

# LCD for Oprelvekin (Neumega®) (L29243)

## Contractor Information

### Contractor Name

First Coast Service Options, Inc.

### Contractor Number

09102

### Contractor Type

MAC - Part B

## LCD Information

### LCD ID Number

L29243

### LCD Title

Oprelvekin (Neumega®)

### Contractor's Determination Number

J2355

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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:

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

### Primary Geographic Jurisdiction

Florida

## **Oversight Region**

Region IV

## **Original Determination Effective Date**

For services performed on or after 02/02/2009

## **Original Determination Ending Date**

## **Revision Effective Date**

For services performed on or after 02/02/2009

## **Revision Ending Date**

## **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.



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

287.4

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

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

### **Diagnoses that DO NOT Support Medical Necessity**

N/A

### **General Information**

#### **Documentation 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**

1999 Physician's Desk Reference

United States Pharmacopoeia Drug Information Update, Volumes I and II (1998). The United States Pharmacopeial 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**

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 (L29243) replaces LCD L6032 as the policy in notice. This document (L29243) is effective on 02/02/2009.

**Reason for Change**

Typographical Correction

**Last Reviewed On Date****Related Documents**

This LCD has no Related Documents.

**LCD Attachments**

There are no attachments for this LCD.

**All Versions**

Updated on 01/06/2009 with effective dates 02/02/2009 - N/A

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