

<b>Policy Name:</b>	<b>Rituxan, Ruxience, Truxima, Riabni (rituximab)</b>	<b>Policy #:</b>	<b>1923P</b>
---------------------	---	------------------	--------------

## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Rituxan (rituximab) and formulary rituximab biosimilars.

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Rituxan (rituximab) and formulary rituximab biosimilars; Ruxience, Truxima, and Riabni under the specialty medical benefit or Rituxan Hycela (where indicated) under the specialty pharmacy benefit when the following criteria have been met.

## Criteria

### 1. Criteria for Coverage of Cancer-Related Indications

1.1 See the [Oncology Regimen Review](#) policy.

### 2. Criteria for Coverage for Autoimmune Hemolytic Anemia

2.1 Diagnosis of Autoimmune Hemolytic Anemia

2.2 Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)

### 3. Criteria for Coverage for Evans Syndrome

3.1 Diagnosis of Evans Syndrome

3.2 Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)

3.3 Documented failure, intolerance, or contraindication to azathioprine or cyclophosphamide

3.4 Documented failure, intolerance, or contraindication to cyclosporine or mycophenolate

### 4. Criteria for Coverage for Immune (idiopathic) Thrombocytopenic Purpura

4.1 Diagnosis of Immune (idiopathic) Thrombocytopenic Purpura

4.2 Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)

4.3 Documented failure, intolerance, or contraindication to immune globulin product

4.4 Documentation of splenectomy or contraindication to splenectomy

### 5. Criteria for Coverage for Polyarteritis Nodosa

5.1 Diagnosis of Polyarteritis Nodosa (inflammation of small and medium-sized arteries)

5.2 Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)

5.3 Documented failure, intolerance, or contraindication to azathioprine or cyclophosphamide

### 6. Criteria for Coverage for Rheumatoid Arthritis

6.1 Diagnosis of Rheumatoid Arthritis

- 6.2 Ordered by a Rheumatologist (musculoskeletal doctor)
- 6.3 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to a DMARD (Disease-Modifying Anti-Rheumatic Drug): Methotrexate, Arava (leflunomide), Plaquenil (hydroxychloroquine), or sulfasalazine
- 6.4 Documented failure to respond to a minimum 3-month trial, intolerance, or contraindication to two of the following preferred products
  - Cimzia
  - Covered adalimumab biosimilars
  - Enbrel
  - Simponi
  - Xeljanz/XR
  - Rinvoq
- 6.5 Documented concurrent use of methotrexate with a preferred biologic immunomodulator

### **7. Criteria for Coverage for Systemic Lupus Erythematosus**

- 7.1 Diagnosis of System Lupus Erythematosus
- 7.2 Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)
- 7.3 Documented compliance with hydroxychloroquine or chloroquine, unless contraindicated
  - Compliance defined as possession of 150 days' worth of drug in 6 months
- 7.4 Documented failure, intolerance, or contraindication to at least 2 of the following: azathioprine, mycophenolate, methotrexate, or cyclophosphamide

### **8. Criteria for Coverage for Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)**

- 8.1 Diagnosis of Granulomatosis with Polyangiitis or Microscopic Polyangiitis
- 8.2 Documentation that Rituxan will be used in combination with glucocorticoids (such as methylprednisolone, prednisone)

### **9. Criteria for Coverage for Multiple Sclerosis**

- 9.1 Diagnosis of Primary Progressive or Relapsing forms of Multiple Sclerosis
- 9.2 Ordered by a Neurologist (nervous system doctor)

### **10. Criteria for Coverage for Pemphigus Vulgaris (Rituxan Only)**

- 10.1 Diagnosis of Pemphigus Vulgaris
- 10.2 Ordered by a Dermatologist (skin doctor), Rheumatologist (nervous system doctor), or Oncologist (cancer doctor)
- 10.3 Documented failure, intolerance, or contraindication to prednisone with azathioprine or mycophenolate

