Clinical Policy: Sargramostim (Leukine)
Reference Number: ERX.SPA.60
Effective Date: 09.01.17
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Sargramostim (Leukine®) is a recombinant human granulocyte-macrophage colony stimulating factor.

FDA approved indication
Leukine is indicated for:
- Use following induction chemotherapy in acute myeloid leukemia (AML) in older patients to shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death
- Use in mobilizing autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, and following transplantation of the autologous peripheral blood progenitor cells
- Use in myeloid reconstitution after autologous bone marrow transplantation (BMT) in patients with
  - Non-Hodgkin's lymphoma (NHL)
  - Acute lymphoblastic leukemia (ALL)
  - Hodgkin's disease
- Use in myeloid reconstitution after allogeneic BMT from human leukocyte antigen (HLA)-matched related donors
- Use in patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Leukine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Myeloid Leukemia (must meet all):
1. Prescribed for use following induction chemotherapy for AML;
2. Age ≥ 55 years;
3. At the time of request, there are no excessive (> 10%) leukemic myeloid blasts in the bone marrow or peripheral blood;
4. Dose does not exceed 250 mcg/m^2/day.

Approval duration: 6 months

B. Bone Marrow Transplantation (must meet all):
1. Prescribed for use for one of the following (a, b, or c):
   a. Following autologous BMT in the presence of one of the following (i, ii, or iii):
      i. NHL;
      ii. ALL;
      iii. Hodgkin's disease;
   b. Following allogenic BMT from HLA-matched related donors;
   c. Following BMT where engraftment is delayed or has failed;

2. At the time of request, there are no excessive (>10%) leukemic myeloid blasts in the bone marrow or peripheral blood;
3. Dose does not exceed 250 mcg/m^2/day.

Approval duration: 6 months

C. Peripheral Blood Progenitor Cell Collection and Transplantation (must meet all):

1. Prescribed for one of the following (a or b):
   a. Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis;
   b. Following myeloablative chemotherapy after transplantation of autologous hematopoietic progenitor cells;
2. At the time of request, there are no excessive (> 10%) leukemic myeloid blasts in the bone marrow or peripheral blood;
3. Dose does not exceed 250 mcg/m^2/day.

Approval duration: 1 month

D. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet 1 or 2)**:**

1. Member must currently meet all initial approval criteria and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia
AML: acute myeloid/myelogenous leukemia
BMT: bone marrow transplantation
FDA: Food and Drug Administration
FN: febrile neutropenia
HLA: human leukocyte antigen
NHL: non-Hodgkin's lymphoma

Appendix B: General Information

Neutropenia is defined as an absolute neutrophil count (ANC) of < 500 neutrophils/mcL or an ANC of < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours. Neutropenia can progress to febrile neutropenia, defined as a single temperature of ≥ 38.8 C orally or ≥ 38.0 C over 1 hour.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AML, BMT	250 mcg/m^2 IV QD	250 mcg/m^2/day
Peripheral blood progenitor cell collection and post-transplantation	250 mcg/m^2 IV or SC QD	250 mcg/m^2/day

VI. Product Availability

- Vial with solution: 500 mcg/mL (1 mL)
- Vial with lyophilized powder for reconstitution: 250 mcg

VII. References

1. Leukine Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S., LLC.; April 2013. Available at http://products.sanofi.us/Leukine/Leukine.html. Accessed July 18, 2017.
2. Myeloid growth factors (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed July 18, 2017.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 18, 2017.
4. DRUGDEX® System [Internet database]. Truven Health Analytics, Ann Arbor, Michigan, USA. http://www.micromedexsolutions.com. Accessed July 18, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from ERX.SPMN.07 Colony Stimulating Factors and converted to new template. Renewal criteria added. Separated criteria by indication rather than by drug. Off-label uses are referred to the off-label use policy. Changed approval duration for peripheral blood progenitor cell collection to reflect actual duration of therapy. Post-consolidation for AML is not a labeled use so was removed.	07.17	08.17

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.