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]
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 Uses[2-10]
1. Sjögren's syndrome[2] (Not addressed in this policy – Refer to Rituxan-RA+Other SGM)
2. Multiple sclerosis[2] (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, refractory[2] (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 lymphoma[3]
   f. Castleman's disease[3]
   g. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma[3]
   h. Hairy cell leukemia[3]
   i. Post-transplant lymphoproliferative disorder (PTLD)[2,3]
   j. Lymphoblastic lymphoma[4,5]

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, refractory[2]
11. Hodgkin's lymphoma, nodular lymphocyte-predominant[2,3]
12. Chronic graft-versus-host disease (GVHD)[2,9]
13. Central nervous system (CNS) cancers[3]
    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 toxicities[3]

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

CRITERIA FOR INITIAL APPROVAL

A. Oncologic indications[1-5]

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 gravis[2]

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

D. Immune checkpoint inhibitor-related toxicities[3]
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.
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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.
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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.