Ascension
Personalized Care

Ascension

Rituximab

(Rituxan®) J9312

Covered with prior authorization

Rituximab (Rituxan®) may be authorized when the following criteria are met:

Oncology Indications
Requests for Rituxan® (rituximab) may be approved for oncology indications if the the following conditions are met:

- The individual has had a trial and intolerance to one biosimilar (preferred) agent; **OR**
- The individual is currently stabilized on requested rituximab (Rituxan®) agent; **AND**
- Dosing for Adult patients with Non-Hodgkin's Lymphoma (NHL) is 375 mg/m^2 **; OR**
- 250 mg/m^2 as a component of Zevalin® (Ibritumomab tiuxetan) with therapeutic regimen; **OR**
- Dosing for adult patients with Chronic Lymphocytic Leukemia (CLL) is 375 mg/m^2 in the first cycle and 500 mg/m^2 in cycles 2–6, in combination with FC, administered every 28 days.

Non-oncology indications
Requests for Rituxan® (rituximab) may be approved for non-oncology indications if the following conditions are met:

- The individual has had a trial and intolerance to one biosimilar (preferred) agent; **OR**
- Diagnosis of rheumatoid arthritis (RA); **AND**
- Individual is 18 years of age or older with moderate to severe RA; **AND**
- Individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
- If methotrexate is not tolerated or contraindicated, individual has had an inadequate response to, is intolerant of, or has a contraindication to other conventional therapy [sulfasalazine, leflunomide, or hydroxychloroquine]; **AND**
- Individual had an inadequate response, is intolerant of, or has a contraindication to one or more tumor necrosis factor (TNF) antagonist therapies; **AND**
- Dose, in combination with methotrexate, is two-1000 mg IV infusions separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks.
- Methylprednisolone 100 mg intravenous or equivalent glucocorticoid is recommended 30 minutes prior to each infusion.

OR

- Diagnosis of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA); **AND**
- Individual is 2 years of age or older; **AND**

- Individual is using concomitantly with glucocorticoids with or without avacopan for induction treatment; **OR**
- Individual is using as follow up treatment after achieving disease control with induction treatment; **AND**
- Dose is age-appropriate:
    - Adult Dosing:
        - Induction dosing: 375 mg/m^2 once weekly for 4 weeks.
        - Follow up dosing:two 500 mg intravenous infusions separated by two weeks, followed by a 500 mg intravenous infusion every 6 months thereafter based on clinical evaluation.
    - Pediatric Dosing:
        - Induction dosing: 375 mg/m^2 once weekly for 4 weeks.
        - Follow up dosing: two 250 mg/m^2 intravenous infusions separated by two weeks, followed by a 250 mg/m^2 intravenous infusion every 6 months thereafter based on clinical evaluation.

OR

- Diagnosis of moderate to severe pemphigus vulgaris (PV); **AND**
- Patient is 18 years or older (adult); **AND**
- Rituxan® is used as first-line treatment for moderate to severe pemphigus vulgaris; **OR**
- Disease is treatment-refractory; **AND**
- Dosing is two-1,000 mg intravenous infusions separated by 2 weeks in combination with a tapering course of glucocorticoids, followed by 500 mg intravenous infusion at Month 12 and every 6 months thereafter or based on clinical evaluation; **OR**
- Relapse dosing a 1,000 mg intravenous infusion with considerations to resume or increase the glucocorticoid dose based on clinical evaluation. Subsequent infusions may be no sooner than 16 weeks after the previous infusion.

AND

- Prescriber specialty is in Oncology, Hematology, Rheumatology, Nephrology, Neurology, or Dermatology

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
rituximab-abbs, biosimilar, Truxima [Q5155]	Rituximab RITUXAN®
rituximab-pvvr, biosimilar, Ruxience [Q5119]	
rituximab-arrx, biosimilar, Riabni [Q5123]	

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Rituxan® (rituximab) is a CD20-directed cytolytic antibody indicated for the treatment of:

- Adult patients with Non-Hodgkin's Lymphoma (NHL)
  - Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent.
  - 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.
  - Non-progressing (including stable disease), low-grade, CD20 positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
  - Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens.
- Adult patients with Chronic Lymphocytic Leukemia (CLL).
  - Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).
- Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies
- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids.
- Moderate to severe Pemphigus Vulgaris (PV) in adult patients.

References:
Ascension. (2021, April). *Rituximab Clinical Evaluation SBAR*. TAG INITIATIVES - PSWP. Retrieved April 22, 2022, from Internal Ascension Google Drive

Burmester, G., Drescher, E., Hrycaj, P., Chien, D., Pan, Z., & Cohen, S. (2020, November). efficacy and safety results from a randomized double-blind study comparing proposed biosimilar ABP 798 with rituximab reference

product in subjects with moderate-to-severe rheumatoid arthritis. *Clinical Rheumatology*, *39*(11), 3341-3352. 10.1007/s10067-020-05305-y

Rituxan® *(rituximab) label*. (2021, June). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103705s5464lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2021	Ascension Therapeutic Affinity Group (TAG) published the *Rituximab Clinical Evaluation SBAR*
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team.

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