

## rituximab

### Commercial Medical Benefit Drug Policy

rituximab (Rituxan)  
rituximab-abbs (Truxima)  
rituximab-arrx (Riabni)  
rituximab-pvvr (Ruxience)

#### Place of Service

Home Infusion  
Hospital Administration  
Infusion Center Administration  
Office Administration  
Outpatient Facility Infusion Administration

For oncology-related indications, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

Ruxience and Truxima are the preferred rituximab products. Request for Rituxan and Riabni for members requesting rituximabtherapy will require treatment failure or intolerance to all the preferred drugs or contraindication to all the preferred drugs for certain indications.

### Drug Details

**USP Category:** ANTINEOPLASTICS

**Mechanism of Action:** chimeric human-murine anti-human antigen CD20 monoclonal antibody

#### HCPCS:

J9312:Injection, rituximab, 10 mg  
Q5115:Injection, rituximab-abbs, biosimilar, (truxima), 10 mg  
Q5119:Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg  
Q5123:Injection, rituximab-arrx, biosimilar, (riabni), 10 mg

#### How Supplied:

100 mg/10 mL, 500 mg/50 mL (single-use)

#### **Condition(s) listed in policy** *(see coverage criteria for details)*

- ANCA-Associated Vasculitis, Microscopic Polyangiitis (MPA), and Granulomatosis with Polyangiitis (GPA) / Wegener's Granulomatosis
- Autoimmune Hemolytic Anemia (AIHA)
- Autoimmune Mucocutaneous Blistering Diseases (AMBDS)
- Graft Versus Host Disease (GVHD)
- Histiocytic Neoplasms for Rosai-Dorfman Disease
- Immunotherapy-Related Toxicities Secondary to Immune-Checkpoint Inhibitor Therapy
- Myasthenia Gravis

- Neuromyelitis Optica Spectrum Disorder
- Primary Immune Thrombocytopenia (ITP)
- Rheumatoid Arthritis (RA)
- Sjogren's Disease
- Solid Organ Transplants

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

### Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

### Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

#### **ANCA-Associated Vasculitis, Microscopic Polyangiitis (MPA), and Granulomatosis with Polyangiitis (GPA) / Wegener's Granulomatosis**

Meets medical necessity if all the following are met:

1. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

#### **Covered Doses:**

##### Treatment:

Adults:

375 mg/m<sup>2</sup> given intravenously (IV) once weekly for 4 doses, or  
1000 mg given IV on Days 1 and 15

Children:

375 mg/m<sup>2</sup> given IV once weekly for 4 doses, or  
BSA ≤ 1.5 m<sup>2</sup>: 575 mg/m<sup>2</sup> given IV on Days 1 and 15, or  
BSA > 1.5 m<sup>2</sup>: 750 mg/m<sup>2</sup> given IV on Days 1 and 15

##### Maintenance of Remission:

Adults:

1000 mg given IV every 4 months

Children:

250 mg/m<sup>2</sup> given IV every 6 months

**Coverage Period:**

Treatment: One course

Maintenance: Yearly

**ICD-10:**

I77.6, M30.1, M31.30, M31.31, M31.7

**Autoimmune Hemolytic Anemia (AIHA)****Meets medical necessity if all the following are met:**

1. Diagnosis of autoimmune hemolytic anemia (including AIHA following allogenic bone marrow transplantation)
2. If for cold-type AIHA, current HgB is less than or equal to 10 mg/dL, and not being used with complement inhibitors (i.e., Enjaymo)
3. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 375 mg/m<sup>2</sup> given intravenously once weekly for up to 4 weeks

**Coverage Period:**

One course

**ICD-10:**

D59.0, D59.10, D59.11, D59.12, D59.13, D59.19

**Autoimmune Mucocutaneous Blistering Diseases (AMBDS)****Meets medical necessity if all the following are met:**

1. Diagnosis of ONE of the following:
  - a. pemphigus foliaceus
  - b. pemphigus vulgaris
  - c. bullous pemphigoid
  - d. cicatricial pemphigoid
  - e. epidermolysis bullosa acquisita
2. Diagnosis is confirmed by lesional tissue biopsy or serology
3. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Initial treatment: up to 2,500 mg given intravenously for the first year of treatment, followed by maintenance treatment of up to 2,000 mg total per subsequent year

Maintenance treatment: Up to 2,000 mg total given intravenously per year

Dose for treatment of relapse: up to 1000 mg given intravenously x1 and no sooner than 4 months (16 weeks) after previous Rituxan infusion.

**Coverage Period:**

rituximab

Yearly

**ICD-10:**

L10.0, L10.2, L12.0, L12.1, L13.8

**Graft Versus Host Disease (GVHD)**

**Meets medical necessity if all the following are met:**

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants)
2. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 375 mg/m<sup>2</sup> given intravenously once weekly for up to 8 doses per course

**Coverage Period:**

Indefinite

**ICD-10:**

D89.810, D89.812, D89.813, T86.09

**Histiocytic Neoplasms for Rosai-Dorfman Disease**

**Meets medical necessity if all the following are met:**

1. Being used as a single agent
2. Being used for nodal and immune-cytopenia diseases
3. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 500 mg/m<sup>2</sup> given intravenously once every one or two weeks for up to 6 cycles

