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DRUG POLICY

Rituximab

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Rituximab policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines for Riabni (rituximab-arxx), Rituxan (rituximab), Ruxience (rituximab-pvvr), and Truxima (rituximab-abbs). The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy. For this program, Riabni and Truxima are the preferred products. Coverage for non-preferred products, Rituxan, Rituxan Hycela, and Ruxience, is provided based on clinical circumstances that would exclude the use of the preferred product(s) and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

FDA-Approved Indications

Riabni, Rituxan, Ruxience, and Truxima 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 (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids
4. Rheumatoid arthritis, in combination with methotrexate, for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Rituxan is also indicated for:

1. The treatment of adult patients with moderate to severe pemphigus vulgaris
2. 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.

Compendial Use

1. Sjögren's syndrome
2. Multiple sclerosis, relapsing remitting
3. Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder [NMOSD], Devic disease)
4. Autoimmune blistering disease
5. Cryoglobulinemia
6. Solid organ transplant
7. Opsoclonus-myoclonus ataxia
8. Systemic lupus erythematosus (SLE)
9. Myasthenia gravis, refractory
10. Membranous nephropathy
11. Eosinophilic granulomatosis with polyangiitis (EGPA)
12. Susac syndrome
13. Autoimmune hemolytic anemia
14. B-cell acute lymphoblastic leukemia (ALL)
15. 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. Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
 - J. Mantle cell lymphoma
 - K. Marginal zone lymphomas
 - 1) Nodal marginal zone lymphoma
 - 2) Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue [MALT] lymphoma)
 - 3) Splenic marginal zone lymphoma
 - L. Post-transplant lymphoproliferative disorder (PTLD)
 - M. Pediatric Aggressive Mature B-Cell Lymphomas
 - N. Primary Mediastinal B-cell lymphoma
16. Central nervous system (CNS) cancers

- A. Leptomeningeal metastases from lymphomas
- B. Primary CNS lymphomas
- 17. Chronic graft-versus-host disease (GVHD)
- 18. CLL/Small lymphocytic lymphoma (SLL)
- 19. Hairy cell leukemia
- 20. Rosai-Dorfman disease
- 21. Hodgkin's lymphoma, nodular lymphocyte-predominant
- 22. Immune checkpoint inhibitor-related toxicities
- 23. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
- 24. Primary cutaneous B-cell lymphoma
- 25. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
- 26. Thrombotic thrombocytopenic purpura
- 27. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/Bing-Neel Syndrome
- 28. Allogeneic transplant conditioning

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Rheumatoid arthritis (RA)

1. For initial requests:
 - A. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
 - B. Laboratory results, chart notes, or medical record documentation of biomarker testing (i.e., rheumatoid factor [RF], anti-cyclic citrullinated peptide [anti-CCP], and C-reactive protein [CRP] and/or erythrocyte sedimentation rate [ESR]) (if applicable).
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Sjögren's syndrome, cryoglobulinemia, opsoclonus-myoclonus-ataxia, and systemic lupus erythematosus (initial requests only)

1. Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Hematologic/Oncologic indications

1. Testing or analysis confirming CD20 protein on the surface of the B cell (if applicable)

Exclusions

1. Coverage will not be provided for requests for the treatment of rheumatoid arthritis (RA) when planned date of administration is less than 16 weeks since date of last dose received.
2. Member will not receive Riabni, Rituxan, Ruxience, or Truxima with other biologics for RA.
3. Member will not receive Riabni, Rituxan, Ruxience, or Truxima with other multiple sclerosis (MS) drugs excluding Ampyra (dalfampridine).
4. Member will not receive Riabni, Rituxan, Ruxience, or Truxima with other biologics for the treatment of neuromyelitis optica.

Preferred Drug Plan Design

1. Coverage for a non-preferred product is provided when the following criteria is met:

- A. The member has had a documented intolerable adverse event to all the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Table. Rituximab Products

Medication	Generic Name
Preferred Products:	
Riabni	rituximab-arrx
Truxima	rituximab-abbs
Targeted Products:	
Ruxience	rituximab-pvvr
Rituxan	rituximab
Rituxan Hycela	rituximab and hyaluronidase human

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Prescriber Specialties (initial requests only)

This medication must be prescribed by or in consultation with one of the following:

1. RA, GPA (Wegener's granulomatosis), MPA, EGPA, pauci-immune glomerulonephritis, SLE: rheumatologist, immunologist, nephrologist
2. Sjogren's syndrome: rheumatologist, ophthalmologist, immunologist
3. Multiple sclerosis, NMOSD, myasthenia gravis, opsoclonus-myoclonus-ataxia, Susac syndrome: neurologist, immunologist, rheumatologist
4. Autoimmune blistering disease: dermatologist, immunologist
5. Cryoglobulinemia: hematologist, rheumatologist, neurologist, nephrologist
6. Solid organ transplant: immunologist, transplant specialist
7. Membranous nephropathy: nephrologist, rheumatologist

Criteria for Initial Approval

Hematologic indications

1. Authorization of 12 months may be granted for treatment of any of the following indications:
 - A. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
 - B. Autoimmune hemolytic anemia
 - C. Thrombotic thrombocytopenic purpura
 - D. Chronic graft-versus-host disease (GVHD)
 - E. Prevention of Epstein-Barr virus (EBV)-related PTLD
 - F. As part of a non-myeloablative conditioning regimen for allogeneic transplant

Oncologic indications

1. 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:
 - A. B-cell acute lymphoblastic leukemia (ALL)
 - B. B-cell lymphomas:
 - 1) HIV-Related B-cell lymphoma

