

## Clinical Policy: Polatuzumab Vedotin-piiq (Polivy)

Reference Number: CP.PHAR.433

Effective Date: 09.01.19

Last Review Date: 08.22

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Polatuzumab vedotin-piiq (Polivy<sup>™</sup>) is a CD79b-directed antibody-drug conjugate with activity against dividing B cells.

### FDA Approved Indication(s)

Polivy is indicated in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), after at least two prior therapies.

Accelerated approval was granted for this indication based on complete response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Polivy is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Diffuse Large B-Cell Lymphoma (must meet all):

1. Diagnosis of DLBCL (*see subtypes at Appendix D*);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. Member is not a candidate for allogeneic or autologous stem cell transplant;
5. Member has received  $\geq$  1 prior therapy (*see Appendix B*);
6. Polivy is prescribed as a single agent or in combination with bendamustine\* and/or a rituximab product\* (*see Appendix B for rituximab products*);  
*\*Prior authorization may be required for bendamustine and rituximab products*
7. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 1.8 mg/kg on Day 1 of a 21-day cycle, for a maximum of 6 cycles;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration: 6 months (medical justification supports requests for cycles beyond 6)**

**B. NCCN Recommended Uses (off-label) (must meet all):**

1. Diagnosis of one of the following (a, b, c, d, or e):
  - a. Follicular lymphoma (FL) (grade 1-2);
  - b. Mantle cell lymphoma;
  - c. Monomorphic post-transplant lymphoproliferative disorder (B-cell type);
  - d. One of the following AIDS-related B-cell lymphoma subtypes (i, ii, iii, or iv):
    - i. AIDS-related DLBCL;
    - ii. Primary effusion lymphoma;
    - iii. HHV8-positive diffuse large B-cell lymphoma, NOS;
    - iv. AIDS-related plasmablastic lymphoma;
  - e. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age  $\geq$  18 years;
4. For requests other than FL grade 1-2, member is not a candidate for allogeneic or autologous stem cell transplant;
5. Member has received  $\geq$  1 prior therapy (*see Appendix B*);
6. Polivy is prescribed as a single agent or in combination with bendamustine\* and/or a rituximab product\* (*see Appendix B for rituximab products*);  
*\*Prior authorization may be required for bendamustine and rituximab products*
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).\*  
*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months (medical justification is required for requests for more than 6 cycles)**

**C. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Polivy for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member meets one of the following (a or b):
  - a. Member has received < 6 cycles of Polivy;
  - b. Member has received less than the number of cycles recommended by NCCN for the covered indication;
4. If request is for a dose increase, request meets one of the following (a or b):\*
  - a. New dose does not exceed 1.8 mg/kg on Day 1 of a 21-day cycle, for a maximum of 6 cycles;
  - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

\*Prescribed regimen must be FDA-approved or recommended by NCCN.

**Approval duration: 12 months (medical justification supports requests for cycles beyond 6)**

### B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

- ### A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies –
- CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

DLBCL: diffuse large B-cell lymphoma

FDA: Food and Drug Administration

FL: follicular lymphoma

HGBL: high-grade B-cell lymphoma

NCCN: National Comprehensive Cancer Network

NOS: not otherwise specified

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| <b>Drug Name</b>   | <b>Dosing Regimen</b> | <b>Dose Limit/ Maximum Dose</b> |
|--|-----------------------|---------------------------------|
| <b>Rituximab Products</b>  |                       |                                 |
| Rituxan <sup>®</sup> (rituximab), Truxima <sup>®</sup> (rituximab-abbs), Rituxan Hycela <sup>®</sup> (rituximab-hyaluronidase)   | Varies                | Varies                          |
| <b>DLBCL Regimen examples (NCCN)</b>   |                       |                                 |
| bendamustine ± rituximab   | Varies                | Varies                          |
| CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± rituximab   | Varies                | Varies                          |
| lenalidomide ± rituximab   | Varies                | Varies                          |
| <b>HGBL Regimen examples (NCCN)</b>  |                       |                                 |
| DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)   | Varies                | Varies                          |
| RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)  | Varies                | Varies                          |
| <b>FL (grade 1-2) Regimen examples (NCCN)</b>  |                       |                                 |
| <u>Anthracycline- or anthracenedione-based regimens:</u><br>CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab<br>CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab | Varies                | Varies                          |
| RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)  | Varies                | Varies                          |
| <b>Mantle Cell Lymphoma Regimen examples (NCCN)</b>  |                       |                                 |
| RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin)  | Varies                | Varies                          |
| VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and prednisone)  | Varies                | Varies                          |
| <b>Post-Transplant Lymphoproliferative Disorder Regimen examples (NCCN)</b>  |                       |                                 |
| CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab  | Varies                | Varies                          |
| CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab  | Varies                | Varies                          |
| <b>AIDS-related B-Cell Lymphoma Regimen examples (NCCN)</b>  |                       |                                 |
| R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)   | Varies                | Varies                          |
| CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab  | Varies                | Varies                          |

