Polivy® (polatuzumab vedotin-piiq)
(Intravenous)

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I. Length of Authorization [1,6]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days; up to 6 cycles of therapy).
- Renewal: Prior authorization validity 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]

Prior authorization validity 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 † ‡ [1-7,3e,9e]

- 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 AND stage II (*with extensive mesenteric disease*) or stage III-IV disease; **OR**
  - Patient has a stage modified IPI (smIPI) score of >1 and stage I-II disease (*excluding use in stage II* disease *with extensive mesenteric disease*); **OR**
- Used as a single agent OR in combination with rituximab, with or without bendamustine; **AND**
  - Used as subsequent therapy; **AND**
    - Used for relapsed disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **OR**
    - Used for primary refractory disease 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; **OR**
  - Used as bridging option for relapsed or refractory disease in candidates for CAR T-cell therapy; **OR**
- Used in combination with mosunetuzumab; **AND**
  - Used as subsequent treatment; **AND**
    - Used for relapsed disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **OR**
    - Used for primary refractory disease or relapsed disease <12 months after completion of first-line therapy or primary refractory disease in non-candidates for CAR T-cell therapy; **OR**
    - Used as alternative systemic therapy (if not previously used) for relapsed or refractory disease AND no intention to proceed to transplant; **OR**

- High-Grade B-Cell Lymphomas (HGBL) or HIV-Related B-Cell Lymphomas *(includes all of the following: DLBCL and HHV8-positive DLBCL [not otherwise specified])*; **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 and stage II (*with extensive disease*) OR stage III-IV disease; **OR**
      - Patient has a staged modified IPI (smIPI) score of >1 and stage I-II disease (*excluding use in stage II disease with extensive mesenteric disease*); **OR**
  - Used as a single agent OR in combination with rituximab, with or without bendamustine; **AND**
    - Used as subsequent therapy; **AND**

- Used for relapsed disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **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; **OR**

▪ Used as bridging option for relapsed or refractory disease in candidates for CAR T-cell therapy; **OR**

○ Used in combination with mosunetuzumab; **AND**

▪ Used as subsequent treatment; **AND**

- Used for relapsed disease >12 months after completion of first-line therapy if no intention to proceed to transplant; **OR**
- Used for primary refractory disease or relapsed disease <12 months after completion of first-line therapy or primary refractory disease in non-candidates for CAR T-cell therapy; **OR**
- Used as alternative systemic therapy (if not previously used) for relapsed or refractory disease AND no intention to proceed to transplant; **OR**

- Histologic Transformation of Indolent Lymphomas ‡
  - Used as a single-agent or in combination with rituximab (with or without bendamustine) 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 disease prior to histologic transformation; **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; **OR**
- Post-Transplant Lymphoproliferative Disorders ‡

- Used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP); **AND**
  - Patient has monomorphic or systemic polymorphic B-cell type disease; **AND**
    - Used as first-line therapy; **AND**
    - Patient has an International Prognostic Index (IPI) score of ≥2; **OR**
- Used as a single-agent or in combination with rituximab (with or without bendamustine); **AND**
  - Used as subsequent therapy for monomorphic B-cell type disease; **AND**
    - Used for relapsed disease >12 months after completion of initial treatment with chemoimmunotherapy if no intention to proceed to transplant; **OR**
    - Used for primary refractory disease* 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; **OR**
  - Used as a bridging option until CAR T-cell product is available; **OR**
- Used in combination with mosunetuzumab; **AND**
  - Used as subsequent therapy for monomorphic B-cell type disease; **AND**
    - Used for relapsed disease >12 months after completion of initial treatment with chemoimmunotherapy if no intention to proceed to transplant; **OR**
    - Used for primary refractory disease 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 or refractory disease AND no intention to proceed to transplant

*****_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.

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); 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 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for polatuzumab vedotin. National Comprehensive Cancer Network, 2026. 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 2026.
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

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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.
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VIII. References (ENHANCED)

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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 1.2026. National Comprehensive Cancer Network, 2026. 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 2026.

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.

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9e. Morschhauser F, Salles G, Sehn LH, Herrera AF, et al. Five-Year Outcomes of the POLARIX Study Comparing Pola-R-CHP and R-CHOP in Patients With Diffuse Large B-Cell Lymphoma. J Clin Oncol. 2025 Dec 10;43(35):3698-3705. doi: 10.1200/JCO-25-00925. Epub 2025 Sep 24. Erratum in: J Clin Oncol. 2025 Nov 20:JCO2502667. doi: 10.1200/JCO-25-02667. PMID: 40991874; PMCID: PMC12680271.

10e. Prime Therapeutics Management. Polivy Clinical Literature Review Analysis. Last updated January 2026. Accessed January 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	No: PA not a priority
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
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

ICD-10	ICD-10 Description
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
C83.398	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

ICD-10	ICD-10 Description
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