Neupogen is a recombinant granulocyte colony stimulating factor (G-CSF) that was initially approved by the FDA in 1991. It has many uses related to oncology and chemotherapy as well as an indication for severe chronic neutropenia (SCN), a group of rare hematologic diseases characterized by a decrease in circulating neutrophils that can lead to recurrent and severe infections. Biosimilar filgrastim products have also been approved. Treatment with filgrastim results in a stimulation of bone marrow production and maturation of neutrophils, increases neutrophils in circulation, and reduces infection-related events. Neutrophils are the dominant type of granulocyte (a type of white blood cell) and are important for fighting infections. A competitor product, Granix (tbo-filgrastim), is only indicated for febrile neutropenia.

Filgrastim will be considered for coverage when the following criteria are met:

### Severe Chronic Neutropenia (SCN)

**For initial authorization:**
1. Medication must be prescribed by or in consultation with a hematologist; AND
2. If the request is for Neupogen, Nivestym, or Reluoko, member must have tried and failed Zarxio; AND
3. Member must have a documented diagnosis of SCN (i.e., congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia) with chart notes confirming both of the following:
   a) Absolute neutrophil count (ANC) < 500/mm³ on three occasions during a 3-month period (or for cyclic neutropenia 5 consecutive days of ANC < 500/mm³ per cycle)
   b) Clinically significant infection during the previous 12 months.
4. **Dosage allowed/Quantity limit:** Varies widely. Recommended starting doses (subQ):
   - Idiopathic neutropenia: 5 mcg/kg once daily
   - Cyclic neutropenia: 5 mcg/kg once daily
   - Congenital neutropenia: 6 mcg/kg twice daily

*If all the above requirements are met, the medication will be approved for 12 months.*

**For reauthorization:**
1. Chart notes must document a positive clinical response to therapy, such as neutrophil count recovery, decreased infection-related events, and/or increased maturing neutrophils on bone marrow aspirate.

*If all the above requirements are met, the medication will be approved for an additional 12 months.*

- **Patients with Cancer Receiving Myelosuppressive Chemotherapy**
Patients with Acute Myeloid Leukemia Receiving Induction or Consolidation Chemotherapy
- Patients with Cancer Undergoing Bone Marrow Transplantation
- Patients Undergoing Autologous Peripheral Blood Progenitor Cell Collection and Therapy
- Patients Acutely Exposed to Myelosuppressive Doses of Radiation

Any oncology related request must be submitted through the NantHealth/Eviti portal and will be reviewed following the Oncology Regimens policy.

CareSource considers filgrastim not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/19/2017</td>
<td>New policy for Neupogen created. Age limits and degree of hematotoxicity were removed; radiation exposure level requirement was decreased. Criteria coverage for Prevention of Febrile Neutropenia was expanded. Chemotherapy regimens with high and intermediate risk of febrile neutropenia were added to the policy’s appendix. Length of therapy of preferred trial agent was deleted. List of not covered diagnoses was added.</td>
</tr>
<tr>
<td>02/19/2020</td>
<td>Requirement for chart notes detailing chemotherapy regimen cycle removed.</td>
</tr>
<tr>
<td>08/15/2022</td>
<td>Transferred to new template. Combined Neupogen with its biosimilars to create a single policy; updated billing codes; added Releuko. Removed criteria for all indications related to cancer and referred to Eviti. Updated and added references. Added specialist. Changed ANC counts over 6 months to ANC counts over 3 months for diagnosis. Corrected dosing. Extended initial approval duration from 6 mo to 12 mo. Specified renewal criteria.</td>
</tr>
<tr>
<td>3/3/2023</td>
<td>Added reference to the Oncology Regimens policy.</td>
</tr>
</tbody>
</table>

References:

1. Neupogen (filgrastim) [prescribing information]. Amgen; 2021.
4. Releuko (filgrastim-ayow) [prescribing information]. Amneal Pharmaceuticals LLC; 2022.

Effective date: 04/14/2023
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