Colony Stimulating Factors: Leukine® (sargramostim)
(Subcutaneous/Intravenous)

Document Number: IC-0237

Last Review Date: 04/03/2019
Date of Origin: 10/17/2008
Dates Reviewed: 06/2009, 12/2009, 06/2010, 07/2010, 09/2010, 12/2010, 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 04/2019

I. Length of Authorization

Coverage will be provided for four months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Leukine 250 mcg vial: 28 vials per 14 days
- Leukine 500 mcg vial: 14 vials per 14 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 15 billable units per day (acute radiation syndrome)
- 10 billable units per day (all other indications)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Myeloid reconstitution after autologous or allogeneic bone marrow transplant (BMT) †

Peripheral Blood Progenitor Cell (PBPC) mobilization and transplant †

Acute Myeloid Leukemia (AML) following induction or consolidation chemotherapy †

Bone Marrow Transplantation (BMT) failure or Engraftment Delay †

Treatment of chemotherapy-induced febrile neutropenia ‡

- Used for the treatment of chemotherapy induced febrile neutropenia in patients who have not received prophylactic therapy with a granulocyte colony stimulating factor; **AND**
- Patient has one or more of the following risk factors for developing infection-related complications:

Proprietary & Confidential
© 2019 Magellan Health, Inc.

- Sepsis Syndrome
- Age >65
- Absolute neutrophil count [ANC] <100/mcL
- Duration of neutropenia expected to be greater than 10 days
- Pneumonia or other clinically documented infections
- Invasive fungal infection
- Hospitalization at the time of fever
- Prior episode of febrile neutropenia

Patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome [H-ARS]) †

† FDA-labeled indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Same as initial prior authorization policy criteria.

V. Dosage/Administration

Indication	Dose
Acute Exposure to Myelosuppressive Doses of Radiation	• 7 mcg/kg in adult and pediatric patients weighing greater than 40 kg • 10 mcg/kg in pediatric patients weighing 15 kg to 40 kg • 12 mcg/kg in pediatric patients weighing less than 15 kg – *Administer Leukine as soon as possible after suspected or confirmed exposure to radiation doses greater than 2 gray (Gy).*
All other indications	250 mcg/m² daily for up to 14 days

VI. Billing Code/Availability Information

Jcode:

- J2820 – Injection, sargramostim (GM-CSF), 50 mcg: 1 billable unit = 50 mcg

NDC:

- Leukine 250 mcg vial– 00024-5843-xx
- Leukine 500 mcg vial– 00024-5844-xx

VII. References

1. Leukine [package insert]. Bridgewater, NJ; Sanofi-aventis U.S. LLC; March 2018. Accessed March 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sargramostim. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management

recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2019.
3. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Human Granulocyte/Macrophage Colony Stimulating Factors (L34699). Centers for Medicare & Medicaid Services, Inc. Updated on 01/24/2019 with effective date 02/01/2019. Accessed March 2019.
4. Palmetto GBA. Local Coverage Determination (LCD): White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 02/22/2019 with effective date 01/01/2019. Accessed March 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C92.00	Myeloid leukemia not having achieved remission
C92.02	Myeloid leukemia in relapse
C92.50	Acute myelomonocytic leukemia not having achieved remission
C92.52	Acute myelomonocytic leukemia in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia in relapse
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia in relapse
C93.10	Chronic myelomonocytic leukemia, not having achieved remission
C94.00	Acute erythroid leukemia not having achieved remission
C94.02	Acute erythroid leukemia in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.22	Acute megakaryoblastic leukemia in relapse
D61.81	Pancytopenia
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.9	Neutropenia, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs sequela
T66.XXXA	Radiation sickness, unspecified, initial encounter
T66.XXXD	Radiation sickness, unspecified, subsequent encounter
T66.XXXS	Radiation sickness, unspecified, sequela
W88.1	Exposure to radioactive isotopes
W88.8	Exposure to other ionizing radiation
Z41.8	Encounter for other procedures for purposes other than remedying health state

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management

ICD-10	ICD-10 Description
Z48.290	Encounter for aftercare following bone marrow transplant
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy
Z51.89	Encounter for other specified aftercare
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z76.89	Persons encountering health services in other specified circumstances
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5,8	**NCD/LCD Document (s):** L34699
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34699&bc=gAAAAAAAAAAA	

Jurisdiction(s): J, M	**NCD/LCD Document (s):** L37176
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L37176&bc=gAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
©2019, Magellan Rx Management