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: January 1, 2026

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

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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

Rituximab is an immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that targets the CD20 antigen, a protein expressed most B cells surface results in B—cell depletion. Initially used for anti-neoplastic therapy, it has been licensed for use in several autoimmune disorders. Rituximab has been used off-label for a multitude of indications. Coverage criteria for non-malignant conditions is based on Local Coverage Determination (LCD) Off-label Use of Rituximab and Rituximab Biosimilars (L39297).

Approval of rituximab in rheumatoid arthritis (RA) was based on two placebo-controlled trials in adults with moderately to severely active disease with a prior inadequate response to at least one tumor necrosis factor inhibitor. Results demonstrated that ACR20, 50, and 70 responses favored rituximab at weeks 24 and 48, respectively.

Approval of rituximab for the treatment of pemphigus vulgaris (PV) was based on a trial in which adults newly diagnosed with moderate to severe PV treated with rituximab demonstrated a higher complete remission (complete epithelialization and absence of new and/or established lesions) rate at Month 24 compared to prednisone alone. In a second trial, the percentage of patients with PV treated with rituximab who achieved sustained complete remission off corticosteroid therapy for a period of 16 weeks or more at Week 52, was significantly higher compared to patients treated with mycophenolate mofetil. Secondary endpoints of glucocorticoid exposure (cumulative oral prednisone dose at Week 52) and a reduction in disease flares also favored treatment with rituximab.

Approval of rituximab for the treatment of Granulomatosis with Polyangiitis and Microscopic Polyangiitis was based on results from a clinical trial demonstrating non-inferiority to cyclophosphamide for complete remission at 6 months.

Food and Drug Administration – 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

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 when the following clinical criteria are met:

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

Non-malignant Conditions

The plan may authorize coverage of a Rituximab Product for Members when all of following criteria are met:

1. Documentation of **one (1)** of the following:
    a. All of the following:
        i. Diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis
        ii. Prescribed by or in consultation with a rheumatologist, nephrologist, or a pulmonologist
        iii. Use in combination with glucocorticoids
    b. All of the following:
        i. Moderate to severe pemphigus vulgaris
        ii. Prescribing physician is a dermatologist
        iii. Previous failure of or clinical inappropriateness with glucocorticoids
    c. All of the following:
        i. Diagnosis of rheumatoid arthritis
        ii. Prescribing physician is a rheumatologist
        iii. Use in combination with methotrexate
    d. Both of the following:
        i. Diagnosis of acquired or refractory hemophilia
        ii. Use in combination with corticosteroids
    e. Both of the following:
        i. Diagnosis of severe, refractory, or relapsed thrombotic thrombocytopenic purpura
        ii. Previous failure of first-line therapy (e.g., plasma exchange, glucocorticoids)
    f. Both of the following:
        i. Diagnosis of refractory or remitting multiple sclerosis
        ii. Previous failure of first-line therapy
    g. Both of the following:
        i. Diagnosis of idiopathic inflammatory myopathies
        ii. Extra muscular (lung) involvement
    h. Both of the following:
        i. Diagnosis of immune-mediated myopathies including dermatomyositis, polymyositis, antisynthetase syndrome, immune-mediated necrotizing myopathy, inclusion body myositis, or nonspecific myositis
        ii. Previous failure of first-line therapy
    i. Both of the following:
        i. Immunoglobulin G4-related disease

ii. Previous failure with or contraindication to glucocorticoids

j. All of the following:
   i. Age less than 18 years of age
   ii. Steroid-dependent, steroid sensitive nephrotic syndrome
   iii. Continued frequent relapses despite optimal combinations of prednisone and corticosteroid- sparing agents or serious adverse effects of therapy

k. All of the following
   i. Age greater than or equal to 18 years of age
   ii. Diagnosis of frequently relapsing or glucocorticoid-dependent minimal change disease
   iii. Previous failure to attain a durable remission with cyclophosphamide or clalcinueurin inhibitors

l. All of the following:
   i. Diagnosis of antibody-mediated rejection in kidney, lung, and cardiac transplant patients
   ii. Either of the following:
      1. Use as second-line therapy
      2. Use as part of a combination treatment

m. All of the following:
   i. Diagnosis of immune thrombocytopenic purpura
   ii. Lack of response of at least one first line therapy
   iii. Patient is at risk of bleeding based on at least one of the following:
      1. Severe immune thrombocytopenic purpura
      2. Risk factors for bleeding are present
      3. Use in preparation for procedures or surgery with risk of bleeding
      4. Professional or lifestyle risk for trauma
   iv. Persistent or chronic disease (defined as greater than six months)

n. All of the following:
   i. Diagnosis of chronic inflammatory demyelinating polyneuropathy
   ii. Previous failure of intravenous immunoglobulin, glucocorticoids, and plasma exchange

o. All of the following
   i. Diagnosis of Sjogren's or systemic sclerosis
   ii. Previous failure of corticosteroids and another immunosuppressive agent

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
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. Local Coverage Article. Off-label Use of Rituximab and Rituximab Biosimilars. L39297. November 2022. 14, 2019. Accessed at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39297&ver=3&stateRegion=s24&contractorNumber=all&lcdStatus=all&sortBy=title&bc=8
2. Rituxan (rituximab) [package insert]. South San Francisco, CA: Genentech, Inc. December 2021.
3. Ruxience (rituximab-pvvr)) [package insert]. Division of Pfizer Inc. NY: Pfizer Inc.; July 2019. Accessed at
4. Riabni (rituximab-arrx) [package insert]. Thousand Oaks, CA: Amgen Inc. June 2022.
5. TRUXIMA (rituximab-abbs) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. Feb 2022.

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)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Updated title of Medical Necessity Guideline from “Rituximab Product for Non-Oncology Indications Only” to “Rituximab Products” Removed Limitations The health plan may authorize coverage of rituximab products for up to 6 months for Members with Granulomatosis with Polyangiitis (GPA, formerly known as Wegener's Granulomatosis), or Microscopic Polyangiitis (MPA), The health plan may authorize coverage of rituximab products for up to 12 months for Members with other covered conditions, and 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. Added the Limitation Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements of Riabni, Rituxan and Rituxan Hycela. Added coverage criteria for off-label indications with supporting information based on the LCD L39297. Updated coverage criteria for FDA-approved indications. (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 (eff 10/1/24)
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/24).
- 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.