Medical Policy:

Epkinly (epcoritamab-bysp) subcutaneous injection

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

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) ± 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

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.