PRIOR AUTHORIZATION POLICY

POLICY: Migraine – Calcitonin Gene-Related Peptide Inhibitors – Ajovy Prior Authorization Policy
- Ajovy® (fremanezumab-vfrm subcutaneous injection – Teva)

REVIEW DATE: 04/10/2024

OVERVIEW
Ajovy, a calcitonin gene-related peptide (CGRP) antagonist, is indicated for the **preventive treatment of migraine** in adults.[1]

Disease Overview
Migraines have been defined as chronic or episodic. Chronic migraine is described by the International Headache Society as headache occurring on ≥ 15 days/month for > 3 months and has the features of migraine headache on ≥ 8 days/month.[2] Episodic migraine is characterized by headaches that occur < 15 days/month.[3,4] Episodic migraine is more common than chronic migraine; however, chronic migraine is associated with a markedly greater personal and societal burden.

Guidelines
An updated assessment of the **preventive and acute treatment of migraine** by the **American Headache Society** (AHS) [2018; update 2021] reaffirms previous migraine guidelines.[5,6] Patients with migraine should be considered for preventive treatment in the following situations: when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly headache days); at least moderate disability (Migraine Disability Assessment [MIDAS] score ≥ 11 or six-item Headache Impact Test [HIT-6] score > 50); contraindication to, failure, overuse, or adverse events with acute treatments; or patient preference. Before developing a preventive treatment plan, the appropriate use (e.g., drug type, route and timing of administration, frequency) of acute treatments should be initiated and coupled with education and lifestyle modifications. All patients with migraine should be offered a trial of acute treatment. Based on the level of evidence for efficacy and the American Academy of Neurology scheme for classification of evidence, the following oral treatments have established efficacy and should be offered for migraine prevention: antiepileptic drugs (**divalproex sodium, valproate sodium, topiramate** [not for women of childbearing potential without a reliable method of birth control]); beta-blockers (**metoprolol, propranolol, timolol**); and **frovatriptan** (for short-term preventive treatment of menstrual migraine). The following treatments are probably effective and should be considered for migraine prevention: antidepressants (**amitriptyline, venlafaxine**); beta-blockers (**atenolol, nadolol**); and angiotensin receptor blockers (**candesartan**).

The **AHS** issued an update to their position statement (2024) specifically regarding therapies targeting CGRP for the prevention of migraine.[7] The evidence for the efficacy, tolerability, and safety of CGRP-targeting migraine preventive therapies (specifically, the monoclonal antibodies: Aimovig [erenumab-aooe subcutaneous {SC} injection], Ajovy® [fremanezumab-vfrm SC injection], Emgality® [galcanezumab-gnlm SC injection], and Vyepti® [eptinezumab-jjmr intravenous infusion], and the gepants: Nurtec® ODT [rimegepant orally disintegrating tablets] and Qulipta® [atogepant tablets]) is substantial and consistent across different individual CGRP-targeting treatments. Extensive "real-world" clinical experience corroborates clinical trials. This data indicates that the efficacy and tolerability of CGRP-targeting therapies are equal to or greater than those of previous first-line therapies. The CGRP-targeting therapies should be considered as a first-line approach for migraine prevention along with previous first-line treatments without a requirement for prior failure of other classes of migraine preventive treatment. Additionally, Botox® (onabotulinumtoxinA SC injection) is considered a first-line therapy for prevention of chronic migraine.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ajovy. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Migraine Headache Prevention.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has ≥ 4 migraine headache days per month (prior to initiating a migraine-preventive medication); AND
   - **C)** If the patient is currently taking Ajovy, the patient has had a significant clinical benefit from the medication, as determined by the prescriber.
     Note: Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Ajovy was initiated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ajovy is not recommended in the following situations:

1. **Acute Treatment of Migraine.** Ajovy has not been studied for the acute treatment of migraine.

2. **Cluster Headache, Treatment or Prevention.** Ajovy has not been found to be effective in Phase III clinical trials in patients with episodic and chronic cluster headache.[7]

3. **Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention.**
   Note: CGRP inhibitors that are indicated for migraine headache prevention include Aimovig (erenumab-aooe subcutaneous injection), Emgality (galcanezumab-gnlm subcutaneous injection), Vyepti (eptinezumab-jjmr intravenous infusion), and Qulipta (atogepant tablets). Ajovy, Aimovig, Emgality, and Vyepti are injectable CGRP inhibitors for migraine prevention and have not been studied for use in combination with another agent in the same class.[9-11] Qulipta is an oral CGRP inhibitor for the preventive treatment of migraine in adults.[12]

4. **Concurrent use with Nurtec ODT (rimegepant sulfate orally disintegrating tablet) when used as a preventive treatment of migraine.** Nurtec ODT is an oral CGRP inhibitor for the acute treatment of migraine and for the preventive treatment of episodic migraine in adults.[13]

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

REFERENCES

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5. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
6. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;00:1–19.
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8. Teva announces update on fremanezumab clinical development for use in episodic cluster headache [press release]. North Wales, PA: Teva Pharmaceuticals USA; April 23, 2019. Available at: https://www.tevapharm.com/news-and-media/latest-news/. Accessed on May 18, 2023.
9. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; October 2022.
10. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; May 2022.
11. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; October 2022.
12. Qulipta® tablets [prescribing information]. Madison, NJ: AbbVie; April 2023.
13. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2022.