Prior Authorization Review Panel

Prior Authorization Review Panel

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: 02/01/2020**
Policy Number: PA.CP.PHAR.433	**Effective Date: 01/15//2020** **Revision Date: 01/15/2020**
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:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Polatuzumab Vedotin-piiq (Polivy)

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

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. Documentation indicates partial response, no response, relapsed, progressive or refractory disease after ≥ 2 prior therapies (*prior therapies can include a first-line and second-line/subsequent therapy, see Appendix B for examples of prior therapies*);
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

B. 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. Diffuse Large B-Cell Lymphoma (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 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 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
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		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rituxan® (rituximab), Truxima® (rituximab-abbs), Rituxan Hycela® (rituximab-hyaluronidase)	Varies	Varies
Diffuse Large B-Cell Lymphoma: Examples of ≥ 2 Prior Therapies can include a First-Line and Second-Line/Subsequent Regimen		
First-Line Treatment Regimens (per NCCN)		
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, doxorubicine) + rituximab	Varies	Varies
RCEOP (rituximab, cyclophosphamide, etoposide, vincristine, prednisone)	Varies	Varies
RGCVP (rituximab, gemcitabine, cyclophosphamide, vincristine, prednisone)	Varies	Varies
Second-Line Treatment (per NCCN for Relapsed or Refractory Disease) – Examples of Regimens for Non-Candidates for Transplant		
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® (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: 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/hitiocyte-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/or 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)

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. 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. 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. 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.	01/2020	