RITUXAN® (rituximab)  
Pharmacy Coverage Policy

Brand Name | Generic Name  | GPI                  | Drug Class               |
------------|--------------|----------------------|--------------------------|
RITUXAN     | rituximab    | 213530600013**       | Monoclonal Antibody      |

CRITERIA FOR COVERAGE/NONCOVERAGE

RITUXAN® (rituximab) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The patient is 18 years of age or older
- The patient has a diagnosis one of the following diagnoses:
  - Non-Hodgkin’s lymphoma (NHL)
  - Chronic lymphocytic leukemia (CLL)
  - Granulomatosis with polyangiitis (GPA; Wegener’s granulomatosis) AND is receiving concurrent glucocorticoid therapy
  - Microscopic polyangiitis (MPA) AND is receiving concurrent glucocorticoid therapy
  - Moderate to severe rheumatoid arthritis (RA) AND
    - Medication will be used in combination with methotrexate AND
    - Patient has had an inadequate response to, intolerance to, or contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs; see Table 1) for at least 3 consecutive months AND
    - Patient has failed to achieve symptom control after an adequate therapy with, is intolerant to, or is contraindicated to both adalimumab [HUMIRA®] AND certolizumab pegol [CIMZIA]
  - Lymphocyte Predominant CD20+ Hodgkin Lymphoma
  - Acquired hemophilia/Factor VIII inhibitor and patient is resistant to standard immune tolerance
  - Autoimmune Hemolytic Anemia and patient has tried and had an inadequate response to steroids.
  - GVHD, chronic, steroid refractory
  - Relapsed/refractory Hairy cell leukemia in combination with purine analogs
  - Idiopathic thrombocytopenic Purpura and Patient has tried and had an inadequate response to corticosteroids, IVIG, or splenectomy.
  - Pemphigus vulgaris, severe
  - Primary Sjogren’s syndrome
  - Waldenstrom macroglobulinemia/Lymphoplasmacytic Lymphoma
### Table 1: Non-biologic Disease-Modifying Anti-rheumatic Drugs (DMARDs)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Treatment Period</th>
<th>Usual Maintenance Dose</th>
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</thead>
<tbody>
<tr>
<td>Hydroxychloroquine</td>
<td>2 to 6 months</td>
<td>200 mg twice daily</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>1 to 3 months</td>
<td>1000 mg 2 to 3 times daily</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>1 to 2 months</td>
<td>7.5-20 mg weekly</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>4 to 12 weeks</td>
<td>10-20 mg daily</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>2 to 3 months</td>
<td>50-150 mg daily</td>
</tr>
<tr>
<td>Cyclosporine</td>
<td>2 to 4 months</td>
<td>2.5-4 mg/kg/day</td>
</tr>
</tbody>
</table>

AND
- Patient has been screened for hepatitis B virus infection AND does not have HBV reactivation AND
- Patient does not have a severe, active infection (including HBV infection) AND
- The medication will not be used in combination with another biologic agent.

**Initial Authorization Duration:**
- RA: 1 month
- All other indications: 6 months

**Reauthorization Criteria and Duration:**
Authorization for continued use shall be reviewed when the following criteria are met:
- Patient has stable disease or has improved while on therapy (e.g., improvement in tender/swollen joint count, improvement in ACR scoring, or remission or low disease activity).
- It has been at least 16 weeks since the last course of treatment.

Authorization for continued use of RITUXAN will be every 6 months for all other indications to confirm that current coverage policy criteria are met.

Off label uses for oncology drugs are approvable if considered medically acceptable as described in the Supporting Information section.

RITUXAN (rituximab) is considered experimental/investigational for conditions not listed in this coverage policy section.