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) in 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), in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL.

3. Granulomatosis with polyangiitis (Wegener’s Granulomatosis) 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

1. Sjögren’s syndrome (Not addressed in this policy – Refer to Rituxan-RA SGM)
2. Multiple sclerosis (Not addressed in this policy – Refer to Rituxan-RA SGM)
3. Non-Hodgkin’s lymphoma
   a. Small lymphocytic lymphoma (SLL)
   b. Mantle cell lymphoma
   c. Marginal zone lymphomas (nodal, splenic, MALT)
   d. Burkitt lymphoma
   e. Primary cutaneous B-cell lymphoma
   f. Castleman’s disease
   g. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
   h. Hairy cell leukemia
   i. Post-transplant lymphoproliferative disorder (PTLD)
   j. Lymphoblastic lymphoma
4. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
5. Autoimmune hemolytic anemia
6. Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
7. Thrombotic thrombocytopenic purpura
8. Myasthenia gravis, refractory
9. Hodgkin’s lymphoma, nodular lymphocyte-predominant
10. Chronic graft-versus-host disease (GVHD)
11. Central nervous system (CNS) cancers
a. Leptomeningeal metastases from lymphomas  
b. Primary CNS lymphoma  
12. Acute lymphoblastic leukemia (ALL)  
13. 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.

**CRITERIA FOR INITIAL APPROVAL**

**A. Oncologic indications**
Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

1. Non-Hodgkin's lymphoma (NHL) with any of the following subtypes:
   a. Diffuse large B-cell lymphoma  
   b. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)  
   c. Follicular lymphoma  
   d. Mantle cell lymphoma  
   e. Marginal zone lymphomas (nodal, splenic, MALT)  
   f. Burkitt lymphoma  
   g. Primary cutaneous B-cell lymphoma  
   h. Castleman’s disease  
   i. AIDS-related B-cell lymphoma  
   j. Hairy cell leukemia  
   k. Post-transplant lymphoproliferative disorder (PTLD)  
   l. Lymphoblastic lymphoma

2. Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)  
3. Hodgkin’s lymphoma, nodular lymphocyte-predominant  
4. Central nervous system (CNS) cancers with either of the following:
   a. Leptomeningeal metastases from lymphomas  
   b. Primary CNS lymphoma  
5. Acute lymphoblastic leukemia (ALL)

**B. Hematologic indications**
Authorization of 12 months may be granted for treatment of any of the following indications:

1. Refractory immune or idiopathic thrombocytopenic purpura (ITP)  
2. Autoimmune hemolytic anemia  
3. Thrombotic thrombocytopenic purpura  
4. Chronic graft-versus-host disease (GVHD)  
5. Prevention of Epstein-Barr virus (EBV)-related PTLD

**C. Myasthenia gravis**
Authorization of 12 months may be granted for treatment of refractory myasthenia gravis.

**II. CONTINUATION OF THERAPY**

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

**III. REFERENCES**
