



**Colony Stimulating Factors (Short) Step Therapy
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"/> NEW START - Start Date: _____	<input type="checkbox"/> Continuation (within 365 days): Date of last treatment _____
<input type="checkbox"/> 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 <input type="checkbox"/> Self-administered	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

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)
 Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.
 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#

CLINICAL / CMS
ONLY