Policy Name:	Rituxan (rituximab) and biosimilars	Policy #:	1923P

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 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 (muscloskeletal 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 ≥64 at 4°C

11.2 Age 18 years or older

11.3 Hemoglobin level ≤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

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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.
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11. Berentsen S, Barcellini W. Autoimmune Hemolytic Anemias. N Engl J Med 2021; 385:1407.
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13. Rituxan (rituximab) Member Friendly (Plain Language) policy

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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.