Draft Revision Policy: Do Not Implement

Glofitamab-gxbm (Columvi™)

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

Columvi is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.

Compendial Uses

- B-Cell Lymphomas
- Diffuse Large B-Cell Lymphoma
- High Grade B-Cell Lymphoma
- Histologic Transformation of Indolent Lymphoma to Diffuse Large B-Cell Lymphoma
- Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma
- ~~HIV-Related Diffuse Large B-cell Lymphoma~~
- ~~Primary Effusion Lymphoma~~
- ~~Human Herpes Virus Type 8 (HHV8)-Positive Diffuse Large B-cell Lymphoma~~
- ~~Monomorphic~~ Post-Transplant Lymphoproliferative Disorder

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

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

B-cell Lymphoma

Authorization of 12 months may be granted for treatment of B-cell lymphoma when the member will be pretreated with a single dose of obinutuzumab (Gazyva) 7 days before initiation with the requested medication and either ~~as a single agent after at least 2 prior lines of systemic therapy when the member has partial response, no response, progressive, relapsed or refractory disease and both~~ of the following criteria is ~~are~~ met:

- The requested medication will be used as subsequent therapy in combination with GemOx (gemcitabine and oxaliplatin) for relapsed/refractory disease with any of the following subtypes:

~~The member has any of the following subtypes~~

- Diffuse large B-cell lymphoma (DLBCL)
- High grade B-cell lymphoma
- ~~Histologic Transformation of Indolent Lymphoma to DLBCL~~
- HIV-related B-cell lymphoma including HIV-related DLBCL, primary effusion lymphoma, ~~and~~ HHV8-positive DLBCL, not otherwise specified ~~as a single agent~~, and HIV-related plasmablastic lymphoma
- ~~Monomorphic~~ Post-transplant lymphoproliferative disorders ~~(B-cell type)~~

~~The member will be pretreated with a single dose of obinutuzumab (Gazyva) 7 days before initiation with the requested medication.~~

- The requested medication will be used as a single agent after at least 2 prior lines of systemic therapy when the member has partial response, no response, progressive, relapsed or refractory disease with any of the following subtypes:
  - Diffuse large B-cell lymphoma (DLBCL)
  - High grade B-cell lymphoma
  - Histologic Transformation of Indolent Lymphoma to DLBCL
  - HIV-Related B-Cell Lymphoma including HIV-related DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL, not otherwise specified
  - Monomorphic Post-Transplant Lymphoproliferative Disorder (B-cell type)

CONTINUATION OF THERAPY

Authorization of 12 months (up to a maximum of 12 cycles) 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.

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. Columvi [package insert]. South San Francisco, CA: Genentech, Inc.; June 2023.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 10, 2025.

BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual

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EFFECTIVE DATE

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