

Medical Affairs Policy & Procedure

Title/Service: Rituxan (rituximab)

Revised	11/18/11
Reviewed	07/27/10
Developed	
Policy Committee Approval	11/18/11

Description:

Rituxan is a monoclonal antibody with effect on lymphocyte activity. Rituxan binds to the CD 20 markers on the surface of B cells (a type of lymphocyte which play a role in the immune system), and works with the human immune system to induce B-cell lysis through several proposed mechanisms, including cytotoxicity and apoptosis.

Indications of Coverage:

1. Oncology Indications (**refer to NCCN guidelines for specifics**):

- Intracerebrospinal fluid (CSF) treatment for leptomeningeal metastases
- Primary CNS Lymphoma
- Hodgkin Lymphoma - Lymphocyte-predominant Hodgkin lymphoma
- Non-Hodgkin's Lymphomas
 - AIDS-related B-cell lymphoma
 - Burkitt lymphoma
 - Chronic lymphocytic leukemia/Small lymphocytic lymphoma
 - Diffuse large B-cell lymphoma
 - Follicular lymphoma and Nodal marginal zone lymphoma
 - Gastric MALT lymphoma
 - Lymphoblastic lymphoma
 - Mantle cell lymphoma
 - Nongastric MALT lymphoma
 - Posttransplant lymphoproliferative disorder (PTLD)
 - Primary cutaneous B-cell lymphoma
 - Splenic marginal zone lymphoma
- Waldenström's macroglobulinemia/Lymphoplasmacytic lymphoma

The use of Rituxan for other oncologic indications not mentioned above will be reviewed on a case-by-case basis.

2. For the treatment of adults with autoimmune hemolytic anemia following the failure of conservative therapy (for example, systemic steroids or IVIG). Additional courses after relapse will be considered only if there was a favorable response to the initial treatment.

3. For the treatment of adults with idiopathic thrombocytopenic purpura, following the failure of conservative therapy (for example, systemic steroids or IVIG). Additional courses after relapse will be considered only if there was a favorable response to the initial treatment.
4. Rituximab in combination with methotrexate is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Two infusions (one cycle) of Rituxan, separated by two weeks, may be approved. Additional cycles should be given no sooner than six months since the previous cycle. Subsequent cycles will be reviewed on a case-by-case basis and require physician or pharmacist approval. Repeat cycles will be considered medically necessary when the patient has return of symptoms, with evidence of painful, swollen joints and morning stiffness lasting more than forty-five minutes.
5. For the treatment of Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

Dosage and Administration: Intravenous infusion.

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

Documentation Required:

- Medical records
- Lab reports (if necessary), pathology reports (if necessary)
- Prescription medication usage data

Rationale:

Rituxan, by blocking the action of abnormal cells, reduces the activity of those cells in certain autoimmune diseases and malignancies. This effect has been demonstrated in lymphomas, rheumatoid arthritis, and certain other autoimmune diseases.

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Approved by the Medical Director