SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab)
Treatment of Hematologic and Oncologic Conditions

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Non-Hodgkin's Lymphoma (NHL)
   Rituxan is indicated for the treatment of patients with:
   a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
   b. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as single-agent maintenance therapy
   c. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
   d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. Chronic Lymphocytic Leukemia (CLL)
   Rituxan is indicated, in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL.
3. Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA) (Not addressed in this policy –Refer to Rituxan-RA SGM)
4. Rheumatoid Arthritis (Not addressed in this policy – Refer to Rituxan-RA SGM)

B. Compendial Uses
A. Sjögren's syndrome (Not addressed in this policy – Refer to Rituxan-RA SGM)
B. Acute lymphoblastic leukemia (ALL)
C. Central nervous system (CNS) cancers
   - Leptomeningeal metastases from lymphomas
   - Primary CNS lymphoma

D. Hodgkin's lymphoma, lymphocyte-predominant
E. Non-Hodgkin's lymphoma
   - Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
   - Burkitt lymphoma,
   - Castleman's disease
   - Small lymphocytic lymphoma (SLL)
   - Diffuse large B-cell lymphoma
   - Marginal zone lymphomas (splenic, MALT)
   - Hairy cell leukemia, relapsed or refractory
   - Lymphoblastic lymphoma
   - Mantle cell lymphoma
   - Post-transplant lymphoproliferative disorder (PTLD)
   - Primary cutaneous B-cell lymphoma

F. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
G. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)

H. Autoimmune hemolytic anemia
I. Chronic graft-versus-host disease (GVHD)
J. Thrombotic thrombocytopenic purpura
K. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:
1. Testing or analysis confirming CD20 protein on the surface of the B-cell (if applicable)
2. Hepatitis B screening with serologic assays prior to starting treatment with Rituxan

II. CRITERIA FOR INITIAL APPROVAL

A. Hematologic indications

Authorization of 12 months may be granted for treatment of any of the following indications:
1. Autoimmune hemolytic anemia
2. Chronic graft-versus-host disease (GVHD)
3. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
4. Thrombotic thrombocytopenic purpura
5. Prevention of Epstein-Barr virus (EBV)-related PTLD

B. Oncologic indications

For oncologic disorders, the tumor must be CD20-positive as confirmed by testing or analysis to identify the CD20 protein on the surface of the B-cell.

1. Acute lymphoblastic leukemia (ALL)

Authorization of 12 months may be granted for members who are prescribed Rituxan as a component of a chemotherapy regimen.

2. Central nervous system (CNS) cancers

Authorization of 12 months may be granted for members who are prescribed Rituxan for any of the following indications:
a. Leptomeningeal metastases from lymphomas
b. Primary CNS lymphoma

3. Hodgkin's lymphoma, lymphocyte-predominant

Authorization of 12 months may be granted for members who are prescribed Rituxan for the treatment of lymphocyte-predominant Hodgkin's lymphoma.

4. Non-Hodgkin's lymphoma (NHL)

i. Authorization of 12 months may be granted for the treatment of ANY of the following indications:
a. AIDS-related B-cell lymphoma
b. Castleman's disease
c. Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
d. Diffuse large B-cell lymphoma
e. Follicular lymphoma
f. Marginal zone lymphomas (splenic, MALT)
g. Hairy cell leukemia, relapsed or refractory
h. Lymphoblastic lymphoma
i. Mantle cell lymphoma
j. Post-transplant lymphoproliferative disorder (PTLD)
k. Primary cutaneous B-cell lymphoma

ii. Authorization of 12 months may be granted for members who are prescribed Rituxan as a component of a chemotherapy regimen for the treatment of Burkitt lymphoma.

5. **Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)**
Authorization of 12 months may be granted for the treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; August 2014.
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3. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 5, 2016.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed April 5, 2016.
5. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. April 2008.
6. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. July 2009.
7. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. July 2013.
8. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. *Biol Blood Marrow Transplant.* 2009; 15(10):1143-1238. URL: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103296/pdf/nihms205400.pdf. Accessed August 2, 2013.