Reference number(s)
1704-A

Specialty Guideline Management Rituximab Products

Treatment of Hematologic and Oncologic Conditions

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rituxan	rituximab
Ruxience	rituximab-pvvr
Truxima	rituximab-abbs
Riabni	rituximab-arrx

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[1,2,9,10]

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:

- Non-Hodgkin's lymphoma (NHL) in adult 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 a rituximab product 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), in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CD20-positive CLL.
- 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)
- 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)

Compendial Uses[3-8]

- Autoimmune hemolytic anemia[7]
- B-cell acute lymphoblastic leukemia (ALL)[4]
- B-cell lymphomas[4-6]
  - Human Immunodeficiency Virus (HIV) Related B-Cell lymphomas[4]
  - B-cell lymphoblastic lymphoma[5,6]
  - Burkitt lymphoma[4]
  - Castleman's disease[4]
  - Diffuse Large B-Cell lymphoma[4]
  - Follicular lymphoma[4]
  - 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)[4]
  - Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma[4]
  - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements[4]
  - Mantle cell lymphoma[4]
  - Marginal zone lymphomas[4]

        - Nodal marginal zone lymphoma
        - Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT} lymphoma)
        - Splenic marginal zone lymphoma
    - Post-transplant lymphoproliferative disorder (PTLD)[4]
    - Pediatric Aggressive Mature B-Cell Lymphomas[4]
    - Primary Mediastinal Large B-Cell Lymphoma[4]
- Central nervous system (CNS) cancers[4]
    - Leptomeningeal metastases from lymphomas
    - Primary CNS lymphomas
- Chronic graft-versus-host disease (GVHD)[4]
- CLL/Small lymphocytic lymphoma (SLL)[4]
- Hairy cell leukemia[4]
- Rosai-Dorfman disease[4]
- Hodgkin's lymphoma, nodular lymphocyte-predominant[4]
- Immune checkpoint inhibitor-related toxicities[4]
- Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients[8]
- Primary cutaneous B-cell lymphoma[4]
- Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)[7]
- Thrombotic thrombocytopenic purpura[7]
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/ Bing-Neel syndrome[4]
- Allogeneic transplant conditioning[4]
- For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM.

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

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).

Coverage Criteria

Oncologic Indications[1-6,9,19]

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:

- B-cell acute lymphoblastic leukemia (ALL)
- B-cell lymphomas:

  - HIV-Related B-Cell Lymphomas
  - B-cell lymphoblastic lymphoma
  - Burkitt lymphoma
  - Castleman's disease
  - Diffuse large B-cell lymphoma
  - Follicular lymphoma
  - 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)
  - Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
  - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
  - Mantle cell lymphoma
  - Marginal zone lymphomas
    - Nodal marginal zone lymphoma
    - Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
    - Splenic marginal zone lymphoma
  - Post-transplant lymphoproliferative disorder (PTLD)
  - Pediatric Aggressive Mature B-Cell Lymphomas
  - Primary Mediastinal Large B-Cell Lymphoma
- Central nervous system (CNS) cancers:
  - Leptomeningeal metastases from lymphomas
  - Primary CNS lymphoma
- CLL/Small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Rosai-Dorfman disease
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Primary cutaneous B-cell lymphoma
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/Bing-Neel syndrome

Hematologic Indications[3,7,8]

Authorization of 12 months may be granted for treatment of any of the following indications:

- Refractory immune or idiopathic thrombocytopenic purpura (ITP)
- Autoimmune hemolytic anemia
- Thrombotic thrombocytopenic purpura
- Chronic graft-versus-host disease (GVHD)
- Prevention of Epstein-Barr virus (EBV)-related PTLD
- As part of a non-myeloablative conditioning regimen for allogeneic transplant

Immune Checkpoint Inhibitor-Related Toxicities[4]

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

Continuation of Therapy

Oncologic indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in coverage criteria section when there is no evidence of unacceptable toxicity.

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.

All other indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are experiencing benefit from therapy.

References

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2. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.: February 2022.
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4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2025.
5. Arber D, Orazi A, Vardiman J, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. Blood. May 19, 2016;127(20):2391-2405.
6. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 3.2024). © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 15, 2025.
7. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed April 15, 2025.
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 April 30, 2019.
9. Ruxience [package insert]. NY, NY: Pfizer Inc; October 2023.
10. Riabni [package insert]. Thousand Oaks, CA: Amgen Inc.; February 2023.