

Title: *sargramostim, GM-CSF (Leukine)*

Origination: 12/01/93	Revised: 08/18/10	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:

Medication Summary

- Filgrastim and sargramostim are human granulocyte colony-stimulating factors that aid in regulating the production of neutrophils in the bone marrow.
- Absolute neutrophil count (ANC or GRAN) level can be calculated using the white blood cell (WBC) count and the neutrophil percentage level using the following formula:
 - $WBC \times \text{Neutrophil \%}$ (i.e. $WBC=4.3$ and $\text{Neutrophil \%}=50\%$; multiply to get 215; move decimal two (2) places for ANC of 2.15);
- Initial doses of filgrastim or sargramostim are initiated within 24-72 hours after completion of chemotherapy at daily doses until the post-nadir absolute neutrophil count (ANC/GRAN) recovers to normal or near-normal levels by laboratory standards. Same day administration is not recommended.
- Filgrastim and sargramostim are indicated:
 - To decrease the incidence of infection in members with non-myeloid malignancies receiving myelosuppressive chemotherapy medications with a clinically significant incidence of febrile neutropenia;
 - For reducing the time to neutrophil recovery and duration of fever following induction or consolidation chemotherapy in members with acute myeloid lymphoma (AML);
 - To reduce the duration of neutropenia in members with non-myeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation;
 - For the mobilization of hematopoietic progenitor cells into the peripheral blood for collection for leukapheresis;
 - For chronic administration to reduce the incidence and duration of neutropenia in symptomatic Members with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
- If the ANC/GRAN is greater than $1500/\text{mm}^3$ for three (3) consecutive days filgrastim or sargramostim may be discontinued and must be discontinued when ANC/GRAN reaches $10,000/\text{mm}^3$.

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Background Information, continued:

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.

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.**
- For Commercial Members: Neupogen or Leukine will be a:
 - Medical benefit (authorization to be loaded in the claims system) when diagnosis is neutropenia secondary to:
 1. Chemotherapy (when chemotherapy given within the past 30 days);
 2. Peripheral blood stem cell (PBSC) mobilization;
 3. Febrile neutropenia;
 - Pharmacy benefit (authorization to be loaded by PBM) with applicable co-payment, when the diagnosis is neutropenia secondary non-chemotherapy drug-induced neutropenia.
- For Medicare Members: will need to determine if Part B versus Part D depending on location (in-office or outpatient as Part B; self-injecting at home or via HHC as Part D).

Exclusion Criteria

- Hypersensitivity to *E. coli*-derived proteins, filgrastim or sargramostim, or any component of the products.

Additional Information

Requests received **for Medicare Members** will be reviewed using Center for Medicare & Medicaid Services (CMS) “LCD for Filgrastim (Neupogen - L29180)” and “LCD for Sargramostim (Leukine - L29275) – Refer to Attachment A and B or view on-line at: http://www.cms.hhs.gov/mcd/results_index.asp?from=%27lmpcontractor%27&contractor=197&name=First+Coast+Service+Options%2C+Inc%2E+%2809102%2C+MAC+%2D+Part+B%29&letter_range=4&retired

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Procedure:

- 1.0 Request for Leukine for **bone marrow transplant BMT patient or undergoing Peripheral Blood Progenitor Cell mobilization (PBPC)** requires the following:
 - 1.1 Leukine is approvable for four (4) months.
- 2.0 Request for Leukine for a **patient with non-myeloid malignancy undergoing myelosuppressive chemotherapy** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 2.1 In addition to the risk of the chemotherapy regimen, the following may be considered risk factors requiring use of Leukine:
 - 2.1.1 Elderly patients (65 or older);
 - 2.1.2 History of previous chemo or radiation;
 - 2.1.3 Pre-existing neutropenia or bone marrow involvement with tumor: (Neutropenia, Infection/open wounds, Recent surgery)
 - 2.1.4 Poor performance status;
 - 2.1.5 Poor renal function;
 - 2.1.6 Liver dysfunction (elevated bilirubin);
 - 2.2 If criteria are met, Leukine is approvable for four (4) months.
- 3.0 Request for Leukine for a **patient who experienced neutropenic complication from a prior cycle of the same chemotherapy** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 3.1 Leukine is approvable for four (4) months.
- 4.0 Request for Leukine for **Acute Myeloid Leukemia (AML) patient following induction or consolidation chemotherapy** requires documentation from the Member's medical records maintained by the requesting independent practitioner:
 - 4.1 Leukine is approvable for four (4) months.
- 5.0 Request for Leukine for **bone marrow transplantation failure or engraftment delay** requires documentation from the Member's medical records maintained by the requesting independent practitioner:
 - 5.1 Leukine is approvable for four (4) months.

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References:

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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.