

Filgrastim Products (Neupogen®, Nivestym™, Nypozi™, Releuko®, Zarxio®)

When requesting a filgrastim product for non-oncology indications, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-oncology Indication

Filgrastim, a leukocyte growth factor, is 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 Uses

- 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 Recommendations

- 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; June 2025.
2. Zarxio™ subcutaneous or intravenous injection [prescribing information]. Princeton, NJ: Sandoz; August 2025.
3. Nivestym™ subcutaneous or intravenous injection [prescribing information]. Lake Forest, IL and New York, NY: Hospira and Pfizer; July 2025.
4. 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.
5. 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.
6. Kuritzkes DR. Neutropenia, neutrophil dysfunction, and bacterial infection in patients with human immunodeficiency virus disease: The role of granulocyte colony-stimulating factor. *Clin Infect Dis*. 2000;30:256-260.
7. Mitsuyasu R. Prevention of bacterial infections in patients with advanced HIV infection. *AIDS*. 1999;13(Suppl 2):S19-S23.
8. Tesfa D, Keisu M, Palblad J. Idiosyncratic drug-induced agranulocytosis: Possible mechanism and management. *Am J Hematol*. 2009;84:428-434.
9. Andersohn F, Konzen C, Garbe E. Systematic review: Agranulocytosis induced by nonchemotherapy drugs. *Ann Intern Med*. 2007;146:657-665.
10. Beauchesne MF, Shalansky SJ. Nonchemotherapy drug-induced agranulocytosis: A review of 118 patients treated with colony-stimulating factors. *Pharmacother*. 1999;19(3):299-305.
11. Bhatt V, Saleem A. Review: Drug-induced neutropenia-pathophysiology, clinical features, and management. *Ann Clin Lab Sci*. 2004;34(2):131-136.
12. Curtis BR. Drug-induced immune neutropenia/agranulocytosis. *Immunohematology*. 2014;30(2):95-101.
13. Andres E, Mourot-Cottet R. Non-chemotherapy drug-induced neutropenia – an update. *Expert Opin Drug Saf*. 2017;16(11):1235-1242.
14. Andres E, Mourot-Cottet R, Maloisel F, et al. Idiosyncratic drug-induced neutropenia and agranulocytosis. *QJM*. 2017 Jan 9.
15. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; April/Colon 2025.
16. Nypozi™ subcutaneous or intravenous injection [prescribing information]. San Diego, CA: Tanvex, June 2024.