Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Rituximab Products for Non-oncology Indications: Riabni™ (rituximab-arrx), Rituxan® (rituximab), Ruxience® (rituximab-pvvr), Truxima® (rituximab-abbs)

Effective: May 12, 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

Public Plans Products

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

☐ Tufts Health Together – MassHealth 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 617-673-0965

*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 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0965

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 (Non-oncology)

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

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

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

Clinical Guideline Coverage Criteria

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

Limitations

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

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
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

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4. Castillo-Trivino T, Braithwaite D, Bacchetti P, Waubant E. Rituximab in relapsing and progressive forms of multiple sclerosis: a systematic review. *PLoS One*. 2013 Jul 2;8(7):e66308.
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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: 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 (effective 1/1/24).
- September 10, 2024: No changes (eff 9/1024).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- May 12, 2026: No changes, template updated to remove CareLink from the Medical Necessity Guideline template. Administrative update from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”

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.