PrimeWest HEALTH™
Your greater Minnesota health plan
3905 Dakota St
Alexandria, MN 56308
primewest.org

Rituximab (Rituxan) and rituximab-hyaluronidase (Rituxan Hycela) Part B Step Therapy Criteria

Effective 1/1/2022
Reviewed 02/2023

- Documentation demonstrates member has used requested therapy in previous 365 days; OR:
- Clinical reasoning why rituximab biosimilar cannot be used, such as contraindication to or adverse event from biosimilar; AND:
- Use is for FDA-approved indication and dosing; AND:
- If Rituxan Hycela, why IV biosimilar cannot be used; AND:
- Meets criteria for FDA approved diagnosis below:

I. Initial Approval Criteria

A. B-Cell Lymphomas (includes CLL) (must meet all):
   1. Diagnosis of any of the following non-Hodgkin's lymphoma (NHL) subtypes (a-m):
      a. AIDS-related B-cell lymphomas
      b. B-cell acute leukemia
      c. Burkitt lymphoma or Burkitt-like lymphoma;
      d. Castleman's disease
      e. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
      f. Diffuse large B-cell lymphoma (DLBCL)
      g. Follicular lymphoma (FL)
      h. Hairy cell leukemia;
      i. Low- or high-grade B-cell lymphoma
      j. MALT lymphoma (gastric or non-gastric)
      k. Mantle cell lymphoma
      l. Marginal zone lymphoma (nodal or splenic)
      m. Post-transplant lymphoproliferative disorder
      n. Primary cutaneous B-cell lymphoma
   2. Prescribed by or in consultation with an oncologist or hematologist
   3. Member meets one of the following (a or b):
      a. Age ≥ 18 years
      b. Age < 18 years with mature B-cell lymphoma
   4. Member must have tried and failed two biosimilars such as, but not limited to, Truxima, Riabni, and Ruxience or have a contraindication
   5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors
   6. Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 6 months

B. Rheumatoid Arthritis (must meet all):
   1. Diagnosis of RA
   2. Prescribed by or in consultation with a rheumatologist;

3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
    a. Failure of a ≥ 3 consecutive month trial of MTX at up to maximally indicated doses;
    b. Member has intolerance or contraindication to MTX, and failure of a ≥ 3 consecutive month trial of at least ONE conventional disease-modifying antirheumatic drug [DMARD] (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of Avsola, Inflectra, Ixifi, or Renflexis, unless contraindicated or clinically significant adverse effects are experienced;
6. Documentation of one of the following baseline assessment scores (a or b):
    a. Clinical disease activity index (CDAI) score;
    b. Routine assessment of patient index data 3 (RAPID3) score;
7. Member must have tried and failed Truxima, Riabni, and Ruxience or have a contraindication
8. Administered in combination with MTX unless contraindicated or clinically significant adverse effects are experienced;
9. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors;
10. Dose does not exceed two-1,000 mg IV infusions separated by 2 weeks followed by two-1,000 mg IV infusions every 16 weeks.

Approval duration: 6 months

C. Granulomatosis with Polyangiitis (Wegener's Granulomatosis) and Microscopic Polyangiitis (must meet all):
    1. Diagnosis of GPA or MPA;
    2. Prescribed by or in consultation with a rheumatologist;
    3. Age ≥ 2 years;
    4. For age ≥ 18 years, member must have tried and failed Truxima, Riabni, and Ruxience or have a contraindication
    5. Prescribed in combination with a glucocorticoid (e.g. prednisone, prednisolone, dexamethasone);
    6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors;
    7. Dose does not exceed (a or b):
        a. Induction: 375 mg/m2 weekly for 4 weeks;
        b. Follow up treatment: two-500 mg infusions separated by 2 weeks, then 500 mg every 6 months.

Approval duration: 6 months

D. Pemphigus Vulgaris and Pemphigus Foliaceus (must meet all):
    1. Diagnosis of PV or pemphigus foliaceus (PF);
    2. Prescribed by or in consultation with a dermatologist;
    3. Age ≥ 18 years;
    4. Member must have tried and failed Truxima, Riabni, and Ruxience or have a contraindication
    5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors;
    6. Dose does not exceed (a or b):
        a. Initial: two-1,000 mg infusions separated by 2 weeks;

b. Maintenance: 500 mg every 6 months (starting 12 months after initial dose).

Approval duration: 6 months

II. Continued Approval

1. For PV or PF: Member is responding positively to therapy, or member has experienced relapse; OR
2. For RA: member is responding positively to therapy as evidenced by one of the following (i or ii):
   a. A decrease in CDAI (see Appendix G) or RAPID3 (see Appendix H) score from baseline;
   b. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;

   OR:

   For all other indications: Member is responding positively to therapy;

   AND:

   Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors;

   AND:

   If request is for a dose increase, new dose is supported by practice guidelines or peer-reviewed literature

Approval duration: 12 months

References

1. Micromedex, (electronic version), IBM Watson Health information, URL address (https://www.micromedexsolutions.com/) date accessed 12/2022.
2. 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.
3. Rituxan® intravenous infusion [prescribing information]. South San Fransisco, CA: Genentech,Inc.; December 2021 2.
4. Rituxan Hycela™ injection for SC use [prescribing information]. South San Francisco, CA:Biogen and Genentech/Roche; June 2021.
5. Truxima [prescribing information]. North Wales, PA: Teva Pharmaceuticals;February 2022.
6. Ruxience [prescribing information]. Cork, Ireland: Pfizer; July 2019.