



epcoritamab-bysp (Epkinly)

Medical Benefit Drug Policy

Place of Service

Office Administration

Outpatient Facility Administration

Hospital Administration

Infusion Center Administration

Drug Details

USP Category: Antineoplastics, Monoclonal antibodies

Mechanism of Action: Bispecific CD20-directed CD3 T-cell engager

HPCS:

- Effective through 12/30/2023: C9155 per 0.16 mg
- Effective 1/1/2024 and after: J9321 per 0.16 mg

How supplied

NDC:

- 82705-002-01: one 4 mg/0.8 mL single-dose vial
- 82705-010-01: one 48 mg/0.8 mL single-dose vial

Condition(s) listed in policy (*see coverage criteria for details*)

- [B-cell lymphomas](#)

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure member has met all medical necessity requirements.

Covered under the Medical Benefit, please submit clinical information for prior authorization review

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice:

B-cell lymphomas

1. One of the following B-cell lymphomas:
 - a. Diffuse large B-cell lymphoma (DLBCL, including histologic transformation of follicular lymphoma or all subtypes of marginal zone lymphoma to DLBCL), or
 - b. High-grade B-cell lymphomas (HGBL), or

- c. HIV-related B-cell lymphomas: HIV-related DLBCL, primary effusion lymphoma, HHV8-positive DLBCL not otherwise specified, or
- d. Monomorphic post-transplant lymphoproliferative disorders (PTLD)

AND

- 2. Being used as a single agent, AND
- 3. Being used for third-line and beyond therapy

Covered Doses

Given as a SC injection at the following schedule

A cycle consists of 28 days

Cycle of treatment	Day of treatment	Dose	
Cycle 1	1	Step up dose 1	0.16 mg
	8	Step up dose 2	0.8 mg
	15	First full dose	48 mg
	22		48 mg
Cycles 2 and 3	1, 8, 15, 22		48 mg
Cycles 4 to 9	1 and 15		48 mg
Cycles 10 and beyond	1		48 mg

Coverage Period

Indefinite

Additional Information:

Epkinly is the first subcutaneous bispecific antibody for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBL) after 2 or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

References

- 1. AHFS®. Available by subscription at <http://www.lexi.com>
- 2. DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- 3. Epkinly (epcoritamab-bysp). [Prescribing information]. Plainsboro, NJ: Genmab US, Inc.; May 2023.

Policy Update

Date of Last Annual Review: 8/30/2023

Date of last revision: 1/3/2024

Changes from previous policy version:

- Added HCPCS J9321 per 0.16 mg, effective 1/1/2024 and after.



Promise Health Plan

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*

Blue Shield of California Promise Health Plan is an independent member of the Blue Shield Association

epcoritamab-bysp (Epkinly™)