FIRST COAST SERVICE OPTIONS  
MAC - PART A/B  
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33747

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida  
09201 – Puerto Rico/Virgin Islands  
09102 – Florida  
09202 – Puerto Rico  
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Pegfilgrastim (Neulasta®)

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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, Chapter 1, Section 30-30.5  
CMS Manual System, Pub 100-02, Chapter 15, Section 50
Pegfilgrastim (Neulasta®) AB

Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region I

Original Determination Effective Date

10/01/2015

Original Determination Ending Date

N/A

Revision Effective Date

10/01/2016

Revision Ending Date

09/30/2016

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. The following off-label exception to this rule will be allowed 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.
Type of Bill Code

Hospital - 13x
Skilled Nursing Facility - 21x, 23x
Critical Access Hospital – 85x

Revenue Codes

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

J2505 Injection, pegfilgrastim, 6 mg

ICD-10 Codes that Support Medical Necessity

C00.0-C14.8 Malignant neoplasms of lip, oral cavity and pharynx
C15.3-C26.9 Malignant neoplasms of digestive organs
C30.0-C39.9 Malignant neoplasms of respiratory and intrathoracic organs
C40.00-C41.9 Malignant neoplasms of bone and articular cartilage
C43.0-C44.99 Melanoma and other malignant neoplasms of skin
C45.0-C49.9 Malignant neoplasms of mesothelial and soft tissue
C49.A0-C49.A9 Gastrointestinal stromal tumor, unspecified site - Gastrointestinal stromal tumor of other sites
C50.011-C50.929 Malignant neoplasm of breast
C51.0-C58 Malignant neoplasms of female genital organs
C60.0-C63.9 Malignant neoplasms of male genital organs
C64.1-C68.9 Malignant neoplasms of urinary tract
C69.00-C72.9 Malignant neoplasms of eye, brain and other parts of central nervous system
C73-C75.9 Malignant neoplasms of thyroid and other endocrine glands
C7A.1-C7A.8 Malignant neuroendocrine tumors
C76.0-C80.2 Malignant neoplasms of ill-defined, other secondary and unspecified sites
C81.00-C81.99 Hodgkin lymphoma
C82.00-C82.99 Follicular lymphoma
C83.00-C83.99 Non-follicular lymphoma
C84.00-C84.99 Mature T/NK-cell lymphomas
C85.10-C85.99 Other specified and unspecified types of non-Hodgkin lymphoma
C86.0-C86.6 Other specified types of T/NK-cell lymphoma
C88.0-C88.9 Malignant immunoproliferative diseases and certain other B-cell lymphomas
C90.00-C90.32 Multiple myeloma and malignant plasma cell neoplasms
C91.00-C91.22 Lymphoid leukemia
C96.0 Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.A Histiocytic sarcoma
C96.2 Malignant mast cell tumor
D03.0-D03.9 Melanoma in situ
T45.1X5A-T45.1X5S Adverse effect of antineoplastic and immunosuppressive drugs
T50.905A-T50.905S Adverse effect of unspecified drugs, medicaments and biological substances
Z41.8 Encounter for other procedures for purposes other than remedying health state
Z51.89 Encounter for other specified aftercare

Diagnoses that Support Medical Necessity

See ICD-10 Codes that Support Medical Necessity.
ICD-10 Codes that DO NOT Support Medical Necessity

All other diagnosis codes not listed as covered in the “ICD-10 Codes that Support Medical Necessity” section of this LCD.

Diagnoses that DO NOT Support Medical Necessity

All other diagnoses not listed in the “ICD-10 Codes that Support Medical Necessity” section of this LCD.

Associated Information

Documentation 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.

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

FCSO reference LCD number(s) – L28967, L29254, L29463


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.


Start Date of Comment Period

N/A

End Date of Comment Period

N/A
Start Date of Notice Period

04/01/2014

Revision History

Revision History Number: R1

Revision Number: 1
Publication: October 2016 Connection
LCR A/B2016-097

Explanation of Revision: Based on CR 9677 (Annual 2017 ICD-10-CM Update) the LCD was revised to add ICD-10-CM diagnosis code range C49.A0-C49.A9. The effective date of this revision is based on date of service.

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments

N/A

Document formatted: 09/03/2016 (NM/dc)