

POLICY NAME	Rituxan (rituximab) and biosimilars	POLICY #	1923P
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Criteria

Criteria for Coverage of Cancer-Related Indications

- ☐ See the Oncology Regimen Review policy.

Criteria for Coverage for Autoimmune Hemolytic Anemia

- ☐ Diagnosis of Autoimmune Hemolytic Anemia
- ☐ Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)

Criteria for Coverage for Evans Syndrome

- ☐ Diagnosis of Evans Syndrome
- ☐ Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)
- ☐ Documented failure, intolerance, or contraindication to azathioprine or cyclophosphamide
- ☐ Documented failure, intolerance, or contraindication to cyclosporine or mycophenolate

Criteria for Coverage for Immune (idiopathic) Thrombocytopenic Purpura

- ☐ Diagnosis of Immune (idiopathic) Thrombocytopenic Purpura
- ☐ Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)
- ☐ Documented failure, intolerance, or contraindication to immune globulin product
- ☐ Documentation of splenectomy or contraindication to splenectomy

Criteria for Coverage for Polyarteritis Nodosa

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

- ☐ Documented failure, intolerance, or contraindication to corticosteroids (such as methylprednisolone, prednisone)
- ☐ Documented failure, intolerance, or contraindication to azathioprine or cyclophosphamide

Criteria for Coverage for Rheumatoid Arthritis

- ☐ Diagnosis of Rheumatoid Arthritis
- ☐ Ordered by a Rheumatologist (musculoskeletal doctor)
- ☐ 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
- ☐ 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 Statement of the Policy Criteria
 - Simponi
 - Xeljanz/XR
 - Rinvoq
- ☐ Documented concurrent use of methotrexate with a preferred biologic immunomodulator

Criteria for Coverage for Systemic Lupus Erythematosus

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

Criteria for Coverage for Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA)

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

Criteria for Coverage for Multiple Sclerosis

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

Criteria for Coverage for Pemphigus Vulgaris (Rituxan Only)

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

Criteria for Coverage for Cold Agglutinin Disease

- ☐ 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
- ☐ Age 18 years or older
- ☐ Hemoglobin level ≤ 10.0 g/dL
- ☐ Bilirubin level above normal reference range
- ☐ Prescribed by or in consultation with a hematologist (blood doctor) or other CAD specialist
- ☐ 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
- ☐ Documented trial of cold avoidance efforts (utilizing warm clothing when outdoors, avoiding cold rooms or environments, cold liquids, etc)