SmartHealth Ascension

Rituximab and hyaluronidase human

(Rituxan Hycela®) J9311

Rituximab and hyaluronidase human (Rituxan Hycela®) may be authorized when the following criteria are met:

- Individual has a diagnosis of follicular lymphoma (FL); **AND**
- One of the following applies:
    - Using as single-agent maintenance therapy for individuals
        - With previously untreated disease where Rituxan Hycela® is used in combination with first line chemotherapy; **OR**
        - In patients achieving a complete or partial response to Rituxan Hycela® in combination with chemotherapy; **OR**
    - As a single-agent therapy
        - After first line cyclophosphamide, vincristine, and prednisone chemotherapy for individuals with non-progressing (including stable disease) disease; **OR**
        - For individuals with relapsed or refractory disease; **AND**
- Dosing is condition-appropriate:
    - Relapsed-Refractory: 1,400 mg/23,400 U subcutaneously weekly up to 7 doses; **OR**
    - Previously Untreated
        - Initiation: 1,400 mg/23,400 U subcutaneously every 21 days x 7 doses
        - Maintenance: 1,400 mg/23,400 U subcutaneously every 8 weeks x 12 doses; **OR**
    - Non-progressing (after first line CVP chemotherapy): 1,400 mg/23,400 U subcutaneously weekly x 3 doses at 6 month intervals (up to a maximum of 16 doses).

OR

- Individual has a diagnosis of diffuse large B cell lymphoma (DLBCL); **AND**
- Previously untreated disease with Rituxan Hycela® used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone or with another anthracycline-based chemotherapy regimen; **AND**
- Dosing is 1,400 mg/23,400 U subcutaneously every 21 days x 7 doses.

OR

- Individual has a diagnosis of chronic lymphocytic leukemia (CLL); **AND**
    - Using Rituxan Hycela® as monotherapy; **OR**
    - In combination with fludarabine and cyclophosphamide; **AND**
- Dosing is 1,600 mg/26,800 U subcutaneously every 28 days x 5 doses.

AND

- Age ≥ 18 years; AND
- At least one full doses of rituximab has been administered; **AND**
- Dose does not exceed: 1,600 mg/26,800 units subcutaneously; **AND**
- Individual is unable achieve treatment goals with Rituxan (rituximab), Ruxience (rituximab-pvvr), Riabni (rituximab-arrx), or Truxima (rituximab-abbs); **AND**
- Prescriber is an oncologist or hematologist.

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Treatment of non-malignant conditions;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Step/Alternative Therapies:

Preferred Product(s) [No PA Required]	Non-Preferred Product(s) [PA Required]
rituximab-abbs, biosimilar, Truxima [Q5155]	Rituximab and hyaluronidase human, RITUXAN HYCELA®
rituximab-pvvr, biosimilar, Ruxience [Q5119]	Rituximab, RITUXAN
rituximab-arrx, biosimilar, Riabni [Q5123]	

Initial authorization for approved indications is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Rituxan Hycela® is a combination of rituximab, a CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase, indicated for the treatment of adult patients with:

- Follicular Lymphoma (FL)
    - Relapsed or refractory, follicular lymphoma as a single agent
    - 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
    - Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
- Diffuse Large B-cell Lymphoma (DLBCL)

    - Previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens
- Chronic Lymphocytic Leukemia (CLL)
    - Previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC)

References:

Rituxan Hycela® *(rituximab and hyaluronidase human) label*. (2017, June). Accessdata.fda.gov. Retrieved April 22, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761064s000lbl.pdf
Rituximab and hyaluronidase human (Rituxan Hycela); National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved April 26, 2022, from https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type
Genentech. (2021). Rituxan Hycela® *(rituximab hyaluronidase human)* [prescribing information]. San Francisco, CA. https://www.rituxanhycela.com/hcp/dosing-and-administration/product-information.html
van Oers MH, Van Glabbeke M, Giurgea L, et al. Rituximab maintenance treatment of relapsed/resistant follicular non-Hodgkin's lymphoma: long-term outcome of the EORTC 20981 phase III randomized intergroup study. J Clin Oncol. 2010;28(17):2853-2858.

Criteria History/ Revision Information:

Date	Summary of Changes
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.