

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Leukine (sargamostim)
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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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<sup>3</sup> for 3 consecutive days) up to a maximum of 42 days.
6. **Dosage allowed:** 250 mcg/m<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> 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<sup>3</sup>).
5. **Dosage allowed:** 250 mcg/m<sup>2</sup> 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)  $\leq$  100 cells/mm<sup>3</sup> by day 28 post-transplant;
  - b) ANC  $\leq$  100 cells/mm<sup>3</sup> by day 21 post-transplant with evidence of an active infection;
  - c) ANC  $\geq$  500 cells/mm<sup>3</sup> for at least one week followed by loss of engraftment with ANC < 500 cells/mm<sup>3</sup> 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<sup>2</sup> per day for the first 2 courses of therapy; 500 mcg/m<sup>2</sup> 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.

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.

Effective date: 11/08/2017

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