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

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

- Polivy 30 mg single-dose vial: 2 vials per 21 days
- Polivy 140 mg single-dose vial: 1 vial per 21 days

B. 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** 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 **†**; **AND**
    - Patient has an International Prognostic Index (IPI) score of ≥2; **OR**
  - Used in combination with rituximab OR bendamustine and 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

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); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,3,4]

Coverage cannot be renewed.

V. Dosage/Administration [1,6]

Indication	Dose
Previously untreated DLBCL or HGBL	Administer 1.8 mg/kg intravenously every 21 days for 6 cycles in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone. • Administer Polivy, cyclophosphamide, doxorubicin, and a rituximab product in any order on Day 1 after the administration of prednisone. Prednisone is administered on Days 1–5 of each cycle.
Relapsed/refractory DLBCL	Administer 1.8 mg/kg intravenously every 21 days for 6 cycles in combination with bendamustine and rituximab product. • Administer Polivy, bendamustine, and rituximab product in any order on Day 1 of each cycle.
All Other Indications	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 June 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for polatuzumab vedotin. 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 June 2024.
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 2.2024. National Comprehensive Cancer Network, 2024. 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 June 2024.

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. Prime Therapeutics Management. Polivy Clinical Literature Review Analysis. Last updated June 2024. Accessed June 2024.

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
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
C83.90	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

ICD-10	ICD-10 Description
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

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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