Rituximab (Rituxan®) **Rituximab-abbs (Truxima®)** **Rituximab-arrx (Riabni™)** **Rituximab-pvvr (Ruxience™)**	**Place of Service** **Home Infusion** **Hospital Administration** **Office Administration** **Outpatient Facility Infusion Administration** **Infusion Center Administration** **HCPCS** **Rituxan: J9312** per 10 mg **Truxima: Q5115** per 10 mg **Ruxience: Q5119** per 10 mg **Riabni: Q5123** per 10 mg

Conditions listed in policy (*see criteria for details*)

- ANCA-associated vasculitis, microscopic polyangiitis, and granulomatosis with polyangiitis/ Wegener's granulomatosis
- Autoimmune hemolytic anemia
- Autoimmune mucocutaneous blistering diseases (AMBDs)
- B-cell mediated cancers
- Graft versus host disease
- Histiocytic neoplasms for Rosai-Dorfman disease
- Immunotherapy-related toxicities secondary to immune-checkpoint inhibitor therapy
- Leptomeningeal metastases
- Myasthenia gravis
- Neuromyelitis optica spectrum disorder
- Primary immune thrombocytopenia (ITP)
- Rheumatoid arthritis
- Sjogren's syndrome
- Solid organ transplants

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: chimeric human-murine anti-human antigen CD20 monoclonal antibody.

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for rituximab must be sent for clinical review and receive authorization prior to drug administration or claim payment.

ANCA-associated vasculitis, microscopic polyangiitis (MPA), and Granulomatosis with polyangiitis (GPA) / Wegener's granulomatosis

1. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Treatment:
Adults:
375 mg/m^2 IV infusion once weekly for 4 doses, or
1000 mg IV infusion on Days 1 and 15

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

Maintenance of remission:
Adults:
1000 mg IV infusion every 4 months

Children:
250 mg/m^2 IV infusion every 6 months

Coverage Period
Treatment: One course
Maintenance: Yearly

ICD-10:
ANCA positive vasculitis I77.6
Microscopic polyangiitis M31.7
Wegener's M30.1, M31.30, M31.31

Autoimmune hemolytic anemia (AIHA)

1. Diagnosis of autoimmune hemolytic anemia (including AIHA following allogenic bone marrow transplantation), **AND**
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), **AND**
3. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 375 mg/m^2 weekly for up to 4 weeks

Coverage Period
One course

ICD-10:
D59.0, D59.1

Autoimmune mucocutaneous blistering diseases (AMBDs)

1. Diagnosis of one of the following:
    a. pemphigus foliaceus
    b. pemphigus vulgaris

c. bullous pemphigoid
d. cicatricial pemphigoid
e. epidermolysis bullosa acquisita

AND

2. Diagnosis is confirmed by lesional tissue biopsy or serology, **AND**
3. Not used in combination with another immunomodulator, **AND**
4. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Initial treatment: up to 2,500 mg IV 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 per year
Dose for treatment of relapse: up to 1000 mg IV 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

B-cell mediated cancers

1. Diagnosis of one of the following:
    a. B-cell lymphomas (e.g., AIDS-related B-cell lymphomas, Burkitt, Castleman's disease, Diffuse large B-cell, Follicular lymphoma, Gastric MALT lymphoma, High-grade B-cell lymphomas, Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma, Mantle cell lymphoma, Nodal marginal zone lymphoma, Nongastric MALT lymphoma, Post-transplant lymphoproliferative disorders, Primary cutaneous B-cell lymphoma, Splenic marginal zone lymphoma)
    b. Acute lymphoblastic leukemia (ALL)
    c. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)
    d. Central nervous system cancers – leptomeningeal metastases or primary CNS lymphoma
    e. Hairy cell leukemia
    f. Hodgkin lymphoma, nodular, CD20+, lymphocyte-predominant
    g. Waldenstrom's macroglobulinemia / lymphoplasmacytic lymphoma, macroglobulinemia, or macroglobulinemia (idiopathic) primary

