

Reference number(s)

1704-A

Specialty Guideline Management Rituximab Products Treatment of Rheumatoid Arthritis and Other 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^{1,2,22,23}

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older* in combination with glucocorticoids (*pediatric indication applies to Rituxan only).
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderatelyto severely-active RA who have inadequate response to one or more TNF antagonist therapies.

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- Non-Hodgkin's lymphoma (NHL):
 (Not addressed in this policy Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)
- Chronic lymphocytic leukemia (CLL):
 (Not addressed in this policy Refer to Rituxan-Ruxience-Truxima-Riabni-Oncology SGM)
- Pemphigus Vulgaris (PV): Rituxan is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris.
- Mature B-cell acute leukemia (B-AL):
 Not addressed in this policy Refer to Rituxan-Ruxience-Truxima-Riabni Oncology SGM)

Compendial Uses

- Sjögren's syndrome⁴⁻⁶
- Multiple sclerosis, relapsing-remitting^{4,10}
- Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder, NMOSD, Devic disease)^{11,12,28,32}
- Autoimmune blistering disease^{19,26,27}
- Cryoglobulinemia¹³⁻¹⁵
- Solid organ transplant¹⁷
- Opsoclonus-myoclonus-ataxia¹⁸
- Systemic lupus erythematosus^{20,21}
- Myasthenia gravis, refractory²⁸
- Membranous nephropathy³³
- For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-Oncology 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:

Rheumatoid arthritis (RA)

Initial requests

- 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.
- 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).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

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

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

Prescriber Specialties

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

- RA, GPA (Wegener's granulomatosis), MPA, Churg-Strauss, pauci-immune glomerulonephritis, SLE: rheumatologist, immunologist, nephrologist
- Sjogren's syndrome: rheumatologist, ophthalmologist, immunologist
- Multiple sclerosis, NMOSD, myasthenia gravis, opsoclonus-myoclonus-ataxia: neurologist, immunologist, rheumatologist
- · Autoimmune blistering disease: dermatologist, immunologist
- Cryoglobulinemia: hematologist, rheumatologist, neurologist, nephrologist
- Solid organ transplant: immunologist, transplant specialist
- Membranous nephropathy: nephrologist

Exclusions

- 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.
- Member will not receive Rituxan, Ruxience, Truxima, or Riabni with any other biologic drug or targeted synthetic drug for RA.
- Member will not receive Rituxan, Ruxience, Truxima, or Riabni with other multiple sclerosis (MS) drugs excluding Ampyra.
- Member will not use Rituxan, Ruxience, Truxima, or Riabni concomitantly with other biologics for the treatment of neuromyelitis optica.

Coverage Criteria

Rheumatoid arthritis (RA)^{1,2,4,7-9,22,24,25,29}

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

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(MTX) or leflunomide unless the member has a contraindication (see Appendix section) or intolerance to MTX or leflunomide.

Authorization of 12 months may be granted for treatment of adults with moderately to severely active RA in combination with MTX or leflunomide unless the member has a contraindication (see VII. Appendix) or intolerance to MTX or leflunomide when all of the following criteria are met:

- The member meets either of the following criteria:
 - The member has been tested for either of the following biomarkers and the test was positive:
 - Rheumatoid factor (RF)
 - Anti-cyclic citrullinated peptide (anti-CCP)
 - The member has been tested for ALL of the following biomarkers:
 - RF
 - Anti-CCP
 - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
- The member meets either of the following criteria:
 - 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
 - The member had an intolerable adverse effect or contraindication to MTX (see Appendix section), 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 Churg-Strauss and pauci-immune glomerulonephritis^{1,2,22,23,30,31}

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

Sjögren's syndrome⁴⁻⁶

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

Multiple sclerosis^{4,10}

Authorization of 12 months may be granted for treatment of relapsing-remitting multiple sclerosis (RRMS).

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Neuromyelitis optica (i.e., neuromyelitis optica spectrum disorder, NMOSD, Devic Disease)^{11,12,28,32}

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

Autoimmune blistering disease 19,26,27

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).

Cryoglobulinemia¹³⁻¹⁵

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

Solid organ transplant¹⁷

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-ataxia¹⁸

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^{20,21}

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

Myasthenia Gravis²⁸

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

Membranous nephropathy³³

Authorization of 12 months may be granted for treatment of membranous nephropathy when the member is at moderate to high risk for disease progression.

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Continuation of Therapy

Rheumatoid arthritis^{1,2,4,7-9,22,24,25}

Authorization of 12 months may be granted for continued treatment in all adult members (including new members) who are using the requested medication for moderately to severely active rheumatoid arthritis and who achieve or maintain a positive clinical response after at least two doses of therapy with Rituxan, Ruxience, Truxima, or Riabni as evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability.

Multiple Sclerosis

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

Other indications

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

Appendix

Examples of clinical reasons to avoid pharmacologic treatment with methotrexate or leflunomide

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- History of intolerance or adverse event

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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

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

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- 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 moderatelyto 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

- Autoimmune hemolytic anemia
- B-cell acute lymphoblastic leukemia (ALL)
- B-cell lymphomas
 - Human Immunodeficiency Virus (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

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- 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)
- Pediatric Aggressive Mature B-Cell Lymphomas
- Primary Mediastinal Large B-Cell Lymphoma
- Central nervous system (CNS) cancers
 - Leptomeningeal metastases from lymphomas
 - Primary CNS lymphomas
- Chronic graft-versus-host disease (GVHD)
- CLL/Small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Rosai-Dorfman disease
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Immune checkpoint inhibitor-related toxicities
- Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
- Primary cutaneous B-cell lymphoma
- Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
- Thrombotic thrombocytopenic purpura
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)/ Bing-Neel syndrome
- Allogeneic transplant conditioning
- 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

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:

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- 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

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

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Immune Checkpoint Inhibitor-Related Toxicities

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

Continuation of Therapy

For 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.

For 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.

For 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.

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