

When requesting Neupogen® (filgrastim), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial requirements and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications¹

- To decrease the incidence of infection, as manifested by febrile neutropenia, in an individual with a non-myeloid malignancy receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
- To mobilize hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
- To increase survival in an individual acutely exposed to myelosuppressive doses of radiation
- To reduce the incidence and duration of sequelae of severe neutropenia in a symptomatic individual with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia

Approved Off-label Compendial uses^{2,3,4}

- For treatment of chemotherapy-induced febrile neutropenia³
- Myelodysplastic syndrome^{2,4}
- To reverse neutropenia caused by human immunodeficiency virus (HIV) infection⁴

Coverage Guidelines

For all indications:

- The individual does not have a history of a serious allergic reaction to pegfilgrastim (Neulasta)¹

The individual must have **one** of the following diagnoses for approval:

For prophylaxis of chemotherapy-induced febrile neutropenia^{1,2,3}

- Eligible diagnoses (must have one of the following):
 - Solid tumor or non-myeloid malignancy² **OR**
 - Acute Myeloid Leukemia (AML) receiving post-remission treatment.⁵
- Increased risk for febrile neutropenia (at least one of the following):
 - The individual has experienced hospitalization due to febrile neutropenia or a dose-limiting neutropenic event while on the current regimen³ **OR**
 - The individual is receiving chemotherapy with high risk ($\geq 20\%$) for febrile neutropenia:^{2,3} **OR**
 - The individual is receiving chemotherapy with intermediate risk (10-19%) for febrile neutropenia and has one or more of the following patient risk factors for developing febrile neutropenia:⁴

- Prior chemotherapy or radiation therapy
- Persistent neutropenia
- Bone marrow involvement by tumor
- Recent surgery and/or open wounds
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (creatinine clearance <50)
- Age >65 years receiving full chemotherapy dose intensity
- Poor performance status
- HIV infection (in particular, individuals with low CD4 counts)
- Chronic immunosuppression in the post-transplant setting, including organ transplant

For treatment of chemotherapy-induced febrile neutropenia³

- The individual has received Neulasta® (filgrastim) as prophylaxis **OR** has presence of risk factors for an infection associated complication as referenced by NCCN below³:
 - Sepsis syndrome
 - Age >65 years
 - Severe neutropenia [absolute neutrophil count <100/mcL]
 - Neutropenia expected to be more than 10 days in duration
 - Pneumonia or other clinically documented infections
 - Invasive fungal infection
 - Hospitalization at the time of fever
 - Prior episode of febrile neutropenia

For myelodysplastic syndrome:²

- The individual has symptomatic anemia with low risk disease² **AND**
- The individual has serum erythropoietin level less than or equal to 500 mU/mL **AND**
- Neupogen® (filgrastim) will be used in combination with epoetin alfa or darbepoetin alfa²

For mobilization of hematopoietic progenitor cells as an allogeneic donor^{1,4}

For acute exposure of myelosuppressive radiation doses¹

For severe chronic neutropenia¹

For neutropenia caused by human immunodeficiency virus (HIV)⁴

Approval duration (initial and renewal): 180 days

Additional Information for Prescribers

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Contraindicated in an individual with a history of a serious allergic reaction to pegfilgrastim¹
- *Do not administer Neupogen® (filgrastim) within 24 hours prior to or within 24 hours after completion of chemotherapy¹
- When mobilizing hematopoietic progenitor cells as an allogeneic donor, discontinue Neupogen® (filgrastim) if WBC count exceeds 100,000/mm³¹
- When treating severe chronic neutropenia, monitor CBCs with differential and platelet count during the initial 4 weeks of Neupogen® (filgrastim) therapy and for 2 weeks following any dosing adjustment. Once the individual is clinically stable, monitor CBCs with differential and platelet count monthly during the first year of treatment; this can be done less frequently thereafter so long as the individual is clinically stable¹
- For treatment of acute exposure of myelosuppressive radiation doses, continue administration of Neupogen® (filgrastim) until the Absolute Neutrophil Count (ANC) remains greater than 1,000/mm³ for 3 consecutive CBCs or exceeds 10,000/mm³ after the radiation-induced nadir¹
- Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture¹

References

1. Neupogen® prescribing information. Thousand Oaks, California: Amgen; Revised June 2016. Accessed February 27, 2017. http://pi.amgen.com/united_states/neupogen/neupogen_pi_hcp_english.pdf
2. National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN Compendium®) Accessed February 27, 2017. http://www.nccn.org/professionals/drug_compendium/content/contents.asp Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™). ©2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines™ and illustrations herein may not be reproduced in any form for any purpose without the express written permission of the NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to [NCCN.org](http://www.nccn.org).
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors. Version 2.2016. Accessed February 27, 2017. http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf
4. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed February 27, 2017.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 1.2017. Accessed March 10, 2017. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

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