Corporate Medical Policy: Rituximab for the Treatment of Rheumatoid Arthritis **"Notification"** **POLICY EFFECTIVE JANUARY 1, 2026**

Restricted Product(s):

- *rituximab (Rituxan®) intravenous infusion for administration by a healthcare professional
- ***rituximab-arrx (Riabni®) intravenous infusion for administration by a healthcare professional
- ***rituximab-pvvr (Ruxience®) intravenous infusion for administration by a healthcare professional
- ***rituximab-abbs (Truxima®) intravenous infusion for administration by a healthcare professional
- *Any other approved rituximab biosimilars

*****preferred agent(s)**
***non-preferred agent(s)**

Indications for Use:

- For the treatment of rheumatoid arthritis (RA) in combination with methotrexate in adults with moderately to severely active RA who have inadequate response to one or more TNF antagonist therapies

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary for covered when the following criteria are met:

1. If the request is for rituximab (Rituxan) or a non-preferred rituximab biosimilar product, ONE of the following:
    a. The patient has tried and had an inadequate response to ALL of the following preferred rituximab biosimilar products: rituximab-arrx (Riabni), rituximab-pvvr (Ruxience), AND rituximab-abbs (Truxima) **[medical record documentation required]**; **OR**
    b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL preferred rituximab biosimilar products (i.e., rituximab-arrx [Riabni], rituximab-pvvr [Ruxience], AND rituximab-abbs [Truxima]) that is NOT expected to occur with the requested product **[medical record documentation required]**; **OR**
    c. The patient has a documented serious adverse event that required medical intervention to ALL preferred rituximab biosimilar products (i.e., rituximab-arrx [Riabni], rituximab-pvvr [Ruxience], AND rituximab-abbs [Truxima]) that is NOT anticipated with the requested product **[medical record documentation required]**; **AND**
        i. The prescriber has completed and submitted an FDA MedWatch Adverse Event Reporting Form **[medical record documentation required]**; **AND**

2. The patient has a diagnosis of moderately to severely active **rheumatoid arthritis (RA)**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. ONE of the following:
        i. The patient has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) for at least 3-months **[medical record documentation required]**; **OR**
        ii. The patient has tried and had an inadequate response to another conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA for at least 3-months **[medical record documentation required]**; **OR**
        iii. The patient has an intolerance or hypersensitivity to ONE of the following conventional agents (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **[medical record documentation required]**; **OR**
        iv. The patient has an FDA labeled contraindication to ALL of the following conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **[medical record documentation required]**; **AND**
    c. ONE of the following:
        i. The patient will be taking the requested agent in combination with methotrexate; **OR**
        ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to methotrexate **[medical record documentation required]**; **AND**
    d. ONE of the following:
        i. The patient has tried and had an inadequate response to at least ONE biologic immunomodulator FDA labeled or supported in compendia for the treatment of RA for at least 3-months **[medical record documentation required]**; **OR**
        ii. The patient has an intolerance or hypersensitivity to ONE biologic immunomodulator FDA labeled or supported in compendia for the treatment of RA **[medical record documentation required]**; **OR**
        iii. The patient has an FDA labeled contraindication to ALL biologic immunomodulators FDA labeled for the treatment of RA **[medical record documentation required]**; **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist for RA) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
4. The patient will NOT be using the requested agent in combination with another biologic immunomodulator agent used in the treatment of RA; **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
6. The patient has been screened for hepatitis B infection measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) AND if positive the patient has begun therapy for hepatitis B; **AND**

7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

Duration of Approval: 365 days (1 year)

Note: This policy only applies to rituximab (Rituxan) and rituximab biosimilars (Riabni, Ruxience, and Truxima) when used for the treatment of rheumatoid arthritis

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
rituximab (Rituxan®) intravenous (IV) infusion	Moderately to severely active RA in adults who have inadequate response to one or more TNF antagonist therapies; in combination with methotrexate	**In combination with methotrexate**: Two-1,000 mg IV infusions separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks	J9312	600 units
rituximab-arrx (Riabni®) intravenous (IV) infusion			Q5123	600 units
rituximab-pvvr (Ruxience®) intravenous (IV) infusion			Q5119	600 units

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
rituximab-abbs (Truxima®) intravenous (IV) infusion			Q5115	600 units

***Maximum units allowed for duration of approval**

Other codes that may applicable to this policy:

