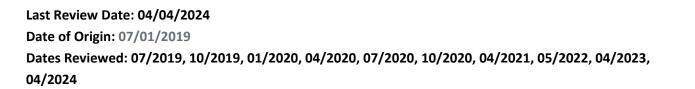


-E

Document Number: IC-0476



Rituxan Hycela[®] (rituximab and hyaluronidase human) (Subcutaneous)



I. Length of Authorization ^{1,7-11}

Coverage will be provided for 6 months and may be renewed, unless otherwise specified.

- Maintenance therapy for Mantle Cell Lymphoma may be renewed until disease progression or intolerable toxicity.
- Hairy Cell Leukemia may be renewed up to a maximum of 11 total doses.
- Maintenance therapy for all other indications may be renewed for up to a maximum of 2 years.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Rituxan Hycela 1,400 mg/23,400 Units per 11.7 mL single-dose vial: 4 vials per 28 day supply
- Rituxan Hycela 1,600 mg/26,800 Units per 13.4 mL single-dose vial: 1 vial per 28 day supply
- B. Max Units (per dose and over time) [HCPCS Unit]:

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL):

- 1,600 mg/26,800 U (160 billable units) every 28 days x 5 doses; **OR**
- 1,600 mg/26,800 U (160 billable units) every 8 weeks (maintenance treatment)

Hairy Cell Leukemia

- 1,400 mg/23,400 U (140 billable units) weekly up x 7 doses; **OR**
- 1,400 mg/23,400 U (140 billable units) every 14 days x 7 doses, then every 28 days x 4 doses

All other indications:

- 1,400 mg/23,400 U (140 billable units) weekly for x 7 doses in a 6-month period; OR
- 1,400 mg/23,400 U (140 billable units) every 8 weeks (maintenance treatment)

III. Initial Approval Criteria¹

Coverage is provided in the following conditions:

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- Patient is at least 18 years of age; AND
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**

Universal Criteria¹

- Patient does not have a severe, active infection; AND
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is CD20 antigen expression positive; AND
- Rituxan Hycela will not be used with intravenous chemotherapy agents or ibritumomab tiuxetan radioimmunotherapy; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) † Φ ^{1,2}

B-Cell Lymphomas † ‡ ^{1,2,6}

- Follicular Lymphoma (FL) $\dagger \Phi$
- Diffuse Large B-Cell Lymphoma (DLBCL) $\dagger \Phi$
- High-Grade B-Cell Lymphomas **‡**
- Extranodal Marginal Zone Lymphoma (EMZL) of the Stomach & Nongastric Sites (Noncutaneous) ‡
- Nodal & Splenic Marginal Zone Lymphoma ‡
- Mantle Cell Lymphoma **‡**
- Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma ‡
- Post-Transplant Lymphoproliferative Disorders (PTLD) **‡**

Castleman Disease ‡ ²

Hairy Cell Leukemia ‡ 2,12

Primary Cutaneous B-Cell Lymphoma ‡²

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma ‡²

Adult Hodgkin Lymphoma ‡ ^{2,3}

• Patient has nodular lymphocyte-predominant disease

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Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

FDA Approved Indication(s); C Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ^{1,2,7-11}

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity or other administration reactions (e.g., local cutaneous reactions), tumor lysis syndrome (TLS), severe mucocutaneous reactions (e.g., paraneoplastic pemphigus, Stevens-Johnson syndrome, lichenoid dermatitis, etc.), progressive multifocal leukoencephalopathy (PML), hepatitis B virus reactivation, serious infections (bacterial, fungal or viral), cardiac adverse reactions, renal toxicity, bowel obstruction and perforation, etc.; AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Patient has not exceeded dosing or duration limits as defined in Sections I, II, and V

V. Dosage/Administration ^{1,3,7-12}

Indication	Dose	
CLL/SLL	1,600 mg/26,800 Units subcutaneously, at a fixed dose, irrespective of patient's BSA.	
	• Administer on Day 1 of Cycles 2–6 (every 28 days) for a total of 5 cycles (i.e., 6 cycles in total); OR	
	Administer once every 8 weeks (maintenance treatment)	
Hairy Cell Leukemia	 1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA. Administer once weekly for 3-7 doses; OR Administer on day 15 of cycle 1 (28 day cycle), then on days 1 and 15 every 28 days for 3 cycles, then once every 28 days for 4 cycles (i.e., up to 8 total cycles or 11 total doses). 	
All other indications	 1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA. Administer up to once weekly for 3-7 doses in a 6-month period; OR Administer once every 8 weeks (maintenance treatment) 	
<u>Note</u> : Must b	e administered by a healthcare provider.	

