JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP057
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Rituxan, Ruxience, Truxima, and Riabni (For Rheumatoid Arthritis and Other Conditions)**	*Revision Date*	04/20/2022
		Page	1 of 5

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Riabni, Rituxan, Ruxience, Truxima

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**3**
IV.	**EXCLUSIONS**	**3**
V.	**RECOMMENDED DOSAGE**	**3**
VI.	**CODES**	**3**
VII.	**REFERENCES**	**4**
VIII.	**APPROVALS**	**5**

I. POLICY

A. Rituxan (rituximab),Ruxience (rituximab-pvvr), Truxima (rituximab-abbs), and Riabni (rituximab-arrx) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Ruxience, Truxima, or Riabni may be approved for patients who meet the following:
   1. Rheumatoid arthritis (RA)
      a. Documentation has been submitted showing the following:
         I. Patient has been diagnosed with moderately to severely active RA
         II. The requested rituximab product will be used in combination with methotrexate or leflunomide, unless the patient has a contraindication or intolerance to these agents
            - Contraindications to methotrexate may include any of the following:
               - Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
               - Breastfeeding
               - Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
               - Elevated liver transaminases
               - History of intolerance or adverse event
               - Hypersensitivity
               - Interstitial pneumonitis or clinically significant pulmonary fibrosis
               - Myelodysplasia
               - Pregnancy or currently planning pregnancy
               - Renal impairment
               - Significant drug interaction
         III. Patient meets one of the following:
            - Either of the following:
               - Patient has previously received biologic disease-modifying antirheumatic drug (DMARD) or targeted synthetic DMARD (such as Xeljanz)

- Patient has received at least two full doses of a rituximab product for the treatment of RA, where the most recent dose was given within 6 months of the request
- All of the following:
  - Patient meeting one of the following:
    - Positive response to one of the following biomarker tests:
      - Rheumatoid factor (RF)
      - Anti-cyclic citrullinated peptide (anti-CCP)
    - Evidence that the patient has been tested for all of the following biomarkers:
      - RF
      - Anti-CCP
      - C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
    - Patient meets one of the following:
      - Experienced an inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to at least 15 mg/week)
      - Had an intolerable adverse effect or contraindication to methotrexate and an inadequate response to another conventional DMARD (such as hydroxychloroquine, leflunomide, sulfasalazine)

2. Granulomatosis with polyangiitis (GPA) (Wegener's granulomatosis) and microscopic polyangiitis (MPA) and Churg-Strauss and pauci-immune glomerulonephritis
   a. Documentation has been submitted showing the patient has been diagnosed with GPA, MPA, Churg-Strauss, or pauci-immune glomerulonephritis.
3. Sjögren's syndrome
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with Sjögren's syndrome
      II. Patient has had trial and inadequate response with corticosteroids and other immunosuppressive agents.
4. Multiple sclerosis (MS)
   a. Documentation has been submitted showing the patient has been diagnosed with relapsing remitting MS (RRMS)
5. Neuromyelitis optica
   a. Documentation has been submitted the following:
      I. Patient has been diagnosed with neuromyelitis optica spectrum disorder (NMOSD) or Devic disease
      II. Patient has had trial and inadequate response to at least one other immunotherapy
      III. The requested rituximab product will not be used concurrently with other biologics for the treatment of NMOSD
6. Autoimmune blistering disease
   a. Documentation has been submitted showing the patient has been diagnosed with an autoimmune blistering disease (such as pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus)
7. Cryoglobulinemia
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with cryoglobulinemia
      II. Patient has had trial and inadequate response with corticosteroids and other immunosuppressive agents.
8. Solid organ transplant

a. Documentation has been submitted showing that the requested rituximab product will be used for treatment of solid organ transplant and prevention of antibody mediated rejection in solid organ transplant

9. Opsoclonus-myoclonus-ataxia
   a. Documentation has been submitted showing that the patient has a diagnosis of opsoclonus-myoclonus-ataxia associated with neuroblastoma when the member is refractory to steroids and chemotherapy.
10. Systemic Lupus Erythematosus
    a. Documentation has been submitted showing that the patient has a diagnosis of systemic lupus erythematosus that is refractory to immunosuppressive therapy
11. Myasthenia Gravis
    a. Documentation has been submitted showing that the patient has a diagnosis of treatment of refractory myasthenia gravis

B. Rituxan may be approved for the following:
   1. Patient meets the initial coverage criteria listed above for the biosimilar products
   2. Documentation has been submitted showing the patient has hypersensitivity to the biosimilar products, or provider has a clinical justification as to why the patient cannot use the biosimilar products

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
   1. Solid organ transplant Caveat: Initial approval will be limited to 3 months of therapy

