

Corporate Medical Policy

Rituximab for the Treatment of Rheumatoid Arthritis

File Name: rituximab_for_the_treatment_of_rheumatoid_arthritis
Policy Number: DRU4160
Origination: 4/2008
Last CAP Review: 1/2010
Next CAP Review: 1/2012
Last Review: 1/2010

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.

*****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

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the 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.
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.

When Rituximab for the Treatment of Rheumatoid Arthritis is not covered

1. 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.

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

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

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specific information needed to make a medical necessity determination is included.

Medical Term Definitions

Antibody

a protein that is produced by the immune system against a specific antigen.

Rheumatoid arthritis

a chronic disease considered to be autoimmune and characterized by pain, stiffness, inflammation, swelling, and sometimes destruction of joints.

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

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)

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

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disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.