

Local Coverage Determination (LCD) for G-CSF (Filgrastim, Neupogen®) (L29180)

Contractor Information

Contractor Name

First Coast Service Options, Inc.

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09102

Contractor Type

MAC - Part B

LCD Information

Document Information

LCD ID Number

L29180

Primary Geographic Jurisdiction

Florida

LCD Title

G-CSF (Filgrastim, Neupogen®)

Oversight Region

Region IV

Contractor's Determination Number

J1440

Original Determination Effective Date

For services performed on or after 02/02/2009

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Original Determination Ending Date**Revision Effective Date****Revision Ending Date**

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 Manual, Chapter 15, Section 50-50.1; 50.4.5

Indications and Limitations of Coverage and/or Medical Necessity

G-CSF is classified as a recombinant hematopoietic stimulant. This is not a cancer chemotherapy agent. It is a class II hematopoietic growth factor which acts on progenitor cells capable of forming a single differentiated cell type, the neutrophilic granulocyte, and is thus lineage-specific. Because Filgrastim acts only on progenitor cells that are already committed to one pathway, it increases only the neutrophil (e.g., granulocyte) count.

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

Cancer patients:

- Bone marrow transplant (BMT) - To reduce the severity of neutropenia in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous BMT.
- Peripheral Blood Progenitor Cell (PBPC) Collection - For use in the mobilization of peripheral stem cells when the bone marrow transplant procedure itself is a covered benefit.
- Progenitor- cell transplantation - As an adjunct to allogeneic and autologous progenitor-cell transplantation, both for mobilization of PBPC and as a means to speed hematopoietic reconstitution following BMT or PBPC transplantation.
- Neutrophil engraftment failure - To assist in the recovery of patients who experience delayed or inadequate neutrophil engraftment following progenitor-cell transplantation.
- Myelosuppressive chemotherapy - 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.
- Acute myelogenous leukemia (AML) - To reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Severe chronic neutropenia (SCN) patients:

- Congenital, cyclic, or idiopathic neutropenia - To reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with SCN.

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

- AIDS leukopenia in children.
- Amelioration of leukopenia in AIDS patients on AZT.
- Amelioration of leukopenia in AIDS patients with chorioretinitis on Ganciclovir.
- Intermittent administration of G-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 G-CSF given to the patient for self administration at home.
- The following unlabeled uses of G-CSF have not been shown to be safe and effective and are noncovered by Medicare: aplastic anemia, hairy cell leukemia, myeloid malignancies (other than AML), drug-induced and congenital agranulocytosis, and alloimmune neonatal neutropenia.
- Therapeutic initiation of G-CSF does not add significantly to the antibiotic treatment outcome of established febrile neutropenia. Exceptions to this rule must be documented.
- There are inadequate data to support the use of G-CSF for patients with afebrile neutropenia.
- In general, for previously untreated patients receiving a chemotherapy regimen, primary administration of G-CSF is not considered medically necessary.
- G-CSF should not be given within 24 hours before or after a dose of a chemotherapeutic agent, as rapidly dividing myeloid cells are potentially sensitive to these agents.
- There is no evidence of benefit from the use of G-CSF to increase chemotherapy dose-intensity.
- G-CSF should not be used concurrently with radiation therapy.

Dosage and Frequency

The package insert instructions for dosage and duration of treatment should not be exceeded.

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

BMT - Recommended dose following BMT is 10 mcg/kg/day given as an IV infusion of 4 or 24 hours or SC. The first dose should be administered at least 24 hours after chemotherapy and at least 24 hours after bone marrow infusion. The dose should be based on the neutrophil response. When the absolute neutrophil count (ANC) is $>1000/\text{mm}^3$ for 3 consecutive days, reduce the G-CSF dosage to 5 mcg/kg/day. If the ANC remains $>1000/\text{mm}^3$ for 3 more consecutive days, discontinue use.

PBPC - Recommended dose is 10 mcg/kg/day SC. G-CSF should be given for at least 4 days before the first leukapheresis procedure and continued until the last leukapheresis.

