Polivy® (polatuzumab vedotin-piiq)
(Intravenous)

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I. Length of Authorization [1,6]

Coverage will be provided for 6 months (up to 6 cycles of therapy) and may NOT be renewed.

II. Dosing Limits

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

- 200 billable units every 21 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient will receive prophylaxis for Pneumocystis jiroveci pneumonia and herpesvirus; **AND**
- Patient does not currently have Grade ≥ 2 peripheral neuropathy; **AND**
- Patient does not have CNS lymphoma; **AND**

B-Cell Lymphomas † ‡ [1-5,3e]

- Diffuse Large B-Cell Lymphoma (DLBCL) **Φ**; **AND**
  - Used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP); **AND**
    - Used as first line therapy **†**; **AND**
    - Patient has an International Prognostic Index (IPI) score of ≥2; **OR**
  - Used as a single agent **Ω** OR in combination with rituximab, with or without bendamustine *(Note: Use for* relapsed *plasmablastic lymphoma excludes use with rituximab)*; **AND**
    - Used as subsequent therapy in patients with no intention to proceed to transplant; **AND**

- Used for relapsed disease >12 months after completion of first-line therapy; **OR**
- Used for primary refractory disease (partial response, no response, or progression) or relapsed disease <12 months after completion of first-line therapy* in non-candidates for CAR T-cell therapy; **OR**
- Used as alternative systemic therapy (if not previously used) for relapsed/refractory disease in non-candidates for CAR T-cell therapy; **OR**

▪ Used as bridging option until CAR T-cell product is available for primary refractory disease or relapsed disease <12 months after completion of first-line therapy

- HIV-Related B-Cell Lymphomas **Ω** *(includes all of the following: diffuse large B-cell lymphoma, primary effusion lymphoma, HHV8-positive diffuse large B-cell lymphoma [not otherwise specified], and plasmablastic lymphoma)* OR High-Grade B-Cell Lymphomas (HGBL); **AND**
  - Used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP); **AND**
    - Used as first line therapy *(Only applies to High-Grade B-Cell Lymphoma)* **†**; **AND**
    - Patient has an International Prognostic Index (IPI) score of ≥2; **OR**
  - Used as a single agent **Ω** OR in combination with bendamustine and/or rituximab *(Note: Use for* relapsed *plasmablastic lymphoma excludes use with rituximab)* **Ω**; **AND**
    - Used as subsequent therapy in patients with no intention to proceed to transplant; **AND**
      - Used for relapsed disease >12 months after completion of first-line therapy; **OR**
      - Used for primary refractory disease (partial response, no response, or progression) or relapsed disease <12 months after completion of first-line therapy* in non-candidates for CAR T-cell therapy; **OR**
      - Used as alternative systemic therapy (if not previously used) for relapsed/refractory disease in non-candidates for CAR T-cell therapy; **OR**
    - Used as bridging option until CAR T-cell product is available for primary refractory disease or relapsed disease <12 months after completion of first-line therapy
- Histologic Transformation of Indolent Lymphomas **‡ Ω**
  - Used as a single-agent or in combination with bendamustine and/or rituximab in patients with no intention to proceed to transplant; **AND**
    - Patient has previously been treated with an anthracycline-based regimen; **AND**
      - Patient had histologic transformation to DLBCL after minimal or no prior treatment; **AND**
        - ➢ Used as additional therapy for partial response, no response, progressive, or relapsed disease following chemoimmunotherapy; **OR**

  - Patient had histologic transformation to DLBCL after multiple lines of prior therapies including ≥2 chemoimmunotherapy regimens for indolent or transformed disease; **OR**
- Used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP); **AND**
  - Patient had histologic transformation to DLBCL or high-grade B-cell lymphoma with MYC and BCL6 rearrangement (without BCL2 rearrangements); **AND**
  - Used after minimal or no prior therapy; **AND**
  - Patient has an IPI score of ≥2

- Post-Transplant Lymphoproliferative Disorders **‡ Ω**
  - Patient has monomorphic B-cell type disease; **AND**
  - Used as a single-agent or in combination with bendamustine and/or rituximab; **AND**
    - Used as subsequent therapy in patients with no intention to proceed to transplant; **AND**
      - Used for relapsed disease >12 months after completion of initial treatment with chemoimmunotherapy; **OR**
      - Used for primary refractory disease (partial response, no response, or progression) or relapsed disease <12 months after completion of initial treatment with chemoimmunotherapy in non-candidates for CAR T-cell therapy; **OR**
      - Used as alternative systemic therapy (if not previously used) for relapsed/refractory disease in non-candidates for CAR T-cell therapy; **OR**
    - Used as a bridging option until CAR T-cell product is available for primary refractory disease or relapsed disease <12 months after completion of initial treatment with chemoimmunotherapy

***Rituximab should be included in second-line therapy if there is relapse after a reasonable remission (>6 mo); however, rituximab should often be omitted in patients with primary refractory disease.*

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.

