## Rituximab and Hyaluronidase Human Injection (Rituxan Hycela®)

Requires 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
   1. Adult patients with follicular lymphoma (FL):
      a. Relapsed or refractory, follicular lymphoma as a single agent
      b. Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy
      c. Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
   2. Adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimens
   3. Adult patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC)

   *Limitations of Use:*
   *Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion.*
   *Rituxan Hycela is not indicated for the treatment of non-malignant conditions.*

B. Compendial Uses
   1. B-cell lymphomas:
      a. Castleman's disease (CD)
      b. 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)
      c. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma

   d. Marginal zone lymphomas
      i. Nodal marginal zone lymphoma
      ii. Splenic marginal zone lymphoma
      iii. Extranodal Marginal Zone Lymphoma (Gastric and Nongastric mucosa associated lymphoid tissue {MALT} lymphoma)
   e. Mantle cell lymphoma
2. Post-transplant lymphoproliferative disorder (PTLD)
3. Hairy cell leukemia
4. Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
5. Small lymphocytic lymphoma (SLL)
6. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
7. Hodgkin lymphoma, nodular lymphocyte-predominant

All other indications are considered experimental/investigational and are 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

## III. CRITERIA FOR INITIAL APPROVAL

Prior to initiating therapy, all members must receive at least one full dose of a rituximab product by intravenous infusion without experiencing severe adverse reactions.

**A. Chronic lymphocytic leukemia (CLL)/ Small lymphocytic lymphoma (SLL)**
Authorization of 12 months may be granted for treatment of CD20 positive CLL or SLL.

**B. Hairy cell leukemia (HCL)**
Authorization of 12 months may be granted for treatment of CD20 positive HCL.

**C. B-cell lymphomas**
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. Castleman's disease (CD)
2. Diffuse large B-cell lymphoma (DLBCL)
3. Follicular lymphoma
4. 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)
5. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
6. Mantle cell lymphoma
7. Post-transplant lymphoproliferative disorder (PTLD)
8. Marginal zone lymphomas
   i. Nodal marginal zone lymphoma
   ii. Extranodal marginal zone lymphoma (gastric and non-gastric MALT lymphoma)
   iii. Splenic marginal zone lymphoma

**D. Primary cutaneous B-cell lymphoma**

Authorization of 12 months may be granted for treatment of CD20 positive primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas).

**E. Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma**
Authorization of 12 months may be granted for treatment of CD20 positive Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma

**F. Hodgkin lymphoma, nodular lymphocyte-predominant**
Authorization of 12 months may be granted for treatment of CD20 positive Hodgkin lymphoma, nodular lymphocyte-predominant.

## IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity.

## 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 Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 4, 2023.

**EFFECTIVE DATE** 5/31/2024

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