CareSource

PHARMACY POLICY STATEMENT **North Carolina Marketplace**	
DRUG NAME	Leukine (sargramostim)
BILLING CODE	For medical - J2820 For Rx - must use valid NDC
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product include Zarxio QUANTITY LIMIT— N/A
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Leukine (sargamostim) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ACUTE MYELOID LEUKEMIA (AML)

For **initial** authorization:

1. Member is 55 years of age or older and is receiving induction chemotherapy with or without consolidation chemotherapy; AND
2. Member must have tried and failed treatment with Zarxio; AND
3. Medication is being used to reduce the time to neutrophil recovery and the duration of fever following induction chemotherapy treatment; AND
4. Member has hypoplastic bone marrow (<5% blasts) following chemotherapy; AND
5. Medication is being administered beginning 4 days after completion of induction chemotherapy until neutrophil recovery (ANC >1000/mm^3 for 3 consecutive days) up to a maximum of 42 days.
6. **Dosage allowed:** 250 mcg/m^2 per day.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all initial criteria.
2. Chart notes have been provided that show the member is stable or has shown improvement on Leukine therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

ALLOGENIC BONE MARROW TRANSPLANT (BMT)

For **initial** authorization:

1. Member is 55 years of age or older; AND

2. Member is receiving myeloablative chemotherapy followed by allogenic BMT from an HLA-matched related donor; AND
3. Medication is being used to accelerate myeloid recovery.
4. **Dosage allowed:** 250 mcg/m^2 per day administered as an IV infusion over a 2 hour period.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Leukine therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

AUTOLOGOUS BONE MARROW TRANSPLANT (BMT)

For **initial** authorization:
1. Member is 55 years of age or older; AND
2. Member has a diagnosis of non-Hodgkin's lymphoma, acute lymphoblastic leukemia, or Hodgkin's disease and is receiving myeloablative chemotherapy followed by autologous BMT; AND
3. Member must have tried and failed treatment with Zarxio.
4. **Dosage allowed:** 250 mcg/m^2 per day administered as an IV infusion over a 2 hour period.

If member meets all the requirements listed above, the medication will be approved for 3 month.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Leukine therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

AUTOLOGOUS PERIPHERAL BLOOD PROGENITOR CELL (PBPC) MOBILIZATION

For **initial** authorization:
1. Member is 55 years of age or older; AND
2. Medication is being used to mobilize autologous peripheral blood progenitor cells for collection by leukapheresis and to reduce neutropenia following PBPC transplantation; AND
3. Member must have tried and failed treatment with Zarxio; AND
4. Medication is being administered daily until leukapheresis is completed and after leukapheresis until neutrophil recovery (ANC >1000/mm^3).
5. **Dosage allowed:** 250 mcg/m^2 per day administered as an IV infusion over 24 hours or subcutaneous injection once daily.

If member meets all the requirements listed above, the medication will be approved for 3 month.

For **reauthorization**:
1. Member must be in compliance with all initial criteria; AND
2. Chart notes have been provided that show the member is stable or has shown improvement on Leukine therapy.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

BONE MARROW TRANSPLANT (BMT) FAILURE OR ENGRAFTMENT DELAY

For **initial** authorization:
1. Member is 55 years of age or older; AND
2. Member has received autologous or allogenic BMT and is experiencing graft failure or myeloid engraftment delay with **one** of the following:
   a) Absolute neutrophil count (ANC) ≤ 100 cells/mm^3 by day 28 post-transplant;
   b) ANC ≤ 100 cells/mm^3 by day 21 post-transplant with evidence of an active infection;
   c) ANC ≥ 500 cells/mm^3 for at least one week followed by loss of engraftment with ANC < 500 cells/mm^3 for at least one week beyond day 21 post-transplant; AND
3. Medication is being administered for no more than 14 days per course for up to 3 courses of therapy that are separated by at least 7 therapy-free days.
4. **Dosage allowed:** 250 mcg/m^2 per day for the first 2 courses of therapy; 500 mcg/m^2 per day for the third course.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:
1. Leukine will not be reauthorized third course of therapy. If another course of therapy needed in a future initial authorization criteria will be applied.

CareSource considers Leukine (sargramostim) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Hematopoietic Subsyndrome of Acute Radiation Syndrome
- Prevention of febrile neutropenia
- Severe chronic neutropenia

DATE	ACTION/DESCRIPTION
10/19/2017	New policy created for Leukine. List of diagnoses covered was expanded. Length of therapy of preferred trial agent was deleted. List of not covered diagnoses was added.
09/16/2021	Annual review, no changes

References:

1. Leukine (sargramostim) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; April 2013.

2. Rowe JM, Anderson JW, Mazza JJ, et al. A randomized placebo-controlled phase III study of granulocyte-macrophage colony-stimulating factor in adult patients (>55 to 70 years of age) with acute myelogenous leukemia: a study of eastern cooperative oncology group. *Blood*. 1995;86(2):457-462.
3. Nemunaitis J, Rabinowe SN, Singer JW, et al. Recombinant granulocyte-macrophage colony-stimulating factor after autologous bone marrow transplantation for lymphoid cancer. *N Eng J Med*. 1991;324:1773-1778. Doi: 10.1056/NEJM199106203242504.

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