

Title: pegfilgrastim (Neulasta)

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| Origination: 08/19/10 | Revised: 11/22/11 | Annual Review: 12/15/11 |
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Pegfilgrastim is a covalent conjugate of recombinant methionyl human granulocyte colony-stimulating factor (filgrastim) and monomethoxypolyethylene glycol. Filgrastim is produced by *Escherichia coli* bacteria into which has been inserted the human gene for granulocyte colony-stimulating factor (G-CSF). To produce pegfilgrastim, a 20 kD monomethoxypolyethylene glycol molecule is covalently bound to the N-terminal methionyl residue of filgrastim.
- 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.
- Neulasta is indicated 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.
- The recommended dosage of Neulasta is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle in adults. Do not administer Neulasta between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Background Information, continued:

Exclusions

- Members with a history of hypersensitivity to *E coli*-derived proteins, pegfilgrastim, filgrastim, or any other component of the product.

Additional Information

- Requests received for **Medicare Members** will be reviewed using CMS “LCD for pegfilgrastim (L29254)” – Refer to Attachment A or view on-line at: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=29254&ContrId=197&ver=7&ContrVer=1&Date=11%2f22%2f2011&DocID=L29254&bc=iAAAAAgAAAA&>

Procedure:

- 1.0 Request for initial therapy with Neulasta for non-myeloid malignancy requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Member is undergoing myelosuppressive chemotherapy; **AND/OR**
 - 1.2 Member has the **at least one (1)** of the following risk factors:
 - 1.2.1 Age 65 or older;
 - 1.2.2 History of previous chemotherapy or radiation;
 - 1.2.3 Pre-existing neutropenia or bone marrow involvement with tumor;
 - 1.2.4 Poor performance status;
 - 1.2.5 Poor renal function;
 - 1.2.6 Liver dysfunction;
 - 1.3 If criteria are met, Neulasta is approvable for up to six (6) months.
- 2.0 Request for *initial therapy* with Neulasta for members who have experienced a neutropenic complication from a prior cycle of the same chemotherapy regimen:
 - 2.1 Member has experienced a neutropenic complication from a prior cycle of the same chemotherapy;
 - 2.2 If criteria are met, Neulasta is approvable for up to six (6) months.

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References:

1. Neulasta (pegfilgrastim) Prescribing Information. Amgen Inc. Thousand Oaks, CA. 2010.
2. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com Updated 2010.
3. National Comprehensive Cancer Network, Inc. (NCCN) Practice Guidelines in Oncology Version 2.2010, March 2010.
Available at: www.nccn.org/professionals/physician_gls/f_guidelines.asp

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.