

Precertification Requirements

The following diagnoses are covered (additional criteria noted for each diagnosis, if applicable):

1. Diffuse large B-cell lymphoma (DLBCL)
 - Previously untreated DLBCL in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens
2. Follicular lymphoma (FL)
 - Relapsed or refractory FL as a single agent
 - Previously untreated FL 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) FL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy
3. Chronic lymphocytic leukemia (CLL)
 - in combination with fludarabine and cyclophosphamide (FC)

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma (FL)
- Chronic lymphocytic leukemia (CLL)
- Other – rationale for use: _____

B. Has or will the patient receive one full dose of Rituxan by IV infusion prior to using Rituxan Hycela?

- Yes
- No; *rationale for use:* _____

For diffuse large B-cell lymphoma:

- A. Has the patient been previously treated?
- No
 - Yes; *rationale for use:* _____
- B. Will Rituxan Hycela be used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or another anthracycline-based chemotherapy regimen?
- Yes
 - No; *rationale for use:* _____

For follicular lymphoma:

- A. Please indicate which of the following best describe the patient's disease type:
- Relapsed or refractory

Will Rituxan Hycela be used in combination with another chemotherapy?

 - No
 - Yes; *rationale for use:* _____
 - Previously untreated

Will Rituxan Hycela be used in combination with another chemotherapy?

 - No
 - Yes; *rationale for use:* _____

Non-progressing (including stable)

Has the patient used cyclophosphamide, vincristine, and prednisone (CVP)?

Yes

No; *rationale for use:* _____

Will Rituxan Hycela be used in combination with another chemotherapy?

No

Yes; *rationale for use:* _____

For chronic lymphocytic leukemia:

A. Will Rituxan Hycela be used in combination with fludarabine and cyclophosphamide (FC)?

Yes

No; *rationale for use:* _____