## Pharmacy Policy

# Rituximab

**Policy Number:** 9.704
**Version Number:** 1
**Version Effective Date:** 1/1/2021

| Product Applicability | ☐ **All Plan[+] Products** |
|---|---|
| **Well Sense Health Plan** | **Boston Medical Center HealthNet Plan** |
| ☐ New Hampshire Medicaid | ☒ MassHealth - MCO<br>☒ MassHealth - ACO<br>☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☐ Senior Care Options |

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

**Products Affected:**

- Ruxience
- Truxima

The Plan may authorize coverage of the above products for members meeting the following criteria:

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| **Covered Use** | All medically accepted indications not otherwise excluded |
| **Required Medical Information** | Diagnosis of one of the following:<br>1. Active rheumatoid arthritis (RA); ***AND***<br>a. An inadequate response, intolerance, or contraindication to Enbrel AND Humira or a clinical rationale for use of the requested agent instead of Enbrel AND Humira; ***OR***<br>2. Chronic Lymphocytic Leukemia (CLL); ***OR***<br>3. Diffuse Large B-cell Lymphoma (DLBCL) ; ***OR***<br>4. Follicular Lymphoma (FL) ; ***OR***<br>5. Non-Hodgkin's Lymphoma (NHL) ; ***OR*** |

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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| | 6. Granulomatosis with polyangitis (GPA) (formerly called Wegener's Granulomatosis) or microscopic polyangitis (MPA) ; ***AND***<br>a. Glucocorticoids to be taken in combination with rituximab during induction therapy (not required during maintenance therapy); ***AND***<br>b. An inadequate response, intolerance, or contraindications to a trial of cyclophosphamide, azathioprine, or methotrexate; ***OR***<br>7. Moderate to severe Pemphigus Vulgaris (PV) ; ***AND***<br>An inadequate response, intolerance, or contraindication to a trial of systemic glucocorticoids |
| **Age Restrictions** | PV, RA: 18 years of age or older<br>GPA, MPA: 2 years of age or older |
| **Prescriber Restriction** | GPA, MPA, RA: Prescribed by or in consultation with a rheumatologist |
| **Coverage Duration** | 12 months |
| **Other criteria** | Reauthorization:<br>1. Patient's clinical condition has improved or stabilized |

**Applicable Coding:**

| Code | Medication |
|---|---|
| **Q5115** | Truxima (rituximab-abbs injection) |

## Clinical Background Information and References


1. Edwards JC, Szczepanski L, Szechinski J, et al. Efficacy of B-cell-targeted therapy with rituximab in patients with rheumatoid arthritis. N Engl J Med. Jun 17 2004; 350(25):2572-2581.
2. George, J and Arnold, D. Immune Thrombocytopenia (ITP) in adults: Second-line and subsequent therapies. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com Last updated: January 2, 2019. (Accessed on April 9, 2019).
3. Higashida J, Wun T, Schmidt S, Naguwa SM, Tuscano JM. Safety and efficacy of rituximab in patients with rheumatoid arthritis refractory to disease modifying antirheumatic drugs and antitumor necrosis factor-alpha treatment. J Rheumatol. Nov 2005; 32(11):2109-2115.
4. Rindfleisch JA, Muller D. Diagnosis and management of rheumatoid arthritis. Am Fam Physician. Sep 15 2005; 72(6):1037-1047.
5. Rituxan (rituximab) [package insert]. South San Francisco, CA: Genentech, Inc.; June 2018.
6. Rituxan Hycela (rituximab and hyaluronidase) [package insert]. South San Francisco, CA: Genentech, Inc.; December 2019

7. Ruxience (rituximab-pvvr) [package insert]. Cork, Ireland: Pfizer Ireland Pharmaceuticals;
8. Singh JA, Furst DE, Bharat A, et al. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease- Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2012 May;64(5):625-39.
9. Summers KM, Kockler DR. Rituximab treatment of refractory rheumatoid arthritis. Ann Pharmacother. Dec 2005; 39(12):2091-2095.
10. Truxima (rituximab-abbs) [package insert]. Yeonsu-gu, Incheon, Republic of Korea; Celltrion, Inc.: November 2019

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|---|---|---|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

| Policy Revisions History | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 12/1/2020 | 9.191 Rituximab Policy retired, new policy created. | 1/1/2021 | P&T Committee |

## Next Review Date

2021

## Other Applicable Policies

9.015 Quantity Limitation Policy

## Reference to Applicable Laws and Regulations, If Any

**Disclaimer Information**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other

Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.