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Pharmacy Solutions

Clinical Policy: Polatuzumab Vedotin-piiq (Polivy)

Reference Number: ERX.SPA.343
Effective Date: 09.01.19
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 subtypes at Appendix D*);
      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 ≥ 2 prior therapies *(see Appendix B*);
      6. Polivy is prescribed in combination with bendamustine* and a rituximab product* (*see Appendix B for rituximab products*);
         **Prior authorization may be 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 is required for requests for more than 6 cycles*)

   B. **NCCN Recommended Uses (off-label)** (must meet all)**:**
      1. Diagnosis of one of the following (a, b, c, d, e, or f):
         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;

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 meets one of the following (a or b):
   a. For FL, member has received ≥ 1 prior therapy (*see Appendix B*);
   b. For all other indications, member has received ≥ 2 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 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 supports requests for cycles beyond 6*)

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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 < 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 is required for requests for more than 6 cycles*)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 or evidence of coverage documents.

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

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
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

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. *(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): 30 mg, 140 mg

VII. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	07.09.19	08.19
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.	05.12.20	08.20
RT4: added 30 mg vial size to product availability.	11.30.20	
3Q 2021 annual review: no significant changes; references reviewed and updated.	04.30.21	08.21

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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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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