Reference number(s)
4488-A

JURISDICTION SPECIFIC MEDICARE PART B

LEUKINE (sargramostim)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. Acute Myeloid Leukemia Following Induction Chemotherapy
B. Autologous Peripheral Blood Progenitor Cells Mobilization and Collection
C. Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation
D. Allogeneic Bone Marrow Transplantation (BMT)
E. Allogenic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure
F. Acute Exposure to Myelosuppressive Doses of Radiation (H-ARS)
G. Adjunctive treatment of neutropenia in certain conditions
H. Dose dense therapy for adjuvant treatment of breast cancer
I. After initial induction chemotherapy or first post-remission course of chemotherapy for acute lymphocytic leukemia
J. Acute myeloid leukemia after the completion of induction or repeat induction chemotherapy
K. Myelodysplastic syndrome with severe neutropenia or recurrent infection
L. Exposure to radiation therapy in the absence of chemotherapy
M. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. The member's medical record must document the medical necessity of services performed for each date of service submitted on a claim
B. For primary or secondary prophylaxis in conjunction with cancer chemotherapy, the record must document risk factors in members receiving agents/doses uncommonly associated with myelosuppression.
C. For prophylaxis of chemotherapy-associated neutropenia, indicate the chemotherapy drug used in the medical record.
D. The member's medical record must clearly document the time the last dose of the cytotoxic chemotherapy cycle ended and the time the G-CSF drug was administered.

E. If Leukine will be administered outside the timeframe specified by the FDA labeling, the reason for the exception should be clearly documented in the medical record.

III. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:
A. Administration of Leukine to increase chemotherapy dose intensity except as noted below
B. Continuous use of Leukine for myelodysplastic syndrome or Felty's syndrome without infections
C. Chemosensitization of myeloid leukemias
D. Continued use if no response is seen within 28-42 days
E. Administration in members with chronic aplastic anemia

IV. CRITERIA FOR APPROVAL

A. Induction chemotherapy in acute myelogenous leukemia
Authorization of 6 months may be granted following induction chemotherapy in members 55 years of age and older with acute myelogenous leukemia to shorten time to neutrophil recovery and reduce the incidence of severe and life-threatening infections.

B. Mobilization and following transplantation of autologous peripheral blood progenitor cells
Authorization of 6 months may be granted for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

C. Autologous peripheral blood progenitor cell and bone marrow transplantation
Authorization of 6 months may be granted for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric members 2 years of age and older with non-Hodgkin's lymphoma, acute lymphoblastic leukemia and Hodgkin's lymphoma.

D. Myeloid reconstitution after allogenic bone marrow transplantation
Authorization of 6 months may be granted for acceleration of myeloid reconstitution in members undergoing allogenic bone marrow transplantation from human leukocyte antigen (HLA)-matched related donors.

E. Bone marrow transplantation failure or engraftment delay
Authorization of 6 months may be granted for members who have undergone allogenic or autologous bone marrow transplant in whom engraftment is delayed or has failed.

F. Other indications
Authorization of 6 months may be granted for treatment of any of the following conditions:
1. Adjunctive treatment of neutropenia when any of the conditions listed below are present:
   i. Expected prolonged (greater than 10 days) and profound (less than 0.1 x 109/L) neutropenia
   ii. Age greater than 65 years
   iii. Uncontrolled primary disease
   iv. Pneumonia
   v. Hypotension and multiorgan dysfunction (sepsis syndrome)
   vi. Invasive fungal infection
   vii. Hospitalization at the time of the development of fever

2. Dose dense chemotherapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant breast cancer
3. After completion of the first few days of initial induction chemotherapy or for first post-remission course of chemotherapy for the treatment of acute lymphocytic leukemia (ALL)
4. After the completion or repeat induction chemotherapy of AML in members over 55 years of age
5. Myelodysplastic syndrome when either of the following criteria is met:
   i. Absolute neutrophil count (ANC) less than or equal to 500/mm^3
   ii. Member is experiencing recurrent infection
6. Member receiving radiation therapy in the absence of chemotherapy if prolonged delays due to neutropenia are expected
7. Accidental or intentional total body irradiation of myelosuppressive doses (greater than 2 Grays [Gy]) such as hematopoietic syndrome of acute radiation syndrome (H-ARS)
8. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for one of the following indications:
   i. To promote myeloid reconstitution
   ii. When engraftment is delayed or has failed
   iii. Mobilization of progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT)

V. DOSAGE AND ADMINISTRATION

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation. Leukine will be covered when administered under direct supervision in the office setting. When administered by the member or caregiver, the drug will be considered self-administered and not payable.

VI. REFERENCES

1. White Cell Colony Stimulating Factors LCD (L37176) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 17, 2022.
2. Billing and Coding: White Cell Colony Stimulating Factors (A56748) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed May 17, 2022.
3. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; May 2022.