SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab)
RUXIENCE (rituximab-pvvr)
TRUXIMA (rituximab-abbs)
RIABNI (rituximab-arrx)

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

Rituxan is indicated for the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy.

Rituxan, Ruxience, Truxima, and Riabni are indicated for:

1. Non-Hodgkin’s lymphoma (NHL) in adult 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 a rituximab product 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 adult patients with previously untreated and previously treated CD20-positive CLL.

3. Granulomatosis with polyangiitis (Wegener’s Granulomatosis) and microscopic polyangiitis (MPA) in combination with glucocorticoids (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

4. Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to-severely active RA who have inadequate response to one or more TNF antagonist therapies. (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

Rituxan is also indicated for:

Rituxan is indicated for moderate to severe pemphigus vulgaris in adult patients
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM)

B. Compendial Uses

1. Autoimmune hemolytic anemia
2. B-cell acute lymphoblastic leukemia (ALL)
3. B-cell lymphomas
   a. Human Immunodeficiency Virus (HIV) Related B-Cell lymphomas
   b. B-cell lymphoblastic lymphoma
   c. Burkitt lymphoma
   d. Castleman’s disease
   e. Diffuse Large B-Cell lymphoma
   f. Follicular lymphoma
   g. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
   h. Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
   i. Mantle cell lymphoma
   j. Marginal zone lymphomas
      i. Nodal marginal zone lymphoma
      ii. Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue (MALT) lymphoma)
      iii. Splenic marginal zone lymphoma
   k. Post-transplant lymphoproliferative disorder (PTLD)
   l. Pediatric Aggressive Mature B-Cell Lymphomas
   m. Primary Mediastinal Large B-Cell Lymphoma

4. Central nervous system (CNS) cancers
   a. Leptomeningeal metastases from lymphomas
   b. Primary CNS lymphomas

5. Chronic graft-versus-host disease (GVHD)

6. CLL/Small lymphocytic lymphoma (SLL)

7. Hairy cell leukemia

8. Rosai-Dorfman disease

9. Hodgkin’s lymphoma, nodular lymphocyte-predominant

10. Immune checkpoint inhibitor-related toxicities

11. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients

12. Primary cutaneous B-cell lymphoma

13. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)

14. Thrombotic thrombocytopenic purpura

15. Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)

16. Allogeneic transplant conditioning

17. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of 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)

III. 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. B-cell acute lymphoblastic leukemia (ALL)
2. B-cell lymphomas:
   i. HIV-Related B-Cell Lymphomas
   ii. B-cell lymphoblastic lymphoma
   iii. Burkitt lymphoma
   iv. Castleman’s disease
   v. Diffuse large B-cell lymphoma
   vi. Follicular lymphoma
   vii. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
   viii. Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
   ix. Mantle cell lymphoma
   x. Marginal zone lymphomas
      a. Nodal marginal zone lymphoma
      b. Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
      c. Splenic marginal zone lymphoma
   xi. Post-transplant lymphoproliferative disorder (PTLD)
   xii. Pediatric Aggressive Mature B-Cell Lymphomas
   xiii. Primary Mediastinal Large B-Cell Lymphoma
3. Central nervous system (CNS) cancers:
   i. Leptomeningeal metastases from lymphomas
   ii. Primary CNS lymphoma
4. CLL/Small lymphocytic lymphoma (SLL)
5. Hairy cell leukemia
6. Rosai-Dorfman disease
7. Hodgkin’s lymphoma, nodular lymphocyte-predominant
8. Primary cutaneous B-cell lymphoma
9. Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)

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
   6. As part of a non-myeloablative conditioning regimen for allogeneic transplant

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

IV. CONTINUATION OF THERAPY

For oncologic indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in Section III A. when there is no evidence of unacceptable toxicity.

For immune checkpoint inhibitor-related toxicities: Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for treatment of immune checkpoint inhibitor-related toxicities who are experiencing benefit from therapy.
For all other indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III B. who are experiencing benefit from therapy.

V. REFERENCES