Diagnoses that are subject to medical necessity review: M05.00, M05.011, M05.012, M05.019, M05.021, M05.022, M05.029, M05.031 M05.032, M05.039, M05.041, M05.042, M05.049, M05.051, M05.052, M05.059, M05.061, M05.062, M05.10, M05.111, M05.112, M05.119, M05.319, M05.069, M05.071, M05.072, M05.079, M05.09, M05.30, M05.311, M05.312, M05.321, M05.322, M05.329, M05.331, M05.332, M05.339, M05.341, M05.342, M05.349, M05.351, M05.352, M05.359, M05.361, M05.362, M05.369, M05.371, M05.372, M05.379, M05.39, M05.60, M05.611, M05.612, M05.619, M05.621, M05.622, M05.629, M05.631, M05.632, M05.639, M05.641, M05.642, M05.649, M05.651, M05.652, M05.659, M05.661, M05.662, M05.669, M05.671, M05.672, M05.679, M05.69, M06.9, M06.80, M06.811, M06.812, M06.819, M06.821, M06.822, M06.829, M06.831, M06.832, M06.839, M06.841, M06.842, M06.849, M06.851, M06.852, M06.859, M06.861, M06.862, M06.869, M06.871, M06.872, M06.879, M06.88, M06.89,M08.00, M08.09, M08.29, M08.011, M08.012, M08.019, M08.021, M08.022, M08.029, M08.031, M08.032, M08.039, M08.041, M08.042, M08.049, M08.051, M08.052, M08.059, M08.061, M08.062, M08.069, M08.071, M08.072, M08.079, M08.08, M08.20, M08.211, M08.212, M08.219, M08.221, M08.222, M08.229, M08.231, M08.232, M08.239, M08.241, M08.242, M08.249, M08.251, M08.252, M08.259, M08.261, M08.262, M08.269, M08.271, M08.272, M08.279, M08.28, M08.29, M08.00, M08.011, M08.012, M08.019, M08.021, M08.022, M08.029, M08.031, M08.032, M08.039, M08.041, M08.042, M08.049, M08.051, M08.052, M08.059, M08.061, M08.062, M08.069, M08.071, M08.072, M08.079, M08.09, M08.40, M08.411, M08.412, M08.419, M08.421, M08.422, M08.429, M08.431, M08.432, M08.439, M08.441, M08.442, M08.449, M08.451, M08.452, M08.459, M08.461, M08.462, M08.469, M08.471, M08.472, M08.479, M08.48, M12.00, M12.011, M12.012, M12.019, M12.021, M12.022, M12.029, M12.031, M12.032, M12.039, M12.041, M12.042, M12.049, M12.051, M12.052, M12.059, M12.061, M12.062, M12.069, M12.071, M12.072, M12.079, M12.08, M12.09, M06.4, M45.A0, M45.A1, M45.A2, M45.A3, M45.A4, M45.A5, M45.A6, M45.A7, M45.A8, M45.AB, M45.0, M45.1, M45.2, M45.3, M45.4, M45.5, M45.6, M45.7, M45.8, M45.9

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Care & Research*. 2021;73(7):924-39.
2. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res*. 2012;64(5):625-639.
3. 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.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

January 2026: Criteria change: Changed requirement for trial and failure of preferred rituximab biosimilar products to include Riabni in addition to existing preferred Ruxience and Truxima; adjusted non-preferred rituximab products to include Rituxan. Adjusted verbiage for methotrexate trial option to indicate that inadequate response to methotrexate includes maximally tolerated dosing for at least 3-months. Listed examples of agents for trial option of other conventional agents used in the treatment of RA and added trial duration for at least 3-months. Added additional allowance within conventional trial verbiage for intolerance/hypersensitivity/contraindication to conventional agents used in the treatment of RA. Adjusted verbiage for required trial and failure of one or more TNF inhibitor to indicate at least one biologic immunomodulator FDA labeled or compendia supported for the treatment of RA for at least 3 months, and added allowance for intolerance/hypersensitivity to at least one biologic immunomodulator for treatment of RA. Added requirements to be prescribed by or in consultation with a specialist, no contraindication to the requested agent, and for hepatitis B screening. Other formatting changes made throughout policy and dosing reference table for clarity. **Policy notification given 11/1/2025 for effective date 1/1/2026**.
September 2024: Criteria change: Updated requirement for use of preferred rituximab biosimilars (Truxima and Ruxience) prior to Rituxan or non-preferred rituximab biosimilars to also allow for trial and failure of both preferred rituximab biosimilars OR presence of an intolerance, FDA labeled contraindication, or hypersensitivity to all preferred rituximab biosimilar products that is NOT expected to occur with the requested product. Updated references.
October 2021: Coding update: Added the following applicable diagnosis codes to policy effective 10/1/2021: M45.A0, M45.A1, M45.A2, M45.A3, M45.A4, M45.A5, M45.A6, M45.A7, M45.A8, and M45.AB.
July 2021: Coding update: Added HCPCS code Q5123 to dosing reference table effective 7/1/2021, deleted non-specific codes C9399, J3490, and J3590 termed 6/30/2021.
June 2021: Criteria change: Medical record documentation required for trial and failure of preferred and conventional agents.
June 2021: Criteria change: Added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.