Mass General Brigham
Health Plan

Rituxan (rituximab)
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)
Rituxan Hycela (rituximab and hyaluronidase)
Effective 06/05/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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.

No PA	Require PA
	Riabni®(rituximab-arrx) Rituxan®(rituximab) Rituxan Hycela®(rituximab/hyaluronidase human) Ruxience® (rituximab-pvvr) Truxima® (rituximab-abbs)

Coverage Guidelines
Authorization may be granted for members new to the plan 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:

Riabni®(rituximab-arrx)
Rituxan®(rituximab)

Ruxience® (rituximab-pvvr)
Truxima® (rituximab-abbs)
Prescriber provides documentation of **ONE** of the following:

1. Diagnosis of Non-Hodgkin's Lymphoma (NHL)*
    a. Appropriate dosing
2. Diagnosis of Rheumatoid Arthritis (RA)
    a. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to **ONE** TNF antagonist
    b. **ONE** of the following:
        i. Paid claims within 30 days or physician attestation that the requested agent will be used in combination with methotrexate
        ii. Contraindication or adverse reaction to methotrexate
    c. Appropriate dosing
3. Diagnosis of induction therapy for Granulomatosis Polyangitis (GPA) or Microscopic Polyangitis (MPA)
    a. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to cyclophosphamide
    b. **ONE** of the following:
        i. Paid claims within 30 days or physician attestation that the requested agent will be used in combination with a glucocorticoid
        ii. Adverse reaction or contraindication to glucocorticoids
    c. Appropriate dosing
4. Diagnosis of maintenance therapy for GPA or MPA
    a. Appropriate dosing

*Appropriate diagnoses include:

- Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL using rituximab product as a single agent
- Previously untreated follicular, CD20-positive, B-cell NHL using rituximab product in combination with first line chemotherapy
- Follicular, CD20-positive, B-cell NHL, 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 using rituximab product as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL using rituximab product in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.

Rituxan® (rituximab)
Prescriber provides documentation of **ONE** of the following:

1. Diagnosis of Pemphigus Vulgaris (PV)
    a. **ONE** of the following:
        i. Requested agent will be used in combination with systemic corticosteroids
        ii. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
    b. Appropriate dosing
2. Diagnosis of mature B-cell NHL or mature B-AL
    a. Member is ≥ six months and < 18 years of age
    b. Physician attestation that the requested agent will be used in combination with systemic Lymphoma Malin B (LMB) chemotherapy (e.g., corticosteroids, vincristine, cyclophosphamide,

methotrexate, cytarabine, doxorubicin, etoposide, and triple drug [methotrexate/cytarabine/corticosteroid] intrathecal therapy)

c. Appropriate dosing

Rituxan Hycela® (rituximab/hyaluronidase human)

1. **ONE** of the following:
    a. Diagnosis of Diffuse Large B-Cell Lymphoma (DLBCL)*
    b. Diagnosis of Follicular Lymphoma (FL)
2. Appropriate dosing

* For non-FDA-approved B-Cell lymphomas, Rituxan Hycela may be substituted for Rituxan if there is documentation that the member has received the first full dose of Rituxan by IV infusion

Riabni® (rituximab-arrx)
Rituxan® (rituximab)
Rituxan Hycela® (rituximab/hyaluronidase human)
Ruxience® (rituximab-pvvr)
Truxima® (rituximab-abbs)

1. Diagnosis of Chronic Lymphocytic Leukemia (CLL)
2. Appropriate dosing

Continuation of Therapy

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

Limitations

1. Initial approvals will be granted for the following:
    a. Non-Hodgkin's Lymphoma (NHL) [including Follicular Lymphoma (FL) and Diffuse Large B-Cell Lymphoma (DLBCL)] and Chronic Lymphocytic Leukemia (CLL), Pediatric patients with mature B-cell NHL and mature B-cell acute leukemia (B-AL): **6 months**
    b. Rheumatoid arthritis (RA): **2 weeks of therapy with 4 month duration**
    c. Pemphigus Vulgaris (PV): **2 weeks of therapy with 6 month duration**
    d. Granulomatosis with Polyangiitis (GPA)/Microscopic Polyangiitis (MPA):
        i. Induction (initial) therapy: 2 or 4 weeks of therapy depending on dosing requested with a **4 month duration**
        ii. Maintenance (subsequent) therapy: **1 week of therapy with 4 month or 6 month duration**
2. Reauthorizations will be granted for the following:
    a. Non-Hodgkin's Lymphoma (NHL) [including Follicular Lymphoma (FL) and Diffuse Large B-Cell Lymphoma (DLBCL)] and Chronic Lymphocytic Leukemia (CLL), Pediatric patients with mature B-cell NHL and mature B-cell acute leukemia (B-AL): **12 months**
    b. Rheumatoid arthritis (RA): **6 weeks of therapy with 12 month duration**
    c. Pemphigus Vulgaris (PV): **2 weeks of therapy with 12 month duration**
    d. Granulomatosis with Polyangiitis (GPA)/Microscopic Polyangiitis (MPA): **3 week of therapy with 12 month duration**

