Mass General Brigham
Health Plan

Rituxan (rituximab)
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Rituxan Hycela (rituximab-hyaluronidase)
Riabni (rituximab-arrx)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Rituximab is a monoclonal antibody directed against the CD20 antigen on the surface of B-lymphocytes. CD20 regulates cell cycle initiation; and, possibly, functions as a calcium channel. Rituximab binds to the antigen on the cell surface, activating complement-dependent B-cell cytotoxicity; and to human Fc receptors, mediating cell killing through an antibody-dependent cellular toxicity. B-cells are believed to play a role in the development and progression of rheumatoid arthritis. Signs and symptoms of rheumatoid arthritis are reduced by targeting B-cells and the progression of structural damage is delayed.

FDA Approved Indications

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. Autoimmune blistering diseases (e.g., pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus).
4. Moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate in patients who have inadequate response to one or more TNF antagonist therapies
5. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids in adults

Compendial Uses

1. Sjögren's syndrome
2. Multiple sclerosis, relapsing remitting
3. Neuromyelitis Optica (Devic disease)
4. Idiopathic inflammatory myopathy, refractory
5. Non-Hodgkin's lymphoma
    a. Small lymphocytic lymphoma (SLL)
    b. Mantle cell lymphoma
    c. Marginal zone lymphomas (nodal, splenic, gastric MALT, nongastric MALT)
    d. Burkitt lymphoma
    e. Primary cutaneous B-cell lymphoma
    f. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
    g. High-grade B-cell lymphoma not otherwise specified
    h. Castleman's disease
    i. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
    j. Hairy cell leukemia
    k. Post-transplant lymphoproliferative disorder (PTLD)
    l. B-cell lymphoblastic lymphoma
6. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
7. Autoimmune hemolytic anemia
8. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
9. Thrombotic thrombocytopenic purpura
10. Myasthenia gravis, refractory
11. Hodgkin's lymphoma, nodular lymphocyte-predominant
12. Chronic graft-versus-host disease (GVHD)
13. Central nervous system (CNS) cancers
    a. Leptomeningeal metastases from lymphomas
    b. Primary CNS lymphoma
14. B-cell acute lymphoblastic leukemia (ALL)
15. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
16. Immune checkpoint inhibitor-related toxicities

Coverage Guidelines

Authorization may be granted for members who are new to the plan within the past 90 days and currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when the following criteria are met, and documentation is provided

AND

For Rituxan: Authorization may be granted for Rituxan, Rituxan Hycela, Riabni and Ruxience when member has a documented inadequate response or an intolerable adverse effect to Truxima or clinical rationale has been submitted why Truxima are not appropriate therapies except for the diagnosis listed under *autoimmune blistering disease.*

For Rituxan Hycela, Riabni and Ruxience: Authorization may be granted for Rituxan, Rituxan Hycela, Riabni and Ruxience when member has a documented inadequate response or an intolerable adverse effect to Truxima or clinical rationale has been submitted why Truxima are not appropriate therapies.

Moderately to severely active rheumatoid arthritis (RA)

Authorization of 12 months may be granted to members who have previously received any biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) indicated for the treatment of moderately to severely active rheumatoid arthritis OR have received at least two full doses of rituximab for the treatment of RA, where the most recent dose was given within 6 months of the request. Rituximab must be prescribed in combination with methotrexate (MTX) unless the member has a contraindication or intolerance to MTX (see Appendix A).

OR

Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:

a. Diagnosis of moderately to severely active rheumatoid arthritis
b. Member is prescribed rituximab in combination with MTX or has a contraindication or intolerance to MTX.
c. Member meets any of the following criteria:
    i. Member has experienced an inadequate response to at least a 3-month trial of MTX despite adequate dosing (i.e., titrated to 20 mg/week)
    ii. Member has an intolerance or contraindication to MTX (see Appendix A)

Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA)

Authorization of 12 months may be granted for treatment of GPA or MPA.

Sjögren's syndrome

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

Multiple sclerosis

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

Neuromyelitis Optica

Authorization of 12 months may be granted for treatment of neuromyelitis optica.

Idiopathic inflammatory myopathy

Authorization of 12 months may be granted for treatment of refractory polymyositis or dermatomyositis.

