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

LCD Database ID Number
L33746

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
Rituximab (Rituxan®)

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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, Medicare Benefit Policy Manual, Chapter 1, Section 30-30.1
CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50
CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 17, Sections 10, 20 and 40
Rituximab (Rituxan®) AB

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.1.3
Social Security Act Section 1861 (t) (2) (b)

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

01/17/2017

Revision Ending Date

01/16/2017

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)]

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

- Second-line or salvage therapy with or without radiation therapy (RT) prior to autologous stem cell rescue for progressive disease or for relapsed disease in patients initially treated with chemotherapy with or without RT in combination with bendamustine
- 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)
- Steroid refractory chronic graft-versus-host disease.
- Neuromyelitis optica for disease progression following failure of standard therapy (e.g. oral immunosuppressant therapy).

LIMITATIONS

Diagnosis code G35 (Multiple Sclerosis) is not a covered diagnosis given its use has not been demonstrated to be a standard of care, and claims can be denied as not medically reasonable and necessary. Claims with this diagnosis will be addressed for individual consideration and records may be requested for prepayment review. The documentation must clearly support that the patient was refractory to standard treatments and that no reasonable alternative treatments were available. The record should clearly outline the indication (diagnostic criteria) and medical need (episode of care).

Type of Bill Code

Hospital - 13x
Skilled Nursing Facility - 21x, 22x, 23x
Critical Access Hospital – 85x
### Revenue Codes

636  Drugs Requiring Detailed Coding

### CPT/HCPCS Codes

J9310  Injection, rituximab, 100 mg

### ICD-10 Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C81.00-C81.09</td>
<td>Nodular lymphocyte predominant Hodgkin lymphoma</td>
</tr>
<tr>
<td>C81.40-C81.49</td>
<td>Lymphocyte-rich Hodgkin lymphoma, unspecified site - Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites</td>
</tr>
<tr>
<td>C82.00-C82.99</td>
<td>Follicular lymphoma</td>
</tr>
<tr>
<td>C83.00-C83.99</td>
<td>Non-follicular lymphoma</td>
</tr>
<tr>
<td>C84.00-C84.79</td>
<td>Mature T/NK-cell lymphomas</td>
</tr>
<tr>
<td>C84.90-C84.99</td>
<td>Mature T/NK-cell lymphomas, unspecified</td>
</tr>
<tr>
<td>C84.A0-C84.Z9</td>
<td>Mature T/NK-cell lymphomas</td>
</tr>
<tr>
<td>C85.10-C86.4</td>
<td>Neoplasms</td>
</tr>
<tr>
<td>C86.5-C86.6</td>
<td>Other specified types of T/NK-cell lymphoma</td>
</tr>
<tr>
<td>C88.0</td>
<td>Waldenström macroglobulinemia</td>
</tr>
<tr>
<td>C88.4</td>
<td>Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]</td>
</tr>
<tr>
<td>C91.10-C91.12</td>
<td>Chronic lymphocytic leukemia of B-cell type</td>
</tr>
<tr>
<td>C91.40-C91.42</td>
<td>Hairy cell leukemia</td>
</tr>
<tr>
<td>C96.0-C96.4</td>
<td>Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue</td>
</tr>
<tr>
<td>C96.9</td>
<td>Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified</td>
</tr>
<tr>
<td>C96.A-C96.Z</td>
<td>Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue</td>
</tr>
<tr>
<td>D59.0*</td>
<td>Drug-induced autoimmune hemolytic anemia</td>
</tr>
<tr>
<td>D59.1</td>
<td>Other autoimmune hemolytic anemias</td>
</tr>
<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
<tr>
<td>D69.41</td>
<td>Evans syndrome</td>
</tr>
<tr>
<td>D89.811*</td>
<td>Chronic graft-versus-host disease</td>
</tr>
<tr>
<td>G36.0</td>
<td>Neuromyelitis optica [Devic]</td>
</tr>
<tr>
<td>M05.00-M05.09</td>
<td>Felty's syndrome</td>
</tr>
<tr>
<td>M05.20-M06.9</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>M30.0</td>
<td>Polyarteritis nodosa</td>
</tr>
<tr>
<td>M30.1</td>
<td>Polyarteritis with lung involvement [Churg-Strauss]</td>
</tr>
<tr>
<td>M30.2</td>
<td>Juvenile polyarteritis</td>
</tr>
<tr>
<td>M30.8</td>
<td>Other conditions related to polyarteritis nodosa</td>
</tr>
<tr>
<td>M31.1</td>
<td>Thrombotic microangiopathy</td>
</tr>
<tr>
<td>M31.30-M31.31</td>
<td>Wegener's granulomatosis</td>
</tr>
<tr>
<td>M31.7</td>
<td>Microscopic polyangiitis</td>
</tr>
<tr>
<td>T86.00-T86.09*</td>
<td>Complications of bone marrow transplant</td>
</tr>
<tr>
<td>T86.11</td>
<td>Kidney transplant rejection</td>
</tr>
<tr>
<td>T86.5*</td>
<td>Complications of stem cell transplant</td>
</tr>
</tbody>
</table>

*According to the ICD-10-CM book, code first T36-T50 to identify drug for D59.0 (drug-induced autoimmune hemolytic anemia). ICD-10 code D89.811 must accompany underlying cause diagnosis code T86.00-T86.09 or T86.5

### Diagnoses that Support Medical Necessity
Rituximab (Rituxan®) AB

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 as covered 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 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.

For the off-label indication of neuromyelitis optica, in addition to the above documentation requirements, the following must be supported in the medical record: documentation of disease breakthrough while on standard therapy (e.g. oral immunosuppressant therapy).

**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**

FCSO reference LCD number(s) – L29013, L29271, L29472

Rituximab (Rituxan®) AB


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.


**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: R4**

Revision Number: 4
Publication: January 2017 Connection
LCR A/B2016-113

**Explanation of Revision:** Based on a reconsideration request, this LCD was revised to add ICD-10 code T86.11 to the “ICD-10 Codes that Support Medical Necessity” section of the LCD for HCPCS code J9310. The effective date of this revision is based on date of service.

**Revision History Number: R3**

Revision Number: 3
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. Descriptor revised for ICD-10-CM diagnosis code range C81.40-C81.49. The effective date of this revision is based on date of service.

**Revision History Number: R2**

Revision Number: 2
Publication: July 2016 Connection
LCR A/B2016-081

Explanation of revision: The LCD section, “Indications and Limitations of Coverage and/or Medical Necessity” was revised based on a reconsideration request to add the off-labeled indication of neuromyelitis optica. Also, the “ICD-10 Codes that Support Medical Necessity” section of the LCD was updated to add ICD-10-CM diagnosis code G36.0. Additionally, the “Documentation Requirements” and “Sources of Information and Basis for Decision” sections of the LCD were updated. The effective date of this revision is based on date of service.
Revision History Number: R1

Revision Number: 1
Publication: October 2015 Connection
LCR A/B2015-015

Explanation of revision: This LCD was revised to add ICD-10-CM diagnosis codes C83.00—C83.99 to the “ICD-10 Codes that Support Medical Necessity” section of the LCD. 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: 12/13/2016 (AC/et)