Clinical Policy: Sargramostim (Leukine)

Reference Number: PA.CP.PHAR.295
Effective Date: 10/18
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).

FDA Approved Indication(s)
Leukine is indicated:

- To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML);
- For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in adult patients;
- For the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL);
- For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older;
- For treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older;
- To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

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. Diagnosis of AML;
2. Prescribed for use following induction therapy for AML;
3. Age ≥ 55 years;
4. Dose does not exceed 500 mcg/m^2 IV daily or 250 mcg/m^2 SC daily.

Approval duration: 6 months

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

1. Prescribed for one of the following (a or b):
   a. Mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation;

b. Following autologous PBPC transplantation in members with NHL, ALL, HL for acceleration of myeloid reconstitution;

2. Age ≥ 2 years;
3. Dose does not exceed 500 mcg/m^2 IV daily or 250 mcg/m^2 SC daily.

Approval duration: 6 months

C. Bone Marrow Transplantation (must meet all):

1. Prescribed for use in one of the following settings (a, b, or c):
   a. Following autologous BMT in members with NHL, ALL, HL for acceleration of myeloid reconstitution;
   b. Following allogeneic BMT for acceleration of myeloid reconstitution;
   c. Following BMT where engraftment is delayed or has failed;
2. Age ≥ 2 years;
3. Dose does not exceed 500 mcg/m^2 IV daily or 250 mcg/m^2 SC daily.

Approval duration: 6 months

Other diagnoses/indications: Refer to PA.CP.PMN.53
Approval duration: 6 months

I. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to CP.PMN.53

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

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
Added new indication for acute radiation syndrome; removed contraindications that are no longer included in the product label; modified age restrictions consistent with label; references reviewed and updated.	05.18	

References

i. Leukine Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S., LLC.; March 2018. Available at: www.leukine.com. Accessed May 2, 2018.
ii. National Comprehensive Cancer Network: Myeloid Growth Factors Version 1.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf. Accessed: May 2, 2018.
iii. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 2, 2018.
iv. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 2, 2018.