**Coverage Period:**

Length of time for use of 6 doses

**ICD-10:**

D76.3

**Immunotherapy-Related Toxicities Secondary to Immune-Checkpoint Inhibitor Therapy**

**Meets medical necessity if all the following are met:**

1. Treatment of the following immunotherapy-related toxicities secondary to immune-checkpoint inhibitor therapy:
  - a. Encephalitis for positive autoimmune encephalopathy antibody or refractory to pulse-dose methylprednisolone
  - b. Severe myasthenia gravis refractory to plasmapheresis or intravenous immune globulin (IVIG)
  - c. Moderate or severe bullous dermatitis
  - d. Steroid-refractory myalgias or myositis

2. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 1000 mg given intravenously for up to two doses

**Coverage Period:**

Per episode

**ICD-10:**

N17.9, D59.0, D59.2, D69.59, G04.81, G04.89, G04.90, G70.00, G70.01, L13.8, L13.9, M60.80, M60.811, M60.812, M60.819, M60.821, M60.822, M60.829, M60.831, M60.832, M60.839, M60.841, M60.842, M60.849, M60.851, M60.852, M60.859, M60.861, M60.862, M60.869, M60.871, M60.872, M60.879, M60.88, M60.89, M79.10, M79.11, M79.12, M79.18

**Myasthenia Gravis**

**Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a neurologist
2. Inadequate response to corticosteroids
3. ONE of the following:
  - a. Inadequate response or intolerance to at least one of the following: mycophenolate, azathioprine, cyclosporine, or cyclophosphamide
  - b. Patient has MuSK (muscle-specific tyrosine kinase)-Ab+ MG
4. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 375 mg/m<sup>2</sup> given intravenously once weekly for 4 doses every 6 months OR

Up to 1000 mg given intravenously for 2 doses, separated by a 2-week interval, every 6 months

**Coverage Period:**

Initial: Yearly

Reauthorization: Yearly, based upon continued response to treatment

**ICD-10:**

G70.00, G70.01

**Neuromyelitis Optica Spectrum Disorder**

**Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a neurologist
2. Not being used in combination with another drug therapy for NMOSD (e.g., eculizumab, inebilizumab, satralizumab)
3. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 375 mg/m<sup>2</sup> given intravenously once weekly for 4 doses every 6 months OR  
Up to 1000 mg given intravenously for 2 doses, separated by a 2-week interval every 6 months

**Coverage Period:**

Initial: Yearly (2 treatment courses)

Reauthorization: Yearly, with documented reduction in frequency of NMO attacks from baseline.

**ICD-10:**

G36.0

**Primary Immune Thrombocytopenia (ITP)**

**Meets medical necessity if all the following are met:**

1. Patient has chronic, refractory ITP
2. Platelet count <30,000/mcl (i.e. <30 x10<sup>9</sup>/L)
3. Either of the following:
  - a. Inadequate response to one of the following treatments: corticosteroids, IVIG, anti-D antibody, or splenectomy or medical rationale why these cannot be used
  - b. Inadequate response, intolerance, or contraindication to Promacta or NPlate after meeting step therapy requirements for either drug.
4. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 375 mg/m<sup>2</sup> given intravenously once weekly for 4 weeks

**Coverage Period:**

Cover for one course

**ICD-10:**

D69.3

**Rheumatoid Arthritis (RA)**

**Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a rheumatologist
2. Inadequate response, intolerable side effect, or contraindication to methotrexate
3. Not used in combination with another targeted immunotherapy (e.g., TNF inhibitors, IL-6 inhibitors, JAK inhibitors)
4. Inadequate response or intolerable side effect with two BSC-preferred agents (e.g., adalimumab-aacf, Enbrel, infliximab (Avsola or Inflectra), Rinvoq, Simlandi, and Xeljanz/Xeljanz XR), or contraindication to all preferred agents
5. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to two 1000 mg given intravenously and separated by 2 weeks, given every 6 months

**Coverage Period:**

Initial: 1 year

Reauthorization: Yearly

**ICD-10:**

(X=0-9) M05.XXX, M06.OXX, M06.2XX, M06.3XX, M06.8XX, M06.9

**Sjogren's Disease**

**Meets medical necessity if all the following are met:**

1. Diagnosis of primary Sjogren's disease
2. Prescribed by or in consultation with a rheumatologist or ophthalmologist
3. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Up to 375 mg/m<sup>2</sup> given intravenously once weekly for 4 doses every 6 months OR

Up to 1000 mg given intravenously for 2 doses, separated by a 2-week interval every 6 months

**Coverage Period:**

Initial: 1 year

Reauthorization: Yearly

**ICD-10:**

M35.00, M35.01, M35.02, M35.03, M35.04, M35.05, M35.06, M35.07, M35.08, M35.09, M35.0A, M35.0B, M35.0C

**Solid Organ Transplants**

**Meets medical necessity if all the following are met:**

1. Documented solid organ transplant, including pre/perioperative prevention or for treatment of antibody-mediated rejection of allograft
2. For Riabni or Rituxan: Intolerance or contraindication with the preferred products, Ruxience and Truxima, that is not expected with requested rituximab product

**Covered Doses:**

Given intravenously. Dose is highly variable

**Coverage Period:**

16 weeks per treatment course

**ICD-10:**

Z94.0, Z94.1, Z94.2, Z94.3, Z94.4, Z94.5, Z94.6, Z94.7, Z94.82, Z94.83, Z94.89, Z94.9

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### Review History

Date of Last Annual Review: 1Q2025

Changes from previous policy version:

- Rheumatoid arthritis Added Simlandi as a qualifying preferred drug (Rationale: Selection of preferred drugs is supported by similar safety and efficacy and are guideline supported agents)

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*