

## Clinical Policy: Sargramostim (Leukine)

Reference Number: CP.PHAR.295

Effective Date: 12/16

Last Review Date: 10/16

[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 sargramostim (Leukine® injection, for subcutaneous or intravenous use).

### Policy/Criteria

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

#### I. Initial Approval Criteria

##### A. Acute Myeloid Leukemia (must meet all):

1. Leukine is prescribed for use following induction therapy for acute myeloid leukemia (AML);
2. Member has none of the following contraindications:
  - a. Excessive leukemic myeloid blasts in the bone marrow/peripheral blood ( $\geq 10\%$ );
  - b. Known hypersensitivity to granulocyte-macrophage colony stimulating factor (GM-CSF), yeast-derived products or any component of the product;
  - c. Concomitant use with chemotherapy/radiotherapy.

**Approval duration: 6 months**

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

1. Leukine is prescribed for either of the following:
  - a. Mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis in anticipation of transplantation after myeloablative chemotherapy;
  - b. Following myeloablative chemotherapy and transplantation of autologous hematopoietic progenitor cells;
2. Member has none of the following contraindications:
  - a. Excessive leukemic myeloid blasts in the bone marrow/ peripheral blood ( $\geq 10\%$ );
  - b. Known hypersensitivity to GM-CSF, yeast-derived products or any component of the product;
  - c. Concomitant use with chemotherapy/radiotherapy.

**Approval duration: 6 months**

##### C. Bone Marrow Transplantation (must meet all):

1. Leukine is prescribed for use in one of the following settings:

- a. Following autologous bone marrow transplantation (BMT) in the presence of one of the following disease states:
    - i. Non-Hodgkin's lymphoma (NHL);
    - ii. Acute lymphoblastic leukemia (ALL);
    - iii. Hodgkin's disease;
  - b. Following allogeneic BMT from HLA-matched related donors;
  - c. Following BMT where engraftment is delayed or has failed;
2. Member has none of the following contraindications:
- a. Excessive leukemic myeloid blasts in the bone marrow/peripheral blood ( $\geq 10\%$ );
  - b. Known hypersensitivity to GM-CSF, yeast-derived products or any component of the product;
  - c. Concomitant use with chemotherapy/radiotherapy.

**Approval duration: 6 months**

**D. Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.

1. Off-label uses:
  - a. Treatment of chemotherapy-induced febrile neutropenia associated with myelosuppressive chemotherapy for non-myeloid cancer if pegfilgrastim (Neulasta) has not been administered in the same chemotherapy cycle;
  - b. Supportive care in the post-hematopoietic cell transplant setting if not covered elsewhere in the policy;
  - c. Treatment of:
    - i. Agranulocytosis;
    - ii. Aplastic anemia;
    - iii. Neutropenia associated with HIV/AIDS;
2. Member has none of the following contraindications:
  - a. Excessive leukemic myeloid blasts in the bone marrow/peripheral blood ( $\geq 10\%$ );
  - b. Known hypersensitivity to GM-CSF, yeast-derived products or any component of the product;
  - c. Concomitant use with chemotherapy/radiotherapy.

**Approval duration: 6 months**

**Background**

*Description/Mechanism of Action:*

Leukine (sargramostim) is a recombinant human granulocyte-macrophage colony stimulating factor (rhu GM-CSF) produced by recombinant DNA technology in a yeast (*S. cerevisiae*) expression system. GM-CSF belongs to a group of growth factors termed colony stimulating factors which support survival, clonal expansion, and differentiation of hematopoietic progenitor cells.

*Formulations:*

Injectable solution for subcutaneous and intravenous use:

- Liquid Leukine
  - Vials: 500 mcg/mL (1 mL) sargramostim

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- Lyophilized Leukine for reconstitution
  - Vials: 250 mcg sargramostim

*FDA Approved Indications:*

Leukine is a leukocyte growth factor/subcutaneous or intravenous formulation with the following indications:

- Use following induction chemotherapy in (AML) in older adult 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 in patients with
  - Non-Hodgkin's lymphoma (NHL)
  - Acute lymphoblastic leukemia (ALL)
  - Hodgkin's disease
- Use in myeloid reconstitution after allogeneic bone marrow transplantation (BMT) from HLA-matched related donors.
- Use in patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed.

**Appendices**

**Appendix A: Abbreviation Key**

- ALL: acute lymphoblastic leukemia  
 AML: acute myeloid/myelogenous leukemia  
 BMT: bone marrow transplantation  
 GM-CSF: granulocyte-macrophage colony stimulating factor  
 NHL: non-Hodgkin's lymphoma

**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.

HCPCS Codes	Description
J2820	Injection, sargramostim (GM-CSF), 50 mcg

Reviews, Revisions, and Approvals	Date	Approval Date
Leukine is split from CP.PHAR.26.Colony Stimulating Factors 2015, and converted to a new template. Contraindications added per PI. Labeled use: post-consolidation for AML is not a labeled use so was removed. Off-label use: Treatment of MDS and FN prophylaxis removed per NCCN;	10/16	12/16

Reviews, Revisions, and Approvals	Date	Approval Date
posttransplant support added per NCCN; Neulasta limitation is added to FN treatment per NCCN.		

**References**

1. Leukine Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S., LLC.; April 2013. Available at <http://products.sanofi.us/Leukine/Leukine.html>. 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. Sargramostim. In: National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, 2015. <http://www.nccn.org>. Accessed October 26, 2016.
4. Sargramostim. In: Micromedex. Ann Arbor, MI: Truven Health Analytics; 2016. Available from: [www.micromedexsolutions.com](http://www.micromedexsolutions.com). 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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