Medical Necessity Guidelines:

Rituximab Products® for non-oncology indications only

Effective: January 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

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 a genetically engineered chimeric murine/human monoclonal IgG1 kappa antibody directed against the CD20 antigen.

Food and Drug Administration (FDA) Approved Indications for Non-Oncology Uses

Rituxan® (rituximab) is a CD20-directed cytolytic antibody indicated for the treatment of patients with:

- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely active RA who have inadequate response to one or more TNF antagonist therapies
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids
- Moderate to severe Pemphigus Vulgaris (PV) in adult patients

Riabni™ (rituximab-arrx) is a CD20-directed cytolytic antibody indicated for the treatment of patients with:

- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids

Ruxience™ (rituximab-pvvr) is a CD20-directed cytolytic antibody indicated for the treatment of patients with:

- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids

Truxima™ (rituximab-abbs) is a CD20-directed cytolytic antibody indicated for the treatment of patients with:

- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids

STEP THERAPY:

Some medically administered Part B drugs may have additional requirements or limits on coverage. These requirements and limits may include step therapy. This is when we require you to first try certain preferred drugs to treat your medical condition before we will cover another non-preferred drug for that condition.

This policy supplements Medicare Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) for the purpose of determining coverage under Medicare Part B medical benefits and applies a step therapy for Riabni (rituximab-arrx) and Rituxan® (rituximab).

This policy applies a step therapy for Riabni (rituximab-arrx) and Rituxan® (rituximab). This list indicates the common uses for which Riabni (rituximab-arrx) or Rituxan® (rituximab) are prescribed. This list can change from time to time.

Drug Class	Non-Preferred Product(s)	Preferred Product(s)
Rituximab	Rituxan® (rituximab) Riabni (rituximab-arrx)	Ruxience™ (rituximab-pvvr) Truxima™ (rituximab-abbs)

Clinical Guideline Coverage Criteria

The health plan may authorize coverage of Rituxan (rituximab), Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), or Truxima (rituximab-abbs) when the following criteria are met:

Note: For Riabni (rituximab-arrx) and Rituxan (rituximab), see additional criteria located at the bottom of this section.

1. The Member has a documented diagnosis of **one** of the following:
    a. Acquired Blood Factor Deficiency
    b. Autoimmune Hemolytic Anemia when refractory
    c. Bullous Pemphigoid disease
    d. Castleman's Disease (angiofollicular lymph node hyperplasia) when systemic and multicentric
    e. Dermatomyositis
    f. Evans Syndrome
    g. Graft-Versus-Host Disease (GVHD)
    h. Granulomatosis with Polyangiitis (GPA, formerly known as Wegener's Granulomatosis)
    i. Graves' disease when refractory to standard therapies
    j. High panel reactive antibody (PRA) levels to human leukocyte antigens pre-transplant
    k. Human Herpes Virus 8 (HHV-8, also known as Kaposi sarcoma-associated herpes virus, etiologic agent of Kaposi sarcoma (KS) and many cases of Castleman disease)
    l. Immune checkpoint inhibitor-related toxicities
    m. Relapsed/refractory immune or Idiopathic Thrombocytopenic Purpura (ITP)
    n. Microscopic Polyangiitis (MPA)
    o. Minimal change nephropathy disease (MCD) when one of the following criteria are met:
        1. Refractory disease
        2. Steroid-dependence
        3. History of steroid-resistance
    p. Primary-Progressive Multiple Sclerosis (PPMS)
    q. Myasthenia gravis, refractory (MG)
    r. Relapsing-Remitting Multiple Sclerosis (RRMS) when the following criteria are met:
        1. The Member has had an inadequate response to two or more disease-modifying drugs indicated for MS despite adequate duration of treatment
    s. Secondary-progressive Multiple Sclerosis (MS)
        1. The Member has a diagnosis of secondary-progressive MS

        AND

        2. Documented positive serology to JC virus
    t. Neuromyelitis Optica
    u. Pemphigus and Pemphigoid Disease
        1. The Member has a diagnosis of moderate to severe pemphigus or pemphigoid disease
    v. Polymyositis
    w. Post-Transplant Lymphoproliferative Disorder
    x. Rheumatoid Arthritis (RA) when **ALL** the following are met:
        1. The Member has had inadequate response to one or more TNF antagonist therapies

        AND

        2. The requested drug will be used in combination with methotrexate
    y. Sjogren's Syndrome
    z. Systemic Lupus Erythematosus (SLE) that is refractory to immunosuppressive therapy
    aa. Thrombocytopenic Purpura when **ANY** of the following criteria are met:
        1. Refractory immune or idiopathic

        OR

2. Refractory thrombotic when prescribed with corticosteroids and therapeutic plasma exchange (TPE) unless failure, contraindication, or intolerance is documented.

STEP THERAPY: Riabni (rituximab-arrx) Rituxan (rituximab) Only Criteria:

In addition to the criteria listed above, the plan may authorize coverage of Riabni (rituximab-arrx) or Rituxan® (rituximab) for Members when one (1) of the following criteria is met:

1. History of prior treatment with Ruxience™ (rituximab-pvvr) ***or*** Truxima™ (rituximab-abbs) resulting in a substandard response to therapy

OR

2. History of intolerance or adverse event to treatment with Ruxience™ (rituximab-pvvr) ***or*** Truxima™ (rituximab-abbs)

OR

3. Rationale that treatment with Ruxience™ (rituximab-pvvr) ***or*** Truxima™ (rituximab-abbs) is not clinically appropriate (Note: Convenience does not qualify as clinical rationale for inappropriateness of Ruxience or Truxima)

OR

4. Continuation of prior therapy with Riabni (rituximab-arrx) or Rituxan (rituximab) within the past 365 days

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.
- 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.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9312	Injection, rituximab, (Rituxan) 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: Billing and Coding: Rituximab (A56380). Centers for Medicare and Medicaid Services. Published online March 14, 2019. Accessed at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56380&ver=43&Date=&DocID=A56380
2. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. Washington, DC. Centers for Medicare & Medicaid Services (CMS). August 7, 2018. Accessed May 11, 2022.
3. Rituxan® (rituximab) [package insert]. South San Francisco, CA: Genentech, Inc. December 2021.
4. Ruxience™ (rituximab-pvvr)) [package insert]. Division of Pfizer Inc. NY: Pfizer Inc.; July 2019. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761103s000lbl.pdf
5. Riabni™ (rituximab-arrx) [package insert]. Thousand Oaks, CA: Amgen Inc. June 2022.
6. 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).

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.

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.