

Polivy (polatuzumab vedotin-piiq)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Polivy (polatuzumab vedotin-piiq)

APPROVAL CRITERIA

Requests for Polivy (polatuzumab vedotin-piiq) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory (Label, NCCN 2A):
 - A. Diffuse large B-cell lymphoma (DLBCL); **OR**
 - B. High-grade B-cell lymphoma; **OR**
 - C. Histologic transformation of indolent lymphomas to DLBCL; **OR**
 - D. HIV-related B-cell lymphoma; **OR**
 - E. Monomorphic post-transplant lymphoproliferative disorder (B-cell type);

AND

- II. Individual is using as a single agent or in combination with bendamustine and/or a rituximab product (including rituximab biosimilars) (Label, NCCN 2A); **AND** Individual has received at least one prior line of therapy (NCCN 2A);

OR

- III. Individual has a diagnosis of relapsed or refractory (NCCN 2A):
 - A. Diffuse large B-cell lymphoma (DLBCL); **OR**
 - B. High-grade B-cell lymphoma; **OR**
 - C. HIV-related B-cell lymphoma; **OR**
 - D. Monomorphic post-transplant lymphoproliferative disorder (B-cell type);

AND

- IV. Individual is using as a bridging option (typically 1 or more cycles as necessary) until CAR T-cell product is available (NCCN 2A);

OR

- V. Individual has a diagnosis of previously untreated (Label, NCCN 1/2A):
 - A. Diffuse large B-cell lymphoma (DLBCL); **OR**
 - B. High-grade B-cell lymphoma; **OR**
 - C. Extracutaneous primary cutaneous DLBCL, leg type; **OR**
 - D. Histologic transformation of indolent lymphomas to DLBCL; **OR**
 - E. Monomorphic or Polymorphic post-transplant lymphoproliferative disorder (B-cell type);

AND

- VI. Individual is using in combination with a rituximab product (including rituximab biosimilars), cyclophosphamide, doxorubicin, and prednisone (Pola-R-CHP); **AND**
- VII. Individual has international prognostic index for diffuse large B-cell Lymphoma (IPI) 2 or higher;

OR

- VIII. Individual has a diagnosis of monomorphic or polymorphic post-transplant lymphoproliferative disorder (B-cell type); **AND**
- IX. Individual is using as second-line therapy for partial response, persistent or progressive disease; **AND**
- X. Individual is using in combination with a rituximab product (including rituximab biosimilars), cyclophosphamide, doxorubicin, and prednisone (Pola-R-CHP); **AND**
- XI. Individual has international prognostic index for diffuse large B-cell Lymphoma (IPI) 2 or higher;

OR

- XII. Individual has a diagnosis of (NCCN 2A):
 - A. Relapsed or refractory Diffuse large B-cell lymphoma (DLBCL); **OR**
 - B. Relapsed or refractory High-grade B-cell lymphoma; **OR**
 - C. Relapsed or refractory HIV-related B-cell lymphoma; **OR**
 - D. Relapsed or refractory Monomorphic post-transplant lymphoproliferative disorder (B-cell type);

AND

- XIII. Individual is using as second-line and subsequent therapy; **AND**
- XIV. Individuals is using in combination with mosunetuzumab-axgb.

Requests for Polivy (polatuzumab vedotin-piiq) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. Morschhauser F, Flinn IW, Advani R, et al. Polatuzumab vedotin or pinatuzumab vedotin plus rituximab in patients with relapsed or refractory non-Hodgkin lymphoma: final results from a phase 2 randomised study (ROMULUS). *Lancet Haematol*. 2019 May;6(5):e254-e265. doi: 10.1016/S2352-3026(19)30026-2. Epub 2019 Mar 29.
5. Sehn LH, Herrera AF, Flowers CR, et al. Polatuzumab Vedotin in Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *J Clin Oncol* 2020; 38:155-165.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed April 10, 2025.
 - a. B-cell Lymphomas. V2.2025. Revised February 10, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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