JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP058
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Rituxan, Ruxience, Truxima, and Riabni (For Oncologic and Hematologic Conditions)**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: riabni, Rituxan, ruxience, truxima

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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. Oncologic indications
a. Documentation has been submitted showing the following:
I. Patient has been diagnosed with any of the following conditions:
- B-cell acute lymphoblastic leukemia (ALL)
- B-cell lymphomas:
  - Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
  - B-cell lymphoblastic lymphoma
  - Burkitt lymphoma
  - Castleman’s disease
  - Diffuse large B-cell lymphoma
  - Follicular lymphoma
  - High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/ triple hit
  - lymphoma)
  - High-grade B-cell lymphoma, not otherwise specified
  - Histological transformation from follicular lymphoma to diffuse large B-cell lymphoma
  - Histological transformation from nodal marginal zone lymphoma to diffuse large B-cell lymphoma
  - Mantle cell lymphoma
  - Marginal zone lymphomas
    - Nodal marginal zone lymphoma

- Gastric mucosa associated lymphoid tissue (MALT) lymphoma
- Nongastric MALT lymphoma
- Splenic marginal zone lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Central nervous system (CNS) cancers:
  - Leptomeningeal metastases from lymphomas
  - Primary CNS lymphoma
- CLL/Small lymphocytic lymphoma (SLL)
- Hairy cell leukemia
- Hodgkin's lymphoma, nodular lymphocyte-predominant
- Primary cutaneous B-cell lymphoma
- Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)

II. Patient has CD20-postive disease as confirmed by laboratory testing

2. Hematologic indications
   a. Documentation has been submitted showing the patient has been diagnosed with any of the following conditions:
      I. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
      II. Autoimmune hemolytic anemia
      III. Thrombotic thrombocytopenic purpura
      IV. Chronic graft-versus-host disease (GVHD)
      V. Prevention of Epstein-Barr virus (EBV)-related PTLD
3. Immune checkpoint inhibitor-related toxicities
   I. Documentation has been submitted showing the patient is being treated for immune checkpoint inhibitor-related toxicities

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 for oncologic and hematologic conditions
B. Initial approval will be limited to 3 months of therapy for treatment of immune checkpoint inhibitor-related toxicities
C. Continuation of therapy may be approved as follows:
   1. Oncologic conditions: Continuation may be approved in 12-month intervals with documentation that the patient is continuing to tolerate the regimen
   2. Hematologic conditions: Continuation may be approved in 12-month intervals with documentation that the patient has had a clinical benefit to treatment
   3. Immune checkpoint inhibitor-related toxicities: Continuation may be approved for 3-months with documentation that the patient has had a clinical benefit to treatment

IV. EXCLUSIONS

A. Rituxan, Ruxience, Truxima, and Riabni will not be covered for the following:
   1. Any indications 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

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.

Medication	HCPCS/CPT 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. APPROVALS

Signature on file at JHHC

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

Review Dates: 04/20/2022

Revision Dates:

VIII. REFERENCES

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