Reference number(s)
6002-A

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 Indications[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.
- Epkinly is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) in combination with lenalidomide and rituximab.
- Epkinly is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) as monotherapy after two or more lines of systemic therapy.

Compendial Uses[2]

- Diffuse Large B-Cell Lymphomas
- High Grade B-Cell Lymphomas
- Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- Human Immunodeficiency Virus (HIV)- Related B-Cell Lymphomas
- Monomorphic Post-Transplant Lymphoproliferative Disorders
- Follicular Lymphoma
- Histologic (Richter) transformation

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 one of the following criteria is met:

- The requested medication will be used as subsequent therapy for follicular lymphoma in combination with lenalidomide and rituximab for up to 12 cycles total for no response, relapsed, or progressive disease.
- 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

Histologic (Richter) Transformation to DLBCL[2]

Authorization of 12 months may be granted for treatment of histologic (Richter) transformation to DLBCL.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Reference number(s)
6002-A

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. A maximum of 12 cycles total will be authorized for members using the requested medication in combination with lenalidomide and rituximab for follicular lymphoma.

References

1. Epkinly [package insert]. Plainsboro, NJ: Genmab US, Inc.; March 2026.
2. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 9, 2026.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.