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.

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 Indications

Polivy in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) is indicated 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.

Polivy in combination with bendamustine and a rituximab product is indicated for the treatment of adult patients with relapsed or refractory DLBCL, NOS, after at least two prior therapies.

Compendial Uses
B-Cell Lymphomas

- Diffuse large B-cell lymphoma (DLBCL)
- High-grade B-cell lymphomas (HGBLs)
- 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
- Histologic transformation of indolent lymphomas to high-grade B-cell lymphoma with MYC and BCL6 without BCL2 rearrangements
- Mantle cell lymphoma
- Burkitt lymphoma

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

COVERAGE CRITERIA

B-Cell Lymphomas

Authorization of 6 months (up to 6 cycles) may be granted for treatment of diffuse large B-cell lymphoma (DLBCL) when any of the following criteria are met:

- The requested medication will be used for subsequent treatment as holding or bridging therapy until CAR T-cell therapy as a single agent or in combination with bendamustine and/or a rituximab product.
- The requested medication will be used as subsequent treatment as a single agent, in combination with bendamustine and/or a rituximab product, in combination with gemcitabine and oxaliplatin with a rituximab product, or in combination with mosunetuzumab-axgb in members with relapsed or refractory disease who are not proceeding to CAR T-cell therapy.
- The requested medication 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.

Authorization of 6 months (up to 6 cycles) may be granted for treatment of 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 medication will be used for subsequent treatment as holding or bridging therapy until CAR T-cell therapy as a single agent or in combination with bendamustine and/or a rituximab product.
- The requested medication will be used as subsequent treatment as a single agent, in combination with bendamustine and/or a rituximab product, in combination with gemcitabine and oxaliplatin with a rituximab product, or in combination with mosunetuzumab-axgb in members with relapsed or refractory disease who are not proceeding to CAR T-cell therapy.
- The requested medication 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 greater than 1 and has MYC and BCL6 without BCL2 rearrangements.

Authorization of 6 months (up to 6 cycles) may be granted for treatment of post-transplant lymphoproliferative disorders (B-cell type) when any the following criteria are met:

- The requested medication will be used for subsequent treatment of monomorphic disease as holding or bridging therapy until CAR T-cell therapy as a single agent or in combination with bendamustine and/or a rituximab product.
- The requested medication will be used for monomorphic disease as subsequent treatment as a single agent, in combination with bendamustine and/or a rituximab product, in combination with gemcitabine and oxaliplatin with a rituximab product, or in combination with mosunetuzumab-axgb in members with relapsed or refractory disease who are not proceeding to CAR T-cell therapy.
- The requested medication 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 in either of the following clinical settings:
  - As first line therapy for monomorphic or systemic polymorphic disease.
  - As subsequent therapy for partial response, persistent, or progressive monomorphic or polymorphic disease.

Authorization of 6 months (up to 6 cycles) may be granted for treatment of 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 of the following criteria are met:

- The requested medication will be used for subsequent treatment as holding or bridging therapy until CAR T-cell therapy as a single agent or in combination with bendamustine and/or a rituximab product.
- The requested medication will be used as subsequent treatment as a single agent, in combination with bendamustine and/or a rituximab product, in combination with gemcitabine and oxaliplatin with a rituximab product, or in combination with mosunetuzumab-axgb in members with relapsed or refractory disease who are not proceeding to CAR T-cell therapy.

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Authorization of 6 months (up to 6 cycles) may be granted for treatment of histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma (DLBCL) when any of the following criteria are met:

- The requested medication will be used as subsequent treatment as a single agent or in combination with bendamustine and/or a rituximab product, and member is not proceeding to transplant.
- The requested medication 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.

Authorization of 6 months (up to 6 cycles) may be granted for treatment of 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.

Authorization of 6 months (up to 6 cycles) may be granted for subsequent treatment of Mantle cell lymphoma when the requested medication will be used in combination with mosunetuzumab-axgb for relapsed, refractory, or progressive disease, or disease with partial or no response to second-line therapy.

Authorization of 6 months (up to 6 cycles) may be granted for subsequent treatment of Burkitt lymphoma when the requested medication will be used as a bridge to transplant in combination with glofitamab-gxbm.

CONTINUATION OF THERAPY

Authorization up to 6 months (maximum of 6 cycles total) may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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.; March 2026.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed March 23, 2026.

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