Appendix

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

Off-Label Uses for Rituximab Products

- Requests may be approvable if conventional therapies have failed (i.e. inadequate response, adverse reaction and/or contraindications)
- Prior authorization requests for any of the following conditions should include details of previous "conventional" therapy trials before the approval of rituximab

Off-Label Use	Approval Criteria
Autoimmune Encephalitis	Prescriber provides documentation of ALL of the following: 1. Diagnosis of autoimmune encephalitis (also includes anti-NMDA receptor encephalitis) 2. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL of the following: a. intravenous glucocorticoids b. intravenous immune globulin c. plasma exchange 3. Paid claims (within the last 30 days) or physician attestation of inadequate response, adverse reaction, or contraindication to cyclophosphamide
Autoimmune Epilepsy	Prescriber provides documentation of ALL of the following: 1. Diagnosis of autoimmune epilepsy 2. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL of the following: a. intravenous glucocorticoids b. intravenous immune globulin c. plasma exchange 3. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL of the following: a. azathioprine b. cyclophosphamide c. mycophenolate
Post-Transplantation Lymphoproliferative Disease (PTLD)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis
Waldenström's macroglobulinemia (WM)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis

Idiopathic membranous nephropathy (IMN)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response, adverse reaction to **ONE** of the following or contraindication to **BOTH** of the following: a. cyclophosphamide b. chlorambucil 3. Paid claims or physician attestation of inadequate response, adverse reaction to **ONE** of the following or contraindication to **BOTH** of the following: a. cyclosporine b. tacrolimus
Lupus nephritis (LN)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following: a. cyclophosphamide b. mycophenolate
Autoimmune Hemolytic Anemia (AIHA)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids
Moderate-to-Severe Cryoglobulinemia Syndrome	Prescriber provides documentation of ALL of the following: 1. Diagnosis of moderate to severe cryoglobulinemia syndrome 2. Requested agent will be used in combination with systemic glucocorticoids
Graft Versus Host Disease (GVHD)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response, or adverse reaction to ONE or contraindication to ALL corticosteroids 3. Paid claims or physician attestation of inadequate response or adverse reaction to TWO of the following or contraindication to ALL of the following: a. abatacept b. alemtuzumab c. belumosudil d. cyclosporine e. etanercept f. everolimus g. hydroxychloroquine h. ibrutinib i. imatinib j. methotrexate k. mycophenolate mofetil l. ruxolitinib m. sirolimus

	n. tacrolimus o. temsirolimus
Idiopathic Thrombocytopenia Purpura (ITP)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids
Neuromyelitis Optica Spectrum Disorders (NMOSD) maintenance therapy	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following: a. azathioprine b. mycophenolate
Thrombotic Thrombocytopenia Purpura (TTP)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Member underwent plasma exchange b. Clinical rationale as to why plasma exchange was not performed 3. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to corticosteroids
Systemic Lupus Erythematosus (SLE)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** of the following OR contraindication to **ALL** of the following: a. azathioprine b. cyclophosphamide c. cyclosporine d. leflunomide e. methotrexate f. mycophenolate
Multiple Sclerosis	<u>Relapsing-Remitting MS (RRMS)</u> Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is a neurologist or consult notes from a neurology office are provided
IgG-related disease	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL glucocorticoids
Minimal change disease	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis

	2. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following: a. cyclophosphamide b. cyclosporine
Polymyositis (PM) and Dermatomyositis (DM)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids 3. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** of the following or contraindication to **ALL** of the following: a. azathioprine b. cyclophosphamide c. cyclosporine d. methotrexate
Myasthenia Gravis, Generalized (MG)	Prescriber provides documentation of ALL of the following: 1. Diagnosis of generalized MG 2. Paid claims (within the last 30 days) or physician attestation of inadequate response, adverse reaction, or contraindication to pyridostigmine 3. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids 4. ONE of the following: a. Member has muscle-specific tyrosine kinase (MuSK)-positive MG (MuSK-positive MG) b. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to ONE or contraindication ALL of the following: i. azathioprine ii. cyclophosphamide iii. cyclosporine iv. eculizumab v. efgartigimod vi. intravenous immune globulin vii. mycophenolate viii. ravulizumab ix. tacrolimus
Pemphigus Foliaceus (PF)	Prescriber provides documentation of ALL of the following: 1. Diagnosis of PF 2. ONE of the following: a. Requested agent will be used in combination with systemic glucocorticoids b. Paid claims (within the last 30 days) or physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids

	3. Appropriate dosing (refer to FDA-approved dosing for PV)
Off-label approval durations	Initial: **3 months** Recertification: **12 months**

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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
05/19/2021 – Updated and Reviewed for May P&T; added Riabni and Rituxan Hycela to criteria

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Added Off-Label indications to appendix. Clarified approval durations. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. A note was added underneath approval criteria for NHL to clarify the subtypes of NHL for which rituximab agents are FDA-approved. The criteria for PV were updated to remove the trial requirement with systemic immunosuppressive therapy as initial therapy with a steroid and rituximab is now preferred. Off-label criteria for GVHD updated to remove thalidomide from the acceptable trials and to add several agents as acceptable trials, as recommended by NCCN. Criteria for ITP updated to remove required splenectomy trial. Several new off label indications were added to the policy. Effective 6/5/23.