Drug Coverage Policy

Effective Date.....7/1/2025
Coverage Policy Number IP0503
Policy Title.....Aimovig

Migraine – Calcitonin Gene-Related Peptide Inhibitors – Aimovig

- Aimovig® (erenumab-aooe subcutaneous injection – Amgen)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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; 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.

Coverage Policy

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

Aimovig is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Migraine Headache Prevention.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   - **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 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.
   - **D)** Preferred product criteria are met for the product(s) as listed in the below table(s):

Individual and Family Plans:

Product	Criteria
Aimovig® (erenumab-aooe subcutaneous injection)	Failure, contraindication, or intolerance to Emgality.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Aimovig for any other use is considered not medically necessary , including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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

2. **Cluster Headache, Treatment or Prevention.** Clinical data is currently lacking for the use of Aimovig in patients with cluster headache. The pivotal trials of Aimovig excluded patients with this condition.[8,9]

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.[10-12] Qulipta is an oral CGRP inhibitor for the preventive treatment of migraine in adults.[13]

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.[14]

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.[8,9]

References

1. Aimovig® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; March 2025.
2. Headache Classification Subcommittee of the International Headache Society. The International Classification of Headache Disorders: 3rd edition. *Cephalalgia*. 2018;38:1-211.
3. Damen JAA, Yang B, Idema DL, et al. Comparative effectiveness of pharmacologic treatments for the prevention of episodic migraine headache: A systematic review and network meta-analysis for the American College of Physicians. *Ann Intern Med*. 2025;178(3):369-380.
4. Burch R. Chronic migraine in adults. *JAMA*. 2025;333(5):423-424.
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.
7. Charles AC, Digre KB, Goadsby PJ, et al; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341.
8. Goadsby PJ, Reuter U, Hallstrom Y, et al. A controlled trial of erenumab for episodic migraine. *N Engl J Med*. 2017;377:2123-2132.
9. 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.
10. Ajovy® subcutaneous injection [prescribing information]. North Wales, PA: Teva; March 2025.
11. Emgality® subcutaneous injection [prescribing information]. Indianapolis, IN: Lilly; March 2025.
12. Vyepti® intravenous infusion [prescribing information]. Bothell, WA: Lundbeck; March 2025.
13. Qulipta® tablets [prescribing information]. Madison, NJ: AbbVie; March 2025.
14. Nurtec® ODT [prescribing information]. New York, NY: Pfizer; March 2025

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** coverage policy title from *Erenumab* to *Migraine – Calcitonin Gene-Related Peptide Inhibitors – Aimovig*. **Migraine Headache Prevention:** **Removed** the criteria requiring a patient to have tried either Botox or at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy	7/15/2024

	or adverse event(s) severe enough to warrant discontinuation of those therapies. **Added** preferred product table with criteria to support non-formulary use of Aimovig for IFP plans. **Authorization Duration:** **Updated** initial approval duration updated from 6 months to 1 year.	
Annual Revision	No criteria changes.	7/1/2025

The policy effective date is in force until updated or retired.