

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Filgrastim (Neupogen, Zarxio, Nivestym, Releuko)
BILLING CODE	J1442, Q5101, Q5110, J3590
BENEFIT TYPE	Medical
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:

- Medication must be prescribed by or in consultation with a hematologist; AND
- If the request is for Neupogen, Nivestym, or Releuko, member must have tried and failed Zarxio; AND
- 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:
 - 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)
 - Clinically significant infection during the previous 12 months.
- 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**:

- 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

Revised date: 03/03/2023