

SPECIALTY GUIDELINE MANAGEMENT

LEUKINE (sargramostim)

POLICY

I. INDICATIONS

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

A. FDA-Approved Indications

1. Use Following Induction Chemotherapy in Acute Myelogenous Leukemia
 - a. Leukine is indicated for use following induction chemotherapy in older adult patients with acute myelogenous leukemia to shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections and infections resulting in death.
2. Use in Mobilization and Following Transplantation of Autologous Peripheral Blood Progenitor Cells
 - a. Leukine is indicated for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis. Mobilization allows for the collection of increased numbers of progenitor cells capable of engraftment as compared with collection without mobilization. After myeloablative chemotherapy, the transplantation of an increased number of progenitor cells can lead to more rapid engraftment, which may result in a decreased need for supportive care. Myeloid reconstitution is further accelerated by administration of Leukine following peripheral blood progenitor cell transplantation.
3. Use in Myeloid Reconstitution After Autologous Bone Marrow Transplantation
 - a. Leukine is indicated for acceleration of myeloid recovery in patients with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's disease undergoing autologous bone marrow transplantation (BMT).
4. Use in Myeloid Reconstitution After Allogeneic Bone Marrow Transplantation
 - a. Leukine is indicated for acceleration of myeloid recovery in patients undergoing allogeneic BMT from HLA-matched related donors.
5. Use in Bone Marrow Transplantation Failure or Engraftment Delay
 - a. Leukine is indicated in patients who have undergone allogeneic or autologous BMT in whom engraftment is delayed or has failed.

B. Compendial Uses

1. Prophylaxis and treatment of chemotherapy-induced febrile neutropenia in non-myeloid malignancies
2. Treatment of neutropenia in patients with myelodysplastic syndromes (MDS)
3. AML following consolidation chemotherapy
4. ALL following induction or consolidation chemotherapy
5. Agranulocytosis
6. Aplastic anemia
7. Neutropenia related to HIV/AIDS
8. Stem cell transplantation-related indications

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Neutropenia in cancer patients receiving myelosuppressive chemotherapy

Authorization of 6 months may be granted for prevention or treatment of febrile neutropenia when both of the following criteria are met:

- a. Member has a non-myeloid malignancy and has received, is currently receiving, or will be receiving myelosuppressive anti-cancer therapy
- b. Leukine will not be administered less than 24 hours before or after chemotherapy or radiotherapy

B. Other indications

Authorization of 6 months may be granted for members with any of the following indications:

1. Agranulocytosis
2. Aplastic anemia
3. Neutropenia related to HIV/AIDS
4. Acute myeloid leukemia
5. Myelodysplastic syndrome
6. Stem cell transplantation-related indications

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Leukine [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; April 2013. (no change)
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 29 , 2017.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed July 7, 2017.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed July 7, 2017.
5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors. Version 1.2017. http://www.nccn.org/professionals/physician_gls/pdf/myeloid_growth.pdf. Accessed July 7, 2017.
6. 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.