LEUKINE  
(sargramostim)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Leukine 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 (1-4).

Regulatory Status
FDA-approved indications: Leukine is indicated for use in the following (4):
1. Acute myelogenous leukemia following induction chemotherapy
2. Mobilization and following transplantation of autologous peripheral blood progenitor cells
3. Myeloid reconstitution after autologous bone marrow transplantation
4. Myeloid reconstitution after allogeneic bone marrow transplantation
5. Bone marrow transplantation failure or engraftment delay

Leukine use is contraindicated 24 hours before and after administration of myelosuppressive chemotherapy or radiation (4).

Summary
Leukine 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 (1-4).

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