

## SPECIALTY GUIDELINE MANAGEMENT

### POLIVY (polatuzumab vedotin-piiq)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indication

1. Polivy in combination with bendamustine and a rituximab product is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies.
2. Polivy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) 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.

###### B. Compendial Uses

###### B-Cell Lymphomas

1. High-grade B-cell lymphomas (HGBLs)
2. Monomorphic post-transplant lymphoproliferative disorders (B-cell type)
3. Human Immunodeficiency Virus (HIV) Related B-Cell Lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HIV-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma)
4. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
5. Follicular lymphoma
6. Diffuse large B-cell lymphoma (DLBCL)

All other indications are considered experimental/investigational and not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

###### **B-Cell Lymphomas**

Authorization of 6 months (up to 6 cycles) may be granted for treatment of B-cell lymphomas with any of the following subtypes:

###### A. Diffuse Large B-cell Lymphoma (DLBCL) when any of the following criteria are met:

1. The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine with or without rituximab for relapsed or refractory disease when the member is not a candidate for transplant, or the requested medication will be used as a bridging option until CAR T-cell product is available.

Reference number(s)
3095-A

2. The requested drug will be used as first line therapy for stage II-IV disease in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) in members who have an International Prognostic Index score of 2 or greater (low intermediate-high).
- B. High-grade B-cell lymphomas (HGBLs) (also referred to as “double-hit” or “triple-hit” lymphomas) when any of the following criteria are met:
  1. The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine with or without rituximab, and member is not a candidate for transplant or the requested medication will be used as a bridging option until CAR T-cell product is available.
  2. The requested drug will be used as first line therapy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater.
- C. Monomorphic post-transplant lymphoproliferative disorders (B-cell type) when all the following criteria are met:
  1. The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine with or without rituximab, and
  2. Member is not a candidate for transplant or the requested medication will be used as a bridging option until CAR T-cell product is available.
- D. Human Immunodeficiency Virus (HIV) -related B-cell lymphomas (HIV-related diffuse large B-cell lymphoma, primary effusion lymphoma, HIV-related plasmablastic lymphoma, and human herpesvirus-8 (HHV8)-positive diffuse large B-cell lymphoma) when all of the following criteria are met:
  1. The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine with or without rituximab, and
  2. Member is not a candidate for transplant or the requested medication will be used as a bridging option until CAR T-cell product is available.
- E. Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma (DLBCL) when all of the following criteria are met:
  1. The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine with or without rituximab, and
  2. Member is not a candidate for transplant
- F. Follicular lymphoma when the requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine with or without rituximab.

### III. CONTINUATION OF THERAPY

Authorization up to 6 months (6 cycles total) may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and who have not received 6 or more cycles of the requested drug.

### IV. REFERENCES

1. Polivy [package insert]. South San Francisco, CA: Genentech, Inc.; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 4, 2023.
3. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed April 4, 2023.
4. Tilly H, Morschhauser F, Sehn LH, et al. Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. *N Engl J Med*. 2022;386:351-363. DOI: 10.1026/NEJMoa2115304.
5. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Hematology – Oncology Clinical Programs. July 2022.