blue california
Promise Health Plan

sargramostim (Leukine) IV and SC

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration
Self-Administration - *may be covered under the Pharmacy Benefit*

Drug Details

USP Category: BLOOD PRODUCTS AND MODIFIERS
Mechanism of Action: Granulocyte-macrophage colony stimulating factor (GM-CSF)
HCPCS:
J2820:Injection, sargramostim (gm-csf), 50 mcg
How Supplied:
250 mcg single dose vial (powder for solution)

Condition(s) listed in policy *(see coverage criteria for details)*

- Aplastic Anemia
- Bone Marrow Transplantation
- Drug-induced Agranulocytosis
- Febrile Neutropenia
- HIV patients on Myelosuppressive Drugs
- Peripheral Blood Stem Cell Mobilization

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

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The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Aplastic Anemia

Meets medical necessity if all the following are met:

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

Covered Doses:
Not to exceed 500 mcg/m^2 given by subcutaneous injection once daily

Coverage Period:
3 months

ICD-10:
D61.9

Bone Marrow Transplantation

Meets medical necessity if all the following are met:

1. Diagnosis of bone marrow transplantation

Covered Doses:
Not to exceed 500 mcg/m^2 given as an intravenous infusion once daily

Coverage Period:
3 months

CPT:
38240, 38241

ICD-10:
Z94.81

Drug-induced Agranulocytosis

Meets medical necessity if all the following are met:

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

Covered Doses:

Not to exceed 250 mcg/m^2 given by subcutaneous or intravenous injection once daily

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
Meets medical necessity if all the following are met:
1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses:
Not to exceed 250 mcg/m^2 given by subcutaneous injection once daily

Coverage Period:
2 months

ICD-10:
D70.9 with R50.81

HIV patients on Myelosuppressive Drugs
Meets medical necessity if all the following are met:
1. Initial absolute neutrophil count ANC ≤800/mm3 or ANC ≤ 1000/mm3 with expected neutropenia of > 5 days

Covered Doses:
Not to exceed 250 mcg/m^2 given by subcutaneous or intravenous injection once daily

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 with D70.2

Peripheral Blood Stem Cell Mobilization
Meets medical necessity if all the following are met:
1. Drug will be administered at home by the patient or the patient's caregiver

Covered Doses:
Not to exceed 250 mcg/m^2 given by subcutaneous or intravenous injection once daily

Coverage Period:
3 months

ICD-10:
Z48.290, Z52.001, Z52.011, Z52.091, Z94.81, Z94.84

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Leukine (sargramostim) Prescribing Information. Partner Therapeutics, Inc.; Lexington, MA: 8/2023.
4. National Comprehensive Cancer Network. Hematopoietic Growth Factors (Version 2.2025). Available at: www.nccn.org.
5. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (Version 2.2025). Available at: www.nccn.org.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- For oncology-related indications, coverage will be made based on medical necessity

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee