

**Rituxan®**

To Initiate a Coverage Review, call 1 800 753-2851

Covered Medication
➤ Rituximab ( <i>Rituxan</i> )

What it does and how it's used
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| <ul style="list-style-type: none"> <li>➤ The lymphatic system is an essential component of the immune system dedicated to fighting infections. Lymphatic tissue makes and stores lymphocytes: white blood cells responsible for immunity and defense against infections or other foreign invaders. The two main types of lymphocytes are B lymphocytes (B cells) and T lymphocytes (T cells).</li> <li>➤ B cells normally help protect the body against bacteria or viruses by producing proteins called antibodies. The antibodies attach to the bacteria or viruses and attract immune system cells that surround and digest the antibody-coated germs.</li> <li>➤ Normal B cells and T cells are recognized by the body through specific identifying substances on their cell surfaces. Certain substances are found only on B cells and others only on T cells.</li> <li>➤ <b>Non-Hodgkin's lymphoma (NHL)</b> is the seventh most common cancer in the United States. It affects more males than females, and the incidence rises with age. Approximately 66,000 people were diagnosed with Non-Hodgkin's Lymphoma in 2009. In NHL, infected B cells develop a protein known as the CD-20 antigen on their surfaces and divide uncontrollably, resulting in tumor formation.</li> <li>➤ Rituximab is a genetically engineered chimeric murine/human monoclonal antibody that works by binding to the CD-20 antigen on the surface of NHL-infected B cells. Rituximab attacks and kill these marked B cells. This in turn allows healthy B cells that do not have the CD-20 antigen to develop and reproduce successfully.</li> <li>➤ The recommended dose for rituximab for patients with NHL is 375 mg/m<sup>2</sup> IV infusion once weekly for 4 to 8 doses.</li> <li>➤ <b>Chronic lymphocytic leukemia (CLL)</b> is the second most common type of leukemia in adults. It is a blood and bone marrow disease that often occurs during or after middle age; it rarely occurs in children. In CLL, a mutation occurs that causes too many blood stem cells to develop into abnormal lymphocytes, resulting in less room for healthy cells. These leukemic cells are not able to fight infection.</li> <li>➤ Several treatment options exist, and the goal of therapy is to slow the growth of CLL cells and provide long periods of remission. Recommended <i>Rituxan</i>® dosing for CLL is 375 mg/m<sup>2</sup> the day prior to the initiation of FC chemotherapy (fludarabine and cyclophosphamide) and then 500 mg/m<sup>2</sup> on Day 1 of Cycles 2 through 6 (every 28 days).</li> <li>➤ <b>Rheumatoid arthritis (RA)</b> is characterized by painful inflammation of the synovial tissue lining the joints. Chronic joint inflammation eventually leads to tissue destruction, cellular damage to the bone along with edema (swelling), warmth, redness, joint stiffness, and pain. B cells are believed to play a role in RA and joint inflammation.</li> <li>➤ Rituximab, in combination with methotrexate, is indicated for reducing the signs and symptoms and reducing structural damage in adult patients with moderately to severely active RA who have an inadequate response to one or more TNF-alpha antagonist therapies.</li> <li>➤ The recommended dose of rituximab for patients with RA is two 1,000-mg IV infusions separated by 2 weeks. Subsequent courses should be administered every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks.</li> </ul> |
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Rationale for prior authorization
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To reduce costs associated with the use of rituximab for treatment of conditions other than NHL, CLL, or for the treatment of moderately to severely active RA in situations where use of a TNF-alpha inhibiting drug (for example, <i>Remicade</i> ®, <i>Enbrel</i> ®, <i>Humira</i> ®) is warranted.
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Benefit design
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Coverage is determined through prior authorization for every claim.
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Prior authorization criteria
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| <p>Coverage for <i>Rituxan</i>® is provided in accord with the following:</p> <ol style="list-style-type: none"> <li>1. For the treatment of non-Hodgkin's lymphoma (NHL)<br/>OR</li> <li>2. For the treatment of chronic lymphocytic leukemia (CLL)<br/>OR</li> <li>3. For the treatment of moderately to severely active rheumatoid arthritis (RA) <ul style="list-style-type: none"> <li>➤ In patients 18 years of age or older</li> </ul> </li> </ol> |
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- AND
- The patient is using *Rituxan*<sup>®</sup> in combination with methotrexate
- AND
- The patient has had an inadequate response OR intolerance to at least one TNF-alpha inhibitor (for example, *Remicade*<sup>®</sup>, *Enbrel*<sup>®</sup>, *Humira*<sup>®</sup>).

Benefit coverage is not provided for use of *Rituxan*<sup>®</sup> in combination with other biologics or TNF antagonists.

Coverage duration:

NHL – 6 months. Coverage may be renewed for an additional 6 months for re-treatment of NHL.

CLL – 6 months. Coverage may be renewed.

RA – 1 month. Coverage is renewed after at least 6 months have passed from the last course of treatment

OR

- At least 16 weeks have passed

AND

As determined by clinical evaluation by the prescriber, re-treatment is necessary to control the patient's arthritis symptoms.

**Reference**

- American College of Rheumatology. Guidelines for the management of Rheumatoid Arthritis, 2002 Updated. Available from URL: <http://www.rheumatology.org/publications/guidelines/raguidelines02.asp>. Accessed March 25, 2008.
- National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphoma. Version 2.2009 Available at: [http://www.nccn.org/professionals/physician\\_gls/PDF/nhl.pdf](http://www.nccn.org/professionals/physician_gls/PDF/nhl.pdf). Accessed August 2009.
- *Rituxan*<sup>®</sup> (rituximab) prescribing information. South San Francisco: Genentech, Inc., February 2010.
- The Leukemia & Lymphoma Society. Available from URL: [http://www.leukemia.org/all\\_page?item\\_id=8965#\\_newcases](http://www.leukemia.org/all_page?item_id=8965#_newcases). Non-Hodgkin Lymphoma Facts & Statistics. Accessed May 12, 2010