



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARGRAMOSTIM

Generic	Brand	HICL	GCN	Exception/Other
SARGRAMOSTIM	LEUKINE	06074		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the requested medication prescribed by or currently being supervised by a Hematologist or Oncologist?

If yes, **approve for 3 months or requested duration of treatment up to 1 year.**
If no, continue to #2.

2. Is the request for **ONE** of the following indications?

- To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years or older
- For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years or older
- For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years or older
- For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years or older
- For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years or older
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

If yes, **approve for 3 months or requested duration of treatment up to 1 year.**
If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **SARGRAMOSTIM (Leukine)** requires that the requested medication is prescribed by or currently being supervised by a hematologist or oncologist, OR is being used for **ONE** of the following indications:

- To shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in a patient with acute myeloid leukemia (AML) AND the patient is 55 years or older
- For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis, the patient is undergoing autologous transplantation AND the patient is 18 years or older
- For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation, in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) or Hodgkin's lymphoma AND the patient is 2 years or older
- For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation from HLA-matched related donors AND the patient is 2 years or older
- For the treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation AND the patient is 2 years or older
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS])

RATIONALE

Ensure appropriate utilization of sargramostim based on its FDA approved indications.

FDA APPROVED INDICATIONS

LEUKINE is a leukocyte growth factor indicated:

- To shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML)
- For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in adult patients
- For the acceleration of myeloid reconstitution following autologous bone marrow or peripheral blood progenitor cell transplantation in adult and pediatric patients 2 years of age and older
- For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older
- For treatment of delayed neutrophil recovery or graft failure after autologous or allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older
- To increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

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FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

- Acute Myeloid Leukemia (AML), Neutrophil recovery following chemotherapy:
 - 250 mcg/m²/day administered intravenously over a 4-hour period
- Mobilization of peripheral blood progenitor cells:
 - 250 mcg/ m²/day administered intravenously over 24 hours or subcutaneous injection once daily
- Post peripheral blood progenitor cell transplantation:
 - Autologous peripheral blood progenitor cell transplantation:
 - 250 mcg/ m²/day administered intravenously over 24 hours or subcutaneous injection once daily
 - Autologous bone marrow transplantation:
 - 250 mcg/ m²/day administered intravenously over 2 hours
- Myeloid reconstitution after autologous or allogeneic BMT:
 - 250 mcg/ m²/day administered intravenously over a 2-hour period
- BMT failure or engraftment delayed:
 - 250 mcg/ m²/day for 14 days as a 2-hour intravenous infusion
- Patients acutely exposed to myelosuppressive doses of radiation, administer once daily as subcutaneous injection:
 - Adults and pediatric patients weighing >40 kg: 7 mcg/kg
 - Pediatric patients 15 kg to 40 kg: 10 mcg/kg
 - Pediatric patients <15 kg: 12 mcg/kg

REFERENCES

- Leukine [Prescribing Information] Bridgewater, NJ: Sanofi-aventis U.S. LLC. April 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/18

Created: 02/03

Client Approval: 05/18

P&T Approval: 04/18