Health Alliance™

Pharmacy Drug Policy & Procedure

Policy Name:	Rituxan, Ruxience, Truxima, Riabni (rituximab)	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

References

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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.
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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.
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

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DISCLAIMER
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