RITUXAN

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Length of Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituxan</td>
<td>rituximab</td>
<td>Per Medical Guidelines</td>
</tr>
</tbody>
</table>

**Approvable Criteria:**

1. Is the member 18 years of age or older?
   - If yes continue to #2
   - If no, do not approve.

2. Has the member been diagnosed with moderately to severely active Rheumatoid Arthritis?
   - If yes, continue to #3.
   - If no, continue to #6.

3. Has the member tried and failed a one month trial of one or more disease-modifying antirheumatic drugs (DMARDS), such as methotrexate, hydroxychloroquine, sulfasalazine, azathioprine, or leflunomide?
   - If yes, continue to #4.
   - If no, do not approve.

4. Has member tried and failed a one month trial of Remicade, Enbrel, or Cimzia?
   - If yes, continue to #5.
   - If no, do not approve.

5. Has the member been treated with Rituxan within the past 4 months?
   - If yes, do not approve.
   - If no, approve for 1 month (see dosing below). Repeated courses of Rituxan may be approved every 4 months.

6. Is the member diagnosed with Non-Hodgkin’s Lymphoma (NHL) or Chronic Lymphocytic Leukemia (CLL) and Rituxan is prescribed by, or in consultation with, an oncologist?
   - If yes, approve for 6 months (approve per dosing schedule below).
   - If no, continue to #7.

7. Will Rituxan be used for the treatment of Wegener’s Granulomatosis or Microscopic Polyangiitis in combination with glucocorticoids?
   - If yes, approve for once weekly dosing for 4 weeks.
   - If no, do not approve.

**FDA-Approved Indications:**

**RA:** Rituximab is given as two 1,000 mg IV infusions separated by 2 weeks. Rituximab is given in combination with methotrexate. Glucocorticoids administered as methylprednisolone 100 mg IV or its equivalent 30 minutes prior to each infusion are recommended to reduce the incidence and severity of infusion reactions. Safety and efficacy of re-treatment have not been established in controlled trials.

Continued on Following Page...
RITUXAN

- **Re-treatment in members with RA:** Safety and efficacy of re-treatment have not been established in controlled trials. A limited number of patients have received 2 to 5 courses (2 infusions per course) of treatment in an uncontrolled setting. In clinical trials in patients with RA, most of the patients who received additional courses did so 24 weeks after the previous course and none were re-treated sooner than 16 weeks.

**NHL:** Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL: 375 mg/m² given as an intravenous (IV) infusion once weekly for 4 or 8 doses.

- **Previously untreated follicular, CD20-positive, B-cell NHL in combination with chemotherapy:** 375 mg/m² IV infusion given on day 1 of each cycle of chemotherapy, for up to 8 doses.

- **Maintenance therapy for follicular, CD20-positive, B-cell NHL in patients who have achieved a complete or partial response following first-line treatment with Rituxan in combination with chemotherapy:** 375 mg/m² IV every 8 weeks for 12 doses as maintenance therapy starting 8 weeks after completion of induction chemotherapy with 8 doses of Rituxan plus 6-8 cycles of cyclophosphamide, vincristine, and prednisone (R-CVP); 4-6 cycles of cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP); or 4-6 cycles of fludarabine, cyclophosphamide.

- **Maintenance therapy for low-grade, CD20-positive, B-cell NHL in patients with nonprogressing disease following first-line treatment with cyclophosphamide, vincristine, and prednisone (CVP):** 375 mg/m² IV infusion given once weekly for 4 weeks repeated every 6 months for up to 2 years (16 doses) starting 4 weeks after the completion of first-line chemotherapy with 6 to 8 cycles of cyclophosphamide, vincristine, and prednisone (CVP).

- **Diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimen:** 375 mg/m² IV infusion given on day 1 of each cycle of chemotherapy for up to 8 infusions.

**CLL:** In combination with fludarabine and cyclophosphamide for the treatment of patients with previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL).

Continued on Following Page...
**Wegener’s Granulomatosis and Microscopic Polyangiitis:** In combination with glucocorticoids. Adults: 375 mg/m² IV once weekly for 4 weeks, with glucocorticoids to begin within 14 days before rituximab use or along with its initiation. Administer methylprednisolone 1000 mg/day IV for 1-3 days then oral prednisone 1 mg/kg/day up to 80 mg/day; taper per clinical need. Glucocorticoid receipt may continue during and after the 4-week rituximab course. The safety and efficacy of subsequent rituximab course have not been established.

*For Baptist Health Plan to recognize a chemotherapy regimen as an accepted approach to treatment it must be included in the National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology (NCCN Guidelines®).*

---

*References:*