



## **LEUKINE (sargramostim)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

Leukine (sargramostim) is a man-made form of granulocyte-macrophage colony-stimulating factor (GM-CSF) which is a type of protein that your body produces to help increase the number of white blood cells (WBCs). Some cancer treatments, including chemotherapy, can kill healthy cells like WBCs in addition to killing cancer cells. Leukine is used to help increase the number and function of white blood cells after bone marrow transplantation, in cases of bone marrow transplantation failure or engraftment delay, before and after peripheral blood stem cell transplantation, and following induction chemotherapy in older patients with acute myelogenous leukemia (1).

Leukine may treat other conditions such as neutropenia that is HIV associated, chemotherapy associated, or hepatitis C treatment associated and in the treatment of severe chronic, congenital neutropenia (1-2).

#### **Regulatory Status**

FDA-approved indications: Leukine is a leukocyte growth factor indicated: (1)

1. 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)
2. For the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation in adult patients
3. 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
4. For the acceleration of myeloid reconstitution following allogeneic bone marrow transplantation in adult and pediatric patients 2 years of age and older
5. 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
6. 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])

#### **Off-Label Uses: (2-3)**

1. Neutropenia



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- a. Prophylaxis and treatment of chemotherapy-induced febrile neutropenia in non-myeloid malignancies
  - b. Chemotherapy associated
  - c. Neutropenia related to HIV/AIDS
  - d. Hepatitis C therapy associated
  - e. Chronic congenital (Kostmann's Syndrome)
2. Acute myelogenous leukemia following induction or consolidation chemotherapy in pediatrics and adults
  3. Mobilization and following transplantation of autologous peripheral blood progenitor cells in pediatric patients
  4. Agranulocytosis
  5. Aplastic anemia
  6. Stem cell transplantation-related indications

Leukine use is contraindicated 24 hours before and after administration of myelosuppressive chemotherapy or radiation (1).

### **Summary**

Leukine (sargramostim) is a recombinant human granulocyte-macrophage colony-stimulating factor (GM-CSF) that facilitates the proliferation and differentiation of cells including neutrophils and macrophages. Leukine prevents the growth of tumor cells and increases activity against cancer cells. Leukine use is contraindicated 24 hours before and after administration of myelosuppressive chemotherapy or radiation (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Leukine while maintaining optimal therapeutic outcomes.

### **References**

1. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
2. NCCN Drugs & Biologics Compendium® Sargramostim 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.
3. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2015;33(28):3199-3212.