Reference number
4475-A

Aetna Medicare Part B Drug Criteria

Rituxan Hycela

This policy is for Aetna Medicare members. Find the Aetna Commercial Medical Drug Criteria.

For Aetna Medicare members, National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) will be applied to Part B drug requests when applicable. Aetna Medicare Part B Drug Criteria documents will be used in the absence of an NCD and LCD.

POLICY

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 human

Indications

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

FDA-Approved Indications[1]

- 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 CVP (cyclophosphamide, vincristine, and prednisone) chemotherapy
- 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
- Adult patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL), in combination with fludarabine and cyclophosphamide (FC)

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.

Compendial Uses[2]

- B-cell lymphomas:
  - Castleman's disease (CD)
  - High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
  - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
  - Marginal zone lymphomas
    - Nodal marginal zone lymphoma
    - Extranodal Marginal Zone Lymphoma (Gastric and Nongastric mucosa associated lymphoid tissue {MALT} lymphoma)
    - Splenic marginal zone lymphoma
  - Mantle cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Hairy cell leukemia
- Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
- Small lymphocytic lymphoma (SLL)
- Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
- Hodgkin lymphoma, nodular lymphocyte-predominant

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

Documentation

The following documentation must be available, upon request, for all submissions: Testing or analysis confirming CD20 protein on the surface of the B-cell.

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.

Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)[1,2]

Authorization of 12 months may be granted for treatment of CD20 positive CLL or SLL.

Hairy cell leukemia (HCL)[2]

Authorization of 12 months may be granted for treatment of CD20 positive HCL.

B-cell lymphomas[1,2]

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:

- Castleman's disease (CD)
- Diffuse large B-cell lymphoma (DLBCL)
- Follicular lymphoma
- High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Mantle cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Marginal zone lymphomas
    - Nodal marginal zone lymphoma
    - Extranodal Marginal Zone Lymphoma (Gastric and Nongastric MALT lymphoma)
    - Splenic marginal zone lymphoma

Primary cutaneous B-cell lymphoma[2]

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).

Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma[2]

Authorization of 12 months may be granted for treatment of CD20 positive Waldenström macroglobulinemia/ lymphoplasmacytic lymphoma.

Hodgkin lymphoma, nodular lymphocyte-predominant[2]

Authorization of 12 months may be granted for treatment of CD20 positive Hodgkin lymphoma, nodular lymphocyte-predominant.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as no unacceptable toxicity while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Rituxan Hycela.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- NCCN Guideline: Hairy cell leukemia
- NCCN Guideline: Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma
- NCCN Guideline: Hodgkin lymphoma
- NCCN Guideline: Primary cutaneous lymphomas
- NCCN Guideline: Chronic lymphocytic leukemia/small lymphocytic lymphoma
- NCCN Guideline: B-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Rituxan Hycela are covered in addition to the following:

- B-cell lymphomas:
  - Castleman's disease (CD)
  - High grade B-cell lymphoma (including high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
  - Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
  - Marginal zone lymphomas
    - Nodal marginal zone lymphoma
    - Extranodal Marginal Zone Lymphoma (Gastric and Nongastric mucosa associated lymphoid tissue {MALT} lymphoma)
    - Splenic marginal zone lymphoma
  - Mantle cell lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Hairy cell leukemia
- Primary cutaneous B-cell lymphoma (e.g., cutaneous marginal zone lymphoma or cutaneous follicle center lymphomas)
- Small lymphocytic lymphoma (SLL)
- Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma
- Hodgkin lymphoma, nodular lymphocyte-predominant.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Rituxan Hycela for the compendial uses listed above can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Rituxan Hycela [package insert]. South San Francisco, CA: Genentech, Inc.; June 2021.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed April 14, 2025.

References

CPT Codes / HCPCS Codes / ICD-10 Codes

Code	Description
Other CPT codes related to the Med B Drug Criteria:	
96365-96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug)
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401 - 96417	Chemotherapy administration
HCPCS codes covered if selection criteria are met:	
J9311	Injection, rituximab 10 mg and hyaluronidase
Other HCPCS codes related to the Med B Drug Criteria:	
J8530	Cyclophosphamide; oral, 25 mg
J9071	Injection, cyclophosphamide (auromedics), 5 mg
J9072	Injection, cyclophosphamide (dr. reddy's), 5 mg
J9073	Injection, cyclophosphamide (ingenus), 5 mg
J9074	Injection, cyclophosphamide (sandoz), 5 mg
J9075	Injection, cyclophosphamide, not otherwise specified, 5 mg
J9312	Injection, rituximab, 10 mg

J9370	Vincristine sulfate, 1 mg
ICD-10 codes covered if selection criteria are met:	
C81.00 – C81.09	Nodular lymphocyte predominant Hodgkin lymphoma
C82.00 - C82.9A	Follicular lymphoma
C83.00 - C83.09	Small cell B-cell lymphoma
C83.10 - C83.19	Mantle cell lymphoma
C83.30 - C83.3A	Diffuse large B-cell lymphoma
C83.50 - C83.59	Lymphoblastic (diffuse) lymphoma
C83.80 - C83.99	Other non-follicular lymphoma
C85.10 - C85.19	Unspecified B-cell lymphoma
C85.20 - C85.29	Mediastinal (thymic) large B-cell lymphoma
C88.00-C88.01	Waldenstrom's macroglobulinemia
C88.40-C88.41	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
C91.10 - C91.12	Chronic lymphocytic leukemia of B-cell type
C91.40 - C91.42	Hairy cell leukemia
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z2	Castleman disease

Revision History

Date	Version	Update	Revisions
01/01/2024	2022	New Criteria	Policy effective.
02/27/2025	2024	Annual Review	Medicare Utilization Management Committee approved.
01/01/2026	2025	Criteria Change	Added documentation section.

See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.