Ω *Please note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.*

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

IV. Renewal Criteria [1,3,4]

- Duration of authorization has not been exceeded (refer to Section I)

V. Dosage/Administration [1,6]

Indication	Dose
B-cell Lymphomas	Administer 1.8 mg/kg intravenously every 21 days for 6 cycles.

VI. Billing Code/Availability Information

HCPCS Code:

- J9309 – Injection, polatuzumab vedotin-piiq 1 mg; 1 mg = 1 billable unit

NDC(s):

- Polivy 30 mg lyophilized powder for injection, single-dose vial: 50242-0103-xx
- Polivy 140 mg lyophilized powder for injection, single-dose vial: 50242-0105-xx

VII. References (STANDARD)

1. Polivy [package insert]. South San Francisco, CA; Genentech, Inc; April 2023. Accessed January 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for polatuzumab vedotin. 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 January 2025.
3. Sehn LH, Kamdar M, Herrera AF, et al. Randomized phase 2 trial of polatuzumab vedotin (pola) with bendamustine and rituximab (BR) in relapsed/refractory (r/r) FL and DLBCL. J Clin Oncol 2018; 36:15_suppl, 7507-7507. doi:10.1200/JCO.2018.36.15_suppl.7507
4. Sehn LH, Herrera AF, Matasar MJ, et al. Polatuzumab vedotin (Pola) plus bendamustine (B) with rituximab (R) or obinutuzumab (G) in relapsed/refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL): Updated results of a phase (Ph) Ib/II study (abstract). Blood 2018;132:Abstract 1683.
5. Tilly H, Morschhauser F, Sehn LH, et al. Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. N Engl J Med. 2022 Jan 27;386(4):351-363. doi: 10.1056/NEJMoa2115304.
6. 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. doi: 10.1200/JCO.19.00172.

VIII. References (ENHANCED)

1e. Mounier N, El Gnaoui T, Tilly H, et al. Rituximab plus gemcitabine and oxaliplatin in patients with refractory/relapsed diffuse large B-cell lymphoma who are not candidates for high-dose therapy. A phase II Lymphoma Study Association trial. Haematologica. 2013;98(11):1726–1731. doi:10.3324/haematol.2013.090597.

2e. Morschhauser F, Flinn IW, Advani R, et al. Polatuzumab vedotin or pinatuzumab vedotin plus rituximab in patients with relapsed or refractory non-Hodgkin lymphoma: final results from a phase 2 randomised study (ROMULUS). Lancet Haematol. 2019 May;6(5):e254-e265. doi: 10.1016/S2352-3026(19)30026-2.

3e. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas 1.2025. 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 January 2025.

4e. Liebers N, Duell J, Fitzgerald D, et al. Polatuzumab vedotin as a salvage and bridging treatment in relapsed or refractory large B-cell lymphomas. Blood Advances. 2021;5(13):2707-2716. doi:https://doi.org/10.1182/bloodadvances.2020004155

5e. Sehn LH, Hertzberg MP, Opat S, et al. Polatuzumab vedotin plus bendamustine and rituximab in relapsed/refractory DLBCL: survival update and new extension cohort data. 2022;6(2):533-543. doi:https://doi.org/10.1182/bloodadvances.2021005794.

6e. Palanca-Wessels MC, Czuczman M, Salles G, et al. Safety and activity of the anti-CD79B antibody-drug conjugate polatuzumab vedotin in relapsed or refractory B-cell non-Hodgkin lymphoma and chronic lymphocytic leukaemia: a phase 1 study. Lancet Oncol. 2015;16(6):704-715. doi:10.1016/S1470-2045(15)70128-2.

7e. 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.

8e. 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.

9e. Prime Therapeutics Management. Polivy Clinical Literature Review Analysis. Last updated January 2025. Accessed January 2025.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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 of 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
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

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/LCA/LCD): 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