Reference number(s)
4892-A

Jurisdiction Specific Medicare Part B Rituximab Products

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

Covered Uses

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.

- Non-Hodgkin's Lymphoma (NHL)
- 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 in combination with glucocorticoids.
- Rheumatoid Arthritis (RA)
- Pemphigus Vulgaris (PV)
- B-cell lymphoma
    - Human Immunodeficiency Virus (HIV)-related B-cell lymphoma
    - Burkitt lymphoma
    - Castleman's disease
    - Diffuse large B-cell lymphoma

  - 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 from follicular lymphoma to diffuse large B-cell lymphoma
  - Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
  - Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
  - Follicular lymphoma
  - Mantle cell lymphoma
  - Marginal zone lymphoma (nodal, extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT} lymphoma) splenic)
  - Post-transplant lymphoproliferative disorder (PTLD)
  - B-cell lymphoblastic lymphoma
  - Primary Mediastinal Large B-Cell Lymphoma
- Malignant ascites, in advanced low-grade non-Hodgkin lymphoma
- B-cell acute lymphoblastic leukemia (ALL)
- CLL/small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Hodgkin's lymphoma, CD20-positive, relapsed or progressive
- Primary cutaneous B-cell lymphoma
- Primary Mediastinal Large B-Cell Lymphoma
- Central nervous system (CNS) cancers
  - Leptomeningeal metastases from lymphomas
  - Primary CNS lymphoma
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome
- Rheumatoid arthritis, moderate or high disease activity despite disease-modifying anti-rheumatic drug (DMARD) monotherapy
- Autoimmune hemolytic anemia
- Immune or idiopathic thrombocytopenic purpura (ITP), as initial therapy
- Immune or idiopathic thrombocytopenic purpura (ITP), relapsed/refractory to standard therapy (e.g., corticosteroids, immune globulin)
- Thrombotic thrombocytopenic purpura
- Relapsing-remitting multiple sclerosis
- Primary progressive multiple sclerosis
- Myasthenia gravis, refractory to standard therapy (e.g., corticosteroids, immunosuppressants)
- Systemic lupus erythematosus, refractory to standard therapy (e.g., corticosteroids, immunosuppressants)
- Sjögren's syndrome
- Chronic graft-versus-host disease (GVHD)
- Prevention of Epstein-Barr virus (EBV)-related PTLD in hematopoietic stem cell transplant in (HSCT) recipients
- Evans syndrome

- Nephrotic syndrome, refractory to standard therapy (e.g., corticosteroids, immunosuppressants)
- Acquired factor VIII deficiency (acquired hemophilia A)
- Idiopathic inflammatory myopathy, refractory
- Immune checkpoint inhibitor-related toxicities
- Allergic purpura
- Rosai-Dorfman disease
- Allogeneic transplant conditioning
- Lung disease with systemic sclerosis
- Thyroid eye disease (moderate to severe)
- Neuromyelitis optica spectrum disorder
- Polyarteritis nodosa
- Antibody-mediated rejection

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Rheumatoid arthritis[1,2,4,7]

Authorization of 12 months may be granted for treatment of rheumatoid arthritis when any of the following criteria are met.

- The member has previously received treatment with a biologic or targeted synthetic DMARD (e.g., TNF inhibitor, JAK inhibitor) for the treatment of rheumatoid arthritis.
- The member has had an inadequate response to methotrexate or there is a clinical reason to avoid treatment with methotrexate (e.g., renal or hepatic impairment).

Oncologic indications[1-6,8,9]

Oncologic disorders must be CD20-positive as confirmed by testing or analysis to identify the CD20 protein on the surface of the B-cell.

B-cell lymphoma[1-6,8,9]

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

- Non-Hodgkin's Lymphoma (NHL)
- HIV-related B-cell lymphoma
- Burkitt lymphoma
- Castleman's disease
- Diffuse large B-cell lymphoma
- 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 from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
- Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
- Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
- Follicular lymphoma
- Mantle cell lymphoma
- Marginal zone lymphoma (nodal, extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma), splenic)
- Post-transplant lymphoproliferative disorder
- B-cell lymphoblastic lymphoma
- Primary Mediastinal Large B-Cell Lymphoma

Malignant ascites[5]

Authorization of 12 months may be granted for treatment of malignant ascites in patients with advanced low-grade non-Hodgkin lymphoma.

B-cell acute lymphoblastic leukemia (ALL)[3]

Authorization of 12 months may be granted for treatment of B-cell ALL.

Chronic lymphocytic leukemia/Small lymphocytic lymphoma[1-3,9]

Authorization of 12 months may be granted for treatment of CLL/SLL.

