

## Clinical Policy: Pegfilgrastim (Neulasta)

Reference Number: CP.PHAR.296

Effective Date: 12/16

Last Review Date: 11/16

[Coding Implications](#)  
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for pegfilgrastim (Neulasta®).

### Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Neulasta is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Non-Myeloid Malignancy - Febrile Neutropenia Prophylaxis (must meet all):

1. Neulasta is prescribed for use following myelosuppressive chemotherapy for non-myeloid cancer;
2. Member is at risk for febrile neutropenia due to the chemotherapy regimen or patient-related risk factors;
3. Prescribed dose of Neulasta does not exceed 6 mg administered once per chemotherapy cycle;
4. Member has no known history of serious allergic reaction to pegfilgrastim or filgrastim.

**Approval duration: 6 months**

##### B. Acute Radiation Syndrome (must meet all):

1. Neulasta is prescribed for use following suspected or confirmed acute exposure to myelosuppressive doses of radiation (>2 gray [Gy]);
2. Prescribed dose of Neulasta does not exceed two 6-mg doses administered one week apart;
3. Member has no known history of serious allergic reaction to pegfilgrastim or filgrastim.

**Approval duration: 6 months**

##### C. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.

1. Off-label NCCN recommended uses:
  - a. Supportive care in the post-hematopoietic cell transplant setting;
2. Member has no known history of serious allergic reaction to pegfilgrastim or filgrastim.

**Approval duration: 6 months**

**Background**

*Description/Mechanism of Action:*

Neulasta (pegfilgrastim) is a covalent conjugate of recombinant methionyl human granulocyte colony-stimulating factor (G-CSF) (filgrastim) and monomethoxypolyethylene glycol. Filgrastim is obtained from the bacterial fermentation of a strain of E coli transformed with a genetically engineered plasmid containing the human G-CSF gene. Pegfilgrastim is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

*Formulations:*

Injectable solution for subcutaneous use:

- Manual subcutaneous injection\*
  - Prefilled syringes: 0.6 mL of Neulasta
- On-body Injector\*
  - Prefilled syringes: 0.64 mL of Neulasta (to be used with the On-body Injector for Neulasta)

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\*Each prefilled syringe delivers 0.6 mL of Neulasta containing 6 mg pegfilgrastim

*FDA Approved Indications:*

Neulasta is a leukocyte growth factor/subcutaneous formulation with the following indications:

- Patients with cancer receiving myelosuppressive chemotherapy:
  - To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- Patients with hematopoietic subsyndrome of acute radiation syndrome:
  - To increase survival in patients acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of acute radiation syndrome).

*Limitations of use:*

- Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

**Appendices**

**Appendix A: Abbreviation Key**

G-CSF: granulocyte colony stimulating factor

Gy: gray

NCCN: National Comprehensive Cancer Network

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

**CLINICAL POLICY**  
**Pegfilgrastim**

HCPCS Codes	Description
J2505	Injection, pegfilgrastim, 6 mg

Reviews, Revisions, and Approvals	Date	Approval Date
Neulasta is split from CP.PHAR.26.Colony Stimulating Factors 2015, and converted to a new template. Max dose and contraindications added per PI. Labeled use: Acute radiation syndrome added per PI. Removed “Neulasta will not be given from 14 days before to 24 hours after chemotherapy.” Off-label use: Posttransplant support added per NCCN.	11/16	12/16

**References**

1. Neulasta Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; April 2016. Available at [http://pi.amgen.com/united\\_states/neulasta/neulasta\\_pi\\_hcp\\_english.pdf](http://pi.amgen.com/united_states/neulasta/neulasta_pi_hcp_english.pdf). Accessed October 26, 2016.
2. Myeloid growth factors (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed October 26, 2016.
3. Pegfilgrastim. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed October 26, 2016.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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