

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

Reference Number: CP.PHAR.433

Effective Date: 07.09.19

Last Review Date: 08.19

Line of Business: Medicaid, HIM-Medical Benefit

[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 *Appendix D for DLBCL subtypes*);
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. Disease is relapsed or refractory;
6. Member has received  $\geq$  2 prior therapies (*prior therapies can include a first-line and second-line/subsequent therapy, see Appendix B for examples of prior therapies*);
7. Polivy is prescribed in combination with bendamustine and a rituximab product (see *Appendix B for rituximab products*);  
*\*Prior authorization is required for bendamustine and rituximab products*
8. 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**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**II. Continued Therapy**

**A. Diffuse Large B-Cell Lymphoma (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 has received < 6 cycles of Polivy;
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**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

**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.PMN.53 for Medicaid and HIM-Medical Benefit.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

DLBCL: diffuse large B-cell lymphoma

FDA: Food and Drug Administration

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.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Rituximab Products</b>		
Rituxan <sup>®</sup> (rituximab), Truxima <sup>®</sup> (rituximab-abbs), Rituxan Hycela <sup>®</sup> (rituximab-hyaluronidase)	Varies	Varies
<b>Diffuse Large B-Cell Lymphoma: Examples of ≥ 2 Prior Therapies can include a First-Line and Second-Line/Subsequent Regimen</b>		
<i>First-Line Treatment Regimens (per NCCN)</i>		
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine)	Varies	Varies
RCDOP (rituximab, cyclophosphamide, liposomal doxorubicin, vincristine, prednisone)	Varies	Varies
DA-EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) + rituximab	Varies	Varies
RCEOP (rituximab, cyclophosphamide, etoposide, vincristine, prednisone)	Varies	Varies
RGCVP (rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone)	Varies	Varies
<i>Second-Line Treatment (per NCCN for Relapsed or Refractory Disease) – Examples of Regimens for Non-Candidates for Transplant</i>		
bendamustine ± rituximab	Varies	Varies
CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± rituximab	Varies	Varies
CEOP (cyclophosphamide, etoposide, vincristine, prednisone) ± rituximab	Varies	Varies
DA-EPOCH ± rituximab	Varies	Varies
GDP (gemcitabine, dexamethasone, carboplatin) ± rituximab	Varies	Varies
GemOx (gemcitabine, oxaliplatin) ± rituximab	Varies	Varies
gemcitabine, vinorelbine ± rituximab	Varies	Varies
ibrutinib	Varies	Varies
lenalidomide ± rituximab	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: General Information*

- In addition to the FDA-approved DLBCL, NOS subtype, other DLBCL subtypes provided by NCCN include, but are not limited to the following:
  - DLBCL, NOS
    - HGBL with translocations of MYC and BCL2 and/or BCL6
    - HGBL, NOS

- 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 DLBCL
- EBV-positive DLBCL, NOS
- T-cell/histiocyte-rich large B-cell lymphoma
- DLBCL with IRF4/MUM1 rearrangement

**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. ( <i>Administer Polivy, bendamustine, and rituximab product in any order on Day 1 of each cycle.</i> ) <ul style="list-style-type: none"> <li>● <u>Bendamustine</u>: 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>● <u>Rituximab product</u>: 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: 140 mg

**VII. References**

1. Polivy Prescribing Information. South San Francisco, CA: Genentech, Inc.; June 2019. Available at: [https://www.gene.com/download/pdf/polivy\\_prescribing.pdf](https://www.gene.com/download/pdf/polivy_prescribing.pdf). Accessed June 17, 2019.
2. Data on file. Genentech, Inc.; South San Francisco, CA. Polivy in the treatment of relapsed or refractory diffuse large B-cell lymphoma (GO29365 Trial).
3. 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 June 24, 2019.
4. National Comprehensive Cancer Network. B-Cell Lymphomas Version 4.2019. 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 June 24, 2019.

**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
TBD	Injection, polatuzumab vedotin-piiq (Polivy)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	07.09.19	08.19

**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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