Rituximab (Rituxan®) **Rituximab-abbs (Truxima®)** **Rituximab-arrx (Riabni ™)** **Rituximab-pvvr (Ruxience™)**	**Medicare Part B** Blue Shield Medicare (PPO) **HCPCS** Rituxan: **J9312** per 10 mg Truxima: **Q5115** per 10 mg Ruxience: **Q5119** per 10 mg Riabni: **J9999**

Special Instructions and Pertinent Information

These drugs are covered when used to treat a medically accepted indication as established by 1) the Centers for Medicare & Medicaid Services (CMS), and 2) step therapy requirement with the BSC-preferred drugs, Ruxience and Riabni, when applicable.

CMS allows Medicare Advantage (MA) Plans to apply step therapy to physician-administered and other Part B drugs. Blue Shield of California (BSC) requires this drug to be reviewed for step therapy requirements in addition to CMS medical necessity requirements. Step therapy with the BSC-preferred drugs, Ruxience and Riabni, is required for members newly initiating rituximab therapy, when applicable.

Food and Drug Administration (FDA)-Approved Indications for Reference Product

- **Non-Hodgkin's lymphoma**
- **Chronic lymphocytic leukemia**
- **Rheumatoid arthritis**
- **Granulomatosis with polyangiitis / Wegener's granulomatosis and microscopic polyangiitis**
- **Pemphigus vulgaris**

Coverage Criteria for FDA-Approved Indications

Non-Hodgkin's lymphoma

1. 18 years and older, **AND**
2. One of the following:
    a. Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent, OR
    b. Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy, OR
    c. Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line, or cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy, OR
    d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.

    AND

3. One of the following:
    a. ***Through 3/31/2021:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience, OR
    b. ***Effective 4/1/2021 and after:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience and Riabni

Covered Doses

Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL

- Initial: 375 mg/m^2 IV once weekly for 4 or 8 doses
- Retreatment: 375 mg/m^2 IV once weekly for doses

Previously untreated, follicular, CD20-positive, B-cell NHL

- 375 mg/m^2 IV on Day 1 of each cycle of chemotherapy for up to 8 doses
- In patients with complete or partial response, start rituximab maintenance 8 weeks following completion of a rituximab product in combination with chemotherapy. Administer rituximab as a single-agent every 8 weeks for 12 doses.

Non-progressing, low-grade, CD20-positive, B-cell NHL, after first-line CVP chemotherapy following completion of 6−8 cycles of CVP chemotherapy

- 375 mg/m^2 IV once weekly for 4 doses at 6-month intervals to a maximum of 16 doses

Diffuse large B-cell NHL

- 375 mg/m^2 IV on Day 1 of each cycle of chemotherapy for up to 8 infusions

Coverage Period

Plan year

Chronic lymphocytic leukemia (CLL)

1. 18 years and older, **AND**
2. Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC), **AND**
3. One of the following:
    a. ***Through 3/31/2021:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience, OR
    b. ***Effective 4/1/2021 and after:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience and Riabni

Covered Doses

Up to 375 mg/m^2 IV in the first cycle and 500 mg/m^2 IV in cycles 2−6, in combination with FC, administered every 28 days

Coverage Period

Plan year

Rheumatoid arthritis

1. 18 years and older, **AND**
2. Used in combination with methotrexate, **AND**

3. Disease is moderately- to severely-active, **AND**
4. Inadequate response to one or more TNF antagonist therapies, **AND**
5. One of the following:
    a. ***Through 3/31/2021:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience, OR
    b. ***Effective 4/1/2021 and after:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience and Riabni

Covered Doses
Two-1000 mg IV separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks

Coverage Period
Plan year

Granulomatosis with polyangiitis / Wegener's granulomatosis and microscopic polyangiitis

1. 2 years of age and older, **AND**
2. Used in combination with glucocorticoids, **AND**
3. One of the following:
    a. ***Through 3/31/2021:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience, OR
    b. ***Effective 4/1/2021 and after:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience and Riabni

Covered Doses
Adult
Induction: Up to 375 mg/m^2 once weekly for 4 weeks.
Maintenance: Two-500 mg IV doses separated by two weeks, followed by 500 mg IV every 6 months thereafter

Pediatric
Induction: Up to 375 mg/m^2 once weekly for 4 weeks.
Maintenance: Two-250 mg/m^2 IV doses separated by two weeks, followed by 250 mg/m^2 IV every 6 months thereafter based on clinical evaluation

Coverage Period
Plan year

Pemphigus vulgaris

1. 18 years and older, **AND**
2. Disease is moderate to severe, **AND**
3. One of the following:
    a. ***Through 3/31/2021:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience, OR

b. ***Effective 4/1/2021 and after:*** For request for Rituxan or Truxima: Inadequate response, intolerable side effect, or contraindication with Ruxience and Riabni

Covered Doses
Initial treatment: Two-1000 mg IV doses separated by 2 weeks in combination with a tapering course of glucocorticoids, then 500 mg IV at Month 12 and every 6 months thereafter or based on clinical evaluation.

Relapse: 1000 mg IV; Subsequent infusions may be no sooner than 16 weeks after the previous infusion

Coverage Period
Plan year

How Supplied

Rituxan, Truxima, Ruxience:
- 100 mg/10 mL solution (single-use vial)
- 500 mg/50 mL solution (single-use vial)

References

- For CMS Memorandum titled "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage", dated August 7, 2018 see: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf
- Riabni™ (rituximab-arrx) [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc. 12/2020.
- Rituxan® (rituximab) [Prescribing information]. South San Francisco, CA: Genentech, Inc. 8/2020.
- Ruxience™ (rituximab-pvvr) [Prescribing information]. NY, NY: Pfizer, Inc. 5/2020.
- Truxima® (rituximab-abbs) [Prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc. 5/2020.

Policy Update

Date of last review: 1Q2021
Date of next review: 4Q2021
Changes from previous policy version:
- Added new biosimilar drug Riabni (rituximab-arrx) as a preferred rituximab drug.
  Rationale: Preference more cost-effective alternative.