Prior Authorization Approval Criteria

Rituxan (Rituximab)

Generic name: Rituximab
Brand name: Rituxan
Medication class: CD20-directed cytolytic antibody

FDA-approved uses:
- Non-Hodgkin’s Lymphoma (NHL)
- Chronic Lymphocytic Leukemia (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
- Granulomatosis with Polyangiitis (GPA) (Wegener’s Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids

Criteria for approval (bullet points below are all inclusive unless otherwise noted):

FDA-approved uses:
- **NHL or CLL**
  - Patients must be clinically diagnosed with NHL or CLL
  - Patient’s disease is CD20 positive
  - Must be prescribed by an oncologist or hematologist
  - Patients must be 18 years and older
- **RA**
  - Patients must be 18 years and older
  - Patients must be clinically diagnosed RA
  - Must be prescribed by a rheumatologist
  - Must be used in combination with methotrexate unless contraindicated or patient has an intolerance to methotrexate
  - Tried and failed or been intolerant to each of the following:
    - Enbrel
    - Humira
    - Remicade
  - Medical services must meet nationally recognized standard for quality care and are provided at the appropriate level of care and place of service. The first two doses for RA patients may be given at the facility of choice by the physician, and all subsequent doses will be given by home infusion. The following are some exceptions that may be acceptable for services outside the home:
    - Documented history of a severe reaction to Rituxan. The patient should have a history of reactions and not be based on the potential of Rituxan to induce such reactions.
    - Documented intolerance to Rituxan requiring constant telemetry monitoring of vitals.

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
• Unsafe home environment.
• No access to 911 services.
• Patient is severely decompensated.

• GPA and MPA
  o Patients must be clinically diagnosed with GPA or MPA
  o Patients must be 18 years and older
  o Must be used in combination with glucocorticoids
  o Must have tried and failed or have a contraindication to the use of methotrexate

Off-Label Uses:
• Hairy Cell Leukemia
  o Patients must be clinically diagnosed with Hairy Cell Leukemia
  o Must be prescribed by an oncologist or hematologist
  o Patient has relapsed or had less than a complete response after being treated with Cladribine and Pentostatin

• Mantle Cell Lymphoma
  o Patients must be clinically diagnosed with Mantle Cell Lymphoma
  o Must be prescribed by an oncologist or hematologist

• Primary Cutaneous B-cell Lymphoma
  o Patients must be clinically diagnosed with Primary Cutaneous B-cell Lymphoma
  o Must be prescribed by an oncologist or hematologist

• Post-Transplant Lymphoproliferative Disorder
  o Patients must be clinically diagnosed with Post-Transplant Lymphoproliferative Disorder
  o Patient’s disease is CD20 positive
  o Patient has had a solid organ transplant or allogeneic hematopoietic stem cell transplantation.
  o Must be prescribed by an oncologist or hematologist or transplant specialist

• Hodgkin’s Lymphoma
  o Patients must be clinically diagnosed with Hodgkin’s Lymphoma
  o Patient’s disease is CD 20 positive
  o Rituxan is used as monotherapy
  o Must be prescribed by an oncologist or hematologist

• Neuromyelitis Optica
  o Patients must be clinically diagnosed with Neuromyelitis Optica
  o Must be prescribed by a neurologist

• Autoimmune Hemolytic Anemia
  o Patients must be clinically diagnosed with Primary Autoimmune Hemolytic Anemia or Primary Cold Autoimmune Hemolytic Anemia (cold agglutinin

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• **Primary Warm Autoimmune Hemolytic Anemia**
  - Patient must have tried and failed or have a contraindication to the use of corticosteroids

• **Primary Cold Autoimmune Hemolytic Anemia**
  - Meets indication for treatment:
    - Symptomatic anemia
    - Transfusion dependence and/or
    - Severe circulatory symptoms
  - If Rituximab is used in combination therapy rituximab must be used in combination with interferon, prednisone or fludarabine

• **Waldenström’s Macroglobulinemia/Lymphoplasmacytic Lymphoma**
  - Patients must be clinically diagnosed with Waldenström’s Macroglobulinemia
  - Must be prescribed by an oncologist or hematologist

• **Idiopathic (Immune) Thrombocytopenic Purpura (ITP)**
  - Patients must be clinically diagnosed with Idiopathic Thrombocytopenic Purpura
  - Must be prescribed by a hematologist or an oncologist
  - In treatment of newly diagnosed ITP, initiate treatment when platelet count is less than 30x10⁹/L
  - Tried and failed, intolerant, or contraindicated to at least one of the following:
    - Corticosteroids
    - Immune globulin
    - Splenectomy

• **Thrombotic Thrombocytopenic Purpura (TTP)**
  - Patients must be clinically diagnosed with Thrombotic Thrombocytopenic Purpura with refractory and/or severe disease
  - Must be prescribed by a hematologist or an oncologist
  - Patients must have been tried and failed, or had a contraindication to the use of Plasma Exchange (PEX) and high dose glucocorticoids OR had an exacerbation after PEX is stopped

**Criteria for continuation of therapy:**

- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

**Caution:**

- Infusion reactions, some severe and fatal: hypoxia, hypotension, angioedema, bronchospasm, acute respiratory distress syndrome, myocardial infarction, cardiogenic shock, anaphylactic events. During first infusion, premedication recommended, interrupt or slow infusion for infusion reaction, depending on severity.
- Hepatitis B infection, risk of reactivation, and possible fulminating hepatitis, heart failure and death
- Mucocutaneous reactions (i.e. Stevens-Johnson syndrome)
- Live virus vaccine administration is not recommended after treatment with Rituxan

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- Not recommended if patient has current severe infection
- Renal toxicity, especially in patients with hematologic malignancies and a high number of circulating malignant cells, > 25,000/mm3, or high tumor burden and tumor lysis syndrome as well as patients receiving concomitant cisplatin therapy

Special considerations:
- Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation will be considered with proper documentation of diagnosis and medical records.

Approval Duration:
RA:
- Initial 4 months
- Renewal 12 months

All other indications:
- Initial 6 months
- Renewal 1 year

Benefit Type:
- Medical

**Off-label Use:**
Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.
If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts regulations¹ accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature determined by Fallon that sufficient evidence exists to support use.

¹Reference: [https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K](https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K) accessed 7/7/2017

Adopted: 12/14/16
Revised:
Reviewed: 9/13/17 - removed ECOG score from criteria

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