

**Epkinly (epcoritiamab-bysp)**  
**Effective 01/01/2025**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

### Overview

#### FDA-Approved Indication

Epkinly 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.

#### 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

### Coverage Guidelines

Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

**OR**

Authorization may be granted for members meeting ALL the following criteria:

1. Member has partial response, no response, progressive, relapsed or refractory disease with ONE of the following subtypes of B-cell Lymphoma:
  - 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 when the requested medication is used as a single agent
  - e. Monomorphic Post-Transplant Lymphoproliferative Disorder when the requested medication is used as a single agent
2. Member has received 2 prior lines of systemic therapy

**Note:** Medication regimens being used in accordance with National Comprehensive Cancer Network (NCCN) guidelines with at least a 2a or 2b level evidence can be reviewed for medical necessity.

### **Continuation of Therapy**

Authorization may be granted for members when there is no evidence of unacceptable toxicity or disease progression while on current regimen

### **Limitations**

1. Initial approvals and reauthorizations will be granted for 12 months

### **References**

1. Epkinly (epcoritamab-bysp) [prescribing information]. Plainsboro, NJ: Genmab US, Inc.; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed June 5, 2023.

### **Review History**

09/13/2023 - Reviewed at Sept P&T, Effective 11/1/2023.

10/09/2024 – Reviewed and updated at October P&T. Effective 1/1/25, criteria is retired.

