

Epkinly® (epcoritamab-bysp) (Subcutaneous)

-E-

Document Number: IC-0747

Date Reviewed: 05/2026

Date of Origin: 06/04/2024

Dates Approved: 06/2024, 09/2024, 10/02/2025, 01/06/2026, 06/02/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
 - Treatment of follicular lymphoma in combination with rituximab and lenalidomide: Prior authorization validity may be renewed for a maximum of twelve cycles.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1200 billable units per 28 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria ¹

- Prophylaxis for infection will be followed according to local guidelines (e.g., *Pneumocystis jirovecii* pneumonia (PJP), *Herpes virus*, etc.); **AND**
- Member does not have a clinically significant active systemic infection; **AND**
- Member does not have primary central nervous system (CNS) lymphoma or CNS involvement of disease; **AND**

B-Cell Lymphomas † ‡ ^{1-4,6,9,13,2e,4e}

- Used in combination with lenalidomide and rituximab as subsequent therapy; **AND**
 - Member has relapsed or refractory follicular lymphoma; **AND**
 - Member received prior treatment with an anti-CD20 monoclonal antibody in combination with chemotherapy, unless contraindicated; **OR**

- Used as a single agent after at least two prior lines of systemic therapies including at least one anti-CD20 antibody-containing regimen, unless contraindicated; **AND**
 - Member has diffuse large B-cell Lymphoma (DLBCL) (*including DLBCL, not otherwise specified*), high-grade B-cell lymphoma, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL or HHV8-positive DLBCL, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
 - Used for partial response, progressive, relapsed, or refractory disease*; **OR**
 - Member has follicular lymphoma (grade 1-3A) **Φ**; **AND**
 - Used for partial response, no response, progressive, relapsed, or refractory disease; **AND**
 - Prior therapy included an alkylating agent or lenalidomide (in addition to an anti-CD20 monoclonal antibody), unless contraindicated; **AND**
- Use of epcoritamab-bysp will be restricted to members with a contraindication or intolerance to mosunetuzumab-axgb; **OR**
- Member has histologic transformation of an indolent lymphoma (follicular lymphoma or marginal zone lymphoma) to DLBCL*; **AND**
 - Used for partial response, no response, progressive, relapsed, or refractory disease; **OR**
- Used in combination with GemOx (gemcitabine and oxaliplatin) as subsequent therapy; **AND**
 - Member has diffuse large B-cell Lymphoma (DLBCL), high-grade B-cell lymphomas, HIV-related B-cell lymphoma (i.e., HIV-related DLBCL or HHV8-positive DLBCL, not otherwise specified), or monomorphic post-transplant lymphoproliferative disorder (PTLD) (B-cell type); **AND**
 - Used for primary refractory disease or relapsed disease <12 months after completion of first-line therapy AND member is a non-candidate for CAR T-cell therapy; **OR**
 - Used for relapsed disease >12 months after completion of first-line therapy AND no intention to proceed to transplant; **OR**
 - Used as alternative systemic therapy (if not previously used) for relapsed or refractory disease AND no intention to proceed to transplant

* Includes members with disease progression after transplant or CAR T-cell therapy

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) ‡ ^{10,11}

- Member has histologic transformation (Richter); **AND**
- Used as a single agent; **AND**

- Used as additional therapy for partial response, refractory disease, or progression while on prior treatment; **OR**
- Used as first-line treatment for Richter transformation if previously treated for CLL; **OR**
- Used as continuation therapy for complete response until progression

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.

Enhanced Oncology Value (EOV) Program – Redacted indications

Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity.

Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ☐ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity may be renewed based upon the following criteria:

- Member 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**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, serious or life-threatening cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), severe cytopenias (including neutropenia, anemia, and thrombocytopenia), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration ^{1,5,7,9,11}

