

Policy Title:	Rituxan (rituximab) and Biosimilar (Truxima, Riabni, Ruxience) Non-Oncology and Non-Hematology Policy (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
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Purpose: To support safe, effective and appropriate use of Rituxan (rituximab), and biosimilars (Truxima, Riabni, Ruxience).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Rituxan (rituximab), and biosimilars (Truxima, Riabni, Ruxience) are covered under the Medical Benefit when used within the following guidelines for non-oncology and non-hematology indications. Use outside of these guidelines may result in non-payment unless approved under an exception process. **Refer to the Rituxan (rituximab), Truxima (rituximab-abbs), Riabni (rituximab-arrx) & Ruxience (rituximab-pvvr) Policy for oncology indications.**

Procedure:

Coverage of Rituxan (rituximab), and biosimilars (Truxima, Riabni, Ruxience) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria

- Patient must be screened for HBV infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; AND
- For new start to therapy and requesting Rituxan or Riabni, patient must have failure or intolerable side effects to Ruxience or Truxima OR patients that are currently on treatment with Rituxan or Riabni can remain on treatment OR MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Non-Oncology Indications:

Rheumatoid arthritis (RA)

- Adult patient (18 years or older); **AND**
- Documented moderate to severe disease; **AND**
- Must be used in combination with methotrexate unless the patient has a contraindication or intolerance; **AND**
- Patient tried and failed at least a 3 month trial with ONE oral disease modifying antirheumatic drug (DMARD) (e.g., methotrexate, azathioprine, hydroxychloroquine, sulfasalazine, leflunomide, etc.); **AND**
- Previous trial (or lack of response) for a minimum of 3 months with one or more preferred TNF antagonists at least one of which should be a self-injectable; **AND**
- Patient has not had treatment with Rituxan in the previous 4 months

Pemphigus vulgaris

- Patient has a diagnosis of pemphigus vulgaris as determined by the following:
 - One or more of the following clinical features:
 - Appearance of lesions, erosions and/or blisters
 - Nikolsky sign (induction of blistering via mechanical pressure at the edge of a blister or on normal skin)
 - Characteristic scarring and lesion distribution; **AND**
 - Histopathologic confirmation by skin/mucous membrane biopsy; **AND**
 - Presence of autoantibodies as detected by indirect immunofluorescence or enzyme-linked immunosorbent assay (ELISA); **AND**
- Patient has moderate to severe disease as assessed utilizing an objective measure/tool (i.e., PDAI, PSS, ABSIS); **AND**
- Patient is on combination glucocorticoid therapy

Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic polyangiitis (MPA)

- Adult patient (18 years or older); **AND**
- Used in combination with glucocorticoids

Chronic graft-versus-host disease (cGVHD)

- Patient is post-allogeneic stem cell transplant; **AND**
- Patient has glucocorticoid-refractory disease

Autoimmune Hemolytic Anemia (AIHA)

- Patient has warm-reactive disease refractory to or dependent on glucocorticoids; **OR**
- Patient has cold agglutinin disease with symptomatic anemia, transfusion-dependence, and/or disabling circulatory symptoms

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; **AND**
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), viral hepatitis, serious bacterial, fungal, or viral infections, cardiac arrhythmias, renal toxicity, bowel obstruction or perforation; **AND**

Non-Oncology Indications:

Rheumatoid arthritis (RA)

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g., an improvement on a composite scoring index such as Disease Activity Score-28 (DAS28) of 1.2 points or more or a $\geq 20\%$ improvement on the American College of Rheumatology-20 (ACR20) criteria]; **AND**
- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
 - Shown an initial response to therapy; **AND**
 - Received a minimum of one maintenance dose at the dose and interval specified below; **AND**
 - Responded to therapy with subsequent loss of response

Pemphigus vulgaris, Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) and Microscopic polyangiitis (MPA)

- Disease response as indicated by disease control and improvement in signs and symptoms of condition compared to baseline; **AND**
- A decrease frequency in the occurrence of major relapses (defined by the reappearance of clinical and/or laboratory signs of vasculitis activity that could lead to organ failure or damage, or could be life threatening)

