Draft Revision Policy: Do Not Implement

Polatuzumab Vedotin-piiq (Polivy®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

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.

FDA-Approved Indication

- 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.
- 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.

Compendial Uses
B-Cell Lymphomas

- High-grade B-cell lymphomas (HGBLs)
- ~~Monomorphic~~ Post-transplant lymphoproliferative disorders (B-cell type)
- 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)
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma
- Histological transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
- Diffuse large B-cell lymphoma (DLBCL)

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

COVERAGE 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:

- Diffuse Large B-cell Lymphoma (DLBCL) when any of the following criteria are met:
  - The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine and/or 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.
  - The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory disease.
  - The requested drug will be used as first line therapy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) in members who have an International Prognostic Index score greater than 1.
- High-grade B-cell lymphomas (HGBLs) (also referred to as "double-hit" or "triple-hit" lymphomas) when any of the following criteria are met:
  - The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine and/or 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.
  - The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory disease.
  - The requested drug will be used as first line therapy ~~treatment~~ in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score greater than 1 and has MYC and BCL6 without BCL2 rearrangements.
- ~~Monomorphic~~ Post-transplant lymphoproliferative disorders (B-cell type) when any ~~all~~ the following criteria are met:
  - The requested drug is used for monomorphic disease as subsequent treatment as a single agent, or in combination with bendamustine and/or 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.
  - The requested drug is used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater in either of the following clinical settings:
    - As first line therapy monomorphic or systemic polymorphic disease.
    - As subsequent therapy for partial response, persistent, or progressive monomorphic or polymorphic disease.
  - The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory monomorphic disease.
- 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 either ~~all~~ of the following criteria are met:
  - The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine and/or 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.
  - The requested drug is used as subsequent treatment in combination with mosunetuzumab-axgb in members with relapsed or refractory disease.
- Histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma (DLBCL) when any of the following criteria are met:
  - The requested drug is used as subsequent treatment as a single agent, or in combination with bendamustine and/or rituximab, and member is not a candidate for transplant.
  - The requested drug will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater.
- Histologic transformation of indolent lymphomas to high grade B-cell lymphoma with MYC and BCL6 and without BCL2 rearrangements when the requested drug will be used in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) and member has an International Prognostic Index score of 2 or greater.

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 the coverage criteria 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Polivy [package insert]. South San Francisco, CA: Genentech, Inc.; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 18, 2025.

EFFECTIVE DATE

ID_CHS