- 2) B-cell lymphoblastic lymphoma
- 3) Burkitt lymphoma
- 4) Castleman's disease
- 5) Diffuse large B-cell lymphoma
- 6) Follicular lymphoma
- 7) 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)
- 8) Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
- 9) Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
- 10) Mantle cell lymphoma
- 11) Marginal zone lymphomas
 - a. Nodal marginal zone lymphoma
 - b. Extranodal marginal zone lymphoma (gastric and non-gastric mucosa associated lymphoid tissue [MALT] lymphoma)
 - c. Splenic marginal zone lymphoma
- 12) Post-transplant lymphoproliferative disorder (PTLD)
- 13) Pediatric Aggressive Mature B-Cell Lymphomas
- 14) Primary Mediastinal Large B-Cell Lymphomas
- C. Central nervous system (CNS) cancers:
 - 1) Leptomeningeal metastases from lymphomas
 - 2) CLL/Small lymphocytic Primary CNS lymphoma
- D. CLL/Small lymphocytic lymphoma (SLL)
- E. Hairy cell leukemia
- F. Rosai-Dorfman disease
- G. Hodgkin's lymphoma, nodular lymphocyte-predominant
- H. Primary cutaneous B-cell lymphoma
- I. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/Bing-Neel syndrome

Myasthenia gravis

- 1. Authorization of 12 months may be granted for treatment of refractory myasthenia gravis.

Immune checkpoint inhibitor-related toxicities

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

Moderately to severely active rheumatoid arthritis (RA)

- 1. Authorization of 12 months may be granted for adults who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis. The requested medication must be prescribed in combination with methotrexate (MTX) or leflunomide unless the member has a contraindication (see Appendix A) or intolerance to MTX or leflunomide.
- 2. Authorization of 12 months may be granted for treatment of moderately to severely active RA in combination with MTX or leflunomide unless the member has a contraindication (see Appendix A) or intolerance to MTX or leflunomide when all of the following criteria are met:
 - A. The member meets either of the following criteria:
 - 1) The member has been tested for either of the following biomarkers and the test was positive:

- a. Rheumatoid factor (RF)
 - b. Anti-cyclic citrullinated peptide (anti-CCP)
- 2) The member has been tested for ALL of the following biomarkers:
 - a. RF
 - b. Anti-CCP
 - c. C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- B. The member meets either of the following criteria:
 - 1) The member has experienced an inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to at least 15 mg/week); or
 - 2) The member had an intolerable adverse effect or contraindication to MTX (see Appendix A), and an inadequate response to another conventional drug (e.g., hydroxychloroquine, leflunomide, sulfasalazine).

Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) and eosinophilic granulomatosis with polyangiitis (EGPA) and pauci-immune glomerulonephritis

- 1. Authorization of 12 months may be granted for treatment of GPA, MPA, EGPA or pauci-immune glomerulonephritis.

Autoimmune blistering disease

- 1. Authorization of 12 months may be granted for treatment of autoimmune blistering disease (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus).

Cryoglobulinemia

- 1. Authorization of 12 months may be granted for treatment of cryoglobulinemia when corticosteroids and other immunosuppressive agents were ineffective

Sjögren's syndrome

- 1. Authorization of 12 months may be granted for treatment of Sjögren's syndrome when corticosteroids and other immunosuppressive agents were ineffective.

Multiple sclerosis

- 1. Authorization of 12 months may be granted for treatment of relapsing remitting multiple sclerosis.

Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder; NMOSD, Devic disease)

- 1. Authorization of 12 months may be granted for treatment of neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder, NMOSD, Devic disease).

Solid organ transplant

- 1. Authorization of 3 months may be granted for treatment of solid organ transplant and prevention of antibody-mediated rejection in solid organ transplant.

Opsoclonus-myoclonus-ataxia

- 1. Authorization of 12 months may be granted for treatment of opsoclonus-myoclonus-ataxia associated with neuroblastoma when the member is refractory to steroids and chemotherapy.

Systemic Lupus Erythematosus

- 1. Authorization of 12 months may be granted for the treatment of systemic lupus erythematosus that is refractory to immunosuppressive therapy.

Membranous nephropathy

1. Authorization of 6 months may be granted for the treatment of membranous nephropathy when the following criteria are met:
 - A. Member has a diagnosis of membranous nephropathy
 - B. Member is at moderate to high risk for disease progression

Susac syndrome

1. Authorization of 12 months may be granted for treatment of Susac Syndrome.

Continuation of Therapy

Rheumatoid arthritis

1. Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and achieve or maintain positive clinical response after at least two doses of therapy with Riabni, Rituxan, Ruxience, or Truxima as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Multiple Sclerosis

1. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for relapsing remitting multiple sclerosis (MS) who are experiencing disease stability or improvement while receiving Riabni, Rituxan, Ruxience, or Truxima.

Oncologic indications

1. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in criteria for initial approval who have not experienced an unacceptable toxicity.

Immune checkpoint inhibitor-related toxicities

1. 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.

Membranous Nephropathy

1. Authorization of an additional 3 months may be granted for continued treatment in members with the presence of anti-phospholipase A2 receptor (PLA2R) antibodies.

Other indications

1. Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization who meet all initial authorization criteria and are receiving benefit from therapy.

Dosage and Administration

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

Appendices

Appendix A: Examples of contraindications to methotrexate and leflunomide

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding

6. Significant comorbidity prevents use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9312 – Injection rituximab, (Rituxan), 10 mg
- Q5123 – Injection, rituximab-arxx, biosimilar, (Riabni), 10 mg
- Q5115 – Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg (effective 7/1/2019)
- Q5119 – Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg (effective 7/1/2020)

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*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.01.10

Reviewed: August 2026

Revised: October 2025

Current Effective Date: January 1, 2026