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, 1/29/2020, 8/3/2020, 9/9/2020, 1/28/2021, 3/18/2021, 7/15/2021, 9/23/2021, 1/06/2022, 3/17/2022, 3/2/2023, 12/07/2023, 01/10/2024, 05/28/2025, 11/10/2025, 03/17/2026		

Purpose: To support safe, effective, and appropriate use of Rituxan (rituximab), and biosimilars (Truxima, Riabni, Ruxience).

Scope: Medicaid, Commercial, Medicare

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.

Summary of Evidence:

Rituxan (rituximab), along with its biosimilars Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), and Truxima (rituximab-abbs), are CD20-directed cytolytic monoclonal antibodies that have demonstrated efficacy and safety in the treatment of several autoimmune diseases, including rheumatoid arthritis (RA), granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), and severe pemphigus vulgaris (PV). Rituxan's biosimilars have all demonstrated no clinically meaningful differences to the reference product. In RA, two randomized, double-blind, placebo-controlled trials involving over 2,500 members showed that rituximab, in combination with methotrexate, significantly improved disease activity scores - including ACR 20/50/70 responses, physical function, and slowed radiographic joint damage progression compared to placebo. For GPA and MPA, the randomized, double-blind, active-controlled, multicenter, and non-inferiority GPA/MPA Study 1 compared rituximab to cyclophosphamide for induction of remission in 197 adults with active disease. The GPA/MPA study demonstrated non-inferiority through findings of complete remission at 6 months with a similar safety profile, including infection rates, compared to cyclophosphamide. Maintenance studies and pediatric trials further supported rituximab's long-term use. Lastly, PV was studied in a randomized, open-label, controlled multicenter study and comparing rituximab plus prednisone to prednisone alone or other immunosuppressants, with rituximab demonstrating both better remission rates and steroid-sparing effects. The most common adverse reactions in

clinical trials are infusion-related reactions, infections (including upper respiratory infections and bronchitis), hypertension, nausea, diarrhea, headache, leukopenia, dyspnea, cough, fatigue, increases in ALT, rash, muscle spasms, arthralgia, anemia, pyrexia, and pruritus.

Initial Criteria

- Member 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 (rituximab), or Truxima (rituximab-abbs), member must have failure or intolerable side effects to Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), **OR** members that are currently on treatment with Rituxan (rituximab), or Truxima (rituximab-abbs), can remain on treatment **OR** Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; AND
- Member is not on concurrent treatment with another CD20-directed therapy, TNF-inhibitor, IL-inhibitor, biologic response modifier or other non-biologic agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitnib, etc.); **AND**

Non-Oncology Indications:

Rheumatoid arthritis (RA)

- Adult member (18 years or older); **AND**
- Documented moderate to severe disease; **AND**
- Must be used in combination with methotrexate unless the member has a contraindication or intolerance; **AND**
- Member 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 antagonist at least one of which should be a self-injectable; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Member has not had treatment with Rituximab in the previous 4 months

Pemphigus Vulgaris

- Member 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**

- Positive direct immunofluorescence (DIF) microscopy result OR presence of autoantibodies as detected by indirect immunofluorescence (IIF) or enzyme-linked immunosorbent assay (ELISA); **AND**

- Member has moderate to severe disease as assessed utilizing an objective measure/tool (e.g, PDAI, PSS, ABSIS, etc.); **AND**
- Other causes of blistering or erosive skin and mucous membrane diseases have been ruled out; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, prednisolone, etc.)

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

- Member is at least 2 years of age; **AND**
- Used in combination with glucocorticoids (e.g., prednisone, methylprednisolone, etc.)

