Sargramostim (Leukine®)	Place of Service Office Administration Home Infusion Administration Outpatient Facility Administration Infusion Center Administration Self-Administration HCPCS: **J2820** per 50 mcg

Conditions listed in policy *(see criteria for details)*

- Acute myelogenous leukemia (AML) following induction chemotherapy
- Acute exposure to myelosuppressive radiation
- Aplastic anemia
- Bone marrow transplantation
- Drug-induced agranulocytosis
- Febrile neutropenia
- HIV patients on myelosuppressive drugs
- Myelodysplastic syndromes
- Neuroblastoma, high-risk
- Peripheral blood stem cell mobilization
- Prophylaxis in patients with malignancies who are receiving chemotherapy

AHFS therapeutic class: Hematopoietic agent

Mechanism of action: Granulocyte-macrophage colony stimulating factor (GM-CSF)

(1) Special Instructions and Pertinent Information

If covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Leukine® (sargramostim) for indications NOT LISTED in section (3) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute exposure to myelosuppressive radiation

Covered Doses
Given by SC injection for less than or equal to 15 billable units per day

Coverage Period
1 year

ICD-10:
T66.X

Acute myelogenous leukemia (AML) following induction chemotherapy

Covered Doses
Given by IV for less than or equal to 15 billable units per day

Coverage Period
1 year

ICD-10:
C92.00, C92.02, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.90, C92.92, C92.A0, C92.A2

Aplastic anemia

1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses
Up to 250 mcg/m^2/day

Coverage Period
Up to 3 months

ICD-10:
D61.9

Bone marrow transplantation

Covered Doses
Given by IV for less than or equal to 15 billable units per day

Coverage Period
1 year

CPT: 38240, 38241

ICD-10:

Z94.81

Drug-induced agranulocytosis

1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses
Up to 250 mcg/m^2/day

Coverage Period
Up to the length of therapy that the drug causing neutropenia is prescribed or up to one year (whichever is less).

ICD-10:
D70.2

Febrile neutropenia

1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses
Up to 250 mcg/m^2/day

Coverage Period
Up to 2 months

ICD-10:
D70.9 with R50.81

HIV patients on myelosuppressive drugs

1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses
Up to 250 mcg/m^2 SC per day

Coverage Period
Up to the length of therapy that the drug causing neutropenia is prescribed or up to one year (whichever is less).

ICD-10:
B20 plus D70.2

Myelodysplastic syndromes

1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses
Up to 250 mcg/m^2 SC per day

Coverage Period
Up to 3 months. Reauthorization requires continued response to therapy

ICD-10:
46.0, D46.1, D46.2-D46.22, D46.4, D46.9, D46.A-D46.C, D46.Z

Neuroblastoma, high-risk

1. Used in combination with Unituxin (dinutuximab) or Danyelza (naxitamab-gqgk)

Covered Doses
Up to 250 mcg/m^2 SC daily for 5 doses starting 5 days prior to the day 1 Danyelza (naxitamab) infusion followed by up to 500 mcg/m^2 SC daily on days 1, 2, 3, 4, and 5 repeated each cycle in combination with Danyelza (naxitamab).

Coverage Period
1 year

ICD-10:
C74.90

Peripheral blood stem cell mobilization

1. Drug will be administered at home by the patient or the patient's caregiver

Covered Doses
Up to 250 mcg/m^2 SC or IV per day

Coverage Period
Up to 3 months. Reauthorization requires continued response to therapy

ICD-10:
302(X), 3E0(X)

Prophylaxis in patients with malignancies who are receiving chemotherapy

1. Given by SC injection for less than or equal to 15 billable units per day

Coverage Period
1 year

ICD-10:
C00.0-C91.91, D00.00-D49.9, D70.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Leukine® (sargramostim) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Chronic myelogenous leukemia (CML)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

250 mcg single dose vial (Powder for Solution)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Leukine® (sargramostim) [Prescribing Information]. Lexington, MA: Partner Therapeutics, Inc; 5/2022.
- National Comprehensive Cancer Network. Hematopoietic growth factors (Version 2.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee