Reference number(s)
6022-A

SPECIALTY GUIDELINE MANAGEMENT

COLUMVI (glofitamab-gxbm)

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
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.

B. Compendial Uses
B-Cell Lymphomas
1. Diffuse Large B-Cell Lymphoma
2. High Grade B-Cell Lymphoma
3. Histologic Transformation of Indolent Lymphoma to Diffuse Large B-Cell Lymphoma
4. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphoma
    a. HIV-Related Diffuse Large B-cell Lymphoma
    b. Primary Effusion Lymphoma
    c. Human Herpes Virus Type 8 (HHV8)-Positive Diffuse Large B-cell Lymphoma
5. Monomorphic Post-Transplant Lymphoproliferative Disorder

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

II. CRITERIA FOR INITIAL APPROVAL

B-cell Lymphoma
Authorization of 12 months may be granted for treatment of B-cell lymphoma 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 are met:
1. The member has any of the following subtypes
    A. Diffuse Large B-Cell Lymphoma (DLBCL)
    B. High Grade B-Cell Lymphoma
    C. Histologic Transformation of Indolent Lymphoma to DLBCL
    D. HIV-Related B-Cell Lymphoma including HIV-related DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL, not otherwise specified as a single agent
    E. Monomorphic Post-Transplant Lymphoproliferative Disorder (B-cell type)
2. The member will be pretreated with a single dose of obinutuzumab (Gazyva) 7 days before initiation with the requested medication.

III. 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 Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Columvi [package insert]. South San Francisco, CA: Genentech, Inc.; June 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 1, 2024.
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