

Local Coverage Determination (LCD) for Oprelvekin (Neumega®) (L29243)

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

L29243

Primary Geographic Jurisdiction

Florida

LCD Title

Oprelvekin (Neumega®)

Oversight Region

Region IV

Contractor's Determination Number

J2355

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:

Medicare Manual System, Pub 100-02, Medicare Benefit Policy, Chapter 15, Section 50

Indications and Limitations of Coverage and/or Medical Necessity

Oprelvekin (Neumega®) is a thrombopoietic growth factor that directly stimulates the proliferation of hematopoietic stem cells and megakaryocyte progenitor cells, and induces megakaryocyte maturation resulting in increased platelet production.

Thrombocytopenia may compromise cancer treatment, causing a reduction in chemotherapy dosaging, alteration in schedule, or the need for platelet transfusions. Thrombopoietic growth factors may decrease the need for platelet transfusions in patients undergoing dose-intensive chemotherapy.

Medicare will consider the administration of Oprelvekin (Neumega®) medically reasonable and necessary for the following indications:

· To prevent severe thrombocytopenia (platelet counts of \leq 20,000 cells/uL) and to reduce the need for platelet transfusions following myelosuppressive chemotherapy in patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia.

Medicare will consider coverage of Oprelvekin **only** for patients with nonmyeloid malignancies who have/had a platelet count of \leq 50,000 cells/uL, or for patients with nonmyeloid malignancies who required a platelet transfusion after a previous myelosuppressive chemotherapy regimen.

Medicare will not consider coverage of Oprelvekin medically reasonable and necessary when it is administered simply because the patient has received a chemotherapeutic agent that has a high propensity to cause thrombocytopenia.

Oprelvekin is not indicated following myeloablative chemotherapy (e.g., bone marrow transplant or stem cell support). Oprelvekin is also not indicated as a "rescue" agent.

The recommended daily dosage is 50 ug/kg administered subcutaneously. Dosing should be initiated 6-24 hours following the completion of chemotherapy dosing, and discontinued at least 2 days before starting the next planned cycle of chemotherapy.

A single treatment course should not exceed 21 days. The safety and effectiveness of Oprelvekin immediately prior to or concurrently with cytotoxic chemotherapy has not been established.

Platelet counts should be monitored periodically to assess the optimal duration of therapy. Dosing should be continued until adequate recovery of the platelets has occurred (post-nadir platelet count \geq 50,000 cells/uL).

Additionally, a patient should be monitored for fluid retention (e.g., weight gain, edema, shortness of breath) during the course of treatment with Oprelvekin.

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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

J2355	INJECTION, OPRELVEKIN, 5 MG
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ICD-9 Codes that Support Medical Necessity

Note: The billing of Oprelvekin requires dual diagnoses. To ensure reimbursement for this service, dual diagnoses must be submitted. Providers must use ICD-9 codes 140.0-204.92, 273.3 (nonmyeloid malignancy) **and** 287.49 (thrombocytopenia due to drugs) to report the approved indication for J2355.

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 - KAPOSI'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 - 202.98	NODULAR LYMPHOMA UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE 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 - 204.92	ACUTE LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - UNSPECIFIED LYMPHOID LEUKEMIA, IN RELAPSE
273.3	MACROGLOBULINEMIA
287.49	OTHER SECONDARY THROMBOCYTOPENIA

Diagnoses that Support Medical Necessity

N/A

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

N/A

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General Information

Documentations Requirements

Medical record documentation (e.g., office/progress notes, medication records) maintained by the ordering/referring physician must clearly indicate the reason for the use of this drug, the platelet count, the patient's weight, and the dose administered.

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

United States Pharmacopoeia Drug Information Update, Volumes I and II (1998). The United States Pharmacopoeial Convention, Inc. **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 1

Revision History Explanation Revision Number: 1
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. Deleted ICD-9-CM code 287.4. Added ICD-9-CM code 287.49. 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 (L29243) replaces LCD L6032 as the policy in notice. This document (L29243) 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 01/06/2009 with effective dates 02/02/2009 - 09/30/2010

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

Read the **LCD Disclaimer**

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