PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Epkinly Prior Authorization Policy
- Epkinly™ (epcoritamab-bysp subcutaneous injection – Genmab)

REVIEW DATE: 06/12/2024

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]

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 prescription benefit coverage of Epkinly. 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.

Other Uses with Supportive Evidence

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.

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.

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.

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.