B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has experienced clinical benefit from therapy
   1. Diagnosis-Specific requirements:
      a. Rheumatoid arthritis:
         I. Patient has achieved or maintained a positive clinical response after at least two doses of the requested rituximab product, evidenced by disease activity improvement of at least 20% from baseline in tender joint count, swollen joint count, pain, or disability
      b. Multiple Sclerosis:
         I. Patient has experienced RRMS stability or improvement while receiving the requested rituximab product

IV. EXCLUSIONS

A. Rituxan, Ruxience, Truxima, and Riabni will not be covered for the following:
   1. Concurrent use with other biologics for RA
   2. Concurrent use with other multiple sclerosis (MS) drugs excluding Ampyra
   3. Requests for the treatment of RA when planned date of administration is less than 16 weeks since date of last dose received
   4. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

CPT Copyright 2013 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medications	HCPCS/Code
Injection, rituximab, 10 mg	J9312
Injection, rituximab-abbs, biosimilar, (truxima), 10 mg	Q5115
Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg	Q5119
Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	Q5123

VII. REFERENCES

1. Rituxan [prescribing information]. South San Francisco, CA: Genentech, Inc.; December 2021.
2. Truxima [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.: February 2022.
3. Ruxience [prescribing information]. NY, NY: Pfizer Biosimilars; November 2021.
4. Riabni [prescribing information]. Thousand Oaks, CA: Amgen Inc.; December 2020.
5. Methotrexate [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; April 2018.
6. Dass S, Bowman SJ, Vital EM, et al. Reduction of fatigue in Sjögren syndrome with rituximab: results of a double blind, placebo-controlled study. Ann Rheum Dis. 2008;67:1541-1544.
7. Meijer JM, Meiners PM, Vissink A, et al. Effectiveness of rituximab treatment in primary Sjögren's syndrome: a randomized, double-blind, placebo-controlled trial. Arthritis Rheum. 2010;62(4):960-8.
8. Smolen JS, Landewé R, Billsma J, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. Ann Rheum Dis. 2020;79:685-699.
9. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016;68(1)1-26.
10. Saag KG, Teng GG, Patkar NM, et al. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
11. Hauser SL, Waubant E, Arnold DL, et al. B-cell depletion with rituximab in relapsing-remitting multiple sclerosis. N Engl J Med. 2008;358:676-688.
12. Scott, T.F., Frohman, E.M., DeSeze, J., (2011). Evidence-based guideline: Clinical evaluation and treatment of transverse myelitis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. American Academy of Neurology. 77: 2128-2134.
13. Trebst, C., Jarius, S., et al. (2014). Update on the diagnosis and treatment of neuromyelitis optica: Recommendations of the Neuromyelitis Optica Study Group (NEMOS). J Neurol 261: 1-16.
14. De Vita S, Quartuccio L, Isola M, et al. A randomized controlled trial of rituximab for the treatment of severe cryoglobulinemic vasculitis. Arthritis Rheum. 2012;64(3):843-53.
15. Sneller MC, Hu Z, Langford CA. A randomized controlled trial of rituximab following failure of antiviral therapy for hepatitis C virus-associated cryoglobulinemic vasculitis. Arthritis Rheum. 2012 Mar; 64(3):835-42.
16. Terrier B, Krastinova E, Marie I, et al. Management of noninfectious mixed cryoglobulinemia vasculitis: data from 242 cases included in the CryoVas survey. Blood. 2012 Jun 21; 119(25):5996-6004.

17. Trappe R, Oertel S, Leblond V, et al. Sequential treatment with rituximab followed by CHOP chemotherapy in adult B-cell post-transplant lymphoproliferative disorder (PTLD): the prospective international multicentre phase 2 PTLD-1 trial. Lancet Oncol 2012.
18. The American Society of Transplantation Infectious Diseases Guidelines. Am J Transplant 2009; 9 (Suppl 4):S92.
19. Bell J, Moran C, Blatt J. Response to rituximab in a child with neuroblastoma and opsoclonus-myoclonus. Pediatr Blood Cancer 2008; 50:370.
20. Hertl M, Geller S. Initial management of pemphigus vulgaris and pemphigus foliaceus. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed November 2020.
21. Aletaha D, Neogi T, Silman, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis Rheum. 2010;62(9):2569-81.
22. Smolen JS, Aletaha D. Assessment of rheumatoid arthritis activity in clinical trials and clinical practice. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Available with subscription. URL: www.uptodate.com. Accessed March 19, 2021.
23. Murrell DF, Peña S, Joly P, et al. Diagnosis and management of pemphigus: Recommendations of an international panel of experts. J Am Acad Dermatol. 2020;82(3):575-585.e1.
24. Joly P, Horvath B, Patsatsi #, et al. Updated S2K guidelines on the management of pemphigus vulgaris and foliaceus initiated by the european academy of dermatology and venereology (EADV). J Eur Acad Dermatol Venereol. 2020;34(9):1900-1913.
25. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed April 06, 2021.
26. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthrit Care Res. 2021;0:1-16.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Dates: 04/20/2022

Revision Dates: