Medical Coverage Criteria
Rituxan® (rituximab)

This document contains the most current medical coverage criteria using guidance from experts and approved by the Physicians Plus Pharmacy and Therapeutics Committee. This document remains dynamic and will be updated from time to time as new evidence becomes available reflecting substantive changes in care. The most recent version of the medical coverage criteria can be found at www.pplusic.com.

Boxed Warning (see full prescribing information for complete boxed warning)

1. Fatal infusion reactions within 24 hours of Rituximab infusion occur; approximately 80% of fatal reactions occurred with first infusion.
2. Tumor lysis syndrome manifested as acute renal failure, hyperkalemia, hypocalcemia, hyperuricemia, or hyperphosphatemia from tumor lysis, some fatal, can occur within 12−24 hours after the first infusion of Rituximab in patients with NHL.
3. Mucocutaneous reactions, some with fatal outcome, can occur in patients treated with Rituximab. These reactions include paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, vesiculobullous dermatitis, and toxic epidermal necrolysis.
4. Progressive multifocal leukoencephalopathy (PML) occur with hematologic malignancies or with autoimmune disease.

FDA Indications (see full prescribing information for disease specific dosage and administration)

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 Rituxan 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 CVP chemotherapy.
• Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL)
• In combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL.

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.

Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA)
• In adult patients in combination with glucocorticoids

Medical Coverage Criteria
Rituxan® (rituximab)

**Member and Prescriber Information**

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<th>Member Name:</th>
<th>Prescriber Name:</th>
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<th>Member Date of Birth:</th>
<th>Prescriber Phone:</th>
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<tr>
<th>Member PCP Name &amp; Address:</th>
<th>Name &amp; Location of Infusion Center:</th>
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**Criteria**

Complete patient specific and condition specific criteria.
Submit all pages of rituximab Criteria for Coverage document.

Diagnosis of non-FDA approved indications require condition specific specialist referral and submission of institutional treatment guidelines and medical record documentation outlining the treatment and follow-up plan.

**Current status of patient therapy** (check a box)

- [ ] New to rituximab therapy
- [ ] Continuing rituximab therapy
- [ ] Primary use in condition that is non-FDA approved

**Primary indication being treated:**

- [ ] Patient does not have history of Hepatitis B
- [ ] Patient is not pregnant
- [ ] Patient has had a splenectomy
- [ ] Corticosteroid intolerant
- [ ] Other chemotherapeutic agent intolerant
- [ ] Patient undergoes dialysis
- [ ] Other: ____________________________

**Patient Specific Factor(s):** (check all that apply)

- [ ] Patient does not have history of Hepatitis B
- [ ] Patient is not pregnant
- [ ] Patient has had a splenectomy
- [ ] Corticosteroid intolerant
- [ ] Other chemotherapeutic agent intolerant
- [ ] Patient undergoes dialysis
- [ ] Other: ____________________________

**Drug Regimen Detail**

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<th>Anticipated Start Date:</th>
<th># of Cycles:</th>
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<th>Cycle Frequency:</th>
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**Sign and Date**

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Mail or Fax this form and clinical documentation using the number below.

**Mailing Address**
Physicians Plus Insurance Corporation
Attn: Pharmacy Services
P.O. Box 2078
Madison, WI 53701-2078

**Physicians Plus Pharmacy Services Fax**
(608) 327-0324

**Prior Authorization Questions**
(608) 260-7803 or (800) 545-5015
www.pplusic.com/providers
**Medical Coverage Criteria**

**Rituxan® (rituximab)**

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**Condition Specific Criteria**
(complete and submit this page, too)

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- **Step 1:** Choose primary condition being treated
- **Step 2:** Select condition criteria that apply
- **Step 3:** Check all treatment criteria that apply

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- □ Non-Hodgkins lymphoma

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- □ Chronic lymphocytic leukemia

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- □ Rheumatoid arthritis (RA)
  - □ Moderate to severe active RA
  - □ Failed at least two of the following:
    - □ Etanercept (Enbrel)
    - □ Abatacept
    - □ Adalimumab (Humira)
    - □ Golimumab
  - □ Failed methotrexate or Leflunomide in combination with another DMARD
  - □ Failed trial of Infliximab

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- □ ANCA vasculitides
  - □ Wegener’s granulomatosis
  - □ Microscopic polyangitis
  - □ Churg-Strauss Syndrome
  - □ Pauci-Immune nephritis
  - □ Used in combination with corticosteroids
  - □ Failed cyclophosphamide regimen
  - □ Other:________________________

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- □ Post transplant lymphoproliferative disorder
  - □ Transplant:____________________
  - □ Not a surgical candidate
  - □ Chemotherapy contraindicated
  - □ Antiviral agent not indicated

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- □ Thrombocytopenia purpura
  - □ Primary immune
  - □ Idiopathic
  - □ Splenectomy
  - □ Unresponsive to corticosteroids
  - □ Intolerant to corticosteroids

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- □ Refractory autoimmune hemolytic anemia

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- □ Prophylaxis of rejection of kidney transplant with donor specific antibodies

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- □ Waldenstrom’s macroglobulinemia

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- □ Pemphigus vulgaris or Foliaceous
  - □ Failed corticosteroid therapy

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Remember to sign and date request form before submitting