

Neulasta® (pegfilgrastim) Injection J2505



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

FDA-approved indication(s)¹

- To decrease the incidence of infection, as manifested by febrile neutropenia, in individuals with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia¹
- To increase survival in individuals acutely exposed to myelosuppressive doses of radiation¹

Approved Off-label Compendial use(s)²

- No off-label uses meet evidence standards

Coverage Guidelines

For all approved indications, the individual does NOT have a history of serious allergic reactions to filgrastim (Neupogen)¹

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

For acute exposure of myelosuppressive radiation doses¹

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.⁴
- 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

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 to individuals with a history of serious allergic reactions to filgrastim¹
- Do not administer Neulasta® (pegfilgrastim) between 14 days before and 24 hours after cytotoxic chemotherapy¹
- Evaluate patients who report left upper abdominal or shoulder pain for an enlarged spleen or splenic rupture¹

References

1. Neulasta (pegfilgrastim) prescribing information. Thousand Oaks, CA: Amgen Inc.; December 2016. Accessed February 24, 2017. http://pi.amgen.com/united_states/neulasta/neulasta_pi_hcp_english.pdf
2. National Comprehensive Cancer Network Drugs & Biologics Compendium (NCCN Compendium®) Accessed February 24, 2017. https://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=52. 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 December February 24, 2017. http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf
4. 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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