

Clinical Policy: Polatuzumab Vedotin-piiq (Polivy)

Reference Number: PA.CP.PHAR.433

Effective Date: 01/2020

Last Review Date: 07/2023

[Coding Implications](#)

[Revision Log](#)

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 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 PA Health & Wellness® 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, including not otherwise specified (NOS) and high-grade B-cell lymphoma HGBL (see *Appendix D for other DLBCL subtypes*);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
 - a. All of the following (i, ii, and iii):
 - i. 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 International Prognostic Index score ≥ 2 ;
 - b. All of the following (i, ii, and iii):
 - i. Member is not a candidate for allogeneic or autologous stem cell transplant;
 - ii. Member has received ≥ 1 prior therapies (*see Appendix B*);
 - iii. Polivy is prescribed as a single agent or in combination with bendamustine and/or a rituximab product (*see Appendix B for rituximab products*);
5. Request meets one of the following (a or b):

*Prior authorization is required for chemotherapy and rituximab products

- 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*).

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. Monomorphic post-transplant lymphoproliferative disorder (B-cell type);
 - c. One of the following HIV-related B-cell lymphoma subtypes (i, ii, iii, or iv):
 - i. HIV-related DLBCL;
 - ii. Primary effusion lymphoma;
 - iii. HHV8-positive diffuse large B-cell lymphoma, NOS;
 - iv. HIV-related plasmablastic lymphoma;
 - d. Histologic transformation of indolent lymphoma to diffuse large B-cell lymphoma;
 - e. Other category 1, 2A, or 2B NCCN recommendation;
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 at least the number of prior therapies recommended per the applicable category 1, 2A, or 2B NCCN recommendation;
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*).

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

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 practice guidelines or peer-reviewed literature 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*).

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

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

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

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

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

LBCL: large 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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rituximab Products		
Rituxan [®] (rituximab), Truxima [®] (rituximab-abbs), Rituxan Hycela [®] (rituximab-hyaluronidase)	Varies	Varies
DLBCL Regimen examples (NCCN)		
bendamustine ± rituximab	Varies	Varies
CEPP (cyclophosphamide, etoposide, prednisone, procarbazine) ± rituximab	Varies	Varies
lenalidomide ± rituximab	Varies	Varies
HGBL Regimen examples (NCCN)		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)	Varies	Varies
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
FL (grade 1-2) Regimen examples (NCCN)		
<i>Anthracycline- or anthracenedione-based regimens:</i> CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab	Varies	Varies
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
Post-Transplant Lymphoproliferative Disorder Regimen examples (NCCN)		
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + obinutuzumab or rituximab	Varies	Varies
CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab or rituximab	Varies	Varies
HIV-related B-Cell Lymphoma Regimen examples (NCCN)		
R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)	Varies	Varies
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + rituximab	Varies	Varies
Histologic Transformation of Indolent Lymphoma to DLBCL Regimen examples (NCCN)		
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies

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

- Double expressor DLBCL
- Fibrin-associated LBCL
- Mediastinal gray zone lymphoma
- 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 (*FDA-approved use*)
- Primary cutaneous DLBCL

I. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
DLBCL	<p>Previously untreated DLBCL or HGBL 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>Relapsed or refractory DLBCL 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> <ul style="list-style-type: none"> • Bendamustine: The recommended dose of bendamustine is 90 mg/m²/day IV on Day 1 and 2 when administered with Polivy and a rituximab product. • Rituximab product: The recommended dose of rituximab product is 375 mg/m² IV on Day 1 of each cycle. 	1.8 mg/kg (Polivy)

II. Product Availability

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

III. References

1. Polivy Prescribing Information. South San Francisco, CA: Genentech, Inc.; April 2023. Available at: https://www.gene.com/download/pdf/polivy_prescribing.pdf. Accessed May 17, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 17, 2023.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed May 17, 2023.

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.	01/2020	
3Q 2020 annual review: 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.	07/2020	
3Q 2021 annual review: no significant changes; HCPCS code updated; added 30 mg vial size to product availability; references reviewed and updated.	07/2021	
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.	07/2022	
3Q 2023 annual review: RT4: 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.	07/2023	