

Corporate Medical Policy

Rituximab for the Treatment of Rheumatoid Arthritis

File Name: rituximab_for_the_treatment_of_rheumatoid_arthritis
Origination: 4/2008
Last CAP Review: 2/2011
Next CAP Review: 2/2012
Last Review: 8/2011

Description of Procedure or Service

Rituxan® (rituximab) is a genetically engineered chimeric mouse/human monoclonal antibody directed against the DC20 antigen found on the surface of normal and malignant B lymphocytes. This monoclonal antibody recognizes and sticks to the surface of white blood cells called B cells. These B cells produce the harmful antibodies like the rheumatoid factors. After Rituxan® (rituximab) labels the B cells, the body's immune system activates and kills the bad cells. These B cells return in about 1 month. Rituxan® is given intravenously (IV).

Rheumatoid arthritis is a chronic condition where the person's own immune system causes inflammation of the joints and the tissue around the joints. The body is equipped with a defense mechanism called the immune system which protects itself from disease and infection. When a person has an autoimmune condition, the immune system creates antibodies that attack its own tissues. Rheumatoid arthritis usually starts between the age of 25 and 55 and the cause is unknown. Symptoms of rheumatoid arthritis (RA) are described as painful inflammation of the synovial tissue lining the joints. These patients have elevated levels of tumor necrosis factor-alpha (TNF-a) in their joints. Chronic joint inflammation leads to tissue break down, cell damage to the bone, edema, warmth, redness, joint stiffness, and pain. These patients are also fatigued, weak, have a low-grade fever, and loss of appetite.

Tumor necrosis factor inhibiting drugs such as Remicade® (infliximab), Enbrel® (etanercept), or Humira® (adalimumab) are considered first line treatment before considering the use of Rituxan® (rituximab). Patients will sometimes become intolerant or unresponsive to TNF inhibiting therapy and for these; Rituxan® (rituximab) may be considered.

Note***This policy only applies to Rituximab (Rituxan®) when used for the treatment of Rheumatoid Arthritis.

For oncologic uses of Rituximab, please see BCBSNC Corporate Medical Policy, Monoclonal Antibodies for Non-Hodgkin Lymphoma, including Chronic Lymphocytic, & Acute Myeloid Leukemia in the Non-Hematopoietic Stem Cell Transplant Setting.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Rituxan® (rituximab) for the treatment of rheumatoid arthritis when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Rituximab may be subject to prior review requirements.

When Rituximab for the Treatment of Rheumatoid Arthritis is covered

Rituxan® (rituximab) may be medically necessary for the treatment of rheumatoid arthritis when the medical criteria and guidelines shown below are met:

1. The patient has moderate to severe rheumatoid arthritis; and
2. The patient has failed to respond adequately to at least one Tumor Necrosis Factor (TNF) inhibiting drug or is intolerant to all TNF-inhibiting drugs (i.e., Remicade® (infliximab), Enbrel® (etanercept), or Humira® (adalimumab); and
3. Rituxan® (rituximab) is to be used preferably in combination with methotrexate unless contraindicated; and
4. The patient is 18 years old or older.

When Rituximab for the Treatment of Rheumatoid Arthritis is not covered

1. Rituximab for the treatment of rheumatoid arthritis is considered not medically necessary when the criteria stated above are not met.
2. Rituxan® should not be used in combination with TNF-inhibiting drugs.

Policy Guidelines

The recommended dose of Rituxan® (rituximab) for the treatment of rheumatoid arthritis is two 1000mg IV infusions separated by 14 days. Subsequent courses of Rituxan® (rituximab) should be administered every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: J9310

Diagnoses that are subject to medical necessity review: 714, 714.0, 714.1, 714.2, 714.3, 714.30, 714.31, 714.32, 714.33, 714.4, 714.8, 714.81, 720.0

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

Genetech Inc. Rituxan® (rituximab) targeted B-cell therapy, product information. Retrieved 3/12/08 from <http://www.rituxan.com/>

Senior Medical Director review, 3/20/2008.

Genetech Inc. Rituxan® (rituximab) targeted B-cell therapy, full prescribing information. Retrieved 10/29/09 from <http://www.gene.com/gene/products/information/pdf/rituxan-prescribing.pdf>

Specialty Matched Consultant Panel - 1/2010

Genetech Inc. Rituxan® (rituximab) targeted B-cell therapy, product information. Retrieved 3/30/10 from <http://www.rituxan.com/>

Specialty Matched Consultant Panel- 2/2011

Genetech Inc. Rituxan® (rituximab) targeted B-cell therapy, product information. Retrieved 1/21/11 from <http://www.rituxan.com/>

Policy Implementation/Update Information

- 4/1/08 New policy developed. Under the "When Covered" section; "Rituxan® (rituximab) may be medically necessary for the treatment of rheumatoid arthritis when the medical criteria and guidelines shown below are met: 1. The patient has moderate to severe rheumatoid arthritis; and 2. The patient has failed to respond adequately to at least one Tumor Necrosis Factor (TNF) inhibiting drug or is intolerant to all TNF-inhibiting drugs (i.e., Remicade (infliximab), Enbrel (etanercept), or Humira (adalimumab); and 3. Rituxan® (rituximab) is to be used in combination with methotrexate; and 4. The patient is 18 years old or older. 5. Continued use of Rituxan® (rituximab) can only be renewed after 6 months have passed from the last course of treatment and retreatment is necessary to control symptoms." Under the "When Not Covered" section; " 1. When the criteria stated above are not met. 2. Rituxan® should not be used in combination with TNF-inhibiting drugs." Senior Medical Director review, 3/20/2008. References added. Notification given April 1, 2008. Policy effective 7/1/2008. References added.
- 11/3/08 Added "Note" at the end of the "Description" section indicating; "NOTE: This policy only applies to Rituximab (Rituxan®) when used for the treatment of Rheumatoid Arthritis." (btw)
- 3/2/10 Specialty Matched Consultant Advisory Panel review 1/5/2010. Updated "Description" section. No change to policy statement. Added wording to clarify #3 in the "When Covered" section to indicate; "Rituxan (rituximab) is to be used **preferably** in combination with methotrexate **unless contraindicated**". References added. (btw)
- 5/11/10 Under the "When Covered" section, updated guideline #5 to indicate "Subsequent courses of Rituxan (rituximab) should be administered every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks." Update due to a change in Rituxan's FDA-approved labeling. References added. (LR)
- 10/26/10 Added diagnoses codes to the "Billing/Coding" section. (lpr)

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- 3/15/11 Specialty Matched Consultant Advisory Panel review 2/2011. Under “When Covered” section, moved #5 “Subsequent courses of Rituxan (rituximab) should be administered every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks” to Policy Guidelines section since this refers to continuation of treatment and not initial approval. Under “When Not Covered” section, added phrase “not medically necessary” to statement #1 “Rituximab for the treatment of rheumatoid arthritis is considered not medically necessary when the criteria stated above are not met. (lpr)
- 8/16/11 In the description section, added a cross reference to the Corporate Medical Policy, Monoclonal Antibodies for Non-Hodgkin Lymphoma, including Chronic Lymphocytic, & Acute Myeloid Leukemia in the Non-Hematopoietic Stem Cell Transplant Setting. (lpr)
- 11/22/11 Removed the x from the ICD-9 codes 714.0, 714.4, 714.8, 720.0 in the Billing/Coding section since there are no 5th digits for these codes. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.