Policy Title:	**Rituxan (rituximab) and Biosimilar (Truxima, Riabni, Ruxience) Non-Oncology and Non-Hematology Policy** (Intravenous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	09/25/2019, 12/20/2019, 1/29/20, 8/3/2020, 9/9/20, 1/28/2021		
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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 (rtuximab-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, patient must have failure or intolerable side effects to Riabni, Ruxience or Truxima OR Patients that are currently on treatment with Rituxan (rituximab) 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, auranofin, hydroxychloroquine, penicillamine, sulfasalazine, leflunomide, etc.); AND
- Previous failure 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 failed previous conventional therapy with corticosteroids and/or azathioprine

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 compared to baseline such as the number of tender and swollen joint counts.

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

- Disease response as indicated by improvement in signs and symptoms of condition compared to baseline

Chronic graft-versus-host disease (cGVHD)

- Disease response as indicated by improvement in patient-reported symptoms or clinician assessments (e.g., manifestations of disease to the skin, oral cavity, musculoskeletal system, etc.)

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.
GPA(WG)/MPA:	Induction (Pediatric and Adult): • 375 mg/m² weekly x 4 doses, initially Maintenance: • 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 500mg every 6 months thereafter based on clinical evaluation
AIHA	375 mg/m² weekly x 4 doses in a 6 month period
cGVHD	375 mg/m² weekly x 4 doses, then 375 mg/m² monthly x 4 months

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	Induction: 100 units per dose weekly x 4 doses in a 4 month period Initial Maintenance: 100 units x 2 doses in a 6 month period Subsequent Maintenance: 50 units every 6 months
Pemphigus	Initiation: 100 units every 14 days x 2 doses in a 12 month period Maintenance: 50 units every 16 weeks
cGVHD	100 units per dose weekly x 4 doses, then 100 units monthly x 4 months
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
C9399	Unclassified drugs or biologicals (Riabni)

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2. Truxima [package insert]. Incheon, Korea; Celltrion, Inc; May 2019. Accessed February 2020.
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4. Riabni [package insert]. Thousand Oaks, CA;Amgen, Onc; December 2020. Accessed January 2021.
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