| Drug Name   | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|----------------|--------------------------|
| <b>Histologic Transformation of Nodal Marginal Zone Lymphoma to DLBCL Regimen examples (NCCN)</b> |                |                          |
| RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)                         | Varies         | Varies                   |

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: DLBCL Subtypes per the National Comprehensive Cancer Network (NCCN)*

- DLBCL, NOS (FDA-approved use)
- DLBCL coexistent with follicular lymphoma of any grade
- DLBCL coexistent with gastric MALT lymphoma
- DLBCL coexistent with nongastric MALT lymphoma
- Follicular lymphoma grade 3
- Intravascular large B-cell lymphoma
- DLBCL associated with chronic inflammation
- ALK-positive LBCL
- EBV-positive DLBCL, NOS
- T-cell/histiocyte-rich large B-cell lymphoma
- LBCL with IRF4/MUM1 rearrangement
- Double expressor DLBCL
- Primary mediastinal LBCL
- Gray zone lymphoma
- High-grade B-cell lymphomas with translocations of MYC and BCL2 and/or BCL6
- High-grade B-cell lymphomas, NOS
- Primary cutaneous DLBCL

**V. Dosage and Administration**

| Indication | Dosing Regimen  | Maximum Dose       |
|------------|---|--------------------|
| DLBCL      | 1.8 mg/kg IV over 90 minutes every 21 days for 6 cycles in combination with bendamustine and a rituximab product. (Administer Polivy, bendamustine, and rituximab product in any order on Day 1 of each cycle.) <ul style="list-style-type: none"> <li>• <b>Bendamustine:</b> The recommended dose of bendamustine is 90 mg/m<sup>2</sup>/day IV on Day 1 and 2 when administered with Polivy and a rituximab product.</li> <li>• <b>Rituximab product:</b> The recommended dose of rituximab product is 375 mg/m<sup>2</sup> IV on Day 1 of each cycle.</li> </ul> | 1.8 mg/kg (Polivy) |

**VI. Product Availability**

Single-dose vial for injection after reconstitution: 30 mg, 140 mg

**VII. References**

1. Polivy Prescribing Information. South San Francisco, CA: Genentech, Inc.; September 2020. Available at: [https://www.gene.com/download/pdf/polivy\\_prescribing.pdf](https://www.gene.com/download/pdf/polivy_prescribing.pdf). Accessed May 2, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed May 2, 2022.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2022. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/b-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf). Accessed May 2, 2022.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description                                  |
|-------------|--|
| J9309       | Injection, polatuzumab vedotin-piiq (Polivy) |

| Reviews, Revisions, and Approvals  | Date     | P&T Approval Date |
|--|----------|-------------------|
| Policy created.  | 07.09.19 | 08.19             |
| 3Q 2020 annual review: HIM and Commercial lines of business added; NCCN off-label uses added for HGBL, follicular and mantle cell lymphomas, post-transplant lymphoproliferative disorder, AIDS-related B-cell lymphoma, histologic transformation of nodal marginal lymphoma to DLBCL; 6 cycles total highlighted in approval section; more than 6 cycles added if supported by NCCN compendium in continuation section; references reviewed and updated.                                     | 05.12.20 | 08.20             |
| RT4: added 30 mg vial size to product availability.  | 11.30.20 |                   |
| 3Q 2021 annual review: no significant changes; HCPCS code updated; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.  | 04.30.21 | 08.21             |
| 3Q 2022 annual review: for DLBCL per NCCN modified to only require one prior therapy and allow use as a single agent, updated Appendix D with DLBCL subtypes to align with NCCN; for Section I,B Other NCCN Recommended Uses criteria set, removed HGBL as this is considered a DLBCL subtype, per NCCN modified to only require at least one prior therapy for all requests and require member is not a transplant candidate for all requests other than FL; references reviewed and updated. | 05.02.22 | 08.22             |

| Reviews, Revisions, and Approvals                        | Date     | P&T Approval Date |
|--|----------|-------------------|
| Template changes applied to other diagnoses/indications. | 09.26.22 |                   |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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