

LCD for Sargramostim (GM-CSF, Leukine®) (L29275)

Contractor Information

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09102

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L29275

LCD Title

Sargramostim (GM-CSF, Leukine®)

Contractor's Determination Number

J2820

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CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub 100-02, Medicare Benefit Policy, Chapter 15, Section 50
CMS Manual System, Pub 100-04, Medicare Claims Processing, Chapter 17, Section 10
CMS Manual System, Pub 100-08, Medicare Program Integrity, Chapter 13, Section 13.13

Primary Geographic Jurisdiction

Florida

Oversight Region

Region I

Original Determination Effective Date

For services performed on or after 02/02/2009

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) is an antineutropenic, hematopoietic growth factor, which supports survival, clonal expansion, and differentiation of hematopoietic progenitor cells. GM-CSF is also capable of activating mature granulocytes and macrophages. This drug is not a cancer chemotherapy agent.

The drug appears to elicit the pharmacologic effects usually produced by endogenous human GM-CSF. Endogenous GM-CSF is a multilineage colony-stimulating factor that principally affects the proliferation, differentiation, and activation of granulocytes and macrophages by inducing partially committed progenitor cells to divide and differentiate in the granulocyte-macrophage pathways.

Endogenous GM-CSF acts on various progenitor target cells by binding to GM-CSF specific receptors on their cell surfaces. Biosynthetic GM-CSF principally affects cells in the granulocyte-macrophage lineage. In patients receiving low doses of biosynthetic GM-CSF, the leukocyte response is composed principally of neutrophils; at higher concentrations, the leukocyte response also involves proliferation of monocytes and eosinophils.

Indications

Medicare will consider GM-CSF medically reasonable and necessary for the treatment of the following FDA approved indications when it is not self/caregiver administered:

- Primary neutropenia
- Promotion of myeloid engraftment following bone marrow transplant (BMT):
 - For acceleration of myeloid recovery in patients with non-Hodgkin's lymphomas, acute lymphoblastic leukemia, and Hodgkin's disease undergoing autologous BMT.
 - For acceleration of myeloid recovery in patients undergoing

autologous or allogenic BMT following myeloablative chemotherapy for non-myeloid malignancies.

- For acceleration of myeloid recovery in patients undergoing allogenic BMT following myeloablative chemotherapy for myeloid malignancies.
- For treatment of failure or delay of myeloid engraftment following autologous or allogenic BMT, in the presence or absence of infection.
- Enhancement of peripheral blood progenitor cell (PBPC) collection when the bone marrow transplant procedure itself is a covered benefit.
- For acceleration of myeloid recovery in patients undergoing hematopoietic stem cell transplantation following myeloablative chemotherapy.
- To reduce the duration of neutropenia, following induction chemotherapy treatment of adults with acute myelocytic leukemia (AML).

Medicare will consider GM-CSF medically reasonable and necessary for the treatment of the following off-label indications when it is not self/caregiver administered:

- Failure or delay of myeloid engraftment in patients who have undergone autologous or allogenic hematopoietic stem cell transplantation, in the presence or absence of infection.
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe febrile neutropenia.
- Acquired immunodeficiency syndrome (AIDS)-associated neutropenia caused by the disease (AIDS) itself or infection with opportunistic organisms (such as cytomegalovirus), or antiretroviral agents (zidovudine, ganciclovir).
- Intermittent administration of GM-CSF for a subset of patients with Myelodysplastic syndromes (MDS) who have severe neutropenia and recurrent infections.

Limitations

A physician is not to bill Medicare for a supply of GM-CSF given to the patient for self-administration at home.

The following off-labeled uses of GM-CSF have not been shown to be safe and effective and are noncovered by Medicare: aplastic anemia, hairy cell leukemia, severe chronic neutropenia which includes congenital (Kostmann's syndrome), idiopathic and cyclic.

Treatment of drug-induced neutropenia, except when associated with the use of antiretroviral agents is an off-labeled indication and noncovered by Medicare.

There is no evidence that GM-CSF is an important benefit in patients with refractory or relapsed myeloid leukemia.

Therapeutic initiation of GM-CSF does not add significantly to the antibiotic treatment outcome of established febrile neutropenia.

CSFs should not be routinely used as adjunct therapy for the treatment of uncomplicated fever and neutropenia. Uncomplicated fever and neutropenia are defined as follows:

- Fever of < 10 days in duration, and
- No evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection, and
- No uncontrolled malignancies.

There is inadequate data to support the use of GM-CSF for patients with afebrile neutropenia.

GM-CSF is contraindicated in patients with excessive leukemic myeloid blasts in the bone marrow or peripheral blood (> 10%).

In general, for previously untreated patients receiving a chemotherapy regimen, primary prophylactic administration of GM-CSF is not considered medically necessary.

Due to the potential sensitivity of rapidly dividing hematopoietic cells, GM-CSF should not be administered simultaneously with cytotoxic chemotherapy or radiotherapy or within 24 hours preceding or following chemotherapy or radiotherapy.

There is no evidence of benefit from the use of GM-CSF to increase chemotherapy dose-intensity.

Dosage and Frequency

The following is the recommended dosage and frequency when administering this drug:

Myelosuppressive chemotherapy - recommended dose is 250 mcg/m²/day. Administered no earlier than 24 hours after cytotoxic chemotherapy and not in the 24 hours before administration of chemotherapy.

