

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Colony Stimulating Factors – Leukine Utilization Management Medical Policy

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

**REVIEW DATE:** 10/22/2025

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### OVERVIEW

Leukine, a granulocyte-macrophage colony stimulating factor (GM-CSF), is indicated for the following uses:<sup>1</sup>

- **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  $\geq 55$  years of age.
- **Allogeneic bone marrow transplantation**, for acceleration of myeloid reconstitution in patients  $\geq 2$  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  $\geq 2$  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  $\geq 2$  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), a glycolipid disialoganglioside (GD2)-binding monoclonal antibody, 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.<sup>2</sup> Danyelza® (naxitamab-gqgk intravenous infusion), a GD2-binding monoclonal antibody, 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.<sup>3</sup>

### Guidelines

The National Comprehensive Cancer Network (NCCN) addresses the use of Leukine in guidelines.

- **Hematopoietic Cell Transplantation:** Guidelines (version 3.2025 – September 24, 2025) recommend sargramostim for hematopoietic cell mobilization for autologous donors in combination with other treatments.<sup>4</sup>
- **Hematopoietic Growth Factors:** Guidelines (version 1.2025 – October 11, 2024) state to consider sargramostim for treatment of chemotherapy-induced febrile neutropenia in patients who have not received prophylactic granulocyte colony-stimulating factors but who have risk factors for an

infection-associated complication.<sup>5</sup> Sargramostim is also recommended as an appropriate option for the treatment of patients with radiation-induced myelosuppression following a radiologic/nuclear incident (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

- **Neuroblastoma:** Guidelines (version 1.2025 – April 16, 2025) recommend the use of sargramostim in combination with anti-GD2 monoclonal antibodies as part of chemoimmunotherapy regimens for patients with high-risk disease.<sup>6</sup>

## 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/m<sup>2</sup> 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/m<sup>2</sup> 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 who specializes in transplantation.

**Dosing.** Approve up to 250 mcg/m<sup>2</sup> 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 who has expertise in treating acute radiation syndrome.
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**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/m<sup>2</sup> per day by subcutaneous injection.

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### 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<sup>®</sup> intravenous or subcutaneous injection [prescribing information]. Lexington, MA: Partner Therapeutics; December 2024.
2. Unituxin<sup>™</sup> intravenous infusion [prescribing information]. Silver Springs, MD: United Therapeutic; December 2024.
3. Danyelza<sup>®</sup> intravenous infusion [prescribing information]. New York, NY: Y-mAbs Therapeutics; September 2025.
4. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2025 – September 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 7, 2025.
5. The NCCN Hematopoietic Growth Factors Clinical Practice Guidelines in Oncology (version 1.2025 – October 11, 2024). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 7, 2025.
6. The NCCN Neuroblastoma Clinical Practice Guidelines in Oncology (version 1.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on October 7, 2025.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/20/2023
Selected Revision	<p><b>Neuroblastoma:</b> 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).”</p>	01/10/2024
Annual Revision	<p><b>Acute Myeloid Leukemia (AML) in a Patient Receiving Chemotherapy:</b> The diagnosis was updated from “Acute Myeloid Leukemia” to as written.</p> <p><b>Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy:</b> The dosing limitation was updated from “Approve up to 500 mcg/m<sup>2</sup> 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<sup>2</sup> per day by intravenous or subcutaneous injection.”</p> <p><b>Neuroblastoma:</b> 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”.</p>	10/09/2024
Annual Revision	No criteria changes.	10/22/2025