AND

2. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses and Coverage Period

	Per Treatment Course	Maintenance

• AIDS-related B-cell lymphomas • Burkitt lymphoma • Castleman's disease • Diffuse large B-cell lymphoma • High-grade B-cell lymphoma • Histologic transformation of marginal zone lymphoma to diffuse large B-cell lymphoma • Primary cutaneous B-cell lymphoma	375 mg/m^2 IV for up to 8 doses	
• Post -transplant lymphoproliferative disorders	375 mg/m^2 IV for up to 8 doses	375 mg/m^2 IV for up to 8 doses over 2 years
• Mantle cell lymphoma	375 mg/m^2 IV for up to 18 doses	375 mg/m2 IV every 2 months
• Gastric MALT lymphoma • Nodal marginal zone • Nongastric MALT lymphoma • Splenic marginal zone	375 mg/m^2 IV for up to 20 doses	375 mg/m2 IV for up to 12 doses over 2 years
• Follicular lymphoma	375 mg/m^2 IV for up to 16 doses	375 mg/m2 IV for up to 12 doses over 2 years
• Acute lymphoblastic leukemia (ALL)	375 mg/m^2 IV for up to 12 doses	375 mg/m^2 IV for up to 6 doses
• Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)	375 mg/m^2 IV for up to 15 doses 375 mg/m^2 IV for the 1st dose followed by 500 mg/m^2 IV for up to 7 doses	375 mg/m2 IV for 8 doses over 2 years 500 mg/m2 IV for 12 doses over 2 years
• Hairy cell leukemia	375 mg/m^2 IV up to 12 doses	
• Hodgkin lymphoma, nodular, CD20+, lymphocyte-predominant	375 mg/m^2 IV for up to 8 doses	375 mg/m^2 IV once weekly for 4 weeks for up to 4 treatments over 2 years
• Primary central nervous system lymphoma	500 mg/m^2 IV for up to 20 doses 25 mg intrathecal/intraventricular for up to 30 doses	25mg intrathecal/intraventricular every 2 weeks
• Waldenstrom's macroglobulinemia / lymphoplasmacytic lymphoma, macroglobulinemia, or macroglobulinemia (idiopathic) primary	375 mg/m^2 IV up to 20 doses	375 mg/m^2 IV weekly for 4 doses for up to 4 treatments for 2 years 375 mg/m2 IV for 8 doses over 2 years

ICD-10:
B20, C79.32, C81.00-C81.09, C82.00-C82.09, C82.60-C82.69, C82.10-C82.19, C82.20-C82.29, C82.30-C82.39, C82.40-C82.49, C82.50-C82.59, C82.60-C82.69, C82.80-C82.89, C82.90-C82.99, C83.00-C83.09, C83.10-C83.19, C83.30-C83.39, C83.50-C83.59, C83.70-C83.79, C83.80-C83.89, C83.90-C83.99, C85.20-C85.29, C85.80-C85.89, C88.0, C88.4, C91.00-C91.02, C91.10, C91.12, C91.40, C91.42, D36.0, D47.Z, D47.Z2, R59.0, R59.1, R59.9, Z85.71, Z85.72, Z85.79

Graft versus host disease

1. Inadequate response to at least one prior drug for GVHD (i.e., systemic corticosteroids, immunosuppressants), **AND**
2. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 375 mg/m^2 IV once weekly for up to 8 doses per course

Coverage Period
Indefinite

ICD-10:
D89.810, D89.12, D89.813, T86.09

Histiocytic neoplasms for Rosai-Dorfman disease

1. Being used as a single agent therapy, **AND**
2. Being used for nodal and immune-cytopenia diseases, **AND**
3. If request is for Rituxan or Truxima: Intolerable side effect with the preferred rituximab products, Ruxience and Riabni, that is not expected with the requested drug, or contraindication to Ruxience and Riabni

Covered Doses
Up to 500 mg/m^2 IV 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

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

AND

2. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 1000 mg per dose for up to two doses

Coverage Period
Per episode

ICD-10:
G04.81

Leptomeningeal metastases

1. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Initial Therapy or Retreatment of active disease:
Up to 25 mg intrathecal/intraventricular on Days 1 and 4 of a 7-day cycle for 4 cycles

Maintenance:
Up to 25 mg intrathecal/intraventricular on Days 1 and 4 of a 28-day cycle

Coverage Period
Initial and Retreatment of active disease:
Up to 8 doses per treatment course

