

## sargramostim (Leukine) IV and SC

### Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

#### 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*)

- Acute Exposure to Myelosuppressive Radiation
- 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 Health and Safety Code section 1367.21 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.

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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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.

Zarxio and Nivestym are the BSC preferred granulocyte colony stimulating factor (G-CSF). For many indications, treatment failure, intolerance or contraindication to Zarxio and Nivestym will be required for members newly initiating G-CSF therapy.

### **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  $ANC \leq 800/mm^3$  or  $ANC \leq 1000/mm^3$  with expected neutropenia of  $> 5$  days
2. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with Leukine

#### **Covered Doses:**

500 mcg/m<sup>2</sup> given by subcutaneous injection once daily

#### **Coverage Period:**

3 months

#### **ICD-10:**

D61.9

#### **Drug-induced Agranulocytosis**

**Meets medical necessity if all the following are met:**

1. Initial absolute neutrophil count  $ANC \leq 800/mm^3$  or  $ANC \leq 1000/mm^3$  with expected neutropenia of  $> 5$  days
2. Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with Leukine

#### **Covered Doses:**

250 mcg/m<sup>2</sup> 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  $ANC \leq 800/mm^3$  or  $ANC \leq 1000/mm^3$  with expected neutropenia of  $> 5$  days

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- Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with Leukine

**Covered Doses:**

250 mcg/m<sup>2</sup> 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:**

- Initial absolute neutrophil count ANC  $\leq 800/\text{mm}^3$  or ANC  $\leq 1000/\text{mm}^3$  with expected neutropenia of > 5 days
- Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with Leukine

**Covered Doses:**

250 mcg/m<sup>2</sup> 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:**

- Drug will be administered at home by the patient or the patient's caregiver
- Intolerance or contraindication with preferred products (Nivestym and Zarxio) that is not expected with Leukine
- Leukine is NOT covered under a transplant case rate

**Covered Doses:**

250 mcg/m<sup>2</sup> given by subcutaneous or intravenous injection once daily

**Coverage Period:**

3 months

Reauthorization requires continued response to therapy

**ICD-10:**

302(X), 3E0(X) [X can be any variety of numbers and letters]

**The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.**

### **Acute Exposure to Myelosuppressive Radiation**

1. Diagnosis of acute exposure to myelosuppressive radiation

#### **Covered Doses:**

15 billable units given as a subcutaneous injection once daily

#### **ICD-10:**

T66.XXXA, T66.XXXD, T66.XXXS

### **Bone Marrow Transplantation**

1. Diagnosis of bone marrow transplantation

#### **Covered Doses:**

20 billable units given as an intravenous injection once per day

#### **CPT:**

38240, 38241

#### **ICD-10:**

Z94.81

### **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](http://www.nccn.org).
5. National Comprehensive Cancer Network. Hematopoietic Cell Transplantation (Version 2.2025). Available at: [www.nccn.org](http://www.nccn.org).

### **Review History**

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

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- For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

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