

Local Coverage Determination (LCD) for Pegfilgrastim (Neulasta™) (L29254)

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

L29254

Primary Geographic Jurisdiction

Florida

LCD Title

Pegfilgrastim (Neulasta™)

Oversight Region

Region IV

Contractor's Determination Number

J2505

Original Determination Effective Date

For services performed on or after 02/02/2009

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Original Determination Ending Date**Revision Effective Date**

For services performed on or after 10/01/2010

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, Chapter 15, Section 50
CMS Manual System, Pub 100-04, Chapter 17, Section 10
CMS Manual System, Pub 100-08, Chapter 13, Section 13.1.3
Program Memorandum B-03-048 (Change Request 2798)

Indications and Limitations of Coverage and/or Medical Necessity

Pegfilgrastim (Neulasta™) is a colony stimulating factor (CSF) that acts on hematopoietic cells by binding to specific cell surface receptors thereby, stimulating proliferation, differentiation, commitment, and end cell functional activation.

Pegfilgrastim (Neulasta™) is approved by the Food and Drug Administration 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 clinically significant incidence of febrile neutropenia.

Prophylactic use of Neulasta in patients undergoing chemotherapy reduces the risk of febrile neutropenia and infections. Prophylactic therapy can be considered for patients receiving myelosuppressive chemotherapy if the risk of febrile neutropenia is 20% or greater.

The recommended dosage of pegfilgrastim is 6 mg administered once per chemotherapy cycle.

The administration should not occur within 14 days before, and 24 hours after, administration of cytotoxic chemotherapy. Medicare will allow the following off-label exception to this rule as follows:

- If the patient is on a dose dense 14 day chemotherapy cycle, it would be acceptable to administer Neulasta outside of the 14 day before and 24 hour after rule for chemotherapy. Neulasta would typically be administered on the second day of the 14-day dose dense chemotherapy cycle. An example of this would be a patient receiving dose dense cytoxan/adriamycin and taxol for breast cancer. The chemotherapy drug record/orders should indicate that the patient is on a 14-day dose dense chemotherapy schedule.

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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

J2505	INJECTION, PEGFILGRASTIM, 6 MG
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ICD-9 Codes that Support Medical Necessity

140.0 - 149.9	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE LIP AND ORAL CAVITY
150.0 - 159.9	MALIGNANT NEOPLASM OF CERVICAL ESOPHAGUS - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE DIGESTIVE ORGANS AND PERITONEUM
160.0 - 165.9	MALIGNANT NEOPLASM OF NASAL CAVITIES - MALIGNANT NEOPLASM OF ILL-DEFINED SITES WITHIN THE RESPIRATORY SYSTEM
170.0 - 176.9	MALIGNANT NEOPLASM OF BONES OF SKULL AND FACE EXCEPT MANDIBLE - KAPOSII'S SARCOMA UNSPECIFIED SITE
179 - 189.9	MALIGNANT NEOPLASM OF UTERUS-PART UNS - MALIGNANT NEOPLASM OF URINARY ORGAN SITE UNSPECIFIED
190.0 - 199.2	MALIGNANT NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID - MALIGNANT NEOPLASM ASSOCIATED WITH TRANSPLANT ORGAN
200.00 - 200.88	

	RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
201.00 - 201.98	HODGKIN'S PARAGRANULOMA UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.08	NODULAR LYMPHOMA UNSPECIFIED SITE - NODULAR LYMPHOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
202.10 - 202.18	MYCOSIS FUNGOIDES UNSPECIFIED SITE - MYCOSIS FUNGOIDES INVOLVING LYMPH NODES OF MULTIPLE SITES
202.20 - 202.28	SEZARY'S DISEASE UNSPECIFIED SITE - SEZARY'S DISEASE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.30 - 202.38	MALIGNANT HISTIOCYTOSIS UNSPECIFIED SITE - MALIGNANT HISTIOCYTOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.40 - 202.48	LEUKEMIC RETICULOENDOTHELIOSIS UNSPECIFIED SITE - LEUKEMIC RETICULOENDOTHELIOSIS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.50 - 202.58	LETTERER-SIWE DISEASE UNSPECIFIED SITE - LETTERER-SIWE DISEASE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.60 - 202.68	MALIGNANT MAST CELL TUMORS UNSPECIFIED SITE - MALIGNANT MAST CELL TUMORS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.70 - 202.78	PERIPHERAL T CELL LYMPHOMA, UNSPECIFIED SITE, EXTRANODAL AND SOLID ORGAN SITES - PERIPHERAL T CELL LYMPHOMA, LYMPH NODES OF MULTIPLE SITES
202.80 - 202.88	OTHER MALIGNANT LYMPHOMAS UNSPECIFIED SITE - OTHER MALIGNANT LYMPHOMAS INVOLVING LYMPH NODES OF MULTIPLE SITES
203.00 - 203.82	MULTIPLE MYELOMA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER IMMUNOPROLIFERATIVE NEOPLASMS, IN RELAPSE
204.00 - 204.02	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - ACUTE LYMPHOID LEUKEMIA, IN RELAPSE
204.10 - 204.12	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
204.20 - 204.22	SUBACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - SUBACUTE LYMPHOID LEUKEMIA, IN RELAPSE
204.80 - 204.82	OTHER LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - OTHER LYMPHOID LEUKEMIA, IN RELAPSE
273.3	MACROGLOBULINEMIA
995.20	UNSPECIFIED ADVERSE EFFECT OF UNSPECIFIED DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
995.29	UNSPECIFIED ADVERSE EFFECT OF OTHER DRUG, MEDICINAL AND BIOLOGICAL SUBSTANCE
V07.8	OTHER SPECIFIED PROPHYLACTIC OR TREATMENT MEASURE
V66.2	CONVALESCENCE FOLLOWING CHEMOTHERAPY

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 LCD.

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 in the "ICD-9 Codes that Support Medical Necessity" section of this LCD.

General Information

Documentations Requirements

Medical record documentation maintained by the ordering/referring provider must substantiate the medical necessity for the use of this drug by clearly indicating the type of cancer being treated as well as the drug(s) used in the chemotherapy treatment(s). A medication administration record should also be maintained in each patient's record.

For patients on a 14 day dose dense chemotherapy cycle, the chemotherapy record/orders should support this type of schedule is being followed.

Appendices

Utilization Guidelines It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. Services performed in excess of established parameters 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. Available: http://www.asco.org/prof/pp/html/guide/color/m_colorintro.htm.

Drug Facts and Comparisons NEWS. (January 2006). Pegfilgrastim, 2.

Holmes, F., O'Shaughnessy, S., Vukelja, S., et al. (2002). Blinded, randomized, multicenter, study to evaluate single administration pegfilgrastim once per cycle versus daily filgrastim as an adjunct to chemotherapy in patients with high risk stage II or stage III/IV breast cancer. *Journal of Clinical Oncology*, 20(3), 727-731.

The United States Pharmacopeia Drug Information (USP DI). (November 2005). Oncology drug information. The Association of Community Cancer Centers (ACCC). [On-Line]. Available: www.accc-cancer.org/.

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 10/01/2010

Revision History Number 2

Revision History Explanation Revision Number:2

Start Date of Comment Period:N/A

Start Date of Notice Period:10/01/2010

Revised Effective Date: 10/01/2010

LCR B2010-071
September 2010 Update

Explanation of Revision: Annual 2011 ICD-9-CM Update. Revised descriptor for ICD-9-CM code V07.8. The effective date of this revision is based on date of service

Revision Number:1
Start Date of Comment Period:N/A
Start Date of Notice Period:03/01/2009
Revised Effective Date: 03/10/2009

LCR B2009-049
March 2009 Update

Explanation of Revision: Revision to add an off-label dosing schedule for chemotherapy patients who receive a dose dense chemo cycle. This off-label schedule will allow patients to receive Neulasta outside of the warning that states Neulasta should not be administered 14 days before and 24 hours after chemotherapy. The effective date of this revision is based on date of service.

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 B2009-044FL
December 2008 Update

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 (L29254) replaces LCD L14000 as the policy in notice. This document (L29254) is effective on 02/02/2009.

09/06/2010 - This policy was updated by the ICD-9 2010-2011 Annual Update.

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 09/16/2010 with effective dates 10/01/2010 - N/A
[Updated on 09/06/2010 with effective dates 03/10/2009 - 09/30/2010](#)
[Updated on 03/27/2009 with effective dates 03/10/2009 - N/A](#)
[Updated on 11/30/2008 with effective dates 02/02/2009 - N/A](#)
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