Rituxan (rituximab)

Line(s) of Business: 
HMO; PPO; QUEST Integration Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 12/01/2018

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Non-Hodgkin’s Lymphoma (NHL)
  Rituxan is indicated for the treatment of patients with:
  o Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
  o 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
  o Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL, as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
  o Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Chronic Lymphocytic Leukemia (CLL)
  o Rituxan is indicated, in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated CD20-positive CLL.
- Rheumatoid Arthritis
  o Rituxan in combination with methotrexate (MTX) is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.
- Wegener’s Granulomatosis* (WG) and Microscopic Polyangiitis (MPA)
  o Rituxan, in combination with glucocorticoids, is indicated for the treatment of adult patients with WG and MPA.
    *Also known as granulomatosis with polyangiitis (GPA)
- Refer to HMSA’s Global Oncology Policy for all other FDA approved indications.

Compendial Uses
- Acute lymphoblastic leukemia in combination with chemotherapy
- Central nervous system (CNS) cancers
  - Primary CNS lymphoma
• Leptomeningeal metastases from lymphomas
  • Hodgkin’s lymphoma, nodular lymphocyte-predominant
  • Non-Hodgkin’s lymphoma
    o Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
    o Burkitt lymphoma, in combination with chemotherapy
    o Castleman’s disease
    o Diffuse large B-cell lymphoma
    o Hairy cell leukemia, relapsed or refractory
    o Lymphoblastic lymphoma
    o Mantle cell lymphoma
    o Marginal zone lymphomas (gastric/non-gastric MALT, nodal, splenic marginal zone lymphoma)
    o Post-transplant lymphoproliferative disorder (PTLD)
    o Primary cutaneous B-cell lymphoma
    o Small lymphocytic lymphoma (SLL)
  • Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma
  • Myasthenia gravis, refractory
  • Management of immunotherapy-related toxicities
  • Autoimmune hemolytic anemia, refractory
  • Immune or idiopathic thrombocytopenic purpura, refractory
  • Thrombotic thrombocytopenic purpura, refractory
  • Refer to HMSA’s Global Oncology Policy for all other compendial uses.

B. PRESCRIBER RESTRICTION
For all hematologic indications, Rituxan must be recommended by an oncologist or a hematologist.

C. CRITERIA FOR APPROVAL
1. Oncologic or Hematologic Indications

1.1. Acute lymphoblastic leukemia (ALL)
Refer to HMSA’s Global Oncology Criteria.

1.2. Central nervous system (CNS) cancers
Refer to HMSA’s Global Oncology Criteria.

1.3. Hodgkin’s lymphoma
Refer to HMSA’s Global Oncology Criteria.

1.4. Non-Hodgkin’s lymphoma (NHL)
Refer to HMSA’s Global Oncology Criteria.

1.5. Waldenström’s macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
Refer to HMSA’s Global Oncology Criteria.

1.6. Autoimmune hemolytic anemia
Initial authorization of 6 months may be granted for members who are prescribed Rituxan for the treatment of autoimmune hemolytic anemia that is refractory to steroids.
1.7. **Immune or Idiopathic thrombocytopenic purpura**
Initial authorization of 6 months may be granted for members who are prescribed Rituxan for the treatment of immune or idiopathic thrombocytopenic purpura that is refractory to steroids or intravenous immunoglobulin (IVIG).

1.8. **Thrombotic thrombocytopenic purpura**
Initial authorization of 6 months may be granted for members who are prescribed Rituxan for the treatment of thrombotic thrombocytopenic purpura that is refractory to plasma exchange or steroids.

2. **Moderately to severely active rheumatoid arthritis (RA)**
Initial authorization of 6 months may be granted to members who meet both of the following criteria:
   i. Member has either of the following:
      a) Inadequate response to at least a 3-month trial of a TNF inhibitor (e.g., Cimzia, Enbrel, Humira, Remicade, Simponi, Simponi Aria)
      b) Intolerance or contraindication to a TNF inhibitor
   ii. Member is prescribed Rituxan in combination with MTX or has a contraindication or intolerance to MTX.

3. **Granulomatosis with polyangiitis (GPA; Wegener’s granulomatosis) and microscopic polyangiitis (MPA)**
Initial authorization of 6 months may be granted to members who are prescribed Rituxan for the treatment of GPA or MPA.

4. **Myasthenia gravis**
Initial authorization of 6 months may be granted to members who are prescribed Rituxan for the treatment of myasthenia gravis that is refractory to corticosteroids and/or immunomodulating drugs (eg, azathioprine, IVIG).

5. **Immunotherapy-related toxicities**
Initial authorization of 6 months may be granted to members who are prescribed Rituxan for the treatment of immunotherapy-related encephalitis who meet the following criteria:
   i. Viral causes have been excluded
   ii. Member tests positive for autoimmune encephalopathy antibody
   iii. Member has had limited improvement or no improvement on methylprednisolone with or without intravenous immune globulin

D. **CONTINUATION OF THERAPY**
1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.

2. Reauthorization:
   a. ALL, CNS cancers, Hodgkin’s lymphoma, NHL, and Waldenstrom’s macroglobulinemia/lymphoplasmacytic lymphoma:
      Refer to HMSA’s Global Oncology Criteria.
   b. All other indications:
Authorization of an additional 12 months may be granted to members requesting authorization for continuation of therapy who are benefitting from Rituxan therapy as evidenced by low disease activity or improvement in signs and symptoms of the condition, and were previously authorized by HMSA/CVS.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. REFERENCES

Document History

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<tr>
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