Pemphigus vulgaris

- Patient is currently receiving tapering doses of corticosteroids or has discontinued use of corticosteroids; **AND**
 - Disease response as indicated by complete epithelialization of lesions and improvement in signs and symptoms of condition compared to baseline; **OR**
 - Patient has not experienced continued development of new lesions, continued extension of old lesions, or failure of established lesions to begin to heal despite therapy; **OR**
 - For Relapses ONLY: Patient has previously had active disease control; **AND**
 - Patient has the appearance of 3 or more new lesions a month that do not heal spontaneously within 1 week, or by the extension of established lesions

Chronic graft-versus-host disease (cGVHD)

- Coverage cannot be renewed

Autoimmune hemolytic anemia (AIHA)

- Disease response as indicated by improvement in anemia signs and symptoms (e.g., dyspnea, fatigue, etc.) as well as: improvement in laboratory values (Hb/Hct), reduced transfusion needs, and/or reduced glucocorticoid use

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months, unless otherwise stated in continuation of therapy criteria

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	Dose
RA	1,000 mg on days 1 and 15, repeated up to every 16 weeks
Pemphigus	Initiation: 1,000 mg on days 1 and 15 in combination with tapering doses of glucocorticoids Maintenance: 500 mg at month 12 and repeat every 6 months thereafter or based on clinical evaluation.

	<p><u>Relapse</u></p> <ul style="list-style-type: none"> Administer 1,000 mg IV upon relapse, resumption of glucocorticoids may be considered <p><i>*Subsequent infusions (maintenance and relapse) should be no sooner than 16 weeks after the previous infusion.</i></p>
GPA(WG)/MPA	<p>Induction (Pediatric and Adult):</p> <ul style="list-style-type: none"> 375 mg/m² weekly x 4 doses, initially <p>Maintenance:</p> <ul style="list-style-type: none"> Pediatric: 250 mg/m² on days 1 and 15, then 250 mg/m² every 6 months thereafter based on clinical evaluation Adult: 500 mg on days 1 and 15, then 500 mg every 6 months thereafter based on clinical evaluation
AIHA	375 mg/m ² weekly x 4 doses in a 6 month period
cGVHD	<p>375 mg/m² weekly x 4 doses, then 375 mg/m² monthly x 4 months</p> <p>OR</p> <p>375 mg/m² IV weekly for 4 doses (Note: A second course of 4 weekly doses may be administered 8 weeks after initial therapy for patients with lack of or incomplete response.)</p> <p>-OR-</p> <p>375 mg/m² IV weekly for 4 - 8 doses</p>

Dosing Limits:

Indication	Maximum dose (1 billable unit = 10 mg)
RA	100 units per dose every 14 days x 2 doses in a 16 week period
GPA(WG)/MPA	<p>Induction: 100 units per dose weekly x 4 doses in a 4 month period</p> <p>Initial Maintenance: 50 units x 2 doses in a 6 month period</p> <p>Subsequent Maintenance: 50 units every 6 months</p>
Pemphigus	<p>Initiation: 100 units every 14 days x 2 doses in a 12 month period</p> <p>Maintenance: 50 units every 16 weeks</p>
cGVHD	<p>100 units per dose weekly x 4 doses, then 100 units monthly x 4 months; OR</p> <p>100 units per dose weekly for 8 doses</p>
All other non-oncology indications	100 units per dose weekly x 4 doses in a 6 month period

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any

one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J9312	Injection, rituximab, 10mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10mg
Q5115	Injection rituximab-abbs, biosimilar, (Truxima), 10mg
Q5123	Injection rituximab-arrx, biosimilar, (Riabni), 10mg

References:

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2. Truxima [package insert]. Incheon, Korea; Celltrion, Inc; May 2020. Accessed May 2021.
3. Ruxience [package insert]. New York, NY; Pfizer, Inc; May 2020. Accessed May 2021.
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