Reference number(s)
6002-A

SPECIALTY GUIDELINE MANAGEMENT

EPKINLY (epcoritamab- bysp)

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. Epkinly is indicated for the treatment of adult patients with relapsed or refractory diffuse large b-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B–cell lymphoma (HGBL), after two or more lines of systemic therapy.
2. Epkinly is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

B. Compendial Uses
B-Cell Lymphomas:
1. Diffuse Large B-Cell Lymphomas
2. High Grade B-Cell Lymphomas
3. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma
4. Human Immunodeficiency Virus (HIV)- Related B-Cell Lymphomas
   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, not otherwise specified
5. Monomorphic Post-Transplant Lymphoproliferative Disorders
6. Follicular Lymphoma

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

II. CRITERIA FOR INITIAL APPROVAL

B-Cell Lymphomas
Authorization of 12 months may be granted as a single agent for treatment of B-cell lymphoma 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:
1. Diffuse Large B-Cell Lymphoma (DLBCL)
2. High Grade B- Cell Lymphoma
3. Histologic Transformation of Indolent Lymphoma to DLBCL
4. HIV-Related B- Cell Lymphoma including HIV-related DLBCL, primary effusion lymphoma, and HHV8-positive DLBCL, not otherwise specified
5. Monomorphic Post-Transplant Lymphoproliferative Disorder
6. Follicular Lymphoma

III. CONTINUATION OF THERAPY

Authorization of 12 months 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. Epkinly [package insert]. Plainsboro, NJ: Genmab US, Inc.; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 9, 2024.