

Reference number(s)
1704-A

SPECIALTY GUIDELINE MANAGEMENT

RITUXAN (rituximab) Treatment of Hematologic and Oncologic Conditions

POLICY

I. 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.

A. FDA-Approved Indications¹

1. Non-Hodgkin's lymphoma (NHL) in patients with:
 - a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent
 - b. 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
 - c. 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
 - d. Previously untreated diffuse large B-cell, CD20-positive NHL in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. 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.
3. Granulomatosis with polyangiitis (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) (Not addressed in this policy –Refer to Rituxan-RA+Other SGM)
4. Moderately to severely active rheumatoid arthritis (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
5. Moderate to severe pemphigus vulgaris in adult patients (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)

B. Compendial Uses²⁻¹⁰

1. Sjögren's syndrome² (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
2. Multiple sclerosis² (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
3. Neuromyelitis optica (Devic disease)^{11,12} (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
4. Idiopathic inflammatory myopathy, refractory² (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
5. Non-Hodgkin's Lymphoma^{2,3}
 - a. Small lymphocytic lymphoma (SLL)³
 - b. Mantle cell lymphoma^{2,3}
 - c. Marginal zone lymphomas (nodal, splenic, gastric MALT, nongastric MALT)³
 - d. Burkitt lymphoma^{2,3}
 - e. Primary cutaneous B-cell lymphoma³
 - f. Castleman's disease³
 - g. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma³
 - h. Hairy cell leukemia³
 - i. Post-transplant lymphoproliferative disorder (PTLD)^{2,3}
 - j. Lymphoblastic lymphoma^{4,5}

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6. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)^{2,6}
7. Autoimmune hemolytic anemia^{2,7}
8. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)^{2,3}
9. Thrombotic thrombocytopenic purpura^{2,8}
10. Myasthenia gravis, refractory²
11. Hodgkin's lymphoma, nodular lymphocyte-predominant^{2,3}
12. Chronic graft-versus-host disease (GVHD)^{2,9}
13. Central nervous system (CNS) cancers³
 - a. Leptomeningeal metastases from lymphomas
 - b. Primary CNS lymphoma
14. Acute lymphoblastic leukemia (ALL)³
15. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients^{2,8,10}
16. Immune checkpoint inhibitor-related toxicities³

All other indications are considered experimental/investigational and are not a covered benefit.

CRITERIA FOR INITIAL APPROVAL

A. Oncologic indications¹⁻⁵

Authorization of 12 months may be granted for treatment of any of the following oncologic disorders that are CD20-positive as confirmed by testing or analysis:

1. Non-Hodgkin's lymphoma (NHL) with any of the following subtypes:
 - a. Diffuse large B-cell lymphoma
 - b. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
 - c. Follicular lymphoma
 - d. Mantle cell lymphoma
 - e. Marginal zone lymphomas (nodal, splenic, gastric/non-gastric MALT)
 - f. Burkitt lymphoma
 - g. Primary cutaneous B-cell lymphoma
 - h. Castleman's disease
 - i. AIDS-related B-cell lymphoma
 - j. Hairy cell leukemia
 - k. Post-transplant lymphoproliferative disorder (PTLD)
 - l. Lymphoblastic lymphoma
2. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
3. Hodgkin's lymphoma, nodular lymphocyte-predominant
4. Central nervous system (CNS) cancers with either of the following:
 - a. Leptomeningeal metastases from lymphomas
 - b. Primary CNS lymphoma
5. Acute lymphoblastic leukemia (ALL)

B. Hematologic indications^{2,6-10}

Authorization of 12 months may be granted for treatment of any of the following indications:

1. Refractory immune or idiopathic thrombocytopenic purpura (ITP)
2. Autoimmune hemolytic anemia
3. Thrombotic thrombocytopenic purpura
4. Chronic graft-versus-host disease (GVHD)
5. Prevention of Epstein-Barr virus (EBV)-related PTLD

C. Myasthenia gravis²

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Authorization of 12 months may be granted for treatment of refractory myasthenia gravis.

D. Immune checkpoint inhibitor-related toxicities³

Authorization of 3 months may be granted for treatment of immune checkpoint inhibitor-related toxicities.

II. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

III. REFERENCES

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; June 2018.
2. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed March 30, 2018.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 30, 2018.
4. Arber D, Orazi A, Vardiman J, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood*. May 19, 2016;127(20):2391-2405.
5. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2018). © 2018 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 30, 2018.
6. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com> [available with subscription]. Accessed March 30, 2018.
7. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. April 2008.
8. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. July 2013.
9. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology-Oncology Clinical Programs. July 2009.
10. Tomblyn M, Chiller T, Einsele H, et al. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: a global perspective. *Biol Blood Marrow Transplant*. 2009; 15(10):1143-1238. URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103296/pdf/nihms205400.pdf>. Accessed August 2, 2013.
11. Scott, T.F., Frohman, E.M., DeSeze, J., (2011). Evidence-based guideline: Clinical evaluation and treatment of transverse myelitis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. *American Academy of Neurology*. 77: 2128-2134.
12. Trebst, C., Jarius, S., et al. (2014). Update on the diagnosis and treatment of neuromyelitis optica: Recommendations of the Neuromyelitis Optica Study Group (NEMOS). *J Neurol* 261: 1-16.