### **11. Criteria for Coverage for Cold Agglutinin Disease**

- 11.1 Diagnosis of primary cold agglutinin disease (CAD) as evidenced by the following:
  - Evidence of hemolysis (eg, high reticulocyte count, high LDH, low haptoglobin)
  - Positive direct antiglobulin (Coombs) test for C3
  - Cold agglutinin titer of  $\geq 64$  at 4°C
- 11.2 Age 18 years or older
- 11.3 Hemoglobin level  $\leq 10.0$  g/dL
- 11.4 Bilirubin level above normal reference range
- 11.5 Prescribed by or in consultation with a hematologist (blood doctor) or other CAD specialist
- 11.6 Presence of one or more symptoms associated with CAD: symptomatic anemia, acrocyanosis, Raynaud's phenomenon, hemoglobinuria, disabling circulatory symptoms, or a major adverse vascular event
- 11.7 Documented trial of cold avoidance efforts (utilizing warm clothing when outdoors, avoiding cold rooms or environments, cold liquids, etc)

### **12. Approval Period**

- 12.1 Initial Authorization will be placed for 12 months
- 12.2 All subsequent authorizations will be placed for 12 months, based upon clinical response to therapy

## CPT Codes

83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified [anti-chimeric antibody testing and/or chimeric anti-TNF antibody testing for Rituxan therapy]
96401 – 96450	Chemotherapy Administration

## HCPCS Codes

J9312	Injection, rituximab, 10 mg [Rituxan]
J9311	Injection, rituximab 10 mg and hyaluronidase [Rituxan Hycela]
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg

## References

1. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2021 Jul;73(7):924-939.
2. Neunert C, Terrell DR, Arnold DM, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. *Blood Adv*. 2019 Dec 10;3(23):3829-3866.
3. Chung SA, Gorelik M, Langford CA, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Polyarteritis Nodosa. *Arthritis Care Res (Hoboken)*. 2021 Aug;73(8):1061-1070.
4. Fanouriakis A, Kostopoulous M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. *Ann Rheum Dis*. 2019 Jun;78(6):736-745.
5. Maz M, Chung SA, Abril A, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of giant cell arteritis and Takayasu arteritis. *Arthritis Rheumatol*. 2021;73(8):1349-1365.
6. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. *Arthritis Rheumatol*. 2021 Aug;73(8):1366-1383.
7. Gokcebay DG, Tavit B, Fettah A, et al. Evaluation of children with chronic immune thrombocytopenic purpura and Evans syndrome treated with rituximab. *Clin Appl Thromb Hemost*. 2013 NovDec;19(6):663-7.
8. Weidenbusch M, Römmele C, Schröttele A, Anders HJ. Beyond the LUNAR trial. Efficacy of rituximab in refractory lupus nephritis. *Nephrol Dial Transplant*. 2013;28(1):106-111.
9. Tian X, Chen C, Ma L, et al. Efficacy and safety of rituximab in relapsing-remitting multiple sclerosis: A systematic review and meta-analysis. *J Neuroimmunol*. 2020 Oct 15;347:577317.
10. Thomas RM, Colon A, Motaparathi K. Rituximab in autoimmune pemphigoid diseases: Indications, optimized regimens, and practice gaps. *Clin Dermatol*. 2020 May-Jun;38(3):384-396.
11. Berentsen S, Barcellini W. Autoimmune Hemolytic Anemias. *N Engl J Med* 2021; 385:1407.
12. Berentsen S, Ulvestad E, Gjertsen BT, et al. Rituximab for primary chronic cold agglutinin disease: a prospective study of 37 courses of therapy in 27 patients. *Blood* 2004; 103:2925.
13. [Rituxan \(rituximab\)](#) Member Friendly (Plain Language) policy

Created Date: 08/01/12

Effective Date: 07/01/24

Posted to Website: 04/03/24

Revision Date: 04/03/24

#### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.