Rituximab Products (Rituxan®, Rituximab-abbs [Truxima®], Rituximab-arrx [Riabni™] and Rituximab-pvvr [Ruxience®])

(Hematologic and Oncology Indications)

Some agents on this policy may require step therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at:
https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

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
Rituxan is indicated for the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy.

Rituxan, Ruxience, Truxima, and Riabni are indicated for:
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) (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM-Non-Oncology)
4. Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely active RA who have inadequate response to one or more TNF antagonist therapies. (Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM -Non-Oncology)

Rituxan is also indicated for:
Moderate to severe pemphigus vulgaris in adult patients
(Not addressed in this policy – Refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM-Non-Oncology)

B. Compendial Uses
1. Autoimmune hemolytic anemia
2. B-cell acute lymphoblastic leukemia (ALL)
3. B-cell lymphomas
   a. Human immunodeficiency Virus (HIV) Related B-cell lymphomas
   b. B-cell lymphoblastic lymphoma
   c. Burkitt lymphoma
   d. Castleman's disease
   e. Diffuse Large B-Cell lymphoma
   f. Follicular lymphoma
   g. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
   h. Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
   i. Mantle cell lymphoma
   j. Marginal zone lymphomas
      i. Nodal marginal zone lymphoma
      ii. Extranodal marginal zone lymphoma gastric and nongastric mucosa associated lymphoid tissue (MALT) lymphoma
      iii. Splenic marginal zone lymphoma
   k. Post-transplant lymphoproliferative disorder (PTLD)
   l. Pediatric Aggressive Mature B-Cell Lymphomas
   m. Primary Mediastinal Large B-Cell Lymphoma
4. Central nervous system (CNS) cancers
   a. Leptomeningeal metastases from lymphomas
   b. Primary CNS lymphomas
5. Chronic graft-versus-host disease (GVHD)
6. CLL/Small lymphocytic lymphoma (SLL)
7. Hairy cell leukemia
8. Rosai-Dorfman disease
9. Hodgkin's lymphoma, nodular lymphocyte-predominant
10. Immune checkpoint inhibitor-related toxicities
11. Prevention of Epstein-Barr virus (EBV)-related PTLD in high risk patients
12. Primary cutaneous B-cell lymphoma
13. Relapsed/refractory immune or idiopathic thrombocytopenic purpura (ITP)
14. Thrombotic thrombocytopenic purpura
15. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)
16. Allogeneic transplant conditioning

17. For other compendial uses, refer to Rituxan-Ruxience-Truxima-Riabni-RA+Other SGM-Non-Oncology

All other indications are considered experimental/investigational and not medically necessary.

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. B-cell acute lymphoblastic leukemia (ALL)
2. B-cell lymphomas:
   - i. HIV-related B-cell lymphomas
   - ii. B-cell lymphoblastic lymphoma
   - iii. Burkitt lymphoma
   - iv. Castleman's disease
   - v. Diffuse large B-cell lymphoma
   - vi. Follicular lymphoma
   - vii. High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
   - viii. Histological transformation of indolent lymphomas to diffuse large B-cell lymphoma
   - ix. Mantle cell lymphoma
   - x. Marginal zone lymphomas
     - a. Nodal marginal zone lymphoma
     - b. Extranodal marginal zone lymphoma (gastric and non-gastric (MALT) lymphoma)
     - c. Splenic marginal zone lymphoma
   - xi. Post-transplant lymphoproliferative disorder (PTLD)
   - xii. Pediatric Aggressive Mature B-Cell Lymphomas
   - xiii. Primary Mediastinal Large B-Cell Lymphoma
3. Central nervous system (CNS) cancers:
   - i. Leptomeningeal metastases from lymphomas
   - ii. Primary CNS lymphoma
4. CLL/Small lymphocytic lymphoma (SLL)
5. Hairy cell leukemia
6. Rosai-Dorfman disease
7. Hodgkin's lymphoma, nodular lymphocyte-predominant
8. Primary cutaneous B-cell lymphoma
9. Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma (LPL)

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
6. As part of a non-myeloablative conditioning regimen for allogeneic transplant

C. 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. when there is no evidence of 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. who are experiencing benefit from therapy.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Rituxan [package insert]. South San Francisco, CA: Genentech, Inc.; December 2021.
2. Truxima [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.: February 2022.
3. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed April 5, 2023.
4. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 4, 2023.
5. 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.
6. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2022). © 2022 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 5, 2023.
7. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed April 5, 2023.

8. 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.
9. Ruxience [package insert]. NY, NY: Pfizer Biosimilars; November 2021.
10. Riabni [package insert]. Thousand Oaks, CA: Amgen Inc.; June 2022.

EFFECTIVE DATE 5/31/2024

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