SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab)
Treatment of Hematologic and Oncologic Conditions

POLICY

A. 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.

FDA-Approved Indications

- Non-Hodgkin's Lymphoma (NHL)
  Rituxan is indicated for the treatment of patients with:
  - Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
  - 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
  - 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
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens

- 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.

- Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA) (Not addressed in this policy – Refer to Rituxan-RA SGM)

- Rheumatoid Arthritis (Not addressed in this policy – Refer to Rituxan-RA SGM)

Compendial Uses

- Sjögren’s syndrome (Not addressed in this policy – Refer to Rituxan-RA SGM)
- Acute lymphoblastic leukemia (ALL) in combination with chemotherapy regimen
- Central nervous system (CNS) cancers
  - Primary CNS lymphoma
  - Leptomeningeal metastases from lymphomas
- Hodgkin’s lymphoma, lymphocyte-predominant
- Non-Hodgkin’s lymphoma
  - Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
  - Burkitt lymphoma, in combination with chemotherapy regimen
  - Small lymphocytic lymphoma (SLL)
  - Diffuse large B-cell lymphoma, in combination with chemotherapy or as a single agent in non-transplant candidates
  - 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
  - Castleman’s disease

- Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
- Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
- Acquired blood factor VIII deficiency
- Autoimmune hemolytic anemia
• Chronic graft-versus-host disease (GVHD)
• Thrombotic thrombocytopenic purpura
• 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.

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

C. CRITERIA FOR APPROVAL

1. Hematologic Indications
Authorization of 12 months may be granted for members who are prescribed Rituxan for any of the following indications:
   a. Acquired blood factor VIII deficiency
   b. Autoimmune hemolytic anemia
   c. Chronic graft-versus-host disease (GVHD)
   d. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
   e. Thrombotic thrombocytopenic purpura
   f. Prevention of Epstein-Barr virus (EBV)-related PTLD

2. 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.

2.1. Acute lymphoblastic leukemia (ALL)
Authorization of 12 months may be granted for members who are prescribed Rituxan as a component of a chemotherapy regimen.

2.2. 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. Primary CNS lymphoma
   b. Leptomeningeal metastases from lymphomas

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

2.4. Non-Hodgkin’s lymphoma (NHL)
   a. Authorization of 12 months may be granted for members who are prescribed Rituxan for any of the following indications:
      i. AIDS-related B-cell lymphoma
      ii. Chronic Lymphocytic Leukemia (CLL) / Small lymphocytic lymphoma (SLL)
      iii. Follicular lymphoma
      iv. Hairy cell leukemia, relapsed or refractory
      v. Lymphoblastic lymphoma
      vi. Mantle cell lymphoma
      vii. Marginal zone lymphoma (splenic, MALT)
      viii. Post-transplant lymphoproliferative disorder (PTLD)
      ix. Primary cutaneous B-cell lymphoma
      x. Castleman’s disease
   b. 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.
   c. Authorization of 12 months may be granted for members who are prescribed Rituxan for the treatment of diffuse large B-cell lymphoma and meet ANY of the following criteria:
      i. Rituxan is prescribed as a component of a chemotherapy regimen
      ii. Member has relapsed or refractory disease and meets one of the following criteria:
Member is not a candidate for high-dose therapy with autologous stem cell rescue.
Member is a candidate for high-dose therapy with autologous stem cell rescue and Rituxan is prescribed as a component of a chemotherapy regimen.

2.5. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
Authorization of 12 months may be granted for members who are prescribed Rituxan for the treatment of Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL).

D. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

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

REFERENCES