

Specialty Guideline Management

Epkinly

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Epkinly	epcoritamab-bysp

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 Indications¹

- 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.
- Epkinly is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

Compendial Uses²

B-Cell Lymphomas:

- Diffuse Large B-Cell Lymphomas
- High Grade B-Cell Lymphomas
- Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma
- Human Immunodeficiency Virus (HIV)- Related B-Cell Lymphomas

- Monomorphic Post-Transplant Lymphoproliferative Disorders
- Follicular Lymphoma

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

Coverage Criteria

B-Cell Lymphomas^{1,2}

Authorization of 12 months may be granted for treatment of B-cell lymphoma when either of the following criteria is 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:
 - Diffuse large B-cell lymphoma (DLBCL)
 - High grade B-cell lymphoma
 - HIV-related B-cell lymphoma including HIV-related DLBCL, primary effusion lymphoma, HHV8-positive DLBCL, not otherwise specified, and HIV-related plasmablastic lymphoma
 - Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
- 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)
 - Follicular lymphoma

Continuation of Therapy

Authorization of 12 months 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.

References

1. Epkinly [package insert]. Plainsboro, NJ: Genmab US, Inc.; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 9, 2025.