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-progressive (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+Other SGM)
   4. Moderately to severely active rheumatoid arthritis (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
   5. Moderate to severe pemphigus vulgaris in adult patients (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)

B. Compendial Uses
   1. Sjögren’s syndrome (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
   2. Multiple sclerosis (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
   3. Neuromyelitis optica (Devic disease) (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
   4. Idiopathic inflammatory myopathy, refractory (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
   5. Non-Hodgkin’s lymphoma
      a. Small lymphocytic lymphoma (SLL)
      b. Mantle cell lymphoma
      c. Marginal zone lymphomas (nodal, splenic, gastric MALT, nongastric 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

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6. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)²,⁶
7. Autoimmune hemolytic anemia²,⁷
8. Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)²,³
9. Thrombotic thrombocytopenic purpura²,⁸
10. Myasthenia gravis, refractory²
11. Hodgkin’s lymphoma, nodular lymphocyte-predominant²,³
12. Chronic graft-versus-host disease (GVHD)²,⁹
13. Central nervous system (CNS) cancers³
   a. Leptomeningeal metastases from lymphomas
   b. Primary CNS lymphoma
14. Acute lymphoblastic leukemia (ALL)³
15. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients²,⁸,¹⁰
16. Immune checkpoint inhibitor-related toxicities³

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

CRITERIA FOR INITIAL APPROVAL

A. Oncologic indications¹-⁵

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, gastric/non-gastric 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 indications²,⁶-¹⁰

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 gravis²
Authorization of 12 months may be granted for treatment of refractory myasthenia gravis.

D. Immune checkpoint inhibitor-related toxicities

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

II. CONTINUATION OF THERAPY

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

III. REFERENCES