

Local Coverage Determination (LCD) for Rituximab (Rituxan®) (L29271)

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

L29271

Primary Geographic Jurisdiction

Florida

LCD Title

Rituximab (Rituxan®)

Oversight Region

Region IV

Contractor's Determination Number

J9310

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 04/19/2011

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, Chapter 15, Section 50

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Section 40

CMS Manual System, Pub. 100-08, Medicare Program Integrity, Chapter 13, Section 13.1.3

Social Security Act Section 1861 (t) (2) (b)

Indications and Limitations of Coverage and/or Medical Necessity

Rituximab (Rituxan®)—J9310

Rituxan (Rituxan®) is a monoclonal antibody that targets a specific protein, known as CD20, on the surface of immune cells known as B-cells. Rituxan binds to CD20 and is believed to work with the body's own immune system to attack and kill the marked B-cells.

Rituximab is FDA approved for the treatment of the following indications:

Non-Hodgkins Lymphoma (NHL)

. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as single-agent maintenance therapy.]

- Patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell, NHL as a single agent.
- Previously untreated diffuse large B-cell, CD20-positive, NHL in combination with CHOP or other anthracycline-based chemotherapy regimens.
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line treatment with CVP chemotherapy.

Rheumatoid Arthritis (RA)

· In combination with methotrexate to reduce signs and symptoms and to slow the progression of structural damage in adult patients with moderately-to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Chronic Lymphocytic Leukemia (CLL)

- In combination with fludarabine and cyclophosphamide (Fc), for the treatment of patients with previously untreated and previously treated CD20-positive CLL.

Wegener's Granulomatosis and Microscopic Polyangiitis

- In combination with glucocorticoids, for the treatment of adult patients with Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

Medicare will consider the use of Rituximab as medically reasonable and necessary for the FDA approved uses as well as the following off-labeled indications:

- Low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphomas (re-induction treatment appropriate for responders and patients with stable disease)
- Intermediate and high grade NHL when used as a single agent, in combination with a CHOP (Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone) chemotherapy regimen, or in combination with other agents active in the disease
- Immune or idiopathic thrombocytopenia purpura
- Evans' syndrome
- Waldenstrom's Macroglobulinemia
- For the treatment of refractory thrombotic thrombocytopenic purpura (TTP) for patients who do not respond to plasmapheresis.
- Autoimmune hemolytic anemia
- Rituximab is covered for those patients with autoimmune hemolytic anemia condition that is refractory to conventional treatment (e.g., corticosteroid treatment and splenectomy).

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

J9310	INJECTION, RITUXIMAB, 100 MG
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ICD-9 Codes that Support Medical Necessity

200.00 - 200.88	RETICULOSARCOMA UNSPECIFIED SITE - OTHER NAMED VARIANTS OF LYMPHOSARCOMA AND RETICULOSARCOMA 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
204.10 - 204.12	CHRONIC LYMPHOID LEUKEMIA, WITHOUT MENTION OF HAVING ACHIEVED REMISSION - CHRONIC LYMPHOID LEUKEMIA, IN RELAPSE
273.3	MACROGLOBULINEMIA
283.0	AUTOIMMUNE HEMOLYTIC ANEMIAS
287.31	IMMUNE THROMBOCYTOPENIC PURPURA
287.32	EVANS' SYNDROME
446.0	POLYARTERITIS NODOSA
446.4	WEGENER'S GRANULOMATOSIS
446.6	THROMBOTIC MICROANGIOPATHY
714.0	RHEUMATOID ARTHRITIS
714.1	FELTY'S SYNDROME
714.2	OTHER RHEUMATOID ARTHRITIS WITH VISCERAL OR SYSTEMIC INVOLVEMENT

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

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General Information

Documentations Requirements

Medical record documentation maintained by the ordering/referring physician must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the condition for which these drugs are being used. This might include the type of cancer, staging, if applicable, prior therapy and the patient's response to that therapy. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician's order for the chemotherapy drug. The physician must state the clinical indication/medical need for using the chemotherapy drug in the order.

For patients receiving Rituximab, an explanation of lymphoma type and previous treatment(s) should be maintained in the patient's medical record.

For the off-label indication of autoimmune hemolytic anemia, in addition to the above documentation requirements, the following documentation must be supported in the medical record: Hgb and Hct, reticulocyte count, bilirubin, hepatoglobulin, indirect and direct hepatoglobulintests), patients subjective complaints.

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.

Dosage for the off label indication of autoimmune hemolytic anemia is as follows: 375 mg/m² once weekly for four consecutive weeks.

See the Food and Drug Administration (FDA) drug label for recommended dosages for specific FDA indications.

Rituximab (Rituxan®) is supplied as a 100mg/10mL and 500mg/50mL solution in a single-use vial.

