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 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 SGM)
4. Rheumatoid Arthritis (Not addressed in this policy – Refer to Rituxan-RA SGM)

B. Compendial Uses
1. Sjögren's syndrome (Not addressed in this policy – Refer to Rituxan-RA SGM)
2. Multiple sclerosis (Not addressed in this policy – Refer to Rituxan-RA SGM)
3. Non-Hodgkin's lymphoma
   a. Small lymphocytic lymphoma (SLL)
   b. Mantle cell lymphoma
   c. Marginal zone lymphomas (nodal, splenic, MALT)
   d. Burkitt lymphoma
   e. Primary cutaneous B-cell lymphoma
   f. Castleman's disease
   g. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphoma
   h. Hairy cell leukemia
   i. Post-transplant lymphoproliferative disorder (PTLD)
   j. Lymphoblastic lymphoma
4. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
5. Autoimmune hemolytic anemia
6. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
7. Thrombotic thrombocytopenic purpura
8. Myasthenia gravis, refractory
9. Hodgkin's lymphoma, nodular lymphocyte-predominant

10. Chronic graft-versus-host disease (GVHD)
11. Central nervous system (CNS) cancers
    a. Leptomeningeal metastases from lymphomas
    b. Primary CNS lymphoma
12. Acute lymphoblastic leukemia (ALL)
13. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients

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

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. Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
    c. Follicular lymphoma
    d. Mantle cell lymphoma
    e. Marginal zone lymphomas (nodal, splenic, 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

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.

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.; April 2016.
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3. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 24, 2017.
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. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Lymphoblastic Leukemia V.1.2017. © National Comprehensive Cancer Network, Inc 2017. Available at: http://www.nccn.org. Accessed June 29, 2017.
6. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed March 28, 2017.
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 August 2, 2013.