Multiple Sclerosis (MS) ‡

- Member must have a confirmed diagnosis of multiple sclerosis (MS) as documented by laboratory report (i.e., MRI); **AND**
- Member has a diagnosis of a relapsing form of MS [i.e., relapsing-remitting MS (RRMS)*, active secondary progressive disease (SPMS)**, or clinically isolated syndrome (CIS)***]
- ** or *** See Appendix below

Autoimmune Hemolytic Anemia (AIHA)

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

Systemic Lupus Erythematosus (SLE)

- Member has a confirmed diagnosis of SLE as evidenced by all of the following:
  - Confirmed SLE classification criteria score $\geq$ 10***** (*Note: must include clinical and immunologic domains criteria)* Anti-nuclear antibody (ANA) titer of $\geq$ 1:80 measured via indirect immunofluorescence (IIF) on human epithelial (HEp-2) cells (or an equivalent ANA positive test) at least once; **AND**
- Member has moderate to severe active disease defined as a Physician's Global Assessment (PGA) score of > 1 AND one of the following:
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K) score of $\geq$ 6

  - Disease activity with ≥ 2 systems with British Isles Lupus Assessment Group-2004 (BILAG) B scores
  - ≥ 1 system(s) with British Isles Lupus Assessment Group-2004 (BILAG) A score(s)
- Member has failed to respond adequately to at least two standard therapies such as anti-malarials (i.e. hydroxychloroquine, chloroquine), corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, immunosuppressives (i.e. azathioprine, methotrexate, cyclosporine, oral cyclophosphamide, or mycophenolate); **AND**
- Will not be used in combination with Lupkynis (voclosporin) or Saphnelo (anifrolumab); **AND**
- Member does not have severe active central nervous system lupus and/or active lupus nephritis

Lupus Nephritis

- Member has active lupus nephritis Class III, IV, or V as confirmed by renal biopsy; **AND**
- Member has disease that is non-responsive or refractory to standard first line therapy [i.e.., mycophenolate mofetil, mycophenolic acid, cyclophosphamide, or calcineurin inhibitors (e.g., tacrolimus)]; **AND**
- Used as a single agent or add-on therapy in combination with mycophenolate mofetil, mycophenolic acid, cyclophosphamide; AND
- Baseline measurement of one or more of the following is provided: urine protein:creatinine ratio (uPCR), estimated glomerular filtration rate (eGFR), or urine protein; AND
- Member does not have severe active central nervous system lupus

Myasthenia Gravis (unrelated to immunotherapy-related toxicity)

- Member has muscle-specific tyrosine kinase (MuSK)-antibody positive disease; **AND**
- Member is refractory to standard first-line therapy (e.g., glucocorticoids, azathioprine, mycophenolate mofetil, etc.)

Continuation of Therapy Criteria:

- Member continues to meet initial criteria; **AND**
- Member 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 member 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 ≥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 member 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

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 decreased 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

- Member 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**
    - Member 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: Member has previously had active disease control; **AND**
        - Member 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

Multiple Sclerosis (MS)

- Continuous monitoring of response to therapy indicates a beneficial response***** [manifestations of MS disease activity include, but are not limited to, an increase in annualized relapse rate (ARR), development of new/worsening T2 hyperintensities or enhancing lesions on brain/spinal MRI,

and progression of sustained impairment as evidenced by expanded disability status scale (EDSS), timed 25-foot walk (T25-FW), 9-hole peg test (9-HPT)]

*Note: – Inadequate response, in those who have been adherent and receiving therapy for sufficient time to realize the full treatment effect, is defined as ≥ 1 relapse, ≥ 2 unequivocally new MRI-detected lesions, or increased disability on examination over a one-year period.

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

Systemic Lupus Erythematosus (SLE)

- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
  - Improvement in the SELENA-SLEDAI-2K; **OR**
  - Reduction of baseline BILAG-2004 from A to B or from B to C/D, and no BILAG-2004 worsening in other organ systems, as defined by ≥2 new BILAG-2004 B; **OR**
  - No worsening (<0.30 points increase) in Physician's Global Assessment (PGA) score; **OR**
  - Seroconverted (negative)

Lupus Nephritis

- Coverage may only be renewed in members experiencing a disease relapse (e.g., increased serum creatinine, increase in protein urine excretion, decrease in eGFR, etc.)

