Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Ajovy® (fremanezumab-vfrm)

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.

Ajovy is indicated for the preventive treatment of migraine in adults. It works by binding to calcitonin gene-related peptide (CGRP) and blocks binding to the

receptor.

Ajovy is supplied as an injection for subcutaneous administration. Two subcutaneous dosing options of Ajovy are available to administer the recommended dosage: 225 mg monthly, or 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each. When switching dosage options, administer the first dose of the new regimen on the next scheduled date of administration. If a dose of Ajovy is missed, administer as soon as possible. Thereafter, Ajovy can be scheduled from the date of the last dose.

The FDA approval of Ajovy was based on two multicenter, randomized, 3-month, double-blind, placebo-controlled studies in adults with a history of episodic migraine (Study 1) or Chronic Migraine (Study 2).

Episodic Migraine:

The trial enrolled 875 adults with a history of episodic migraine (patients with <15 headache days per month). All patients were randomized (1:1:1) to receive subcutaneous injections of either Ajovy 675 mg every three months (quarterly), Ajovy 225 mg monthly, or placebo monthly, over a 3-month treatment period. Patients were allowed to use acute headache treatments during the study. The primary efficacy endpoint was the mean change from baseline in the monthly average number of migraine days during the 3-month treatment period. Both monthly and quarterly dosing regimens of Ajovy demonstrated statistically significant improvements for efficacy endpoints compared to placebo over the 3-month period.

Chronic Migraine:

This trial enrolled 1,130 patients with <15 headache days per month. All patients were randomized (1:1:1) to receive subcutaneous injections of either Ajovy 675 mg starting dose followed by 225 mg monthly, 675 mg every 3 months (quarterly), or placebo monthly, over a 3-month treatment period. Patients were allowed to use acute headache treatments during the study. The subjects treated with Ajovy experienced statistically-significant reduction in the number of monthly headache days of at least moderate.

Food and Drug Administration (FDA) Approved Indications:

Ajovy (fremanezumab-vfrm) is a calcitonin gene-related peptide antagonist indicated for:

- the preventive treatment of migraine in adults.
- the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weight 45kg or more

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Ajovy (fremanezumab-vfrm) when **ALL** the following clinical criteria is met:

Initial Authorization Criteria:

1. Documented diagnosis of chronic migraine headaches in an adult or episodic migraine in pediatric patient

AND

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

AND

3. Member is 18 years of age or older for chronic migraine or 6 to 17 years old for episodic migraine

Reauthorization Criteria:

1. Documented diagnosis of chronic migraine headaches in an adult or episodic migraine in pediatric patient

AND

2. The Member has experienced a positive response to therapy as demonstrated by **one (1)** of the following:
    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 Ajovy (fremanezumab-vfrm) therapy

Limitations

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

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

References

1. Ajovy (fremanezumab-vfrm). North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2025.
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 2025: Added episodic migraine indication (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.