Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Epkinly™ (epcoritamab-bysp)

Effective: January 13, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0965

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0965

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Epkinly (epcoritamab-bysp) is a bispecific CD20-directed CD3 T-cell engager indicated for:

- **Diffuse Large B-cell Lymphoma (DLBCL) and High-grade B-cell Lymphoma**
  The treatment of adult patients with relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two 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).
- **Follicular Lymphoma (FL)**
  Indicated in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).
  Indicated as monotherapy for the treatment of adult patients with relapsed or refractory FL after two or more lines of systemic therapy.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Epkinly for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of **one (1)** of the following:
   a. Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, including diffuse large B-cell lymphoma arising from indolent lymphoma
   b. High-grade B-cell lymphoma
   c. Relapsed or refractory follicular lymphoma

AND

2. The prescribing physician is an oncologist or hematologist

AND

3. Documentation the patient has received at least two prior lines of systemic therapy

Limitations

- For DLBCL or high-grade B-cell lymphoma, the Cycle 1 Day 15 dosage of Epkinly requires inpatient hospitalization for up to 24 hours after administration. Epkinly, even though given in an inpatient setting, still requires prior authorization from the plan.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9321	Injection, epcoritamab-bysp, 0.16 mg

References

1. Epkinly (epcoritamab-bysp) [prescribing information]. Plainsboro, NJ: Genmab US, Inc.; November 2025.

Approval And Revision History

September 12, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2024: Administrative updated: Added new J Code J9321 to Medical Necessity Guideline.
- February 13, 2024: Added Tufts Health Together and Tufts Health RITogether to the Medical Necessity Guideline. Administrative edit to add the Limitation The Cycle 1 Day 15 dosage of Epkinly requires inpatient hospitalization for up to 24 hours after administration. Epkinly, even though given in an inpatient setting, still requires prior authorization from the plan (effective March 1, 2024).
- January 14, 2025: Removed Tufts Health Together from the Medical Necessity Guideline. Coverage for Tufts Health Together will fall under the Unified Medical Policies Medical Necessity Guideline. Added coverage criteria for the supplemental indication in Follicular Lymphoma (eff 2/18/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- January 13, 2026: No clinical changes to criteria. Updated overview section to include expanded indication of follicular lymphoma in line with prescribing information.
- February 2026: Administrative update to remove Carelink from template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.