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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SARGRAMOSTIM

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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SARGRAMOSTIM

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

- Acute Myeloid Leukemia (AML), Neutrophil recovery following chemotherapy:
  - 250 mcg/m^2/day administered intravenously over a 4-hour period
- Mobilization of peripheral blood progenitor cells:
  - 250 mcg/ m^2/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/ m^2/day administered intravenously over 24 hours or subcutaneous injection once daily
  - Autologous bone marrow transplantation:
    - 250 mcg/ m^2/day administered intravenously over 2 hours
- Myeloid reconstitution after autologous or allogeneic BMT:
  - 250 mcg/ m^2/day administered intravenously over a 2-hour period
- BMT failure or engraftment delayed:
  - 250 mcg/ m^2/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

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P&T Approval: 04/18