

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Colony Stimulating Factors – Leukine Utilization Management Medical Policy

- Leukine® (sargramostim intravenous or subcutaneous injection – Partner Therapeutics)

REVIEW DATE: 10/09/2024

OVERVIEW

Leukine, a 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 [H-ARS]).
- **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 (BMT)**, 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 (ALL), 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 medical benefit coverage of Leukine. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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:

FDA-Approved Indications

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

Dosing. Approve up to 250 mcg/m² per day by intravenous or subcutaneous injection.

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2. **Bone Marrow Transplant (BMT).** 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.

Dosing. Approve up to 250 mcg/m² per day by intravenous injection.

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3. **Peripheral Blood Progenitor Cell (PBPC) 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.

Dosing. Approve up to 250 mcg/m² per day by intravenous or subcutaneous injection.

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

Dosing. Approve up to 12 mcg/kg per day as a subcutaneous injection.

Other Uses with Supportive Evidence

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5. **Neuroblastoma.** Approve for 6 months if the patient meets BOTH of the following (A and B):
 - A) Patient is requesting 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.

Dosing. Approve up to 250 mcg/m² per day by subcutaneous injection.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/20/2023
Selected Revision	Neuroblastoma: The age requirement for this diagnosis was removed. The requirement that the “Patient is receiving Leukine in a regimen with Unituxin” was updated to “Patient is receiving Leukine in a regimen that recommends administration in combination with a granulocyte-macrophage colony stimulating factor (GM-CSF)” with the addition of the following note “Note: Examples of medications that are administered in combination with a GM-CSF include Unituxin (dinutuximab intravenous infusion), Danyelza (naxitamab intravenous infusion).”	01/10/2024
Annual Revision	Acute Myeloid Leukemia (AML) in a Patient Receiving Chemotherapy: The diagnosis was updated from “Acute Myeloid Leukemia” to as written. Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy: The dosing limitation was updated from “Approve up to 500 mcg/m ² per day given by intravenous or subcutaneous injection; OR Approve up to 7.5 mcg/kg per day by subcutaneous injection” to “Approve up to 250 mcg/m ² per day by intravenous or subcutaneous injection.” Neuroblastoma: The requirement that the patient is “receiving Leukine in a regimen” was updated to “requesting Leukine”. The dosing requirement was updated to remove “or intravenous injection”.	10/09/2024