Myelosuppressive chemotherapy - Recommended starting dose is 5 mcg/kg/day SC or short IV infusion (15-30 minutes), or by continuous infusion. Doses may be increased in increments of

5 mcg/kg for each chemotherapy cycle, according to duration and severity of the ANC nadir. Administer no earlier than 24 hours after cytotoxic chemotherapy and not in the 24 hours before administration of chemotherapy. The drug should be discontinued when the absolute neutrophil count (ANC) reaches $10,000/\text{mm}^3$ and/or the patient becomes afebrile, or the patient has received the drug for a maximum of 14 days per treatment regimen.

AML - Recommended starting dose is 5mcg/kg/day SC until: ANC $\geq 1,000$ cells/ mm^3 for 3 days or ANC $> 10,000$ cells/ mm^3 for 1 day or for a maximum of 35 days.

SCN - Starting dose for congenital neutropenia is 6 mcg/kg twice daily SC every day. Idiopathic or cyclic neutropenia starting dose is 5 mcg/kg as a single injection SC every day. Chronic daily administration is required to maintain clinical benefit. Individually adjust the dose based on the patient's clinical course, as well as the ANC. Reduce the dose if the ANC is persistently $> 10,000/\text{mm}^3$.

**The guidelines recommended for adults are generally applicable to the pediatric age group.

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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
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CPT/HCPCS Codes

GroupName

J1440	INJECTION, FILGRASTIM (G-CSF), 300 MCG
J1441	INJECTION, FILGRASTIM (G-CSF), 480 MCG

ICD-9 Codes that Support Medical Necessity

238.72	LOW GRADE MYELOYDYSPLASTIC SYNDROME LESIONS
238.73	HIGH GRADE MYELOYDYSPLASTIC SYNDROME LESIONS
238.74	MYELOYDYSPLASTIC SYNDROME WITH 5Q DELETION
238.75	MYELOYDYSPLASTIC SYNDROME, UNSPECIFIED
238.77	POST-TRANSPLANT LYMPHOPROLIFERATIVE DISORDER (PTLD)
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
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
V58.69*	LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS
V59.8	DONORS OF OTHER SPECIFIED ORGAN OR TISSUE

* According to the ICD-9-CM book, diagnosis code V58.69 is a secondary diagnosis code and should not be billed as the primary diagnosis. For V42.81 and V42.82 the underlying condition should be billed as the primary diagnosis code.

Diagnoses that Support Medical Necessity

N/A

ICD-9 Codes that DO NOT Support Medical Necessity

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

Diagnoses that DO NOT Support Medical Necessity

N/A

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General Information

Documentations 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 G-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.

Appendices

Utilization Guidelines N/A

Sources of Information and Basis for Decision

American Society of Clinical Oncology Growth Factor Expert Panel. (2000). Update recommendations for the use of hematopoietic colony-stimulating factors: Evidence-based, clinical practice guidelines. Retrieved from the world wide web: <http://www.asco.org/cgi/content/full/18/20/3558>. This source provided information for the indications section of the policy.

Fauci, A.S., Braunwald, E., Isselbacher, K.J., et. al. (2004). Harrison's Principles of Internal Medicine (16d.). New York: McGraw-Hill.

Fischbach, F.T. (2003). A Manual of Laboratory and Diagnostic Tests (6th ed.). Philadelphia: J.B. Lippincott Company.

Package Insert Neupogen® (Filgrastim). (2002). Amgen Inc.

Physician Desk Reference 2004

The United States Pharmacopoeia Drug Information (USPDI). (2002). Oncology drug information. Maryland: The Association of Community Cancer Centers (ACCC). [on-line]. Available: <http://www.acc-cancer.org/cgi-bin/nds/nvbcgfh.exe>.

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 the 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 (L29180) replaces LCD L6567 as the policy in notice. This document (L29180) is effective on 02/02/2009.

Reason for Change

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

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All Versions

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

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