Reference number(s)
6003-A

Standard Medicare Part B 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
- Human Immunodeficiency Virus (HIV)- Related B-Cell Lymphomas
- Monomorphic Post-Transplant Lymphoproliferative Disorders

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- Follicular Lymphoma
- Histologic (Richter) transformation

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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
    - Follicular Lymphoma

Histologic (Richter) Transformation to DLBCL[2]

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

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Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met. A maximum of 12 cycles total will be authorized for members using the requested medication in combination with lenalidomide and rituximab for follicular lymphoma when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Epkinly.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: CLL/SLL
- NCCN Guideline: B-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Epkinly are covered in addition to the following:

- CLL/SLL - Histologic Transformation (Richter)
- 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

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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Support for using Columvi to treat all indications listed above can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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.

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