Myasthenia Gravis (unrelated to immunotherapy-related toxicity)

Disease response as indicated by a decrease in the daily dose of corticosteroids and/or an improvement in signs and symptoms compared to baseline.

Coverage durations:

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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Rituxan was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Rituxan according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Appendix

***Definitive diagnosis of MS with a relapsing-remitting course is based upon:**

- Dissemination in space *(see below)* AND one or more of the following:
  - Positive cerebrospinal fluid (CSF) (e.g., presence of oligoclonal bands or kappa free light chain index)
  - Positive central vein sign (CVS) (e.g., presence of six or more lesions with CVS; if fewer than 6 white matter lesions are seen on MRI, the number of CVS positive lesions should outnumber the CVS negative lesions)
  - Dissemination in time (DIT) *(see below)*
  - Presence of lesions in at least four of five CNS anatomical locations; **OR**
- Lesions present in one CNS site (including members with 12 months or longer progression from onset) AND one or more of the following:
  - CSF positivity and CVS positivity
  - CSF positivity and paramagnetic rim lesion (PRL) positivity (e.g., presence of one or more PRL)
  - DIT *(see below)* and CVS positivity
  - DIT *(see below)* and PRL positivity

Dissemination in time (*Development/ appearance of new CNS lesions over time*)	**Dissemination in space** (*Development of lesions in distinct anatomical locations within the CNS; multifocal*)
• ≥ 2 clinical attacks; **OR** • Simultaneous presence of gadolinium enhancing and non-enhancing lesions at any time; **OR** • A new T2-hyperintense or gadolinium enhancing lesion on follow-up MRI	• MRI indicating typical lesions in ≥ 2 of 5 areas of the CNS (optic nerve, intracortical or juxtacortical, periventricular, infratentorial, or spinal cord); **OR** • In members with progressive disease (members with 12 months or longer progression from onset), two spinal cord lesions

**Active secondary progressive MS (SPMS) is defined as the following:

• Expanded Disability Status Scale (EDSS) score ≥ 3.0; **AND**
• Disease is progressive ≥ 3 months following an initial relapsing-remitting course (i.e., EDSS score increase by 1.0 in members with EDSS ≤5.5 or increase by 0.5 in members with EDSS ≥6); **AND**
  ○ ≥ 1 relapse within the previous 2 years; **OR**
  ○ Member has gadolinium-enhancing activity OR new or unequivocally enlarging T2 contrast-enhancing lesions as evidenced by MRI

***Definitive diagnosis of CIS is based upon <u>ALL</u> the following:
• A monophasic clinical episode with member-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS • Neurologic symptom duration of at least 24 hours, with or without recovery • Absence of fever or infection • Resembles a typical MS relapse (attack and exacerbation) but occurs in a member not known to have multiple sclerosis

*Classification Criteria for Systemic Lupus Erythematosus (SLE)	
Clinical Score Δ (range: 0-39)	**Clinical Domains and Criteria**
2	**Constitutional:** Unexplained fever > 101°F
	Hematologic:
3	White blood cell count < 4,000/mm^3
4	Platelet count < 100,000/mm^3 or Autoimmune hemolysis
	Neuropsychiatric:
2	Delirium
3	Psychosis
5	Primary generalized seizure or partial/focal seizure
	Mucocutaneous +:
2	Non-scarring alopecia or oral ulcers
4	Subacute cutaneous or discoid lupus
8	Acute cutaneous lupus
	Serosal:
5	Pleural or pericardial effusion
6	Acute pericarditis
6	**Musculoskeletal:** Joint involvement with either synovitis involving 2 or more joints with swelling or effusion OR tenderness in 2 or more joints with at least 30 minutes of morning stiffness
	Renal:
4	Proteinuria > 0.5g/24 hr by a 24-hour urine or equivalent spot urine protein-to-creatinine ratio
8	Renal biopsy class II or V lupus nephritis
10	Renal biopsy Class III or IV lupus nephritis
Immunologic Score	**Immunologic Domains and Criteria**

