

## Filgrastim (Neupogen, Nivestym, Zarxio, Releuko)

When requesting filgrastim (Neupogen, Nivestym, Zarxio, Releuko) for non-oncology indications, the individual requiring treatment must be diagnosed with an FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

### FDA-approved Non-oncology Indication

Neupogen, Nivestym, Zarxio, and Releuko are leukocyte growth factors indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

### Approved Non-oncology Off-label Compendial Use

- Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)
- Drug-induced (non-chemotherapy) agranulocytosis or neutropenia

### Coverage Guidelines

#### **Severe chronic neutropenia (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia)**

- Approve for 6 months if prescribed by or in consultation with a hematologist.

#### **Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)**

- Approve for 4 months if the agent is prescribed by or in consultation with a physician that specializes in infectious diseases, a hematologist, or a physician who specializes in the management of HIV/AIDS.

#### **Drug-induced (non-chemotherapy) agranulocytosis or neutropenia**

- Approve for 1 month

### Dosing Recommendation

#### Severe chronic neutropenia (e.g., congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia):

Administer up to 12 mcg/kg per day by subcutaneous injection.

#### Neutropenia associated with HIV or AIDS:

Administer up to 10 mcg/kg per day as a subcutaneous injection.

**Drug-induced (non-chemotherapy) agranulocytosis or neutropenia**

Administer up to 10 mcg/kg per day as a subcutaneous injection.

## References

1. Neupogen® subcutaneous or intravenous injection [prescribing information]. Thousand Oaks, CA: Amgen; February 2021.
2. Zarxio™ subcutaneous or intravenous injection [prescribing information]. Princeton, NJ: Sandoz; March 2021.
3. Nivestym™ subcutaneous or intravenous injection [prescribing information]. Lake Forest, IL and New York, NY: Hospira and Pfizer; November 2021.
4. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; April 2020.
5. Kuritzkes DR, Parenti D, Ward DJ, et al, and the G-CSF 930101 study group. Filgrastim prevents severe neutropenia and reduces infective morbidity in patients with advanced HIV infection: Results of a randomized, multicenter controlled trial. *AIDS*. 1998;12:65-71.
6. Hermans P, Rozenbaum W, Joy A, et al, and the G-CSF 92105 Study Group. Filgrastim to treat neutropenia and support myelosuppressive medication dosing in HIV infection. *AIDS*. 1996;10:1627-1633.
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15. Andres E, Mourot-Cottet R, Maloisel F, et al. Idiosyncratic drug-induced neutropenia and agranulocytosis. *QJM*. 2017 Jan 9.
16. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; February 2022.