Rituxan Hycela
(rituximab and hyaluronidase human)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy. For this program, Truxima, Ruxience, and Riabni are the preferred products. Coverage for non-preferred products, Rituxan and Rituxan Hycela, is provided based on clinical circumstances that would exclude the use of the preferred product(s) and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

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)

Compendial Indications

1. B-cell lymphomas:
   a) Castleman's disease (CD)

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b) High-grade B-cell lymphoma
c) Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
d) Marginal zone lymphomas
   - Nodal marginal zone lymphoma
   - Gastric mucosa associated lymphoid tissue (MALT) lymphoma
   - Nongastric MALT lymphoma
   - Splenic marginal zone lymphoma
e) Mantle cell lymphoma
f) Post-transplant lymphoproliferative disorder (PTLD)

2. Hairy cell leukemia
3. Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
4. Small lymphocytic lymphoma (SLL)
5. Waldenström macroglobulinemia/lymphoplasmacytic lymphoma

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.

POLICY

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

Coverage for a non-preferred product is provided when the following criteria is met:

- The member has had a documented intolerable adverse event to all the preferred products, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Table. Rituximab Products

Medication	Generic Name
Preferred Products:	
Ruxience	rituximab-pvvr
Truxima	rituximab-abbs
Riabni	rituximab-arrx
Targeted Products:	
Rituxan	rituximab
Rituxan Hycela	rituximab and hyaluronidase human

Required Documentation

Testing or analysis confirming CD20 protein on the surface of the B-cell

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

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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
5. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma
6. Mantle cell lymphoma
7. Nodal marginal zone lymphoma
8. Post-transplant lymphoproliferative disorder (PTLD)
9. Marginal zone lymphomas
    - Nodal marginal zone lymphoma
    - Gastric mucosa associated lymphoid tissue (MALT) lymphoma
    - Nongastric MALT lymphoma
    - 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.

Continuation of Therapy
Authorization of 12 months may be granted for members requesting continuation of treatment who have not experienced an unacceptable toxicity.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9311 – Rituxan Hycela, Injection, rituximab and hyaluronidase, 10 mg (Effective 1.1.2019)

REFERENCES

- Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June,2021.
- The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 11, 2021.

POLICY HISTORY

Policy #: 05.02.28
Reviewed: October 2021
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