

# Jurisdiction Specific Medicare Part B

## Rituxan Hycela

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rituxan Hycela	rituximab and hyaluronidase

### Indications

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:

- Non-Hodgkin's lymphoma (NHL)
- Chronic lymphocytic leukemia (CLL)
- Post-transplant lymphoproliferative disorder
- Waldenstrom's macroglobulinemia
- Hodgkin lymphoma, nodular lymphocyte-predominant

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.

## Coverage Criteria

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.

### Non-Hodgkin's lymphoma<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of non-Hodgkin's lymphoma (NHL) when any of the following criteria are met:

- Member has relapsed or refractory low-grade or follicular CD20-positive B-cell NHL and rituximab will be used as a single agent
- Member has previously untreated follicular CD20-positive B-cell NHL in combination with first-line chemotherapy
- Single-agent maintenance therapy in members who achieved a complete or partial response to rituximab in combination with chemotherapy
- Member has non-progressing (including stable disease), low-grade, CD20-positive NHL and rituximab will be used as a single agent after first-line CVP chemotherapy
- Rituximab will be used for treatment of previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP (Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone) or other anthracycline-based chemotherapy regimens
- Rituximab will be used as re-induction treatment appropriate for responders and members with stable low-grade or follicular CD20-positive B-cell NHL
- Member has intermediate or high-grade NHL and rituximab will be used in one of the following regimens:
  - Single agent
  - In combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone)
  - In combination with other agents active against the disease

### Chronic lymphocytic leukemia<sup>1-2</sup>

Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia (CLL) when both of the following criteria are met:

- Member has either previously untreated or previously treated CD20-positive CLL
- Rituximab will be used in combination with fludarabine and cyclophosphamide

### Post-transplant lymphoproliferative disorder<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of post-transplant lymphoproliferative disorder (PTLD).

Reference number(s)
4487-A

## Waldenstrom's macroglobulinemia<sup>1,2</sup>

Authorization of 12 months may be granted for treatment of Waldenstrom's macroglobulinemia.

## Hodgkin lymphoma, nodular lymphocyte-predominant<sup>4</sup>

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

## References

1. Rituximab LCD (L35026) Version R27. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 15, 2025.
2. Billing and Coding: Rituximab (A56380) Version R20. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed April 15, 2025.
3. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
4. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed April 15, 2025.