Rituximab
[Rituxan (rituximab), Riabni (rituximab-arrx), Ruxience (rituximab-pvvr) or Truxima (rituximab-abbs)]

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year; unless state regulations require otherwise</td>
</tr>
</tbody>
</table>

Medications
- Rituxan (rituximab)
- Riabni (rituximab-arrx)
- Ruxience (rituximab-pvvr)
- Truxima (rituximab-abbs)

Rituximab Dosing Limit

<table>
<thead>
<tr>
<th>Drug</th>
<th>Limit Per Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituxan (rituximab) 100 mg, 500 mg vial; Riabni (rituximab-arrx) 100 mg, 500 mg vial; Ruxience (rituximab-pvvr) 100 mg, 500 mg vial; Truxima (rituximab-abbs) 100 mg, 500 mg vial.</td>
<td><strong>Rheumatoid arthritis (RA):</strong> 1000 mg on days 1 and 15; repeated as frequent as every 16 weeks <strong>Pemphigus Vulgaris &amp; other autoimmune blistering skin diseases; maintenance:</strong> 500 mg as frequently as every 16 weeks* <strong>Granulomatosis with Polyangiitis (GPA) and Microscopic Polyangiitis (MPA) maintenance:</strong> 500 mg every 6 months† <strong>Myasthenia Gravis:</strong> 375 mg/m² monthly (DP)^ <strong>Autoimmune Hemolytic Anemia:</strong> 375 mg/m² weekly for 4 weeks (DP) <strong>Idiopathic Thrombocytopenic Purpura:</strong> 375 mg/m² weekly for up to 6 weeks (DP) <strong>Primary Sjogren’s Syndrome:</strong> 1000 mg on days 1 and 15 (2000 mg total) (DP)</td>
</tr>
</tbody>
</table>

Override Criteria
*For initiation of therapy, may approve two 1000mg doses separated by 2 weeks. May also approve one 1000 mg infusion upon relapse.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0686-21
### APPROVAL CRITERIA

**Non-oncologic Indications**

Requests for Rituxan (rituximab), Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), or Truxima (rituximab-abbs) may be approved for the following:

I. **Rheumatoid arthritis (RA)** when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe (RA); **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, leflunomide, or hydroxychloroquine)] (ACR 2015); **AND**
   C. Individual had an inadequate response, is intolerant of, or has a contraindication to one or more tumor necrosis factor (TNF) antagonist therapies;

**OR**

II. **Granulomatosis with Polyangiitis and Microscopic Polyangiitis (MPA)** when each of the following criteria are met:
   A. Individual is 2 years of age or older with Granulomatosis with Polyangiitis and MPA; **AND**
   B. Individual is using concomitantly with glucocorticoids;

**OR**

III. **Autoimmune blistering skin diseases** (such as but not limited to pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, cicatricial pemphigoid, epidermolysis bullosa acquisita and paraneoplastic pemphigus) (Ahmed 2016, Maley 2016) when either of the following criteria are met:
   A. As first-line treatment in adults with moderate to severe pemphigus vulgaris; **OR**
   B. Disease is treatment-refractory;

**OR**

IV. **Acquired inhibitors in individuals with hemophilia who fail cyclophosphamide and prednisone therapy** (Collins 2009, Rossi 2016); **OR**
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Market Applicability

<table>
<thead>
<tr>
<th>Market</th>
<th>GA</th>
<th>KY</th>
<th>MD</th>
<th>NJ</th>
<th>NY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

**OR**

XIV. Antibody-mediated solid organ transplant rejection (KDIGO 2009, ISHLT 2010);

**OR**

XV. Thrombocytopenic purpura, immune or idiopathic (ASH 2019);

**OR**

XVI. Immune mediated thrombotic thrombocytopenic purpura (TTP) when each of the following criteria are met (Scully 2012):
   A. TTP is confirmed by severely reduced baseline activity of ADAMTS 13 (less than 5%), with the presence of an ADAMTS 13 inhibitor; **AND**
   B. Individual has refractory or relapsing disease as defined by lack of response to plasma exchange therapy and glucocorticoids;

**OR**

XVII. Myasthenia gravis when the following criteria are met (MGFA 2016, DP B I):
   A. Individual is 18 years of age or older with myasthenia gravis; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to two or more immunosuppressive drug agents (such as azathioprine, cyclosporine, or methotrexate);

**OR**

XVIII. Autoimmune encephalitis (AE) when the following criteria are met (Zuliani 2019, Lancaster 2016):
   A. Diagnosis is confirmed by detection of a specific autoantibody associated with AE [including but not limited to: NMDAR, LGI1, Caspr2, AMPAR, GABA-A or GABA-B receptor, IgLON5, DPPX, GlyR, mGluR1, mGluR2, mGluR5, Neurexin 3-alpha, or dopamine-2 receptor (D2R)]; **AND**
   C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to first line agent(s) including immunoglobulin therapy or plasma exchange.

Requests for Rituxan (rituximab), Riabni (rituximab-arrx), Truxima (rituximab-abbs), or Ruxience (rituximab-pvvr) may not be approved when the above criteria are not met and for all other non-oncologic indications.

**Oncologic indications**

Requests for a Rituxan (rituximab) for an **oncologic indication** may be approved when the following criteria are met:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and intolerance to Riabni (rituximab-arrx), OR Ruxience (rituximab-pvvr), OR Truxima (rituximab-abbs).

**OR**

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II. Individual is currently stabilized on Rituxan (rituximab).

Key References:

8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.


Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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