Indication	Dose
Follicular Lymphoma	<u>In combination with rituximab and lenalidomide:</u> Administer subcutaneously in 28-day cycles, for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurs first. • Cycle 1: – Step-up dose one: 0.16 mg on day 1 – Step-up dose two: 0.8 mg on day 8 – Step-up dose three: 3 mg on day 15 – First full dose: 48 mg on day 22 • Cycles 2 and 3: – 48 mg on days 1, 8, 15, 22 • Cycles 4 to 12: – 48 mg on days 1 <u>As single agent:</u> Administer subcutaneously in 28-day cycles, until disease progression or unacceptable toxicity. • Cycle 1: – Step-up dose one: 0.16 mg on day 1 – Step-up dose two: 0.8 mg on day 8 – Step-up dose three: 3 mg on day 15 – First full dose: 48 mg on day 22 • Cycles 2 and 3: – 48 mg on days 1, 8, 15, 22 • Cycles 4 to 9: – 48 mg on days 1 and 15 • Cycles 10 and beyond: – 48 mg on day 1
All other B-Cell Lymphoma Subtypes	Administer subcutaneously in 28-day cycles, until disease progression or unacceptable toxicity. • Cycle 1: – Step-up dose one: 0.16 mg on day 1 – Step-up dose two: 0.8 mg on day 8 – First full dose: 48 mg on day 15 – 48 mg on day 22 • Cycles 2 and 3: – 48 mg on days 1, 8, 15, 22 • Cycles 4 to 9: – 48 mg on days 1 and 15 • Cycles 10 and beyond: – 48 mg on day 1

CLL/SLL	After step-up dosing administer subcutaneously in 28-day cycles, until disease progression or unacceptable toxicity • Cycles 2 and 3: – 48 mg on days 1, 8, 15, 22 • Cycles 4 to 9: – 48 mg on days 1 and 15 • Cycles 10 and beyond: – 48 mg on day 1
Note: – <i>Must be administered by a healthcare professional with appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).</i> – <i>Assess whether hospitalization or outpatient monitoring is appropriate based on comorbidities or other situational factors for the first 48 mg dosage of Epkinly.</i> – <i>Ensure adequate hydration before administering therapy. Premedicate before each dose in Cycle 1.</i>	

VI. Billing Code/Availability Information

HCPCS Code:

- J9321 – Injection, epcoritamab-bysp, 0.16 mg; 1 billable unit = 0.16 mg

NDC(s):

- Epkinly 4 mg/0.8 mL single-dose vial: 82705-0002-xx
- Epkinly 48 mg/0.8 mL single-dose vial: 82705-0010-xx

VII. References (STANDARD)

1. Epkinly [package insert]. Plainsboro, NJ; Genmab US, Inc.; March 2026. Accessed May 2026.
2. Hutchings M, Mous R, Clausen MR, et al. Dose escalation of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin lymphoma: an open-label, phase 1/2 study. *Lancet*. 2021 Sep 25;398(10306):1157-1169. Doi: 10.1016/S0140-6736(21)00889-8. Epub 2021 Sep 8.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) epcoritamab. National Comprehensive Cancer Network, 2025. 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 December 2025.

4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas, Version 3.2025. National Comprehensive Cancer Network, 2025. 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 Guidelines, go online to NCCN.org. Accessed December 2025.
5. Thieblemont C, Phillips T, Ghesquieres H, et al. Epcoritamab, a Novel, Subcutaneous CD3xCD20 Bispecific T-Cell-Engaging Antibody, in Relapsed or Refractory Large B-Cell Lymphoma: Dose Expansion in a Phase I/II Trial. *J Clin Oncol*. 2023 Apr 20;41(12):2238-2247. doi: 10.1200/JCO.22.01725. Epub 2022 Dec 22. PMID: 36548927; PMCID: PMC10115554.
6. Linton KM, Vitolo U, Jurczak W, et al. Epcoritamab monotherapy in patients with relapsed or refractory follicular lymphoma (EPCORE NHL-1): a phase 2 cohort of a single-arm, multicentre study. *Lancet Haematol*. 2024 Jun 13:S2352-3026(24)00166-2. doi: 10.1016/S2352-3026(24)00166-2.
7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Epcoritamab-bysp: Diffuse Large B-Cell Lymphoma Chemotherapy Order Template, DBL85. National Comprehensive Cancer Network, 2025. 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 Guidelines, go online to NCCN.org. Accessed August 2024.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Epcoritamab-bysp: Classic Follicular Lymphoma Chemotherapy Order Template, FOL35. National Comprehensive Cancer Network, 2025. 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 Guidelines, go online to NCCN.org. Accessed August 2024.
9. Brody JD, Jørgensen J, Belada D, et al. Epcoritamab plus GemOx in transplant-ineligible relapsed/refractory DLBCL: Results from the EPCORE NHL-2 trial. *Blood* 2025;145:1621-1631. Available at: <https://ashpublications.org/blood/article/145/15/1621/535030/Epcoritamab-plus-GemOx-in-transplant-ineligible>.
10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Version 1.2026. National Comprehensive Cancer Network, 2025. 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 Guidelines, go online to NCCN.org. Accessed December 2025.

