PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 09/20/2023; selected revision 01/10/2024

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** (AML) **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 patients ≥ 2 years of age undergoing allogeneic bone marrow transplantation from human leukocyte antigen (HLA)-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 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.
- **Autologous peripheral blood progenitor cell** (PBPC) **and bone marrow transplantation,** for acceleration of myeloid reconstitution after autologous PBPC or bone marrow transplantation in patients ≥ 2 years of age with non-Hodgkin's lymphoma, acute lymphoblastic leukemia, and Hodgkin's lymphoma.

Other Uses with Supportive Evidence

Unituxin® (dinutuximab intravenous infusion) 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] Danyelza® (naxitamab-gqgk intravenous infusion) is indicated for use in combination with GM-CSF, for the treatment of patients 1 year of age and older with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy.[3]

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 one of the following criteria:

FDA-Approved Indications

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

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

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

4. **Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome).** Approve for 1 month if the medication 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 (A and B):
   - **A)** Patient is receiving Leukine in a regimen that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (GM-CSF); AND
     Note: Examples of medications that are administered in combination with a GM-CSF include Unituxin (dinutuximab intravenous infusion), Danyelza (naxitamab intravenous infusion).
   - **B)** The medication 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® intravenous or subcutaneous injection [prescribing information]. Lexington, MA: Partner Therapeutics; August 2023.
2. Unituxin™ intravenous infusion [prescribing information]. Silver Springs, MD: United Therapeutic; March 2022.
3. Danyelza® intravenous infusion [prescribing information]. New York, NY: Y-mAbs Therapeutics; November 2020.