

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. Zarxio™ 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.
4. Granix® injection for subcutaneous use [prescribing information]. North Wales, PA: Teva Pharmaceuticals; March 2019.
5. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 2.2020 – January 27, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on July 22, 2020.
6. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 2.2020 – February 28, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed: July 22, 2020.
7. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 2.2020 – January 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at <http://www.nccn.org>. Accessed on July 22, 2020.
8. Smith TJ, Bohlke K, Lyman GH, Carson KR, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-3212.
9. 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.
10. 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.
11. 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.
12. Mitsuyasu R. Prevention of bacterial infections in patients with advanced HIV infection. *AIDS*. 1999;13(Suppl 2):S19-S23.
13. Tesfa D, Keisu M, Palblad J. Idiosyncratic drug-induced agranulocytosis: possible mechanism and management. *Am J Hematol*. 2009;84:428-434.
14. Andersohn F, Konzen C, Garbe E. Systematic review: Agranulocytosis induced by nonchemotherapy drugs. *Ann Intern Med*. 2007;146:657-665.
15. Beaushesne MF, Shalansky SJ. Nonchemotherapy drug-induced agranulocytosis: a review of 118 patients treated with colony-stimulating factors. *Pharmacother*. 1999;19(3):299-305.
16. Bhatt V, Saleem A. Review: Drug-induced neutropenia-pathophysiology, clinical features, and management. *Ann Clin Lab Sci*. 2004;34(2):131-136.
17. Curtis BR. Drug-induced immune neutropenia/agranulocytosis. *Immunohematology*. 2014;30(2):95-101.
18. Andres E, Mourot-Cottet R. Non-chemotherapy drug-induced neutropenia – an update. *Expert Opin Drug Saf*. 2017;16(11):1235-1242.
19. Andres E, Mourot-Cottet R, Maloisel F, et al. Idiosyncratic drug-induced neutropenia and agranulocytosis. *QJM*. 2017 Jan 9. [Epub ahead of print].
20. The NCCN Management of Immunotherapy-Related Toxicities Clinical Practice Guidelines in Oncology (version 1.2020 – December 16, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on July 22, 2020.