Hairy cell leukemia[3]

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

Hodgkin's lymphoma[3]

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

- Nodular lymphocyte-predominant Hodgkin's lymphoma
- CD20-positive relapsed or progressive Hodgkin's lymphoma

Primary cutaneous B-cell lymphoma[3]

Authorization of 12 months may be granted for treatment of primary cutaneous B-cell lymphoma.

Central nervous system (CNS) cancers[3]

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

- Leptomeningeal metastases from lymphomas
- Primary CNS lymphoma

Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome[3,4]

Authorization of 12 months may be granted for treatment of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma or Bing-Neel syndrome.

Rosai-Dorfman Disease[8]

Authorization of 12 months may be granted for treatment of Rosai-Dorfman disease.

Hematologic indications[4-6,8]

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

- Autoimmune hemolytic anemia
- Immune or idiopathic thrombocytopenic purpura
- Thrombotic thrombocytopenic purpura
- Evans syndrome
- Acquired factor VIII deficiency (acquired hemophilia A)
- Allogeneic transplant conditioning

Multiple sclerosis[4]

Authorization of 12 months may be granted for treatment of relapsing-remitting multiple sclerosis and primary progressive multiple sclerosis.

Myasthenia gravis[4]

Authorization of 12 months may be granted for treatment of myasthenia gravis that is refractory to standard therapy (e.g., corticosteroids, immunosuppressants) or if there is a clinical reason to avoid standard therapy.

Systemic lupus erythematosus[6]

Authorization of 12 months may be granted for treatment of systemic lupus erythematosus that is refractory to standard therapy (e.g., corticosteroids, immunosuppressants) or if there is a clinical reason to avoid standard therapy.

Granulomatosis with polyangiitis (Wegener's granulomatosis) and microscopic polyangiitis[1,2,9]

Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis and microscopic polyangiitis.

Sjögren's syndrome[4]

Authorization of 12 months may be granted for treatment of Sjögren's syndrome.

Nephrotic syndrome[4]

Authorization of 12 months may be granted for treatment of nephrotic syndrome that is refractory to standard therapy (e.g., corticosteroids, immunosuppressants) or if there is a clinical reason to avoid standard therapy.

Idiopathic inflammatory myopathy[4,12]

Authorization of 12 months may be granted for treatment of refractory idiopathic inflammatory myopathy.

Immune checkpoint inhibitor-related toxicities[3]

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

Lung disease with systemic sclerosis[4]

Authorization of 12 months may be granted for the treatment of lung disease with systemic sclerosis that is refractory to standard therapy (e.g., cyclophosphamide, mycophenolate) or if there is a clinical reason to avoid standard therapy.

Thyroid eye disease (moderate to severe)[4]

Authorization of 12 months may be granted for the treatment of moderate to severe thyroid eye disease (excluding patients with risk for dysthyroid optic neuropathy) that is refractory to standard therapy (e.g., IV glucocorticoids) or if there is a clinical reason to avoid standard therapy.

Antibodymediated Rejection[4]

Authorization of 12 months may be granted for the treatment and prevention of antibody mediated rejection.

Other indications[1,3,4,6,11,12]

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

- Chronic GVHD
- Prevention of EBV-related PTLD in HSCT recipients
- Pemphigus vulgaris
- Allergic purpura
- Neuromyelitis optica spectrum disorder
- Polyarteritis nodosa

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 3 months may be granted for the diagnosis of immune checkpoint inhibitor-related toxicities when all of the following criteria are met:

- The member is currently receiving therapy with Rituxan, Ruxience, Truxima, or Riabni.
- Rituxan, Ruxience, Truxima, or Riabni is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy.

Authorization for 12 months may be granted for all diagnoses (except immune checkpoint inhibitor-related toxicities) when all of the following criteria are met:

- The member is currently receiving therapy with Rituxan, Ruxience, Truxima, or Riabni.
- Rituxan, Ruxience, Truxima, or Riabni is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy.

References

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
2. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; February 2022.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 16, 2025.
4. IBM Micromedex [Internet database]. Ann Arbor, MI: Truven Health Analytics. Updated periodically. Accessed April 16, 2025.
5. Lexicomp Online®, Lexi-Drugs® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed April 16, 2025.
6. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed April 16, 2025.
7. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2016;68(1):1-25.
8. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 3.2024).© 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 16, 2025.
9. Ruxience [package insert]. NY, NY: Pfizer Biosimilars; October 2023.
10. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.
11. Chemotherapy Drugs and their Adjuncts LCD (L37205) Version R6. Available at: https://www.cms.gov/medicare-coverage-databas/indexes/national-and-local-indexes.aspx Accessed April 16, 2025.
12. Billing and Coding: Chemotherapy Agents for Non-Oncologic Conditions LCA (A55639) Version R17. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 16, 2025.

