Medical Necessity Guidelines

Medical Benefit Drugs

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

Effective: January 1, 2026

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

Public Plans Products

☒ 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 - Approved Indications (Oncology)

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

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

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.

The plan may authorize coverage of a rituximab product for Members when the following clinical criteria are met:

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

Limitations

- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements of Riabni, Rituxan, and Rituxan Hycela.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9312	Injection, rituximab, (Rituxan) 10 MG
J9311	Injection, rituximab 10 MG and hyaluronidase (Rituxan Hycela)
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (riabni)

References

1. Local Coverage Article. Billing and Coding. Rituximab (A56380). https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56380&ver=48&=. Accessed 2023 October.
2. Rituxan Hycela (rituximab and hyaluronidase human) [package insert]. South San Francisco, CA 94080: Genentech, Inc.; 2021 June.
3. Ruxience (rituximab-pvvr)) [package insert]. Division of Pfizer Inc. NY: Pfizer Inc.; November 2021.
4. Riabni (rituximab-arrx) [package insert]. Thousand Oaks, CA: Amgen Inc. December 2020.
5. TRUXIMA (rituximab-abbs) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. Feb 2022.
6. Rituxan (rituximab) [package insert]. South San Francisco, CA; Genentech. December 2021.

Approval And Revision History

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

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Removed the Limitations Coverage of Rituxan® (rituximab) will be authorized for any FDA-approved indication that available biosimilars do not share and Authorizations for a period of up to 12 months will be granted when coverage criteria are met. Removed step therapy coverage criteria and added the Limitation Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements. Updated the coverage criteria to Documentation the use of the requested medication is for the treatment of a malignant condition (eff 2/1/2024).
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- September 10, 2024: No changes
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- December 2025: Administrative update: Remove Harvard Pilgrim Stride Advantage from Medical Necessity Guideline.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines 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.
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