

Clover

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

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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

Zarxio is the preferred Colony Stimulating Factor product.

Patients continuing treatment with a non-preferred Colony Stimulating Factor product are exempt from this requirement.

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:
 - 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 | <ul style="list-style-type: none"> • 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/m ² 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 US LLC; February 2017. Accessed March 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sargramostim. National Comprehensive Cancer Network, 2018. 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 recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2018.

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 1/23/2018 with effective date 02/1/2018. Accessed March 2018.
4. Palmetto GBA. Local Coverage Determination (LCD): White Cell Colony Stimulating Factors (L37176). Centers for Medicare & Medicaid Services, Inc. Updated on 12/7/2017 with effective date 2/26/2018. Accessed March 2018.

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 |
| 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 |
| Z41.8 | Encounter for other procedures for purposes other than remedying health state |
| 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 |

| ICD-10 | ICD-10 Description |
|--------|-------------------------------|
| 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=gAAAAAAAAAAAA | |
| Jurisdiction(s): J, M | NCD/LCD Document (s): L37176 |
| https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L37176&bc=gAAAAAAAAAAAA | |

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 |
| 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 |