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VI. Billing Code/Availability Information

HCPCS Code:

- J9311 Injection, rituximab 10 mg and hyaluronidase: 1 billable unit = 10 mg <u>NDC(s)</u>:
- Rituxan Hycela 1,400 mg rituximab/23,400 Units hyaluronidase human per 11.7 mL singledose vial: 50242-0108-xx
- Rituxan Hycela 1,600 mg rituximab/26,800 Units hyaluronidase human per 13.4 mL singledose vial: 50242-0109-xx

VII. References (STANDARD)

- 1. Rituxan Hycela [package insert]. South San Francisco, CA; Genentech, Inc.; June 2021. Accessed March 2024.
- 2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rituximab and hyaluronidase human. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.
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- Palmetto GBA. Local Coverage Article: Billing and Coding: Rituximab (A56380). Centers for Medicare & Medicaid Services, Inc. Updated on 08/11/2023 with effective date of 10/01/2023. Accessed March 2024.

VIII. References (ENHANCED)

- 1e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Primary Cutaneous Lymphomas. Version 1.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2024.
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Appendix 1 – Covered Diagnosis Codes

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ICD-10	ICD-10 Description	
C81.00	Nodular lymphocyte predominant Hodgkin lymphoma, unspecified site	
C81.01	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of head, face, and neck	
C81.02	Nodular lymphocyte predominant Hodgkin lymphoma, intrathoracic lymph nodes	
C81.03	Nodular lymphocyte predominant Hodgkin lymphoma, intra-abdominal lymph nodes	
C81.04	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of axilla and upper limb	
C81.05	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of inguinal region and lower limb	
C81.06	Nodular lymphocyte predominant Hodgkin lymphoma, intrapelvic lymph nodes	
C81.07	Nodular lymphocyte predominant Hodgkin lymphoma, spleen	
C81.08	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of multiple sites	
C81.09	Nodular lymphocyte predominant Hodgkin lymphoma, extranodal and solid organ sites	
C82.00	Follicular lymphoma grade I, unspecified site	
C82.01	Follicular lymphoma grade I, lymph nodes of head, face and neck	
C82.02	Follicular lymphoma, grade I, intrathoracic lymph nodes	
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes	
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb	
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb	
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes	
C82.07	Follicular lymphoma grade I, spleen	
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites	
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites	
C82.10	Follicular lymphoma grade II, unspecified site	
C82.11	Follicular lymphoma grade II, lymph nodes of head, face and neck	
C82.12	Follicular lymphoma, grade II, intrathoracic lymph nodes	
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes	
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb	
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb	
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes	
C82.17	Follicular lymphoma grade II, spleen	
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites	
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites	
C82.20	Follicular lymphoma grade III, unspecified, unspecified site	
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck	
C82.22	Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes	
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes	
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb	
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb	
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes	

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C82.27	Follicular lymphoma grade III, unspecified, spleen	
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites	
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites	
C82.30	Follicular lymphoma grade IIIa, unspecified site	
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck	
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes	
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes	
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb	
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb	
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes	
C82.37	Follicular lymphoma grade IIIa, spleen	
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites	
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites	
C82.40	Follicular lymphoma grade IIIb, unspecified site	
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face and neck	
C82.42	Follicular lymphoma, grade IIIb, intrathoracic lymph nodes	
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes	
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb	
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb	
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes	
C82.47	Follicular lymphoma grade IIIb, spleen	
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites	
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites	
C82.50	Diffuse follicle center lymphoma, unspecified site	
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face and neck	
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes	
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes	
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb	
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb	
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes	
C82.57	Diffuse follicle center lymphoma, spleen	
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites	
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites	
C82.60	Cutaneous follicle center lymphoma, unspecified site	
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face and neck	
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes	
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes	
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb	



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C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb	
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C83.19	Mantle cell lymphoma, extranodal and solid organ sites	
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C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes	
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C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes	
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C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites	
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites	
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C83.91	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of head, face, and neck	
C83.92	Non-follicular (diffuse) lymphoma, unspecified intrathoracic lymph nodes	
C83.93	Non-follicular (diffuse) lymphoma, unspecified intra-abdominal lymph nodes	
C83.94	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of axilla and upper limb	
C83.95	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of inguinal region and lower limb	
C83.96	Non-follicular (diffuse) lymphoma, unspecified intrapelvic lymph nodes	
C83.97	Non-follicular (diffuse) lymphoma, unspecified spleen	
C83.98	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of multiple sites	
C83.99	Non-follicular (diffuse) lymphoma, unspecified extranodal and solid organ sites	
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$\mathbf{Z85.72}$	Personal history of non-Hodgkin lymphomas	

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The

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following link may be used to search for NCD, LCD, or LCA documents:

<u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

	Medicare Part B Covered Diagnosis Codes			
Jurisdiction	NCD/LCA/LCD	Contractor		
	Document (s)			
J, M	A56380	Palmetto GBA		

	Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor	
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC	
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC	
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)	
6	MN, WI, IL	National Government Services, Inc. (NGS)	
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.	
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)	
N (9)	FL, PR, VI	First Coast Service Options, Inc.	
J (10)	TN, GA, AL	Palmetto GBA	
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA	
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.	
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)	
15	КҮ, ОН	CGS Administrators, LLC	

