Status
Active

Medical and Behavioral Health Policy
Section: Medicine
Policy Number: II-47
Effective Date: 11/18/2013

RITUXIMAB

Description: B cells are believed to play an important role in the pathogenesis of many autoimmune diseases. Selective targeting of these cells has become the focus of treatment approaches for a number of autoimmune conditions. Rituximab (Rituxan®) is a genetically engineered, chimeric monoclonal antibody against CD20, a B cell surface antigen. CD20 is expressed in some B-cell malignancies and is believed to play a role in pathogenesis of rheumatoid arthritis and other autoimmune diseases.

Rituximab was originally approved in 1997 by the U.S. Food and Drug Administration (FDA) for the treatment of relapsed, refractory, low-grade or follicular, B-cell non-Hodgkin lymphoma (NHL). Subsequently, the FDA approved additional specific indications for non-Hodgkin lymphoma and for moderately- to severely-active rheumatoid arthritis when there has been an inadequate response to other treatments. In February 2010, the FDA approved the combined use of rituximab with fludarabine and cyclophosphamide (FC) for the treatment of previously untreated and previously treated CD20+ chronic lymphocytic leukemia (CLL). Two additional FDA approvals were granted in April 2011 for use in combination with glucocorticoids in the treatment of granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) or microscopic polyangiitis (MPA) in adults.

Policy:

I. Rituximab may be considered **MEDICALLY NECESSARY** for the following:

A. Oncologic Indications

1. Non-Hodgkin's lymphoma (NHL) (e.g. AIDS-related B-cell lymphoma, Burkitt's lymphoma, B-cell lymphoma; high-grade B-cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, diffuse large B-cell lymphoma, follicular lymphoma and nodal marginal zone lymphoma, gastric mucosa-associated lymphoid tissue (MALT) lymphoma, lymphoblastic lymphoma, mantle cell

lymphoma, non-gastric MALT lymphoma, post-transplant lymphoproliferative disorders, primary cutaneous B-cell lymphoma, and splenic marginal zone lymphoma)
2. Acute lymphocytic leukemia
3. Chronic lymphocytic leukemia (CLL)
4. Central nervous system cancer – metastatic and primary lesions
5. Hairy cell leukemia
6. Hodgkin's lymphoma
7. Waldenström macroglobulinemia

B. Non-Cancer Indications

1. FDA Approved
   a. In combination with methotrexate for the treatment of adults with moderately-to severely-active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies
   b. In combination with glucocorticoids for the treatment of adults with granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) or microscopic polyangiitis (MPA)
2. Non-FDA approved
   a. Autoimmune hemolytic anemia (AIHA)
   b. Idiopathic or immune thrombocytopenic purpura (ITP)
   c. In combination with glucocorticoids and plasma exchange for the treatment of adults with thrombotic thrombocytopenic purpura (TTP)

II. The use of rituximab for treatment of all other conditions is considered **INVESTIGATIVE** due to a lack of published clinical evidence establishing the role of rituximab in the treatment of these conditions.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical

Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding:

The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPCS:

J9310 Rituximab, 100mg

Policy History:

Developed November 9, 2005

Most recent history:
Revised November 10, 2010
Revised June 8, 2011
Revised August 8, 2012
Revised September 11, 2013

Cross Reference:

Thrombopoietin Mimetic Agents for Treatment of Thrombocytopenia, II-87
Hematopoietic Stem-Cell Transplantation for Waldenstrom Macroglobulinemia, II-154