Medical Necessity Guidelines:

Riabni™ (rituximab-arrx), Rituxan® (rituximab), Rituxan Hycela™ (rituximab and hyaluronidase) (for Oncology Uses)

Effective: November 14, 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

Food and Drug Administration (FDA) Approved Indications:

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

- **Adult patients with 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 a rituximab product 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, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- **Adult patients with Chronic Lymphocytic Leukemia (CLL)**
  - Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)
- **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.

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

Non-Oncology Uses

- **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

Oncology Uses

- **Adult patients with 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 a rituximab product 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, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens

- **Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL)**
    - Previously untreated, advanced stage, CD20-positive, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy
- **Adult patients with Chronic Lymphocytic Leukemia (CLL)**
    - Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)

RITUXAN HYCELA™ is a combination of rituximab, a CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase, indicated for the treatment of adult patients with:

- **Follicular Lymphoma (FL)**
    - Relapsed or refractory, follicular lymphoma as a single agent
    - Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single agent maintenance therapy
    - Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- **Diffuse Large B-cell Lymphoma (DLBCL)**
    - Previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- **Chronic Lymphocytic Leukemia (CLL)**
    - Previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC)

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STEP THERAPY:

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

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

Malignant Conditions

Note: The plan does NOT require prior authorization for coverage of Ruxience (rituximab-pvvr) or Truxima (rituximab-abbs) 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.

Note: For all non-oncology indications, please reference the rituximab (non-oncology) Medical Necessity Guideline.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Riabni (rituximab-arrx), Rituxan (rituximab) or Rituxan Hycela (rituximab and hyaluronidase human) for Members when documentation of **one** (1) of the following criteria has been met:

1. History of prior treatment with or 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), Rituxan (rituximab) or Rituxan Hycela within the past 365 days

Limitations

- Coverage of Rituxan® (rituximab) will be authorized for any FDA-approved indication that available biosimilars do not share
- Authorizations for a period of up to 12 months will be granted when coverage criteria are met.

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)
Q5123	Injection, rituximab-arrx, biosimilar, (riabni)

References:

1. Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). Centers for Medicare and Medicaid Services. Published online November 7, 2019.
2. Local Coverage Article: Billing and Coding: Rituximab, biosimilars and Rituximab and hyaluronidase human (Rituxan Hycela™) (A52452). Centers for Medicare and Medicaid Services. Published online October 01, 2015, accessed at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52452&ver=79&LCDId=33394&bc=AAAAAAAAIAAA&=
3. Rituxan Hycela™(rituximab and hyaluronidase human) [package insert]. South San Francisco, CA 94080: Genentech, Inc.; Last update in June 2021, accessed at https://www.gene.com/download/pdf/rituxan_hycela_prescribing.pdf
4. Ruxience™ (rituximab-pvvr)) [package insert]. Division of Pfizer Inc. NY: Pfizer Inc.; November 2021. Accessed online May 17th, 2022, at https://labeling.pfizer.com/ShowLabeling.aspx?id=12090
5. Riabni™ (rituximab-arrx) [package insert]. Thousand Oaks, CA: Amgen Inc. December 2020. Accessed online May 17th, 2022, at https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Riabni/riabni_pi_english.pdf
6. TRUXIMA™ (rituximab-abbs) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. Feb 2022., Accessed online May 17th, 2022, at https://www.truxima.com/globalassets/truxima-dtc/pdfs/truxima-prescribing-information.pdf
7. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. Washington, DC. Centers for Medicare & Medicaid Services (CMS). August 7, 2018. Accessed online on May 25, 2022, at https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs
8. 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).

Subsequent endorsement date(s) and changes made:

- November 14, 2023: No changes. Effective January 31, 2024 retire Medical Necessity Guideline. As of February 1, 2024, defer to Rituximab Products Medical Necessity Guideline.

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.