Maintenance: Cover yearly

ICD-10:
C79.32

Myasthenia gravis

1. Prescribed by or in consultation with a neurologist, **AND**
2. Inadequate response to corticosteroids, **AND**
3. One of the following:
    a. Inadequate response or intolerance to at least one of the following: mycophenolate, azathioprine, cyclosporine, or cyclophosphamide, or
    b. Patient has MuSK (muscle-specific tyrosine kinase)-Ab+ MG,

AND

4. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 375 mg/m^2 IV infusion once weekly for 4 doses every 6 months OR
Up to 1000 mg IV infusion 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

1. Prescribed by or in consultation with a neurologist, **AND**

2. Not being used in combination with another drug therapy for NMOSD (e.g., eculizumab, inebilizumab, satralizumab), AND
3. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 375 mg/m^2 IV infusion once weekly for 4 doses every 6 months OR
Up to 1000 mg IV infusion 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)

1. Patient has chronic, refractory ITP, **AND**
2. Platelet count <30, 000/mcl (i.e. <30 x10-9/L), **AND**
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, OR
    b. Inadequate response, intolerance, or contraindication to Promacta or NPlate after meeting step therapy requirements for either drug.

AND

4. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 375 mg/m^2 weekly for 4 weeks

Coverage Period
Cover for one course

ICD-10:
D69.3

Rheumatoid arthritis

1. Prescribed by or in consultation with a Rheumatologist, **AND**
2. Inadequate response, intolerable side effect, or contraindication to methotrexate, **AND**
3. Either of the following:
    a. Inadequate response or intolerable side effect with preferred infliximab product (Avsola, Inflectra, Renflexis), or

b. Inadequate response or intolerable side effect with two prior targeted immunomodulators (eg. Anti-TNFs, JAK inhibitors)

AND

4. Not used in combination with Xeljanz or another targeted immunomodulator, **AND**
5. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to two 1000 mg IV infusions separated by 2 weeks, given every 6 months

Coverage Period
Initial: 1 year
Reauthorization: Yearly

ICD-10:
(X=0-9)
M05.X, M06.0X, M06.2X, M06.3X, M06.4, M06.8X, M06.9

Sjogren's disease

1. Diagnosis of primary Sjogren's disease, **AND**
2. Prescribed by or in consultation with a rheumatologist or ophthalmologist, **AND**
3. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Up to 375 mg/m2 IV infusion once weekly for 4 doses every 6 months OR
Up to 1000 mg IV infusion for 2 doses, separated by a 2-week interval every 6 months

Coverage Period
Initial: 1 year
Reauthorization: Yearly

ICD-10:
M35.0

Solid organ transplants

1. Documented solid organ transplant, including pre/perioperative prevention or for treatment of antibody-mediated rejection of allograft, **AND**
2. If request is for Rituxan: Intolerable side effect with the preferred rituximab products, Riabni, Ruxience and Truxima, that is not expected with Rituxan, or contraindication to all (Riabni, Ruxience and Truxima).

Covered Doses
Given intravenously. Dose is highly variable

Coverage Period
Initial: 16 weeks per treatment course

ICD-10:
Z94.0, Z94.1, Z94.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for rituximab must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Other hemolytic anemias (excluding autoimmune hemolytic anemia)
- Autoimmune thrombocytopenias (excluding ITP)
- Systemic Lupus Erythematosus
- Maintenance treatment of Non-indolent B cell lymphoma.

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
Rituxan, Truxima, Ruxience, Riabni:

- 100 mg/10 mL solution in a (single-use vial)
- 500 mg/50 mL solution in a (single-use vial)

(6) References

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- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
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- National Comprehensive Cancer Network. B-cell lymphomas (Version 2.2022). Available at http://www.nccn.org.
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- National Comprehensive Cancer Network. Waldenstrom macroglobulinemia/ Lymphoplasmacytic lymphoma (Version 2.2022). Available at http://www.nccn.org.
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- Riabni™ (rituximab-arrx) [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; 12/2020.
- Rituxan® (rituximab) [Prescribing Information]. South San Francisco, CA: Biogen-Idec/ Genentech; 2021.
- Ruxience® (rituximab-pvvr) [Prescribing Information]. New York, NY: Pfizer; 2021.
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(7) Policy Update

Date of last revision: 1Q2024
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following revision.