(range: 0-12)	
2	**Presence of antiphospholipid antibodies** (i.e., positive lupus anticoagulant, positive anti-ß2GP1 antibodies, and/or anti-cardiolipin antibodies at medium or high titer)
3 4	**Presence of low complement proteins** (below lower limit of normal): Low C3 OR low C4 Low C3 AND C4
6	**Presence of anti-Sm and/or anti-dsDNA antibodies**
A web-based scoring calculator as well as further definitions of each criterion are available at: https://rheumatology.org/criteria Δ Occurrence on at least one occasion is sufficient to count toward score when all other causes have been ruled out. Count only the highest weighted score within each of the 10 domains (7 clinical and 3 immunologic) and any additional criteria within the same domain will not count. + Observed by a physician via clinical exam or photograph review	

Dosage/Administration:

Indication	Dose
RA	1,000 mg on days 1 and 15, repeated up to every 24weeks. May repeat up to every 16 weeks following the previous infusion in members requiring more frequent dosing based on clinical evaluation.
Pemphigus Vulgaris	Initiation: 1,000 mg on days 1 and 15; OR 375 mg/m² IV weekly for 4 doses Maintenance: 500 mg at month 12 and repeat every 6 months thereafter or based on clinical evaluation. Relapse – 1,000 mg IV upon relapse, resumption of glucocorticoids may be considered **Subsequent infusions (maintenance and relapse) should be no sooner than 16 weeks after the previous infusion.*
GPA(WG)/MPA	Induction (Pediatric and Adult): • 375 mg/m² weekly x 4 doses; OR • Adults: 1,000 mg IV on days 1 and 15; **OR** • Pediatric (up to a maximum of 1,000 mg per dose): o 575 mg/m² IV on days 1 and 15 (BSA ≤1.5m²) o 750 mg/m² IV on days 1 and 15 (BSA >1.5m²) 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 500 mg every 6 months thereafter based on clinical evaluation*Initial MAINTENANCE infusions should be no sooner than 16 weeks and no later than 24 weeks after the previous infusion if rituximab was used for initial induction therapy.*Initial MAINTENANCE infusions should be initiated within 4 weeks following disease control when initial induction occurred with other standard of care immunosuppressants.*
AIHA	Warm-reactive disease 375 mg/m² weekly for 4 doses in a 6 month period; OR 1000mg IV days 1 and 15 <u>Cold agglutinin disease</u> 375 mg/m² IV weekly for 4 doses in a 6 month period
Lupus Nephritis	1,000 mg IV on days 1 and 15 **-OR-** 375 mg/m² IV once weekly for 4 doses
Myasthenia Gravis (unrelated to immunotherapy-related toxicity)	1,000 mg IV on days 1 and 15, may repeat a full or partial course every 6 months **-OR-** 375 mg/m² IV once weekly for 4 doses, may repeat a full or partial course every 6 months
SLE	1,000 mg IV on days 1 and 15 **-OR-** 375 mg/m² IV once weekly for 4 doses
Multiple Sclerosis	1,000 mg IV on days 1 and 15, repeat every 6 months

Dosing Limits:

Indication	**Maximum dose (1 billable unit = 10 mg)**
RA	100 units per dose every 14 days x 2 doses in an 18 week period
GPA(WG)/MPA	Induction: 100 units per dose weekly x 4 doses in a 4 month period Initial Maintenance: 50 units x 2 doses in a 6 month period Subsequent Maintenance: 50 units every 6 months
Pemphigus Vulgaris (PV):	Initiation: 100 units weekly x 4 doses in a 12 month period Maintenance and Relapse: 50 units every 16 weeks

Lupus Nephritis & Myasthenia Gravis (unrelated to immunotherapy-related toxicity):	100 billable units per dose every 14 days x 2 doses in a 6 month period; **OR** 100 billable units per dose weekly x 4 doses in a 20-week period
Multiple Sclerosis (MS)	100 billable units every 14 days x 2 doses every 6 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
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10mg

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