Reference number(s)
3868-A

Jurisdiction Specific Medicare Part B Rituximab

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
Riabni	rituximab-arrx
Ruxience	rituximab-pvvr
Truxima	rituximab-abbs

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- The FDA-labeled indications and recognized compendia (off-label) uses are below:
  - Non-Hodgkin's lymphoma
  - Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
  - Rheumatoid arthritis
  - Granulomatosis with polyangiitis (GPA)
  - Microscopic polyangiitis (MPA)
  - Pemphigus vulgaris
  - Acquired hemophilia
  - Autoimmune hemolytic anemia
  - Diffuse large B-cell lymphoma
  - Burkitt's lymphoma
  - Prevention of Epstein-Barr virus-related post-transplant lymphoproliferative disorders
  - Evans syndrome

- Chronic graft-versus-host disease
- Hairy cell leukemia
- Hodgkin's lymphoma
- Idiopathic inflammatory myopathy
- Immune thrombocytopenic purpura (ITP)
- Immune thrombocytopenia
- Lymphoproliferative disorder following transplantation
- Malignant ascites associated with non-Hodgkin's lymphoma
- Mantle cell lymphoma
- Minimal change disease
- Refractory myasthenia gravis
- Acute lymphoblastic leukemia
- Primary cutaneous B-cell lymphoma
- Multiple sclerosis
- Primary Sjogren's syndrome
- Systemic lupus erythematosus
- Thrombotic thrombocytopenic purpura
- Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome
- Follicular lymphoma
- Nodal marginal zone lymphoma
- Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT} lymphoma)
- Splenic marginal zone lymphoma
- Histologic transformation of 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
- High-grade B-cell lymphoma
- HIV-related B-cell lymphoma
- HIV-related diffuse large B-cell lymphoma
- Primary effusion lymphoma
- HHV8-positive diffuse large B-cell lymphoma, not otherwise specified
- Monomorphic (B-cell type) or polymorphic (B-cell type) post-transplant lymphoproliferative disorder
- Primary central nervous system (CNS) post-transplant lymphoproliferative disorder
- Primary Mediastinal Large B-Cell Lymphoma
- Unicentric Castleman's disease
- Multicentric Castleman's disease
- Primary cutaneous marginal zone lymphoma
- Follicle center lymphoma
- Management of immunotherapy-related toxicities
- Pediatric aggressive mature B-cell lymphoma

  - Nodular lymphocyte-predominant Hodgkin lymphoma
  - Primary central nervous system (CNS) lymphoma
  - Leptomeningeal metastases from lymphomas
  - Acute panmyelosis with myelofibrosis
  - Dendritic cell sarcoma
  - Myelodysplastic disease
  - Neuromyelitis optica
  - Rosai-Dorfman Disease
  - Allogeneic transplant conditioning
  - Immune-mediated myopathies
    - Dermatomyositis
    - Polymyositis
    - Antisynthetase syndrome
    - Immune-mediated necrotizing myopathy
    - Inclusion body myositis
    - Nonspecific myositis
  - Immunoglobulin G4-related disease
  - Antibody-mediated rejection
  - Chronic inflammatory demyelinating polyneuropathy
  - Sjogren's and systemic sclerosis
  - Polyarteritis nodosa
  - Antineutrophil cytoplasmic antibody (ANCA)–associated vasculitis (AAV)
  - Susac syndrome
- Compendial Uses- ICD-10 codes supported by the Medicare Administrative Contractor

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx.

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

Coverage Criteria

Non-Hodgkin's Lymphoma[5-7,10]

Authorization of 12 months may be granted for treatment of non-Hodgkin's lymphoma.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma[5-7,11]

Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma.

Rheumatoid arthritis[5-7,10]

Authorization of 12 months may be granted for treatment of rheumatoid arthritis.

Granulomatosis with Polyangiitis (GPA)[5-7,10]

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

Microscopic Polyarteritis (MPA)[5-7,10]

Authorization of 12 months may be granted for treatment of microscopic polyarteritis.

Pemphigus Vulgaris[5]

Authorization of 12 months may be granted for treatment of pemphigus vulgaris.

Acquired hemophilia[1]

Authorization of 12 months may be granted for the treatment of acquired or refractory hemophilia as first-line combination therapy of corticosteroids and rituximab.

Authorization of 12 months may be granted for the treatment of refractory disease as a second-line agent.

Thrombotic thrombocytic purpura (TTP)[1]

Authorization of 12 months may be granted for the treatment of severe, refractory, or relapsed thrombotic thrombocytopenic purpura (acquired) who have failed first-line therapy (plasma exchange and glucocorticoids).

Multiple sclerosis[1]

Authorization of 12 months may be granted as a second-line option for the treatment of refractory or remitting multiple sclerosis who failed first-line therapy.

Authorization of 12 months may be granted for the treatment of primary progressive multiple sclerosis.

Idiopathic inflammatory myopathy[1]

Authorization of 12 months may be granted for the treatment of idiopathic immune myopathies (including but not limited to anti-synthetase syndrome, arthritis, and interstitial lung disease) when the disease has extra muscular involvement (e.g., the condition affects the lungs).

Immune-mediated myopathies[1]

Authorization of 12 months may be granted for the treatment of immune-mediated myopathies when both of the following are met:

- The member has one of the following conditions:
  - Dermatomyositis
  - Polymyositis
  - Antisynthetase syndrome
  - Immune-mediated necrotizing myopathy
  - Inclusion body myositis
  - Nonspecific myositis
- The member has refractory disease that has failed all first-line therapies

Immunoglobulin G4-related disease (IgG4-RD)[1,B]

Authorization of 12 months may be granted for the treatment of immunoglobulin G4-related disease when either of the following is met:

- The member has refractory or relapsed disease and has failed all first line therapies (e.g., glucocorticoids, immunosuppressants).
- The member has an absolute contraindication to glucocorticoid use.

Minimal change disease[1]

Authorization of 12 months may be granted for the treatment of minimal change disease when either of the following is met:

- The member is a child and one of the following is met:
  - The member has steroid-dependent, steroid-sensitive nephrotic syndrome and continues to have frequent relapses despite optimal combinations of prednisone and corticosteroid-sparing agents.
  - The member has steroid-dependent, steroid-sensitive nephrotic syndrome and has serious adverse effects from the therapy
- The member is an adult, and both of the following are met:
  - The member has frequently relapsing or glucocorticoid-dependent minimal change disease
  - The member has failed to attain a durable remission with cyclophosphamide or calcineurin inhibitors

Antibody-mediated rejection[1]

Authorization of 12 months may be granted for antibody-mediated rejection when either of the following are met:

- The requested drug will be used as second-line treatment or as part of a combination treatment for antibody-mediated rejection in kidney, lung and cardiac transplant patients.
- The requested drug will be used in a highly sensitized patient who is awaiting donor transplants as part of a desensitization protocol.

Immune thrombocytopenic purpura[1]

Authorization of 12 months may be granted when all of the following are met:

- There is documentation of a lack of response to at least one first-line therapy
- The member has documentation of at least one of the following risks for bleeding:
  - Severe ITP (bleeding symptoms)
  - Risk factors for bleeding are present
  - In preparation for procedures or surgery with risk for bleeding
  - Professional or lifestyle risk of trauma
- The member has persistent or chronic disease (greater than six months)

Chronic inflammatory demyelinating polyneuropathy (CIDP)[1]

Authorization of 12 months may be granted for the treatment of chronic inflammatory demyelinating polyneuropathy when the member has failed intravenous immune globulin (IVIG), glucocorticoids, and plasma exchange.

Sjogren's and systemic sclerosis[1]

Authorization of 12 months may be granted for the treatment of Sjogren's syndrome and systemic sclerosis when corticosteroids and other immunosuppressive agents are ineffective.

Antineutrophil cytoplasmic antibody (ANCA)–associated vasculitis (AAV)[1]

Authorization of 12 months may be granted for the induction treatment of severe or relapsing antineutrophil cytoplasmic antibody (ANCA)–associated vasculitis (AAV), including granulomatosis with polyangiitis and microscopic polyangiitis, when member is unable to receive first-line therapies (e.g., cyclophosphamide).

Susac syndrome[1]

Authorization of 12 months may be granted for the treatment of severe or extremely severe Susac syndrome when initial treatment with corticosteroids and intravenous immunoglobulin (IVIG) are inadequate.

Compendial Uses[2-4,8,9,A]

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

- Diffuse large B-cell lymphoma
- Burkitt's lymphoma
- Prevention of Epstein-Barr virus-related post-transplant lymphoproliferative disorders
- Hairy cell leukemia
- Hodgkin's lymphoma
- Lymphoproliferative disorder following transplantation
- Mantle cell lymphoma
- Acute lymphoblastic leukemia
- Primary cutaneous B-cell lymphoma
- Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma/Bing-Neel syndrome
- Follicular lymphoma
- Nodal marginal zone lymphoma
- Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
- Splenic marginal zone lymphoma
- Histologic transformation of 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
- High-grade B-cell lymphoma
- HIV-related B-cell lymphoma
- HIV-related diffuse large B-cell lymphoma
- Primary effusion lymphoma
- HHV8-positive diffuse large B-cell lymphoma, not otherwise specified
- Monomorphic (B-cell type) or polymorphic (B-cell type) post-transplant lymphoproliferative disorder
- Primary central nervous system (CNS) post-transplant lymphoproliferative disorder
- Unicentric Castleman's disease
- Multicentric Castleman's disease
- Primary cutaneous marginal zone lymphoma
- Follicle center lymphoma
- Pediatric aggressive mature B-cell lymphoma
- Nodular lymphocyte-predominant Hodgkin lymphoma
- Primary CNS lymphoma
- Primary mediastinal large B-cell lymphoma
- Leptomeningeal metastases from lymphomas
- Acute panmyelosis with myelofibrosis
- Dendritic cell sarcoma
- Myelodysplastic disease
- Malignant ascites associated with non-Hodgkin's lymphoma
- Management of immunotherapy-related toxicities
- Primary Sjogren's syndrome
- Evans syndrome
- Chronic graft-versus-host disease
- Refractory myasthenia gravis

- Systemic lupus erythematosus
- Neuromyelitis optica
- Polyarteritis nodosa
- Rosai-Dorfman Disease
- Allogeneic transplant conditioning

All Other Indications[2]

Authorization of 12 months may be granted for treatment of all other approval indications listed in LCA A59101.

Dosage and Administration

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

References

1. Off-label Use of Rituximab and Rituximab Biosimilars LCD (L39297) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed August 4, 2025.
2. Billing and Coding: Off-label Use of Rituximab and Rituximab Biosimilars (A59101) Version R6. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 15, 2025.
3. Off-Label Use of Chemotherapeutic Drugs and Biologicals for Non-Cancer Indications LCA (A59217). Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 15, 2025.
4. Off-Label Use of Drugs and Biologicals for Anti-Cancer Chemotherapeutic Regimen LCA (A59218). Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 15, 2025.
5. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
6. Ruxience [package insert]. New York, NY: Pfizer Inc.; October 2023.
7. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; February 2022.
8. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 15, 2025.
9. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed April 15, 2025.
10. Riabni [package insert]. Thousand Oaks, CA: Amgen, Inc.; February 2023.

