



**Colony Stimulating Factors (Leukine)  
Leukine (sargramostim) J2820  
Prior Authorization Request  
Medicare Part B Form**

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

New Start or Initial Request: (Clinical documentation required for all requests)  
 **Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.**  
 If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_

Continuation Requests: (Clinical documentation required for all requests)  
 Patient had an adequate response or significant improvement while on this medication.  
 If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group – Colony Stimulating Factor (Leukine) PA

### Drug Name(s):

**LEUKINE (sargramostim)**

### Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and Tiering will be determined by the Plan.

### Exclusion Criteria:

N/A

### Prescriber Restrictions:

N/A

### Coverage Duration:

Approval will be for 6 months

### FDA Indications:

#### Leukine

- Acute myeloid leukemia - Neutrophil recovery, Following induction chemotherapy
- Allogeneic bone marrow transplantation, Myeloid reconstitution
- Autologous bone marrow transplant, Myeloid reconstitution
- Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy
- Bone marrow transplant, Delay or failure of myeloid engraftment
- Hematopoietic subsyndrome of acute radiation syndrome
- Mobilization, Of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis

### Off-Label Uses:

#### Leukine

- Crohn's disease,
- Febrile neutropenia, In non-myeloid malignancies following myelosuppressive chemotherapy; Prophylaxis
- Malignant melanoma, Pulmonary alveolar proteinosis
- HIV infection – neutropenia
- Rhinocerebral mucormycosis; adjunct

### Age Restrictions:

N/A

### Other Clinical Consideration:

- Contraindicated in pure red cell aplasia that begins following treatment with darbepoetin alfa or other erythropoietin protein drugs
- Contraindicated in uncontrolled hypertension



## Part B Prior Authorization Step Therapy Guidelines

### Resources:

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/E294DB/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYNC/0ED355/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=530340&contentSetId=100&title=Sargramostim&servicesTitle=Sargramostim&brandName=Leukine&UserMdxSearchTerm=Leukine&=null#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/E294DB/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/0ED355/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=530340&contentSetId=100&title=Sargramostim&servicesTitle=Sargramostim&brandName=Leukine&UserMdxSearchTerm=Leukine&=null#)

CLINICAL / CMS  
ONLY