Pharmacy Drug Policy Checklist

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

Criteria

Criteria for Coverage of Cancer-Related Indications

- ☐ **1.1** See the Oncology Regimen Review policy.

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)

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

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

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

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 Statement of the Policy Criteria
  - Simponi
  - Xeljanz/XR
  - Rinvoq
- [ ] **6.5** Documented concurrent use of methotrexate with a preferred biologic immunomodulator

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

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)

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)

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

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