Purpose:

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

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored, as indicated, via individual departmental audit process(es).

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

   3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived.

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.
Background Information, continued:

**Medication Summary**
- Sargramostim is a human granulocyte colony-stimulating factor that aids 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 x Neutrophil % (i.e. WBC=4.3 and Neutrophil %=50%; multiply to get 215; move decimal two (2) places for ANC of 2.15).

- Initial doses of 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 contraindicated.

- Sargramostim is 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;
  - To reduce 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.
  - For promotion of myeloid recovery and decreasing the period of neutropenia in Members with Hodgkin’s disease, non-Hodgkin’s lymphoma, or acute lymphocytic leukemia following autologous hematopoietic stem cell transplantation (SCT) or for any Member undergoing HLA-matched related allogeneic SCT.

- If the ANC/GRAN is greater than 1500/mm³ for three (3) consecutive days, sargramostim should be discontinued and must be discontinued when ANC/GRAN reaches 10,000/mm³.
Background Information, continued:

Coverage Guidelines

- 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: 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 to 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 Criterion

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

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
- Requests received for Medicare Members will be reviewed using Center for Medicare & Medicaid Services (CMS) “LCD for Filgrastim (Neupogen)” and “LCD for Sargramostim (Leukine)
Procedure:

1.0 Request for Leukine for bone marrow transplant BMT Member 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 Member 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 Members (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.
Procedure, continued:

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.

References:


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References, continued:

