Reference number(s)
5332-A

Jurisdiction Specific Medicare Part B Rituximab and Biosimilars

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

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.

- Non–Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma (CLL/SLL)
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis (MPA)
- Rheumatoid Arthritis (RA)
- Pemphigus Vulgaris (PV)
- Acquired Hemophilia
- Immune Thrombocytopenic Purpura
- Acquired Thrombotic Thrombocytopenic Purpura
- Autoimmune Hemolytic Anemia (AIHA)
- Evans Syndrome
- Multiple Sclerosis
- Bullous Pemphigoid

- Membranous Nephropathy
- Immunotherapy-Related Encephalitis
- Immune-Mediated Myopathies
- Immunoglobulin G4-Related Disease (IgG4-RD)
- Myasthenia Gravis
- Neuromyelitis Optica
- Lupus Nephritis
- Minimal Change Disease
- Antibody-Mediated Rejection (AMR)
- Hematopoietic Stem Cell Transplant
- Graft vs. Host Disease
- Rosai-Dorfman Disease
- Malignant Ascites With Advanced Low-Grade Non-Hodgkin Lymphoma
- B-cell Acute Lymphoblastic Leukemia (ALL)
- Central Nervous System (CNS) Cancers
    - Leptomeningeal Metastases
    - Primary CNS Lymphoma
- Hairy Cell Leukemia
- CD20-positive Hodgkin Lymphoma
    - Nodular Lymphocyte-Predominant
    - Relapsed or progressive
- Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma/Bing-Neel Syndrome
- Primary Cutaneous B-Cell Lymphomas
- Pediatric Aggressive Mature B-cell Lymphomas
- B-cell Lymphomas
    - Post-Transplant Lymphoproliferative Disorders
    - Castleman Disease
    - High-Grade B-Cell Lymphomas
    - Mantle Cell Lymphoma
    - Splenic Marginal Zone Lymphoma
    - Nodal Marginal Zone Lymphoma
    - Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue {MALT}) lymphoma
    - HIV-Related B-Cell Lymphomas
    - Histologic Transformation of Indolent (Follicular/Nodal Marginal Zone) Lymphomas to Diffuse Large B-Cell Lymphoma
    - Histologic Transformation of Indolent Lymphomas to High-Grade B-cell Lymphoma with MYC and BCL6 without BCL2 Rearrangements
    - Diffuse Large B-cell Lymphoma
    - Burkitt Lymphoma
    - Follicular Lymphoma
    - Primary Mediastinal Large B-Cell Lymphoma

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

Coverage Criteria

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis

Authorization of 12 months may be granted for treatment of granulomatosis with polyangiitis and microscopic polyangiitis when used in combination with glucocorticoids.

Rheumatoid Arthritis (RA)

Authorization of 12 months may be granted for treatment of moderate to severe active rheumatoid arthritis when the member had an inadequate response to one or more TNF antagonist therapies.

Pemphigus Vulgaris (PV)

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

Acquired Hemophilia

Authorization of 12 months may be granted for treatment of acquired hemophilia when used for one of the following conditions:

- Used in combination with corticosteroids as first-line therapy with acquired or refractory disease
- Used as second-line therapy for refractory disease

Immune Thrombocytopenic Purpura (ITP)

Authorization of 12 months may be granted for treatment of immune thrombocytopenic purpura when all of the following criteria are met:

- Documented lack of response of at least one first-line therapy
- Documented risk for bleeding with at least one of the following:
    - Severe ITP (bleeding symptoms)
    - Risk factors for bleeding are present
    - In preparation for procedures or surgery with risk of bleeding
    - Professional or lifestyle risk for trauma
- Persistent or chronic disease (>6 months)

Acquired Thrombotic Thrombocytopenic Purpura

Authorization of 12 months may be granted for treatment of acquired thrombotic thrombocytopenic purpura when all of the following criteria are met:

- Member has severe, refractory, or relapsed disease
- Member failed first-line therapy of plasma exchange and glucocorticoids

Autoimmune Hemolytic Anemia (AIHA)

Authorization of 12 months may be granted for treatment of autoimmune hemolytic anemia when used for one of the following conditions:

- Used as first-line therapy with symptomatic, severe cold AIHA
- Used as second-line therapy for refractory, warm AIHA after failed first-line treatment

Evans Syndrome

Authorization of 12 months may be granted for treatment of Evans syndrome when used as a second-line therapy after failed first-line treatment.

Multiple Sclerosis

Authorization of 12 months may be granted for treatment of refractory or remitting multiple sclerosis when used as a second-line therapy after failed first-line treatment.

Bullous Pemphigoid

Authorization of 12 months may be granted for treatment of refractory bullous pemphigoid after failed first-line treatment.

Membranous Nephropathy

Authorization of 1 month may be granted for treatment of membranous nephropathy when used for one of the following conditions:

- Refractory or resistant disease
- Member has all of the following:
    - Proteinuria of at least 5 grams per 24 hours in quantified creatinine clearance of at least 40 ml per minute per 1.73 m2 of the body surface area
    - Received angiotensin-system blockade for at least three months
    - The dosing will be two infusions (1000mg each) administered 14 days apart

Immunotherapy-Related Encephalitis

Authorization of 3 months may be granted for treatment of immunotherapy-related encephalitis when all of the following criteria are met:

- Positive autoimmune encephalopathy antibodies
- Limited or no improvement with first-line therapy

Immune-Mediated Myopathies

Authorization of 3 months may be granted for treatment of immune-mediated myopathies when all of the following criteria are met:

- The member has one of the following:
  - Dermatomyositis (DM)
  - Polymyositis (PM)
  - Antisynthetase syndrome
  - Immune- mediated necrotizing myopathy (IMNM)
  - Inclusion body myositis (IBM)
  - Nonspecific myositis
- Refractory disease that failed all first-line therapies

Immunoglobulin G4-Related Disease (IgG4-RD)

Authorization of 12 months may be granted for treatment of immunoglobulin g4-related disease when used for one of the following conditions:

- Second-line therapy in refractory or relapsed cases of IgG4-RD that have failed all first-line therapies (e.g., glucocorticoids, immunosuppressants)
- Absolute contraindication to glucocorticoid use

Myasthenia Gravis

Authorization of 12 months may be granted for treatment of myasthenia gravis when used for one of the following conditions:

- MuSK-positive disease with an unsatisfactory response to initial immunotherapy
- Refractory AChR-Ab+ disease in a member who failed or did not tolerate other immunosuppressive agents

Neuromyelitis Optica

Authorization of 12 months may be granted for treatment of refractory neuromyelitis optica when used after failed first-line treatment.

Lupus Nephritis

Authorization of 12 months may be granted for treatment of refractory lupus nephritis when used for one of the following conditions:

- Failed at least six months of conventional therapy with cyclophosphamide or mycophenolate mofetil
- Worsening disease despite 3 months of treatment with glucocorticoids plus cyclophosphamide or mycophenolate mofetil

Minimal Change Disease

Authorization of 12 months may be granted for treatment of minimal change disease when used for one of the following conditions:

- Children with steroid-dependent, steroid-sensitive nephrotic syndrome with frequent relapses despite optimal combinations of prednisone and corticosteroid-sparing agents or who have serious adverse effects of therapy
- Adults with frequently relapsing or glucocorticoid-dependent minimal change disease in a member who failed to attain a durable remission with cyclophosphamide or calcineurin inhibitors

Antibody-Mediated Rejection (AMR)

Authorization of 12 months may be granted for treatment of antibody-mediated rejection when used for one of the following conditions:

- Second-line treatment or as part of a combination treatment in kidney, lung, and cardiac transplant patients
- As part of desensitization protocols in highly sensitized patients awaiting donor transplants

Hematopoietic Stem Cell Transplant

Authorization of 12 months may be granted for hematopoietic stem cell transplant as part of combination treatment for preparative regimens and post-transplantation maintenance.

Graft vs. Host Disease

Authorization of 12 months may be granted for treatment of chronic graft-versus-host disease when not being used as first-line therapy.

Oncologic Indications

Authorization of 12 months may be granted for the following oncologic indications when confirmed to be CD20-positive by testing or analysis:

- Non-Hodgkin's Lymphoma (NHL)
- Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma (CLL/SLL)
- B-cell Acute Lymphoblastic Leukemia (ALL)
- Central Nervous System (CNS) Cancers
    - Leptomeningeal Metastases
    - Primary CNS Lymphoma
- Hairy Cell Leukemia
- CD20-positive Hodgkin Lymphoma
    - Nodular Lymphocyte-Predominant
    - Relapsed or progressive
- Waldenström Macroglobulinemia /Lymphoplasmacytic Lymphoma/Bing-Neel Syndrome
- Primary Cutaneous B-Cell Lymphomas
- Pediatric Aggressive Mature B-cell Lymphomas
- Rosai-Dorfman Disease
- Malignant Ascites with Advanced Low-Grade Non-Hodgkin Lymphoma
- B-cell lymphomas
    - Post-Transplant Lymphoproliferative Disorders
    - Castleman Disease
    - High-Grade B-Cell Lymphomas
    - Mantle Cell Lymphoma
    - Splenic Marginal Zone Lymphoma
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    - HIV-Related B-Cell Lymphomas
    - Histologic Transformation of Indolent (Follicular/Nodal Marginal Zone) 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
    - Diffuse Large B-cell Lymphoma
    - Burkitt Lymphoma
    - Follicular Lymphoma
    - Primary Mediastinal Large B-Cell Lymphoma

Continuation of Therapy

Authorization for continuation of therapy may be granted if there is documentation of a positive response to the requested drug. The specified length of approval will be as stated with the indication in the Coverage Criteria section.

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