Autoimmune blistering disease

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

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:

1. Non-Hodgkin's lymphoma (NHL) with any of the following subtypes:
    a. Diffuse large B-cell lymphoma
    b. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
    c. High-grade B-cell lymphoma, not otherwise specified
    d. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
    e. Follicular lymphoma
    f. Mantle cell lymphoma
    g. Marginal zone lymphomas (nodal, splenic, gastric/non-gastric MALT)

    h. Burkitt lymphoma
    i. Primary cutaneous B-cell lymphoma
    j. Castleman's disease
    k. AIDS-related B-cell lymphoma
    l. Hairy cell leukemia
    m. Post-transplant lymphoproliferative disorder (PTLD)
    n. B-cell lymphoblastic lymphoma
2. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
3. Hodgkin's lymphoma, nodular lymphocyte-predominant
4. Central nervous system (CNS) cancers with either of the following:
    a. Leptomeningeal metastases from lymphomas
    b. Primary CNS lymphoma
5. B-cell acute lymphoblastic leukemia (ALL)

Hematologic indications

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

1. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
2. Autoimmune hemolytic anemia
3. Thrombotic thrombocytopenic purpura
4. Chronic graft-versus-host disease (GVHD)
5. Prevention of Epstein-Barr virus (EBV)-related PTLD

Myasthenia gravis

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

Immune checkpoint inhibitor-related toxicities

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

Note: Medication regimens being used in accordance with National Comprehensive Cancer Network (NCCN) guidelines with at least a 1, 2a, or 2b level evidence can be reviewed for medical necessity.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition

1. All indications: documented inadequate response or an intolerable adverse effect to Truxima or clinical rationale has been submitted why Truxima is not an appropriate therapy
2. Rheumatoid arthritis: Authorization of 12 months may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least two doses of therapy with rituximab as evidenced by low disease activity or improvement in signs and symptoms of the condition.
3. Multiple Sclerosis: 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 therapy.
4. Oncologic indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed above who have not experienced an unacceptable toxicity.
5. 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.

6. Hematologic indication and Myasthenia Gravis: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed under hematologic indications and myasthenia gravis who are experiencing benefit from therapy.
7. Other indications: Authorization of 12 months may be granted for all members (including new members) who meet all initial authorization criteria.

Limitations

1. Coverage will not be provided for requests for the treatment of rheumatoid arthritis when planned date of administration is less than 16 weeks since date of last dose received.
2. Reauthorizations duration will be granted based on indication noted in Continuation of Therapy

Appendices

Appendix A: Examples of contraindications to methotrexate

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction

References

1. Dass S, Bowman SJ, Vital EM, et al. Reduction of fatigue in Sjögren syndrome with rituximab: results of a double blind, placebo-controlled study. Ann Rheum Dis. 2008;67:1541-1544.
2. Hauser SL, Waubant E, Arnold DL, et al. B-cell depletion with rituximab in relapsing-remitting multiple sclerosis. N Engl J Med. 2008;358:676-688.
3. Meijer JM, Meiners PM, Vissink A, et al. Effectiveness of rituximab treatment in primary Sjögren's syndrome: a randomized, double-blind, placebo-controlled trial. Arthritis Rheum. 2010;62(4):960-8.
4. Riabni (rituximab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; December 2020.
5. Rituxan (rituximab) [prescribing information]. South San Francisco, CA: Genentech Inc; August 2020
6. Ruxience (rituximab-pvvr) [prescribing information]. New York, NY: Pfizer Labs; May 2020
7. Truxima (rituximab-abbs) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; May 2020
8. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
9. Scott, T.F., Frohman, E.M., DeSeze, J., (2011). Evidence-based guideline: Clinical evaluation and treatment of transverse myelitis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. American Academy of Neurology. 77: 2128-2134.
10. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis. 2017;0:1-18. 6. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.

11. Trebst, C., Jarius, S., et al. (2014). Update on the diagnosis and treatment of neuromyelitis optica: Recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol 261: 1-16.

Review History

12/16/2019 – add Truxima to criteria
03/18/2020 – Reviewed and switched from SGM to custom criteria; combine Rituxan Oncology and Rituxan RA + Other Conditions (effective 6/1/20)
11/18/2020- Reviewed and changed to reflect that Truxima is non-preferred, preferred agents are Rituxan, Rituxan Hycela, Truxima. Effective 1/1/202; separated out MH vs. Comm/Exch
3/17/2021 – Reviewed and Updated; included new biosimilar Riabni (rituximab-arrx) to criteria as non-preferred agent. References updated. Effective 06/01/2021.
11/17/2021 – Reviewed and Updated; moved continuation criteria from Limitations to Continuation of Therapy.
01/19/2022 – Reviewed and Updated. Criteria updated to reflect Truxima as preferred, non-preferred agents are Rituxan, Rituxan Hycela, Riabni and Ruxience. Effective 01/01/2022.
05/18/2022 – Reviewed and Updated; Criteria updated to allow Rituxan for the treatment of autoimmune blistering diseases without prior treatment of Truxima since biosimilars are not FDA approved for blistering disease. Effective 08/01/2022.
06/14/2023 – Reviewed and Updated for Jun P&T; added NCCN statement
11/13/2024 – Reviewed and updated at November P&T. Specified diagnosis for rheumatoid arthritis. Effective 1/1/2025.
10/08/1025 – Reviewed and updated at October P&T. Updated policy to indicate it no longer applies to the medical benefit. Updated reauthorization criteria to require trial and failure with Truxima. Effective 01/01/2026.