



Filgrastim (Neupogen, Nivestym, Zarxio)

When requesting filgrastim (Neupogen, Nivestym, Zarxio) 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, and Zarxio 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):

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

Neutropenia associated with HIV or AIDS:

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

Drug-induced (non-chemotherapy) agranulocytosis or neutropenia

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

References

1. Neupogen® injection for subcutaneous or intravenous use [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; June 2018.
2. Zarzio™ injection for subcutaneous or intravenous use [prescribing information]. Princeton, NJ: Sandoz; August 2019.
3. Nivestym™ injection for subcutaneous or intravenous use [prescribing information]. Lake Forest, IL and New York, NY: Hospira and Pfizer; July 2018.
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8. Mitsuyasu R. Prevention of bacterial infections in patients with advanced HIV infection. *AIDS*. 1999;13(Suppl 2):S19-S23.
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15. Andres E, Mourot-Cottet R, Maloisel F, et al. Idiosyncratic drug-induced neutropenia and agranulocytosis. *QJM*. 2017 Jan 9. [Epub ahead of print].