

**Rituxan (rituximab)
Truxima (rituximab-abbs)
Ruxience (rituximav-pvvr)
Effective 06/01/20**

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 currently receiving treatment with rituximab 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:

Moderately to severely active rheumatoid arthritis (RA)

1. 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 Rituxan for the treatment of RA, where the most recent dose was given within 6 months of the request. Rituxan must be prescribed in combination with methotrexate (MTX) unless the member has a contraindication or intolerance to MTX (see Appendix A).
2. Authorization of 12 months may be granted for treatment of moderately to severely active RA when all of the following criteria are met:
 - a. Member is prescribed Rituxan in combination with MTX or has a contraindication or intolerance to MTX.
 - b. 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)¹

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.

Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition.

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. Reauthorization criteria:
 - a. 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.
 - b. 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 Rituxan, Ruxience, or Truxima.

- c. 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.
- d. 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.
- e. 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.
- f. Other indications: Authorization of 12 months may be granted for all members (including new members) who meet all initial authorization criteria.

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. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; October 2018.
2. DRUGDEX® System [Internet database]. Ann Arbor, MI: Truven Health Analytics. Updated periodically. Accessed November 19, 2018.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.



9. 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.
10. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed April 17, 2019.
11. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 17, 2019.
12. Arber D, Orazi A, Vardiman J, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood*. May 19, 2016;127(20):2391-2405.
13. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 17, 2019.
14. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com> [available with subscription]. Accessed April 17, 2019.
15. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. *Biol Blood Marrow Transplant*. 2009; 15(10):1143-1238. URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103296/pdf/nihms205400.pdf>. Accessed April 30, 2019.

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 – separated out MH vs. Comm/Exch

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