POLICY: Oncology (Injectable) – Epkinly Utilization Management Medical Policy

- Epkinly™ (epcoritamab-bysp subcutaneous injection – Genmab)

EFFECTIVE DATE: 11/15/2023
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Epkinly, a bispecific CD20-directed CD3 T-cell engager, is indicated for the treatment of relapsed or refractory **diffuse large B-cell lymphoma** (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma, in adults after two or more lines of systemic therapy.[1]

Dosing Information

Epkinly is administered by subcutaneous injection.[1] Table 1 summarizes the dosing schedule for Epkinly.

Table 1. Epkinly Dosing Schedule.[1]

Treatment Cycle	Treatment Day	Dose
Cycle 1	Day 1	0.16 mg
	Day 8	0.8 mg
	Day 15	48 mg
	Day 22	48 mg
Cycle 2 and 3	Days 1, 8, 15, 22	48 mg
Cycle 4 to 9	Days 1 and 15	48 mg
Cycle 10+	Day 1	48 mg

Guidelines

Epkinly has been addressed by National Comprehensive Cancer Network. The **B-cell lymphoma** clinical practice guidelines (version 2.2024 – April 30, 2024) recommend Epkinly for the third-line and subsequent treatment of classic follicular lymphoma, DLBCL, histologic

transformation of indolent lymphomas to DLBCL, high-grade B-cell lymphomas, human immunodeficiency virus (HIV)-related B-cell lymphomas, and post-transplant lymphoproliferative disorders.[2,3]

Safety
Epkinly has Boxed Warnings for cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome.[1]

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Epkinly. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Epkinly as well as the monitoring required for adverse events and long-term efficacy, approval requires Epkinly to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Epkinly is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Diffuse Large B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (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.

   Dosing. 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.

Other Uses with Supportive Evidence

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2. Classic Follicular Lymphoma. Approve for 1 year 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.

Dosing. 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.

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3. Human Immunodeficiency Virus (HIV)-Related B-Cell Lymphomas. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
Note: HIV-related B-cell lymphomas includes HIV-related diffuse large B-cell lymphoma (DLBCL), primary effusion lymphoma, and human herpes virus-8 (HHV8) positive DLBCL.
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 R-EPOCH (rituximab, etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin).
C) Medication is given as a single agent; AND
D) Medication is prescribed by or in consultation with an oncologist.

Dosing. 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.

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4. Post-Transplant Lymphoproliferative Disorders. Approve for 1 year 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 RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) and RCEPP (rituximab, cyclophosphamide, etoposide, prednisone, procarbazine).

C) Medication is given as a single agent; AND

D) Medication is prescribed by or in consultation with an oncologist.

Dosing. 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Epkinly is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Epkinly subcutaneous injection [prescribing information]. Plainsboro, NJ: Genmab; May 2023.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 4, 2024. Search term: epcoritamab.
3. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 4, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/05/2023
Annual Revision	**Classic Follicular Lymphoma:** Added new condition of approval.	06/12/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024