Reference number(s)
3869-A

JURISDICTION SPECIFIC MEDICARE PART B

RITUXAN HYCELA (rituximab and hyaluronidase human)

POLICY

I. **COVERED USES**

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Follicular lymphoma
B. Diffuse large B-cell lymphoma
C. Chronic lymphocytic leukemia/small lymphocytic lymphoma
D. Hairy cell leukemia
E. Gastric MALT lymphoma
F. Nongastric MALT lymphoma
G. Nodal marginal zone lymphoma
H. Splenic marginal zone lymphoma
I. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
J. Mantle cell lymphoma
K. High-grade B-cell lymphoma
L. Post-transplant lymphoproliferative disorders
M. Castleman's disease
N. Primary cutaneous B-cell lymphomas
O. Waldenstrom macroglobulinemia

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. **DOCUMENTATION**

The following documentation must be available, upon request, for all submissions:
A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures

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B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

A. **Follicular Lymphoma**
Authorization of 12 months may be granted for treatment of follicular lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

B. **Diffuse Large B-cell Lymphoma**
Authorization of 12 months may be granted for treatment of diffuse large B-cell lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

C. **Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma** [1]
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

D. **Hairy Cell Leukemia**
Authorization of 12 months may be granted for treatment of hairy cell leukemia when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

E. **Gastric MALT Lymphoma**
Authorization of 12 months may be granted for treatment of gastric MALT lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

F. **Nongastric MALT Lymphoma**
Authorization of 12 months may be granted for treatment of nongastric MALT lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

G. **Nodal Marginal Zone Lymphoma**
Authorization of 12 months may be granted for treatment of nodal marginal zone lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

H. **Splenic Marginal Zone Lymphoma**
Authorization of 12 months may be granted for treatment of splenic marginal zone lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

I. **Histologic Transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-cell Lymphoma**
Authorization of 12 months may be granted for treatment of histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

J. **Mantle Cell Lymphoma**
Authorization of 12 months may be granted for treatment of mantle cell lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

K. **High-Grade B-Cell Lymphoma**
Authorization of 12 months may be granted for treatment of high-grade B-cell lymphoma when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

L. **Post-Transplant Lymphoproliferative Disorders**
Authorization of 12 months may be granted for treatment of post-transplant lymphoproliferative disorders when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

M. **Castleman's disease**
Authorization of 12 months may be granted for treatment of Castleman's disease when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

N. **Primary Cutaneous B-Cell Lymphomas**
Authorization of 12 months may be granted for treatment of primary cutaneous B-cell lymphomas when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

O. **Waldenstrom macroglobulinemia**
Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia when the member has received at least one full dose of a rituximab product by infusion to rule out severe infusion reactions.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 22, 2021.
2. Billing and Coding: Rituximab, Biosimilars and Rituximab and Hyaluronidase Human (A52452) Version R22. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 22, 2021.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R7. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed April 22, 2021.
4. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; December 2019.
5. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 22, 2021.