PBPC - recommended dose is 250 mcg/m²/day. For the mobilization phase, this dosing should continue through the period of PBPC collection. For the post transplantation phase, begin the dose immediately and continue until an ANC > 1500 cells/mm³ for 3 consecutive days is attained.

Myeloid Reconstitution after Autologous or Allogenic BMT - recommended dose following BMT is 250 mcg/m²/day. Patients should not receive the drug until the post marrow infusion ANC is less than 500 cells/mm³. The drug should be continued until an ANC >1500 cells/mm³ for 3 consecutive days is attained.

BMT Failure or Engraftment Delay- recommended dose is 250 mcg/m²/day. Repeat dosage after 7 days off therapy if engraftment has not occurred. If engraftment still has not occurred, a third course of 500 mcg/m²/day for 14 days may be tried after another 7 days off therapy. If there is still no improvement, it is unlikely that further dose escalation will be beneficial.

If the ANC exceeds 20,000 or the platelet count exceeds 500,000, GM-CSF treatment should be discontinued or the dose reduced by half. Excessive blood counts usually return to normal or baseline levels within 3 to 7 days following withdrawal of GM-CSF.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999 Not Applicable

CPT/HCPCS Codes

J2820 INJECTION, SARGRAMOSTIM (GM-CSF), 50 MCG

ICD-9 Codes that Support Medical Necessity

Note: Please refer to coding guidelines for specific requirements regarding the billing of each of these ICD-9 codes.

205.00 - 205.92	ACUTE MYELOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED MYELOID LEUKEMIA, IN RELAPSE
238.71 - 238.79	ESSENTIAL THROMBOCYTHEMIA - OTHER LYMPHATIC AND HEMATOPOIETIC TISSUES
288.00 - 288.09	NEUTROPENIA, UNSPECIFIED - OTHER NEUTROPENIA
995.20	UNSPECIFIED ADVERSE EFFECT OF UNSPECIFIED DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
995.29	UNSPECIFIED ADVERSE EFFECT OF OTHER DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
996.85	COMPLICATIONS OF TRANSPLANTED BONE MARROW
V42.81*	BONE MARROW REPLACED BY TRANSPLANT
V42.82*	PERIPHERAL STEM CELLS REPLACED BY TRANSPLANT

V42.9*	UNSPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V58.11	ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY
V58.44	AFTERCARE FOLLOWING ORGAN TRANSPLANT
V58.69*	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS
V59.02	BLOOD DONORS STEM CELLS
V59.3	BONE MARROW DONORS
V59.8	DONORS OF OTHER SPECIFIED ORGAN OR TISSUE

* According to the ICD-9-CM book, diagnosis codes V42.81, V42.82, V42.9 and V58.69 are secondary diagnosis codes and should not be billed as the primary diagnosis.

Diagnoses that Support Medical Necessity

See ICD-9 Codes that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

All other diagnosis codes not listed as covered in the “ICD-9 Codes that Support Medical Necessity” section of this policy.

XX000	Not Applicable
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ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

All other diagnoses not listed as covered in the “ICD-9 Codes that Support Medical Necessity” section of this policy.

General Information

Documentation Requirements

Medical record documentation maintained by the physician must clearly indicate:

- The patient’s current absolute neutrophil count (ANC);
- The patient’s weight in kilograms;

- The administration and dosage of the GM-CSF;
- The actual indication for which the drug was given and accompanying symptomology (e.g., fever); and
- The patient's response to the treatment.

This information is usually found in the history and physical or the office/progress notes. The ANC may be reported in the patient's laboratory report.

Appendices

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Sources of Information and Basis for Decision

American Society of Clinical Oncology Growth Factor Expert Panel. (2000). 2000 Update of recommendations for the use of hematopoietic colony-stimulating factors: Evidence-based, clinical practice guidelines. Retrieved November 20, 2001 from the World Wide Web:http://www.asco.org/prof/pp/html/guide/color/m_colorintro.htm

Brites, C., Gilbert, M., Pedral-Sampaio, D., et al. (2000). A randomized, placebo-controlled trial of granulocytes-macrophage colony stimulating factor and nucleosides analogue therapy in AIDS. *Journal of Infectious Diseases*, 182, 1531-1535.

McEvoy, G., Litvak, K., & Welsh, O. (Eds.). (2000). Hematopoietic Agents. In *AHFS drug information*® 2000. (pp.1396-1406). Bethesda, MD: American Society of Health-System Pharmacists.

United States Pharmacopeia Drug Information (USP DI). (August 2005). Colony stimulating factors (systemic) monograph.

Advisory Committee Meeting Notes

This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

12/04/2008

Revision History Number

Original

Revision History Explanation

Revision Number:Original

Start Date of Comment Period:N/A

Start Date of Notice Period:12/04/2008

Revised Effective Date:02/02/2009

LCR B2009-

December 2008 Bulletin

This LCD consolidates and replaces all previous policies and publications on this subject by the carrier predecessors of First Coast Service Options, Inc. (Triple S and FCSO).

For Florida (00590) this LCD (L29275) replaces LCD L6423 as the policy in notice. This document (L29275) is effective on 02/02/2009.

Reason for Change**Last Reviewed On Date****Related Documents**

This LCD has no Related Documents.

LCD Attachments

Coding Guidelines (HTM - 15,684 bytes)

All Versions

Updated on 11/30/2008 with effective dates 02/02/2009 - N/A