

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

Reference Number: LA.PHAR.433

Effective Date: 10.25.23

Last Review Date: ~~08.18.25~~09.17.24

Line of Business: Medicaid

[Coding Implications](#)[Revision Log](#)

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

**\*\*Please note: This policy is for medical benefit\*\***

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**Description**

Polatuzumab vedotin-piiq (Polivy®) is a CD79b-directed antibody-drug conjugate with activity against dividing B cells.

**FDA Approved Indication(s)**

Polivy is indicated:

- In combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of 2 or greater
- In combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, NOS, after at least two prior therapies

**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 Louisiana Healthcare Connections® that Polivy is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. B-Cell Lymphoma** (must meet all):

1. Diagnosis of one of the following B-cell lymphomas (a, b, c, d, or e):
  - a. DLBCL (*see Appendix D for DLBCL subtypes*);
  - b. HGBL;
  - c. ~~Monomorphic post~~Post-transplant lymphoproliferative disorder (**PTLD**) (B-cell type) (off-label);
  - d. One of the following HIV-related B-cell lymphoma subtypes (i, ii, iii, or iv) (off-label):
    - i. HIV-related DLBCL;
    - ii. Primary effusion lymphoma;
    - iii. HHV8-positive diffuse large B-cell lymphoma, NOS;
    - iv. HIV-related plasmablastic lymphoma;
  - e. Histologic transformation of indolent lymphoma to DLBCL (off-label);

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2. Prescribed by or in consultation with an oncologist or hematologist;
  3. Age  $\geq$  18 years;
  4. One of the following (a or b):
    - a. For DLBCL (including histologic transformation of indolent lymphoma), HGBL, or HGBL-PTLD only: All of the following (i, ii, and iii):
      - i. If DLBCL or HGBL: Member has not previously received treatment;
      - ii. Polivy is prescribed in combination with R-CHP\* (*see Appendix B for rituximab products*);
      - iii. Member has an IPI or stage modified IPI score  $\geq$  2;
    - b. For any B-cell lymphoma: All of the following (i, ii, and iii):
      - i. One of the following (1 or 2):
        - 1) Member is not a candidate for allogeneic or autologous stem cell transplant; or chimeric antigen receptor (CAR) T-cell therapy (including members who do not have access to CAR T-cell therapy);
        - 2) Prescribed as a bridging therapy while waiting for CAR T-cell therapy product to become available;
      - ii. Member has received  $\geq$  1 prior therapy (*see Appendix B*);\*
      - iii. Polivy is prescribed as in one of the following ways (1, 2, or 3):
        - 1) As a single agent ~~or in~~;
        - 2) Non-transplant or CAR T-cell therapy candidates only: In combination with Lunsumio™;
        - 3) In combination with bendamustine\* and/or a rituximab product\* (*see Appendix B for rituximab products*);\*
- \*Prior authorization may be required for chemotherapy, Lunsumio, bendamustine, and rituximab products
5. 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. 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 LA.PMN.255
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: LA.PMN.53 ~~for Medicaid~~.

## II. Continued Therapy

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

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1. Currently receiving medication via Louisiana Healthcare Connections 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 LA.PMN.255
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: LA.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 policy ~~ies~~ LA.PMN.53 ~~for Medicaid.~~

### IV. Appendices/General Information

#### Appendix A: Abbreviation/Acronym Key

CAR: chimeric antigen receptor  
 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  
PTLD: post-transplant lymphoproliferative disorder

#### 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.

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Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
<b>Rituximab Products</b>		
Rituxan® (rituximab), Truxima® (rituximab-abbs), Rituxan Hycela® (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>Post-Transplant Lymphoproliferative Disorder (PTLD) Regimen examples (NCCN)</b>		
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab	Varies	Varies
CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab	Varies	Varies
<b>HIV-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
<b>Histologic Transformation of Indolent Lymphoma to DLBCL Regimen examples (NCCN)</b>		
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies

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Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) 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 extranodal marginal zone lymphoma (EMZL) of stomach
- DLBCL coexistent with EMZL of nongastric sites
- Follicular lymphoma grade 3
- Intravascular LBCL
- DLBCL associated with chronic inflammation

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- ALK-positive LBCL
- EBV-positive DLBCL, NOS
- T-cell/histiocyte-rich LBCL
- LBCL with IRF4/MUM1 rearrangement
- Double expressor DLBCL
- Fibrin-associated LBCL
- Mediastinal gray zone lymphoma
- Primary mediastinal LBCL
- Gray zone lymphoma
- HGBL with translocations of MYC and BCL2 and/or BCL6
- HGBL, NOS (*FDA-approved use*)
- Primary cutaneous DLBCL

### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DLBCL	<p><b>Previously untreated DLBCL or HGBL</b> 1.8 mg/kg IV every 21 days for 6 cycles in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (<i>Administer Polivy, rituximab product, cyclophosphamide, and doxorubicin in any order on Day 1 after prednisone. Prednisone is administered on Days 1-5 of each cycle.</i>)</p> <p><b>Relapsed or refractory DLBCL</b> 1.8 mg/kg IV 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>)</p>	1.8 mg/kg/dose

### VI. Product Availability

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

### VII. References

1. Polivy Prescribing Information. South San Francisco, CA: Genentech, Inc.; April 2023. Available at: [https://www.gene.com/download/pdf/polivy\\_prescribing.pdf](https://www.gene.com/download/pdf/polivy_prescribing.pdf). Accessed ~~May 20, 2024~~ April 17, 2025.
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 15, 2024~~ April 21, 2025.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 2. ~~2024~~ 2025. 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 17, 2024~~ April 21, 2025.

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#### 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.

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

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created.	05.09.23	09.25.23
Added criteria for new indication as first-line treatment for DLBCL and HGBL, and updated FDA approved indications section to reflect full approval of the third-line DLBCL indication; for off-label uses, removed mantle cell lymphoma, revised nodal marginal zone lymphoma to indolent lymphoma, and revised “AIDs-related” to “HIV-related” per NCCN; updated Appendix D per NCCN; references reviewed and updated.	02.01.24	05.10.24
Annual review: consolidated FDA and NCCN recommended uses into one criteria set under the umbrella diagnosis of B-cell lymphoma; for first-line use, added stage modified IPI score as an alternate pathway per NCCN; allowed first-line use in histologic transformation of indolent lymphoma to DLBCL per NCCN; removed follicular lymphoma as a coverable off-label use as it is no longer supported by NCCN; references reviewed and updated.	09.17.24	01.02.25
<u>Annual review: per NCCN – for PTLD, removed specification that disease must be monomorphic and added option for use in combination with R-CHP for disease with IPI score ≥ 2; for second-line use, added that member is either not a candidate for CAR T-cell therapy or Polivy is prescribed as bridging therapy until CAR T-cell therapy becomes available and added option for use in combination with Lunsumio for non-transplant/CAR T-cell therapy candidates; references reviewed and updated.</u>	08.18.25	

#### 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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing

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this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

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