Clinical Policy: Sargramostim (Leukine)

Reference Number: PA.CP.PHAR.295
Effective Date: 01/18
Last Review Date: 10/16

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for sargramostim (Leukine® injection, for subcutaneous or intravenous use).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Leukine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria (or the Continuity of Care policy (PA.LTSS.PHAR.01) applies):

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 (≥ 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 (≥ 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 (≥ 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 PA.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 (≥ 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
- 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

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. Accessed October 26, 2016.