



Rituxan Hycela[®] (rituximab and hyaluronidase human)

(Subcutaneous)



Last Review Date: 03/31/2023 Date of Origin: 07/01/2019 Dates Reviewed: 07/2019, 10/2019, 01/2020, 04/2020, 07/2020, 10/2020, 04/2021, 05/2022, 04/2023

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 NOT be renewed.
- 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]:

Follicular Lymphoma (FL):

Relapsed-Refractory

1,400 mg/23,400 U (140 billable units) weekly up to 7 doses

Previously Untreated

- 1,400 mg/23,400 U (140 billable units) every 21 days x 7 doses
- 1,400 mg/23,400 U (140 billable units) every 8 weeks x 12 doses (maintenance)

Non-progressing after first line CVP chemotherapy

• 1,400 mg/23,400 U (140 billable units) weekly x 3 doses at 6 month intervals (up to a maximum of 15 doses.

Diffuse Large B-Cell Lymphoma (DLBCL):

• 1,400 mg/23,400 U (140 billable units) every 14 or 21 days x 7 doses

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

• 1,600 mg/26,800 U (160 billable units) every 28 days x 5 doses

Hairy Cell Leukemia

• 1,400 mg/23,400 U (140 billable units) weekly up x 7 doses

All other indications:

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- 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:

• Patient is at least 18 years of age; 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
- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela will not be used with intravenous chemotherapy agents; 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 ‡
- Castleman Disease **‡**
- Extranodal Marginal Zone Lymphoma (EMZL) of the Stomach & Nongastric Sites (Noncutaneous) ‡
- Mantle Cell Lymphoma **‡**
- Nodal & Splenic Marginal Zone Lymphoma ‡
- Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma **‡**
- Post-Transplant Lymphoproliferative Disorders (PTLD) ‡

Hairy Cell Leukemia* ‡²

Primary Cutaneous B-Cell Lymphoma* ‡²

Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma* ‡²

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Adult Hodgkin Lymphoma* ‡ ^{2,3}

• Patient has nodular lymphocyte-predominant disease

*<u>Note</u>: Patient must meet relevant initial criteria and receive at least ONE full dose of the intravenous formulation of rituximab prior to initiating therapy with the subcutaneous formulation. This substitution CANNOT be made for intravenous rituximab when used in combination with ibritumomab tiuxetan.

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 (i.e., local cutaneous reactions), tumor lysis syndrome (TLS), severe mucocutaneous reactions, 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 ^{1,3,7-11}

Indication	Dose
Follicular	1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA,
Lymphoma	according to the following schedules:
(FL)	Relapsed or Refractory
	• Administer once weekly for 3 or 7 weeks following a full dose of a rituximab IV product at week 1 (i.e., 4 or 8 weeks in total)
	Retreatment for Relapsed or Refractory

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	• Administer once weekly for 3 weeks following a full dose of a rituximab IV product at week 1 (i.e., 4 weeks in total)
	Previously Untreated
	• Administer on Day 1 of Cycles 2–8 of chemotherapy (every 21 days), for up to 7 cycles following a full dose of a rituximab IV product on day 1 of cycle 1 (i.e., up to 8 cycles in total). In patients with complete or partial response, initiate maintenance treatment 8 weeks following completion of initial therapy as a single agent every 8 weeks for 12 doses.
	Non-progressing after first line CVP chemotherapy
	• Following completion of 6–8 cycles of CVP chemotherapy and a full dose of a rituximab IV product at week 1, administer once weekly for 3 weeks (i.e., 4 weeks in total) at 6 month intervals to a maximum of 16 doses.
Diffuse Large	1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA.
B-Cell Lymphoma (DLBCL)	• Administer on Day 1 of Cycles 2–8 of chemotherapy for up to 7 cycles (i.e., up to 6-8 cycles in total). Cycle length is either 14 or 21 days.
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). Cycle length is 28 days.
Hairy Cell	1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA.
Leukemia	• Administer once weekly for 3-7 doses
All other	1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA.
indications	• 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 be a	administered by a healthcare provider.

VI. Billing Code/Availability Information

HCPCS Code:

- J9311 Injection, rituximab 10 mg and hyaluronidase: 1 billable unit = 10 mg NDC(s):
- 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 2023.
- Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rituximab and hyaluronidase human. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®.



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- Davies A, Merli F, Mihaljević B, et al. Efficacy and safety of subcutaneous rituximab versus intravenous rituximab for first-line treatment of follicular lymphoma (SABRINA): a randomised, open-label, phase 3 trial. Lancet Haematol. 2017 Jun;4(6):e272-e282. doi: 10.1016/S2352-3026(17)30078-9. Epub 2017 May 2.
- Lugtenburg P, Avivi I, Berenschot H, et al. Efficacy and safety of subcutaneous and intravenous rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone in first-line diffuse large B-cell lymphoma: the randomized MabEase study. Haematologica. 2017 Nov;102(11):1913-1922. doi: 10.3324/haematol.2017.173583. Epub 2017 Sep 21.
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- 6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) B-Cell Lymphomas, Version 2.2023. National Comprehensive Cancer Network, 2023. 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 2023.
- 7. Thomas DA, O'Brien S, Bueso-Ramos C, et al. Rituximab in relapsed or refractory hairy cell leukemia. Blood. 2003 Dec 1;102(12):3906-11. doi: 10.1182/blood-2003-02-0630.
- 8. Nieva J, Bethel K, Saven A. Phase 2 study of rituximab in the treatment of cladribine-failed patients with hairy cell leukemia. Blood. 2003 Aug 1;102(3):810-3.
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 Palmetto GBA. Local Coverage Article: Billing and Coding: Rituximab (A56380). Centers for Medicare & Medicaid Services, Inc. Updated on 08/18/2022 with effective date of 10/01/2022. Accessed March 2023.

