PRIOR AUTHORIZATION POLICY

POLICY: Colony Stimulating Factors – Leukine Prior Authorization Policy
- Leukine® (sargramostim injection – Partner Therapeutics)

REVIEW DATE: 08/19/2020

OVERVIEW

Leukine, a recombinant human granulocyte macrophage colony stimulating factor (GM-CSF), is indicated for the following uses:[1]

- **Acute exposure to myelosuppressive doses of radiation,** 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).
- **Acute myeloid leukemia following induction chemotherapy**, to shorten the time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections in patients ≥ 55 years of age.
- **Allogeneic bone marrow transplantation,** for acceleration of myeloid reconstitution in adult and pediatric patients ≥ 2 years of age undergoing allogeneic bone marrow transplantation from human leukocyte antigen-matched related donors.
- **Allogeneic or autologous bone marrow transplantation: treatment of delayed neutrophil recovery or graft failure,** treatment of patients ≥ 2 years of age who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.
- **Autologous peripheral blood progenitor cell (PBPC) and bone marrow transplantation,** acceleration of myeloid reconstitution after autologous PBPC or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma, acute lymphoblastic leukemia, and Hodgkin's lymphoma.
- **Autologous peripheral blood progenitor cell mobilization and collection,** in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Other Uses With Supportive Evidence

Unituxin® (dinutuximab injection for intravenous use) is indicated for use in combination with GM-CSF, interleukin-2, and 13-cis-retinoic acid for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to first-line, multiagent, multimodality therapy.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Leukine. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Leukine as well as the monitoring required for adverse events and long-term efficacy, approval requires Leukine to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Leukine is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Acute Myeloid Leukemia.** Approve for 6 months if the patient is prescribed by or in consultation with an oncologist or a hematologist.

2. **Peripheral Blood Progenitor Cell Collection and Therapy.** Approve for up to 14 days if the agent is prescribed by or in consultation with an oncologist, a hematologist, or a physician that specializes in transplantation.

3. **Bone Marrow Transplant.** Approve for 1 month if prescribed by or in consultation with a hematologist, an oncologist, or a physician who specializes in transplantation.

4. **Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).** Approve for 1 month if the agent is prescribed by or in consultation with a physician with expertise in treating acute radiation syndrome.

Other Uses with Supportive Evidence

5. **Neuroblastoma.** Approve for 6 months if the patient meets the following criteria (A, B and C):
   - **A)** The patient is < 18 years of age; AND
   - **B)** The patient is receiving Leukine in a regimen with Unituxin® (dinutuximab injection for intravenous use); AND
   - **C)** The agent is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Leukine is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Leukine® injection for intravenous or subcutaneous use [prescribing information]. Lexington, MA: Partner Therapeutics; May 2018.
2. Unituxin™ injection for intravenous use [prescribing information]. Silver Springs, MD: United Therapeutic Corporation; March 2017.