blue california
Promise Health Plan

rituximab

Medical Benefit Drug Policy

For oncology-related indications, coverage will be made based on medical necessity. Medical necessity determinations are made based on U.S. Food and Drug Administration (FDA) labeling, peer-reviewed medical literature, Medi-Cal coverage guidelines, and Centers for Medicare & Medicaid Services (CMS) approved compendia support (i.e., Clinical Pharmacology, National Comprehensive Cancer Network® (NCCN), American Hospital Formulary Service Drug Information, Thomson Micromedex DrugDex,® and Lexicomp®).

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

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

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- 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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:

Treatment:

Adults:

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

Children:

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

Maintenance of Remission:

Adults: Up to 1000 mg given IV every 4 months

Children: Up to 250 mg/m^2 given IV every 6 months

Coverage Period:

Treatment: One course
Maintenance: Yearly

ICD-10:
I77.6, M30.1, M30.3, 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
Up to 375 mg/m^2 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

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:
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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
Up to 375 mg/m^2 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
Up to 500 mg/m^2 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
Up to 375 mg/m^2 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
Up to 375 mg/m^2 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 x10^9/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)
4. For Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
Up to 375 mg/m^2 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. Meets ONE of the following:
   a. Inadequate response or intolerable side effect with preferred infliximab product (e.g., Avsola, Inflectra, Renflexis)
   b. Inadequate response or intolerable side effect with two prior targeted immunomodulators (e.g., Anti-TNFs, JAK inhibitors)
4. Not used in combination with another targeted immunotherapy (e.g., TNF inhibitors, IL-6 inhibitors, JAK inhibitors)
5. For Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

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, M06.0XX, 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

Covered Doses:
- Up to 375 mg/m^2 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 Rituxan: Intolerance or contraindication with the preferred products, Riabni, Ruxience, and Truxima, that is not expected with Rituxan

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:

- For oncology-related indications, coverage will be made based on medical necessity

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