Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Rituximab Products: Riabni™ (rituximab-arrx), Rituxan® (ritixumab), Rituxan Hycela® (rituximab and hyaluronidase), Ruxience® (rituximab-pvvr), Truxima® (rituximab-abbs)

Effective: September 15, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) - Approved Indications

Rituximab is a CD20-directed cytolytic antibody indicated for the treatment of the following types of cancers:

Chronic Lymphocytic Leukemia (CLL)

- In combination with fludarabine and cyclophosphamide, for the treatment of adult patients with previously untreated and previously treated CD-20 positive CLL.

Non-Hodgkin's Lymphoma (NHL)

- Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as single-agent maintenance therapy
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens

Granulomatosis with Polyangiitis (GPA) [Wegener's Granulomatosis] and Microscopic Polyangiitis (MPA)

- In combination with glucocorticoids for the treatment of adult and pediatric patients 2 years of age and older with WG and MPA

Pemphigus Vulgaris (PV)

- Treatment of adult patients with moderate to severe PV

Rheumatoid Arthritis (RA)

- In combination with methotrexate for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more tumor necrosis factor antagonist therapies

Rituximab is also available in combination with hyaluronidase (Rituxan Hycela) which is indicated for the treatment of CLL, follicular lymphoma (FL), and diffuse large B-cell lymphoma (DLBCL). Rituximab/hyaluronidase is not indicated for the treatment of non-malignant conditions and is administered via subcutaneous injection. Treatment should be initiated only after patients have received at least one full dose of a rituximab product by intravenous infusion.

Ruxience (rituximab-pvvr) and Truxima (rituximab-abbs) are preferred rituximab biosimilars.

Clinical Guideline Coverage Criteria

Malignant Conditions

Note: The Plan does **NOT** require prior authorization for coverage of, **Ruxience** or **Truxima** for the treatment of CLL and NHL for claims billed under the medical benefit. For any medical billing claim submitted, utilize the ICD-10 codes C82.00-C83.99, C84.60 – C86.6, C88.4, C91.10 – C91.12, C96.4 – C96.5 as the primary diagnosis codes for NHL and CLL.

Riabni (rituximab-arrx), Rituxan (rituximab) **and Rituxan Hycela** (rituximab/hyaluronidase human)

The Plan may authorize coverage of Riabni, Rituxan, or Rituxan Hycela when the following clinical criteria are met:

1. Documentation the use of the requested medication is for the treatment of a malignant condition

AND

2. Documented previous failure of or clinical inappropriateness of treatment with Ruxience or Truxima

Non-malignant Conditions

The plan may authorize coverage of a Rituximab Product when **ALL** of the following criteria are met:

Granulomatosis with Polyangiitis [Wegener's Granulomatosis] and Microscopic Polyangiitis

1. Documented diagnosis of granulomatosis with polyangiitis **or** microscopic polyangiitis

AND

2. Prescribed by or in consultation with a rheumatologist, nephrologist, or a pulmonologist

AND

3. Documentation that the Member is concurrently taking glucocorticoids (e.g., prednisone)

Pemphigus vulgaris

1. Documented diagnosis of moderate to severe pemphigus vulgaris

AND

2. The prescribing physician is a dermatologist

AND

3. Documentation the Member has demonstrated an inadequate response to or the prescribing physician indicates clinical inappropriateness of systemic glucocorticoids

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. Documentation that the Member has demonstrated an inadequate response to an appropriate trial with at least one (1) of the following: Enbrel, Humira, Remicade, or Simponi/Simponi Aria

AND

4. Documentation of **one (1)** of the following:
    a. The Member is concurrently taking methotrexate
    b. The Member had an inadequate response, intolerance, or contraindication to methotrexate

Multiple Sclerosis - Primary-Progressive, Relapsing-Remitting, and Secondary-Progressive Multiple Sclerosis (MS) (compendial indication)

1. Documented diagnosis of one of the following:
    a. Primary-progressive multiple sclerosis

b. Relapsing-remitting multiple sclerosis
c. Secondary-progressive multiple sclerosis

AND

2. The prescribing physician is a neurologist with expertise in treating multiple sclerosis

Riabni (rituximab-arrx) or Rituxan (rituximab)

In addition to the coverage criteria above, the plan may authorize coverage of Riabni or Rituxan when the following criteria are met:

1. Documented previous failure of or clinical inappropriateness of treatment with Ruxience or Truxima

Off-label Use Coverage for Other Cancer Diagnoses

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provision of the "Sullivan Law": (M.G.L. c.175, s.47K).

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Acceptable Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

Note: *The plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treatment the intended malignancy, including the applicable NCCN guideline(s).*

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, the plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

"Standard Reference Compendia"

1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

"Peer Reviewed Medical Literature"

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

When the plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.

4. Whether the study is appropriate to address the clinical question.
    a. appropriate to address the investigative question (for example, in some clinical studies it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover);
    b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
    c. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Limitations

- Coverage of Riabni, Rituxan or Rituxan Hycela will be authorized for any FDA-approved indication that preferred rituximab biosimilars do not share.
- Documentation of any previous use of Riabni, Rituxan, or Rituxan Hycela does not qualify as a clinically appropriate reason to not prescribe Ruxience or Truxima.
- Authorizations for Riabni, Rituxan, and Rituxan Hycela will be provided for 12 months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
Q5115	Injection, rituximab-abbs, biosimilar (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar (RUXIENCE), 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg

References

1. Cunningham D, Hawkes EA, Jack A, et al. Rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisolone in patients with newly diagnosed diffuse large B -cell non-Hodgkin lymphoma: a phase 3 comparison of dose intensification with 14 -day versus 21-day cycles *Lancet*. 2013 May 25; 381(9880):1817-26.
2. Delarue R, Tilly H, Mounier N, et al. Dose-dense rituximab-CHOP compared with standard rituximab-CHOP in elderly patients with diffuse large B-cell lymphoma (the LNH03-6B study): a randomized phase 3 trial. *Lancet Oncol*. 2013 May; 14(6):525-33.
3. Hauser SL, Waubant E, Arnold DL, et al; HERMES Trial Group. B-cell depletion with rituximab in relapsing-remitting multiple sclerosis. *N Engl J Med*. 2008 Feb 14;358(7):676-88.
4. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology, Non -Hodgkin's Lymphomas. V.1.2013. nccn.org. Accessed August 20, 2013.
5. Riabni (rituximab-arrx) [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2020.
6. Rituxan (rituximab) [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
7. Rituxan Hycela (rituximab and hyaluronidase human) [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
8. Ruxience (rituximab-pvvr) [package insert]. New York, NY: Pfizer; November 2021.
9. Truxima (rituximab-abbs) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA; February 2022.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- October 10, 2023: Added Documentation the use of the requested medication is for the treatment of a malignant condition to the coverage criteria for Malignant Conditions. Removed the Limitation The plan will not authorize the use of rituximab products included in the Medical Necessity Guideline for conditions other than those listed above without appropriate documentation. Ruxience and Truxima are the preferred Rituximab Products. Coverage of Rituximab Products for Tufts Health Together applies to this Medical Necessity Guideline (effective 1/1/24).
- December 2024: Administrative update: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024.

- September 10, 2024: No changes (eff 9/10/24).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- September 9, 2025: No Changes (eff 9/09/25).
- September 15, 2026: No changes (eff 9/15/26).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.