Mass General Brigham
Health Plan

Rituxan (rituximab)
Rituxan Hycela (rituximab and hyaluronidase)
Riabni (rituximab-arrx)
Ruxience (rituximab-pvvr)
Truxima (rituximab-abbs)
Effective 01/04/2027

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 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.

Preferred with PA	Non-Preferred with PA
Riabni (rituximab-arrx) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Rituxan (rituximab)

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

Riabni (rituximab-arrx)
Rituxan (rituximab)
Ruxience (rituximab-pvvr)
Truxima (rituximab-abbs)
Non-Hodgkin's Lymphoma (NHL)

1. Diagnosis of Non-Hodgkin's Lymphoma (NHL) with **ONE** of the following NHL sub-types:
    a. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL using rituximab product as a single agent
    b. Previously untreated follicular, CD20-positive, B-cell NHL using rituximab product in combination with first line chemotherapy
    c. 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
    d. 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
    e. 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.
2. Appropriate dosing
3. For Rituxan, BOTH of the following:
    a. Inadequate response, adverse reaction, or contraindication to ALL of the following:
        i. Riabni
        ii. Ruxience
        iii. Truxima
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

Rheumatoid Arthritis (RA)

1. Diagnosis of RA
2. Inadequate response, adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. Cimzia (certolizumab pegol)
    b. Enbrel (etanercept)
    c. Humira (adalimumab)
    d. infliximab
    e. Simponi Aria (golimumab)
    f. Simponi (golimumab)
3. **ONE** of the following:
    a. Requested agent will be used in combination with methotrexate
    b. Contraindication or adverse reaction to methotrexate
4. Appropriate dosing
5. For Rituxan, BOTH of the following:
    a. Inadequate response, adverse reaction, or contraindication to ALL of the following:
        i. Riabni
        ii. Ruxience
        iii. Truxima
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)

1. Diagnosis of **ONE** of the following:
    a. For <u>induction</u> therapy for GPA or MPA
        i. Inadequate response, adverse reaction or contraindication to cyclophosphamide
        ii. **ONE** of the following:

1. Requested agent will be used in combination with a glucocorticoid within 30 days
2. Adverse reaction or contraindication to glucocorticoids

iii. Appropriate dosing
iv. For Rituxan, **BOTH** of the following:
1. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
a. Riabni
b. Ruxience
c. Truxima
2. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

b. For <u>maintenance</u> therapy for GPA or MPA
i. Appropriate dosing
ii. For Rituxan, **BOTH** of the following:
1. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
a. Riabni
b. Ruxience
c. Truxima
2. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

Pediatric patients with mature B-cell NHL and mature B-cell acute leukemia (B-AL)

1. Diagnosis of mature B-cell NHL or mature B-AL with **ONE** of the following sub-types:
a. Previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL)
b. Burkitt lymphoma (BL)
c. Burkitt-like lymphoma (BLL)
2. Member is ≥ 6 months and < 18 years of age
3. Appropriate dosing
4. For Rituxan, BOTH of the following:
a. Inadequate response, adverse reaction, or contraindication to ALL of the following:
i. Riabni
ii. Ruxience
iii. Truxima
b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

Pemphigus Vulgaris (PV)

1. Diagnosis of PV
2. **ONE** of the following:
a. Requested agent will be used in combination with systemic glucocorticoids
b. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic corticosteroids
3. Appropriate dosing
4. For Rituxan, BOTH of the following:
a. Inadequate response, adverse reaction, or contraindication to ALL of the following:
i. Riabni

ii. Ruxience
iii. Truxima

b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

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
3. For Rituxan, **BOTH** of the following:
    a. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
        i. Riabni
        ii. Ruxience
        iii. Truxima
    b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

<u>Continuation of Therapy</u>

BOTH of the following:

1. Resubmission by prescriber will infer a positive response to therapy.
2. For non-preferred rituximab products, recertification requests must meet initial approval criteria (i.e. required trials with the preferred biosimilar product).

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. 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. Inadequate response, adverse reaction, or contraindication to cyclophosphamide 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents

Autoimmune Epilepsy	Prescriber provides documentation of ALL of the following: 1. Diagnosis of autoimmune epilepsy 2. 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. Inadequate response or adverse reaction to ONE or contraindication to ALL of the following: a. azathioprine b. cyclophosphamide c. mycophenolate 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Post-Transplantation Lymphoproliferative Disease (PTLD)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Waldenström's macroglobulinemia (WM)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Idiopathic membranous nephropathy (IMN)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis

	2. Inadequate response, adverse reaction to **ONE** of the following or contraindication to **BOTH** of the following: a. cyclophosphamide b. chlorambucil 3. Inadequate response, adverse reaction to **ONE** of the following or contraindication to **BOTH** of the following: a. cyclosporine b. tacrolimus 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Lupus nephritis (LN)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response, adverse reaction, or contraindication to **BOTH** of the following: a. cyclophosphamide b. mycophenolate 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Autoimmune Hemolytic Anemia (AIHA)	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. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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. 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 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Idiopathic Thrombocytopenia Purpura (ITP)	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. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following:

	i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Neuromyelitis Optica Spectrum Disorders (NMOSD) maintenance therapy	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following: a. azathioprine b. mycophenolate 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Thrombotic Thrombocytopenia Purpura (TTP)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. History of plasma exchange b. Clinical rationale as to why plasma exchange was not performed 3. Inadequate response or adverse reaction to ONE or contraindication to ALL corticosteroids 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Systemic Lupus Erythematosus (SLE)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. 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 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
IgG-related disease	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response or adverse reaction to ONE or contraindication to ALL glucocorticoids 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Minimal change disease	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response, adverse reaction, or contraindication to **BOTH** of the following: a. cyclophosphamide b. cyclosporine 3. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following:

	i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Polymyositis (PM) **or** Dermatomyositis (DM)	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. 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 e. mycophenolate 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
Myasthenia Gravis, Generalized (MG)	Prescriber provides documentation of ALL of the following: 1. Diagnosis of generalized MG 2. Inadequate response, adverse reaction, or contraindication to pyridostigmine within 30 days 3. 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. 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

	5. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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. Inadequate response or adverse reaction to ONE or contraindication to ALL systemic corticosteroids within 30 days 3. Appropriate dosing (refer to FDA-approved dosing for PV) 4. For Rituxan, BOTH of the following: a. Inadequate response, adverse reaction, or contraindication to ALL of the following: i. Riabni ii. Ruxience iii. Truxima b. Clinical rationale why the requested non-preferred agent is expected to provide a different clinical outcome than the preferred agents
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.
09/11/24 – Reviewed and updated for P&T. Diagnosis criteria update to include NHL subtypes to the criteria rather as a footnote. Per NCCN guidelines, the requirement that Rituxan be used in conjunction with Lymphoma Malin B (LMB) chemotherapy for pediatric oncology was removed. Effective 10/1/24
9/10/25 – Reviewed and updated for P&T. Mycophenolate was added to trials for polymyositis and dermatomyositis diagnosis. Effective 10/1/25
11/4/26 – Reviewed and updated for P&T. Updated formatting and references. Rituxan criteria was updated to prefer Rituxan Hycela, Riabni, Ruxience, or Truxima for initial and reauthorization requests. Effective 1/4/27