VIII. References (ENHANCED)

- 1e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Primary Cutaneous Lymphomas. Version 1.2023. National Comprehensive Cancer Network, 2023. 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 2023.
- 2e. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 2.2023. National Comprehensive Cancer Network, 2023. 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 2023.
- 3e. Magellan Health, Magellan Rx Management. Rituxan Hycela Clinical Literature Review Analysis. Last updated March 2023. Accessed March 2023.

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	

Appendix 1 – Covered Diagnosis Codes



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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	
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	

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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	
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb	
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes	
C82.67	Cutaneous follicle center lymphoma, spleen	
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites	
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites	
C82.80	Other types of follicular lymphoma, unspecified site	
C82.81	Other types of follicular lymphoma, lymph nodes of head, face and neck	
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes	
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes	
C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb	
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb	
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes	
C82.87	Other types of follicular lymphoma, spleen	
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites	
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites	
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C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face and neck	
C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes	
C82.93	Follicular lymphoma, unspecified, intra-abdominal lymph nodes	
C82.94	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb	
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb	
C82.96	Follicular lymphoma, unspecified, intrapelvic lymph nodes	
C82.97	Follicular lymphoma, unspecified, spleen	
C82.98	Follicular lymphoma, unspecified, lymph nodes of multiple sites	
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites	
C83.00	Small cell B-cell lymphoma, unspecified site	
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck	
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes	
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes	
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb	
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb	
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes	
C83.07	Small cell B-cell lymphoma, spleen	
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites	
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites	
C83.10	Mantle cell lymphoma, unspecified site	
C83.11	Mantle cell lymphoma, lymph nodes of head, face and neck	
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes	
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes	
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb	
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb	
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes	
C83.17	Mantle cell lymphoma, spleen	
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites	
C83.19	Mantle cell lymphoma, extranodal and solid organ sites	
C83.30	Diffuse large B-cell lymphoma unspecified site	
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck	
C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes	
C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes	
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb	
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb	
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes	
C83.37	Diffuse large B-cell lymphoma, spleen	
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites	
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C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites	
C83.80	Other non-follicular lymphoma, unspecified site	
C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck	
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes	
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes	
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb	
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb	
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes	
C83.87	Other non-follicular lymphoma, spleen	
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites	
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites	
C83.90	Non-follicular (diffuse) lymphoma, unspecified site	
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	
C85.10	Unspecified B-cell lymphoma, unspecified site	
C85.11	Unspecified B-cell lymphoma, lymph nodes of head, face, and neck	
C85.12	Unspecified B-cell lymphoma, intrathoracic lymph nodes	
C85.13	Unspecified B-cell lymphoma, intra-abdominal lymph nodes	
C85.14	Unspecified B-cell lymphoma, lymph nodes of axilla and upper limb	
C85.15	Unspecified B-cell lymphoma, lymph nodes of inguinal region and lower limb	
C85.16	Unspecified B-cell lymphoma, intrapelvic lymph nodes	
C85.17	Unspecified B-cell lymphoma, spleen	
C85.18	Unspecified B-cell lymphoma, lymph nodes of multiple sites	
C85.19	Unspecified B-cell lymphoma, extranodal and solid organ sites	
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site	
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck	
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes	
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes	
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb	
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb	
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes	



C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen	
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites	
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites	
C85.87	Other specified types of non-Hodgkin lymphoma, spleen	
C88.0	Waldenström macroglobulinemia	
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-lymphoma)	
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission	
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse	
C91.40	Hairy cell leukemia not having achieved remission	
C91.42	Hairy cell leukemia, in relapse	
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)	
D47.Z2	Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue – Castleman	
Z85.71	Personal history of Hodgkin lymphoma	

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

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Additional indications may be covered at the discretion of the health plan.

<u>Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA)</u>:

Jurisdiction(s): 6, K	NCD/LCD/LCA Document (s): A59101		
https://www.cms.gov/medicare-co	https://www.cms.gov/medicare-coverage-database/new-search/search-		
results.aspx?keyword=a59101&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD			
%2C6%2C3%2C5%2C1%2CF%2CP			

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<u>https://www.cms.gov/medicare-coverage-database/new-search/search-</u> results.aspx?keyword=a56380&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD <u>%2C6%2C3%2C5%2C1%2CF%2CP</u>

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)

Moda Health Plan, Inc. Medical Necessity Criteria

Proprietary & Confidential

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	Medicare Part B Administrative	Contractor (MAC) Jurisdictions
Jurisdiction	Applicable State/US Territory	Contractor
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	КҮ, ОН	CGS Administrators, LLC

