Polivy™ (polatuzumab vedotin-piiq)
(Intravenous)

-E-

Document Number: IC-0543

Last Review Date: 01/05/2021
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Dates Reviewed: 06/2020, 08/2020, 01/2021

I. Length of Authorization

Coverage will be provided for six 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**

Universal Criteria [1,3]

- 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 † ‡ [1,2,3,4]

- Patient has diffuse large B-cell lymphoma (DLBCL)**Φ**; **AND**
  - Patient has partial response, no response, relapsed, progressive or refractory disease; **AND**
  - Patient is not a candidate for stem cell transplant; **AND**
  - Used in combination with bendamustine and rituximab; **AND**
  - Used as subsequent treatment after at least two prior therapies

*(**Note: For patients with relapsed disease who received prior bendamustine, response duration must have been >1 year)*

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 [1,3,4]

Indication	Dose
DLBCL	The recommended dose of Polivy is 1.8 mg/kg administered as an intravenous infusion 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.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References

1. Polivy [package insert]. South San Francisco, CA; Genentech, Inc; September 2020. Accessed December 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for polatuzumab vedotin. National Comprehensive Cancer Network, 2020. 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 2020.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas 4.2020. National Comprehensive Cancer Network, 2020. 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 2020.

4. 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.
5. 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. Blood 2018;132:Abstract 1683.
6. 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.
7. Magellan Health, Magellan Rx Management. Polivy Clinical Literature Review Analysis. Last updated December 2020. Accessed December 2020.

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

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 Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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, 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	KY, OH	CGS Administrators, LLC

Appendix 3 – CLINICAL LITERATURE REVIEW

OS = overall survival; PFS = progression-free survival; ORR = objective response rate; CR = complete response; PR = partial response; DoR = duration of response; TTP = time to progression; FFS = failure-free survival; EFS = event-free survival; PFR = progression free rate

Diffuse Large B-cell Lymphoma (DLBCL)

Relapsed or refractory disease							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Polatuzumab vedotin-piiq + bendamustine + rituximab	2A preferred (after ≥ 2 prior therapies)	Yes (after ≥ 2 prior therapies)	Phase 2, randomized, multi-center, open-label	Bendamustine + rituximab	CR	Relapsed or refractory FL or DLBCL	• In a randomized setting, BR+P showed longer survival compared to BR, with median OS surpassing 12 months.
Gemcitabine + oxaliplatin (GemOx) + rituximab	2A preferred (non-candidates for transplant)	No	Phase 2, multi-center	N/A	ORR	Relapsed or refractory DLBCL	• GemOx-R as salvage treatment for DLBCL demonstrated an ORR of 61%

High-Grade B-Cell Lymphoma, Follicular Lymphoma, Mantle Cell Lymphoma, Post-transplant Lymphoproliferative Disorders, AIDS-Related B-Cell Lymphomas, & Histologic Transformation of Nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma

Relapsed or refractory disease							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Polatuzumab vedotin-piiq + bendamustine + rituximab	2A	No	• No clinical literature evidence to support use.				