

Medical Policy:

Epkinly (epcoritamab-bysp) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.384	August 19, 2024	July 6, 2023

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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

Length of Authorization

Coverage will be provided for 12 months and may be renewed.

Dosing Limits [Medical Benefit]

Diffuse Large B-Cell Lymphoma. Approve the following dosing regimen (A and B):

- A. The dose is up to 48 mg administered by subcutaneous injection; **AND**
- B. The agent is given in 28-day cycles that meet the following (i, ii, and iii):
 - i. Cycles 1, 2, and 3: Maximum of 4 injections; **AND**
 - ii. Cycles 4 to 9: Maximum of 2 injections; **AND**

iii. Cycles 10 and beyond: maximum of 1 injection.

Classic Follicular Lymphoma. Approve the following dosing regimen (A and B):

- A. The dose is up to 48 mg administered by subcutaneous injection; **AND**
- B. The agent is given in 28-day cycles that meet the following (i, ii, and iii):
 - i. Cycles 1, 2, and 3: Maximum of 4 injections; **AND**
 - ii. Cycles 4 to 9: Maximum of 2 injections; **AND**
 - iii. Cycles 10 and beyond: maximum of 1 injection.

Guideline

I. INITIAL CRITERIA

1. **Diffuse Large B-Cell Lymphoma.** Approve if the patient meets the following criteria (A, B, C, and D):
Note: Diffuse large B-cell lymphoma (DLBCL) includes DLBCL not otherwise specified, DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma.
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has received two or more lines of systemic therapy; **AND**
Note: Examples of systemic therapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and DHA (dexamethasone, cytarabine) + platinum (carboplatin, cisplatin, or oxaliplatin) \pm rituximab.
 - C. Medication is given as a single agent; **AND**
 - D. Medication is prescribed by or in consultation with an oncologist.
2. **Classic Follicular Lymphoma.** Approve if the patient meets ALL of the following (A, B, C, and D):
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has received two or more lines of systemic therapy; **AND**
Note: Examples of systemic therapy include CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) plus rituximab or Gazyva (Obinutuzumab intravenous infusion) and CVP (cyclophosphamide, vincristine, prednisone) plus rituximab or Gazyva.
 - C. Medication is given as a single agent; **AND**
 - D. Medication is prescribed by or in consultation with an oncologist.

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

1. Patient continues to meet the Initial Criteria; **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, serious or life-threatening cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), severe cytopenias, etc.; **AND**
3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Applicable Procedure Codes

Code	Description
J9321	Injection, epcoritamab-bysp, 0.16 mg

Applicable NDCs

Code	Description
82705-0002-01	Epkinly 4mg/ 0.8mL

82705-0010-01	Epkinly 48mg/0.8mL
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ICD-10 Diagnoses

Code	Description
C83.30	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified
C82.00	Follicular Lymphoma Grade I, Unspecified Site

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	8/19/2024	Revision: added Follicular Lymphoma indication and criteria and C82.00
EmblemHealth & ConnectiCare	3/13/2024	Annual Review: Added renewal criteria, Removed J9999, added J9321
EmblemHealth & ConnectiCare	07/06/2023	New Policy

References

1. Product Information: EPKINLY subcutaneous injection, epcoritamab-bysp subcutaneous injection. Genmab US Inc (per FDA), Plainsboro, NJ, 2023.