Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PHAR.433	**Effective Date: 01/15//2020** **Revision Date: 07/2021**
Policy Name: Polatuzumab Vedotin-piiq (Polivy)	

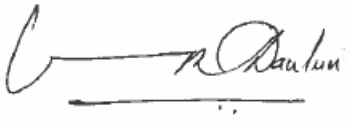
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: no significant changes; HCPCS code updated; added 30 mg vial size to product availability; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Polatuzumab Vedotin-piiq (Polivy)

Reference Number: PA.CP.PHAR.433
Effective Date: 01/2020
Last Review Date: 07/2021

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 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 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 (see *Appendix D for DLBCL subtypes*);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Member is not a candidate for allogeneic or autologous stem cell transplant;
5. Member has received ≥ 1 prior therapies *(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 is 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, e, f, or g):
   a. High-grade B-cell lymphoma (HGBL);
   b. Follicular lymphoma (FL) (grade 1-2);
   c. Mantle cell lymphoma;
   d. Monomorphic post-transplant lymphoproliferative disorder (B-cell type);
   e. 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;
   f. Histologic transformation of nodal marginal zone lymphoma to diffuse large B-cell lymphoma;
   g. Other category 1, 2A, or 2B NCCN recommendation;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. For HGBL or AIDS-related B-cell lymphoma, 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*).*
   **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
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 < 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. 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 policies – 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
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)*		
DA-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab)	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
FL (grade 1-2) *Regimen examples (NCCN)*		
Anthracycline- or anthracenedione-based regimens: 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
Mantle Cell Lymphoma *Regimen examples (NCCN)*		
RDHA (rituximab, dexamethasone, cytarabine) + platinum (carboplatin, ciplatin, or oxaliplatin)	Varies	Varies
VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, and 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
AIDS-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 Nodal Marginal Zone 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 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/hitiocyte-rich large B-cell lymphoma
- DLBCL with IRF4/MUM1 rearrangement

I. 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.)* • Bendamustine: The recommended dose of bendamustine is 90 mg/m^2/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/m^2 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.; September 2020. Available at: https://www.gene.com/download/pdf/polivy_prescribing.pdf. Accessed April 30, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 30, 2021.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed April 30, 2021.

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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	