PRIOR AUTHORIZATION POLICY

POLICY: Calcitonin Gene-Related Peptide Inhibitors – Aimovig Prior Authorization Policy
- Aimovig® (erenumab-aooe subcutaneous injection – Amgen)

REVIEW DATE: 05/18/2022

OVERVIEW

Aimovig, a calcitonin gene-related peptide (CGRP) receptor 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] reaffirms previous migraine guidelines.[5] Patients with migraine should be considered for preventive treatment when attacks significantly interfere with patients' daily routines despite acute treatment; frequent attacks (≥ 4 monthly headache days); 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).[6] 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).

Four injectable preventive therapies for migraine are mentioned in the AHS consensus statement: Botox® (onabotulinumtoxinA subcutaneous injection) and three monoclonal antibodies targeting CGRP (Aimovig, Ajovy® [fremanezumab-vfrm subcutaneous injection], and Emgality® [galcanezumab-gnlm subcutaneous injection]).[5] Of note, Vyepti® (eptinezumab-jjmr intravenous infusion) had not been approved at the time of the consensus statement. The update states that a CGRP inhibitor should only be initiated in patients who are diagnosed with migraine, have ≥ 4 migraine headache days per month, and have intolerance or inadequate response to 6-week trials of at least two traditional oral migraine preventive medications. Additional criteria apply depending on the number and severity of monthly headache days. Clinical judgment may result in an emerging treatment being added to one or more established treatments. If initiating treatment with a CGRP inhibitor in a patient already on a preventive treatment, it is appropriate to add the CGRP inhibitor to the existing regimen and make no other changes until the effectiveness of the CGRP inhibitor is determined since the risk of interactions between traditional oral migraine preventive medications and the CGRP inhibitors is minimal or nonexistent. Making a decision regarding continuation of therapy for a CGRP inhibitor requires a trial of the medication for at least 3 months, and treatment should

be continued only if benefits can be documented during that time (e.g., reduction in mean monthly headache days of ≥ 50% relative to the pretreatment baseline). Since migraine may improve or remit over time, it is important to reevaluate therapeutic response and, if possible, taper or discontinue treatment if patients no longer meet the criteria for offering preventive treatment. However, once control is established, the decision to discontinue or taper treatment should be a shared decision between patient and clinician.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Migraine Headache Prevention.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **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)** Patient has tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class; AND
     Note: Examples of standard prophylactic (preventive) pharmacologic therapies include angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel blocker, tricyclic antidepressant, other antidepressant.
   - **D)** Patient meets ONE of the following criteria (i, ii, or iii):
     - **i.** Patient has had inadequate efficacy to both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber; OR
     - **ii.** Patient has experienced adverse event(s) severe enough to warrant discontinuation of both of those standard prophylactic (preventive) pharmacologic therapies, according to the prescriber; OR
     - **iii.** Patient meets BOTH of the following (a and b):
       a. Patient has had inadequate efficacy to one standard prophylactic (preventive) pharmacologic therapy; AND
       b. Patient has experienced adverse event(s) severe enough to warrant discontinuation to another standard prophylactic (preventive) pharmacologic therapy, according to the prescriber; AND
   - **E)** If a patient is currently taking Aimovig, 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 Aimovig was initiated.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Aimovig is not recommended in the following situations:

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

2. **Cluster Headache, Treatment or Prevention.** Aimovig has not been studied in patients with cluster headache. The pivotal trials of Aimovig excluded patients with this condition.[7,8]

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 Ajovy (fremanezumab-vfrm subcutaneous injection), Emgality (galcanezumab-gnlm subcutaneous injection), Vyepti (eptinezumab-jjmr intravenous infusion), and Qulipta™ (atogepant tablets). Aimovig, Ajovy, 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 episodic 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. **Hemiplegic Migraine, Treatment or Prevention.** Aimovig has not been studied in patients with hemiplegic migraine. The pivotal trials of Aimovig excluded patients with this condition.[7,8]

6. 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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2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition (beta version). *Cephalalgia*. 2013;33:629-808.
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6. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-1345.
7. Goadsby PJ, Reuter U, Hallstrom Y, et al A controlled trial of erenumab for episodic migraine. *N Eng J Med*. 2017;377:2123-2132.
8. Dodick DW, Ashine M, Brandes JL, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. *Cephalalgia*. 2018;38(6):1026-1037.
9. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva; September 2021.
10. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; December 2019.
11. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; February 2020.
12. Qulipta™ tablets [prescribing information]. Madison, NJ: AbbVie; September 2021.
13. Nurtec® ODT [prescribing information]. New Haven, CT: Biohaven; April 2022.