Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Vyepti® (eptinezumab-jjmr)

Effective: January 1, 2026

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

Public Plans Products

☒ 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 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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

Migraine has been estimated to be the third-most prevalent illness in the world. Nearly 1 in 4 U.S. households includes someone with migraine. 12% of the population – including children – suffer from migraine. Approximately 37 million people ages 12 years and older suffer from migraine in the United States (28 million women; 9 million men). Women are affected 3 times more often than men; the higher rate among women is likely hormonally driven. 18% of American women, 6% of men, and 10% of children experience migraines. About half of female sufferers have more than one attack each month, and a quarter experience 4 or more severe attacks per month. Migraines occur most commonly between the ages of 25 and 55 years. Migraine tends to be hereditary, with about 90% of migraine sufferers having a family history of migraine.

Vyepti is the fourth prophylactic anti-CGRP monoclonal antibody (mAb) approved, but it is the first with IV administration, following Amgen's Aimovig, Teva's Ajovy, and Eli Lilly's Emgality. Due to the required professional administration, Vyepti will be a medical benefit (Part B) reimbursed product, compared to self-administration and pharmacy benefit for the competitors. Vyepti's quarterly administration schedule equals that of Ajovy, and compares to monthly for Aimovig, Emgality, and Ajovy (monthly or quarterly administration).

Recommended dosage is 100 mg as an intravenous infusion over approximately 30 minutes once every 3 months. Some patients may benefit from a dosage of 300 mg once every 3 months.

The efficacy and safety of Vyepti was demonstrated in two Phase 3 clinical trials (PROMISE-1 in episodic migraine and PROMISE-2 in chronic migraine). The clinical trial program demonstrated a treatment benefit over placebo that was observed for both doses (100 mg and 300 mg) of Vyepti as early as day 1 post-infusion, and the percentage of patients experiencing a migraine was lower for Vyepti than with placebo for most of the first 7 days (early onset of response). In PROMISE-2, data demonstrated that 26.7% (100 mg) to 33.1% (300 mg), compared to 15% of placebo patients, can achieve reduction in migraine days of at least 75% and maintain a sustained migraine improvement through 6 months (sustained efficacy). There may be some modest differences in the 4 approved prophylactic mAbs, but they look to be fairly close in overall efficacy and safety.

Food and Drug Administration (FDA) Approved Indications:

Vyepti (eptinezumab-jjmr) injection is a calcitonin gene-related peptide antagonist indicated for the preventive treatment of migraine in adults.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Vyepti (eptinezumab-jjmr) when **ALL** the following clinical criteria is met:

Initial Coverage Criteria:

1. Documented diagnosis of chronic migraine headache

AND

2. Documentation of use for the preventive treatment of migraine headaches

Reauthorization Criteria:

1. Documented diagnosis of chronic migraine headache

AND

2. The Member has experienced a positive response to therapy as demonstrated by **one (1)** of the following measures:
    a. Documented reduction in headache frequency, severity, or duration.
    b. Documented reduction in the use of acute migraine medications (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], triptans) since starting Vyepti (eptinezumab-jjmr)

Limitations

- Initial approval of Vyepti will be authorized for six (6) months. Reauthorization of Vyepti will be provided in 12-month intervals.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3032	Injection, eptinezumab-jjmr, 1 mg

References

1. Vyepti (eptinezumab-jjmr). Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2022.
2. American Academy of Neurology: Headache practice guidelines. Accessed October 2024. https://americanheadachesociety.org/resources/information-for-clinicians/practice-parameters-guidelines-and-classification/

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- December 12, 2023: Removed the Limitation Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule (1/1/24).
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- November 12, 2024: Minor wording changes and clarified duration of approval (eff 1/1/25)
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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