

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 Indications

1. Non-Hodgkin's lymphoma (NHL) in adult 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 a rituximab product 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 adult patients with previously untreated and previously treated CD20-positive CLL.
3. Granulomatosis with polyangiitis (Wegener's Granulomatosis) and microscopic polyangiitis (MPA) in adult patients (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
4. Moderately to severely active rheumatoid arthritis in adult patients who have had an inadequate response to one or more TNF antagonist therapies (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 Uses

1. Sjögren's syndrome (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
2. Multiple sclerosis (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
3. Neuromyelitis optica (Devic disease) (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
4. Idiopathic inflammatory myopathy, refractory (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
5. Non-Hodgkin's Lymphoma
 - a. Small lymphocytic lymphoma (SLL)
 - b. Mantle cell lymphoma
 - c. Marginal zone lymphomas (nodal, splenic, gastric MALT, nongastric MALT)
 - d. Burkitt lymphoma
 - e. Primary cutaneous B-cell lymphoma
 - f. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
 - g. High-grade B-cell lymphoma, not otherwise specified
 - h. Castleman's disease

Reference number(s)
1704-A

- i. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
- j. Hairy cell leukemia
- k. Post-transplant lymphoproliferative disorder (PTLD)
- l. B-cell lymphoblastic lymphoma
- 6. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
- 7. Autoimmune hemolytic anemia
- 8. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
- 9. Thrombotic thrombocytopenic purpura
- 10. Myasthenia gravis, refractory
- 11. Hodgkin's lymphoma, nodular lymphocyte-predominant
- 12. Chronic graft-versus-host disease (GVHD)
- 13. Central nervous system (CNS) cancers
 - a. Leptomeningeal metastases from lymphomas
 - b. Primary CNS lymphoma
- 14. B-cell acute lymphoblastic leukemia (ALL)
- 15. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
- 16. Immune checkpoint inhibitor-related toxicities

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming CD20 protein on the surface of the B-cell (if applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Oncologic indications

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. High-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 (double/triple hit lymphoma)
 - c. High-grade B-cell lymphoma, not otherwise specified
 - d. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
 - e. Follicular lymphoma
 - f. Mantle cell lymphoma
 - g. Marginal zone lymphomas (nodal, splenic, gastric/non-gastric MALT)
 - h. Burkitt lymphoma
 - i. Primary cutaneous B-cell lymphoma
 - j. Castleman's disease
 - k. AIDS-related B-cell lymphoma
 - l. Hairy cell leukemia
 - m. Post-transplant lymphoproliferative disorder (PTLD)
 - n. B-cell 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:

Reference number(s)
1704-A

- a. Leptomeningeal metastases from lymphomas
- b. Primary CNS lymphoma
5. B-cell acute lymphoblastic leukemia (ALL)

B. Hematologic indications

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 gravis

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

D. Immune checkpoint inhibitor-related toxicities

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

IV. CONTINUATION OF THERAPY

For oncologic indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an oncologic indication listed in Section III A. who have not experienced an unacceptable toxicity.

For immune checkpoint inhibitor-related toxicities: Authorization of 3 months may be granted for continued treatment in members requesting reauthorization for treatment of immune checkpoint inhibitor-related toxicities who are experiencing benefit from therapy.

For all other indications: Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III B.-C. who are experiencing benefit from therapy.

V. REFERENCES

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; January 2019.
2. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed April 17, 2019.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 17, 2019.
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 1.2019). © 2019 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 17, 2019.
6. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com> [available with subscription]. Accessed April 17, 2019.
7. 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 April 30, 2019.

Reference number(s)
1704-A

8. 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.
9. 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.