovir (for CMV) AND whose neutrophil counts are consistently less than 1000 cells/mm³

xi. Radiation therapy: Neupogen® is NOT medically necessary as primary prophylactic or secondary prophylactic administration or therapy when the member is receiving ONLY radiation therapy

xii. Member does not have any contraindications:
   a. History of hypersensitivity to E. coli-derived proteins, Filgrastim, or any component of the product

Table 1. Chemotherapy agents with a significant risk of neutropenia

<table>
<thead>
<tr>
<th>Busulfan</th>
<th>Daunorubicin</th>
<th>Lomustine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboplatin</td>
<td>Docetaxel</td>
<td>Mitoxentron</td>
</tr>
<tr>
<td>Carmustine</td>
<td>Daxorubicin</td>
<td>Paclitaxel</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>Etoposide</td>
<td>Semustine</td>
</tr>
<tr>
<td>Cytarabine</td>
<td>Fludarabine</td>
<td>Topotecan</td>
</tr>
<tr>
<td>Dacarbazine</td>
<td>Idarubicin</td>
<td>Vinblastine</td>
</tr>
<tr>
<td>Dactinomycin</td>
<td>Ifosfamide</td>
<td>Vinorelbine</td>
</tr>
</tbody>
</table>

Table 2. Dose responsive tumors

<table>
<thead>
<tr>
<th>Acute lymphocytic leukemia</th>
<th>Neuroblastoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>Non-Hodgkins lymphoma</td>
</tr>
<tr>
<td>Bladder</td>
<td>Ovarian</td>
</tr>
<tr>
<td>Hodgkin’s lymphoma</td>
<td>Testicular</td>
</tr>
</tbody>
</table>

Initial authorization:
If candidate meets the above criteria, then an initial authorization for 3 months will be approved.

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

Reference dose range:
- Usual dose: 5 mcg/kg SQ daily for 7-14 days
- High dose: 10 mcg/kg SQ daily for 7-14 days
  Some cancer members with dose intense chemotherapies will require this dose.
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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**