Sources of Information and Basis for Decision

Colombat, et al., (2001). Rituximab (anti-CD20 monoclonal antibody) as a single first-line therapy for patients with follicular lymphoma with a low tumor burden: clinical and molecular evaluation. *Blood*, 97(1), 101-106. This article supports off-labeled indications (1st line therapy) for this drug.

Compendia-Based Drug Bulletin. (February 2007). The Association of Community Cancer Centers. [On-Line]. Available: <http://www.accc-cancer.org/>.

Foran, J., Rohatiner, A., Cunningham, D., Popescu, R., Solal-Celiqny, P., Ghielmini, M., et al., (2000). European phase II study of Rituximab (chimeric anti-CD20 monoclonal antibody) for patients with newly diagnosed mantle-cell lymphoma and previously treated mantle cell lymphoma, immunocytoma, and small B-cell lymphocytic lymphoma. *Journal of Clinical Oncology*, 18(2), 317-324.

Genentech. (2010). Rituxan prescribing information.

Heidel, F., Lipka, D., et al. (2007). Addition of Rituximab to standard therapy improves response rate and progression-free survival in relapsed or refractory thrombotic thrombocytopenia purpura and autoimmune haemolytic anaemia. *Thrombosis and haemostasis* 97(2)228-233.

National Comprehensive Cancer Network (2007). Non-Hodgkin's Lymphomas. Clinical Practice Guidelines in Oncology – V.1.2007.

Pamuk, G., Turgut, B., et al. (2006). The successful treatment of refractory autoimmune hemolytic anemia with rituximab in a patient with chronic lymphocytic leukemia. American Journal of Hematology, 81: 631-633.

Thomson Micromedex (2007). USP DI Drug Information for the Health Care Professional. [On-Line]. Available: <http://www.thomsonhc.com/home/dispatch>

U.S. Food and Drug Administration, Department of Health and Human Services, CDER web site updates, January 2008.

U.S. Food and Drug Administration, Department of Health and Human Services, CDER web site updates, January 2011.

U.S. Food and Drug Administration, Department of Health and Human Services, FDA News Release, April 19, 2011.

Vose, J., Link, B., Grossbard, M., Czuczman, M., Grillo-Lopez, A., Gilman, P., et al., (2001). Phase II study of Rituximab in combination with CHOP chemotherapy in patients with previously untreated, aggressive non-Hodgkin's lymphoma. Journal of Clinical Oncology, 19(2), 389-397.

Wood, A.M. (2001). Rituximab: An innovative therapy for non-Hodgkin's lymphoma. American Journal of Health System Pharmacy, 58(3), 215-232.

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 advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period 05/01/2011

Revision History Number 3

Revision History Explanation Revision Number:3

Start Date of Comment Period:N/A
Start Date of Notice Period:07/01/2011
Revised Effective Date:04/19/2011

LCR B2011-061
June 2011 Connection

Explanation of Revision: Under the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LCD for FDA approved indications, added indications for Wegener's Granulomatosis and Microscopic Polyangiitis. Under the "ICD-9 Codes that Support Medical Necessity" section of the LCD, added diagnosis codes 446.0 and 446.4. In addition, the "Sources of Information and Basis for Decision" section was updated. The effective date of this revision is for dates of service on or after April 19, 2011 for claims processed on or after 06/20/2011.

Revision Number:2
Start Date of Comment Period:N/A
Start Date of Notice Period:05/01/2011

Revised Effective Date 01/28/2011

LCR B2011-047
April 2011 Update

Explanation of Revision: Revised under the "Indications and Limitations of Coverage and/or Medical Necessity" section of the LCD, added additional FDA approval indication for follicular CD20-positive, B-cell NHL. In addition, updated the "Sources of Information and Basis for Decision" section of the LCD. Revision will be effective for dates of service on or after 01/28/2011 for claims processed on or after 03/31/2011.

Revision Number 1
Start Date of Comment Period:N/A
Start Date of Notice Period:05/01/2010
Revised Effective Date 02/18/2010

LCR B2010-035
April 2010 Update

Explanation of Revision: Revised indications and limitations to add CLL as an FDA approved indication and removed CLL from the covered off-label list. Revisions will be effective for dates of services on or after 02/18/2010 for claims processed on or after 04/06/2010.

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
LCR B2009-045PR/VI
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 (L29271) replaces LCD L25077 as the policy in notice. This document (L29271) 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 06/15/2011 with effective dates 04/19/2011 - N/A
[Updated on 04/01/2011 with effective dates 01/28/2011 - 04/18/2011](#)
[Updated on 04/06/2010 with effective dates 02/18/2010 - 01/27/2011](#)
[Updated on 11/30/2008 with effective dates 02/02/2009 - N/A](#)
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