CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Filgrastim (Neupogen, Zarxio, Nivestym, Releuko)
BILLING CODE	For medical - J1442, Q5101, Q5110, J3590 For Rx - must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

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 Releuko, 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/mm^3 on three occasions during a 3-month period (or for cyclic neutropenia 5 consecutive days of ANC < 500/mm^3 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.

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.

DATE	ACTION/DESCRIPTION
10/19/2017	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.
02/19/2020	Requirement for chart notes detailing chemotherapy regimen cycle removed.
08/15/2022	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.

References:

1. Neupogen (filgrastim) [prescribing information]. Amgen; 2021.
2. Zarxio (filgrastim-sndz) [prescribing information]. Sandoz Inc.; 2021.
3. Nivestym (filgrastim-aafi) [prescribing information]. Hospira, Inc., a Pfizer Company; 2021.
4. Releuko (filgrastim-ayow) [prescribing information]. Amneal Pharmaceuticals LLC; 2022.
5. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 1.2022). https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf Accessed August 12, 2022.
6. Dale DC, Bonilla MA, Davis MW, et al. A randomized controlled phase III trial of recombinant human granulocyte colony-stimulating factor (filgrastim) for treatment of severe chronic neutropenia. *Blood*. 1993;81(10):2496-2502.
7. Dale DC, Bolyard AA, Shannon JA, et al. Outcomes for patients with severe chronic neutropenia treated with granulocyte colony-stimulating factor. *Blood Adv*. 2022;6(13):3861-3869. doi:10.1182/bloodadvances.2021005684

Effective date: 01/01/2023
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