11. Kater A, Janssens A, Eradat H, et al. Single-agent epcoritamab leads to deep responses in patients (pts) with richter's transformation (RT): primary results from the EPCORE CLL-1 trial [abstract]. European Hematology Association 2024:Abstract S163.
12. Vose JM, Cheah CY, Clausen MR, et al. 3-year update from the Epcore NHL-1 trial: Epcoritamab leads to deep and durable responses in relapsed or refractory large B-cell lymphoma [abstract]. Blood 2024;144: Abstract 4480.
13. Falchi L, Morschhauser F, Linton K, et al. EPCORE FL-1: phase 3 trial of subcutaneous epcoritamab with rituximab and lenalidomide (R2) vs R2 alone in patients with relapsed or refractory follicular lymphoma. Blood. 2023;142(suppl 1):3053. doi:10.1182/blood-2023-180092.

VIII. References (ENHANCED)

- 1e. Dickinson MJ, Carlo-Stella C, Morschhauser F, et al. Glofitamab for relapsed or refractory diffuse large B-cell lymphoma. *N Engl J Med*. 2022;387(24):2220-2231. doi:10.1056/NEJMoa2206913.
- 2e. Thieblemont C, Phillips T, Ghesquieres H, et al. Epcoritamab, a Novel, Subcutaneous CD3xCD20 Bispecific T-Cell–Engaging Antibody, in Relapsed or Refractory Large B-Cell Lymphoma: Dose Expansion in a Phase I/II Trial. *Journal of Clinical Oncology*. Published online December 22, 2022. doi:https://doi.org/10.1200/jco.22.01725
- 3e. Columvi [package insert]. South San Francisco, CA; Genetech, Inc; October 2025. Accessed December 2025.
- 4e. Bartlett NL, Sehn LH, Matasar MJ, et al. Mosunetuzumab Monotherapy Demonstrates Durable Efficacy with a Manageable Safety Profile in Patients with Relapsed/Refractory Follicular Lymphoma Who Received ≥ 2 Prior Therapies: Updated Results from a Pivotal Phase II Study [abstract]. Blood 2022;140:1467-1470.
- 5e. Abramson JS, Ku M, Hertzberg M, et al. Glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab-GemOx for relapsed or refractory diffuse large B-cell lymphoma (STARGLO): a global phase 3, randomised, open-label trial. *Lancet*. 2024 Nov 16;404(10466):1940-1954.
- 6e. Salles G, Duell J, González Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *Lancet Oncol*. 2020 Jul;21(7):978-988.
- 7e. Sehn LH, Herrera AF, Flowers CR, et al. Polatuzumab Vedotin in Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *J Clin Oncol*. 2020 Jan 10;38(2):155-165.
- 8e. Budde LE, Olszewski AJ, Assouline S, et al. Mosunetuzumab with polatuzumab vedotin in relapsed or refractory aggressive large B cell lymphoma: a phase 1b/2 trial. *Nat Med*. 2024 Jan;30(1):229-239.

- 9e. Carlo-Stella C, Hutchings M, Offner F, et al. Glofitamab monotherapy induces durable complete remissions and has a manageable safety profile in patients with Richter's transformation [abstract]. Hematological Oncology 2023;41:Abstract 28.
- 10e. Budde LE, Zhang H, Kim WS, et al. Mosunetuzumab Plus Polatuzumab Vedotin in Transplant-Ineligible Refractory/Relapsed Large B-Cell Lymphoma: Primary Results of the Phase III SUNMO Trial. J Clin Oncol. Published October 2, 2025. DOI: 10.1200/JCO-25-01957.
- 11e. Prime Therapeutics Management. Epkinly Clinical Literature Review Analysis. Last updated May 2026. Accessed May 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
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
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
C82.90	Follicular lymphoma, unspecified, unspecified site
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
C83.30	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
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.398	Diffuse large B-cell lymphoma of other 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
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face, and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)

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

Page 13

Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2026 Prime Therapeutics Management, LLC

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 following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

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 VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC