Clinical Policy Title:	sargramostim
Policy Number:	RxA.199
Drug(s) Applied:	Leukine®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acute myeloid leukemia (must meet all)**:**

1. Diagnosis of acute myeloid leukemia;
2. Trial and failure of Zarxio®, unless contraindicated or clinically significant adverse effects are experienced;
3. Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Peripheral blood progenitor cell collection and transplantation (must meet all)**:**

1. Prescribed for one of the following (a or b):
   a. Mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis and autologous transplantation; or
   b. Following autologous peripheral blood progenitor cell transplantation in members with non-Hodgkin's lymphoma, acute lymphoblastic leukemia, Hodgkin's lymphoma for acceleration of myeloid reconstitution;
2. Trial and failure of Zarxio®, unless contraindicated or clinically significant adverse effects are experienced;
3. Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle.

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Bone marrow transplantation (must meet all):

1. Prescribed for use in one of the following settings (a, b, or c):
   a. Following autologous bone marrow transplantation in members with non-Hodgkin's lymphoma, acute lymphoblastic leukemia, or Hodgkin's lymphoma for acceleration of myeloid reconstitution;
   b. Following allogeneic bone marrow transplantation for acceleration of myeloid reconstitution;
   c. Following bone marrow transplantation where engraftment is delayed or has failed;
2. Trial and failure of Zarxio®, unless contraindicated or clinically significant adverse effects are experienced;

3. Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle.

Approval Duration
All Lines of Business (except Medicare): 6 months

D. Acute radiation syndrome (must meet all)**:**
1. Prescribed for use following suspected or confirmed acute exposure to myelosuppressive doses of radiation;
2. Trial and failure of Zarxio®, unless contraindicated or clinically significant adverse effects are experienced;
3. Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle.

Approval Duration
All Lines of Business (except Medicare): 6 months

E. Chemotherapy-induced febrile neutropenia (off-label) (must meet all):
1. Prescribed as prevention or treatment of neutropenia in patients receiving chemotherapy or who are at high risk for neutropenic fever;
2. Member has one or more of the following risk factors (a through k):
   a. Age ≥ 65 years;
   b. Absolute neutrophil count less than 100/mcL occurred after previous cycle of similar chemotherapy;
   c. Neutropenia is expected to last greater than 10 days in duration;
   d. Documented active clinical infection, such as pneumonia or fungal infection, open wounds or recent surgery;
   e. Bone marrow involvement by tumor resulting in cytopenia(s);
   f. Previous chemotherapy and/or radiation therapy;
   g. Poor nutritional and/or performance status;
   h. Presence of sepsis syndrome;
   i. Presence of serious comorbidities, including renal dysfunction, hepatic dysfunction, HIV infection or cardiovascular disease;
   j. Member was hospitalized at the time of the development of fever;
   k. Prior episode of febrile neutropenia.
3. Member is not receiving other colony stimulating factors within a chemotherapy regimen.

Approval Duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy .

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network: Hematopoietic Growth Factors. Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network: Acute Myeloid Leukemia. Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial Approval criteria: Commercial and Medicaid approval duration were updated from member's renewal date to 6 months. 6. Continued Approval criteria: Commercial and Medicaid approval duration were updated from length of benefit to 12 months. 7. References were updated.	08/03/2020	09/14/2020
Policy was reviewed: 1. References were updated.	03/01/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, 1.C.4: Updated dosing criteria from Dose does not exceed 500 mcg/m^2 intravenous daily to Dose does not exceed one of the following (a or b): a. For myeloid reconstitution after autologous or allogeneic bone marrow transplantation 250mcg/m^2 daily; b. For bone marrow transplantation failure or engraftment delay 500mcg/m^2 daily. 2. Initial Approval Criteria, 1.D.3: Updated dosing criteria from Dose does not exceed 12 mcg/kg subcutaneously daily to Dose does not exceed one of the following (a, b, or c): a. Weight <15 kg: 12 mcg/kg subcutaneous daily; b. Weight 15 kg to 40 kg: 10	01/17/2022	04/18/2022

mcg/kg subcutaneous daily; c. Weight > 40 kg: 7 mcg/kg subcutaneous daily. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.4, I.B.3, I.C.3, I.D.2: Updated to remove trial and failure of Neupogen®. 2. Initial Approval Criteria, I.A.5, I.B.4, I.C.4 and I.D.3: Updated to include new prescribing criteria Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle; 3. Continued Therapy Approval, I.A.3: Updated to include new prescribing criteria Leukine® will not be prescribed concurrently with other colony stimulating factors (e.g., filgrastim, pegfilgrastim) within any chemotherapy cycle; 4. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 2. Removed age restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed other reauthorization requirements including positive response to therapy. 6. Updated approval duration verbiage.	08/28/2024	9/13/2024

7. References were reviewed and updated.		