CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Aimovig (erenumab-aooe)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Aimovig is a calcitonin gene-related peptide receptor antagonist initially approved by the FDA as the first in its class in 2018. It is indicated for the preventive treatment of chronic migraine and episodic migraine in adults. Aimovig is a fully humanized immunoglobulin G (IgG)-2a monoclonal antibody that works by specifically binding to the calcitonin gene-related peptide (CGRP) ligand and blocking its binding to the CGRP receptor.

Aimovig (erenumab-aooe) will be considered for coverage when the following criteria are met:

Chronic or Episodic Migraine Headache Prophylaxis

For initial authorization:

1. Member is 18 years of age or older with a history of migraine attacks with or without aura; AND
2. Medication is being prescribed for the prevention of chronic or episodic migraine, defined as at least 4 migraines per month, AND
3. Member has tried and failed or been unable to tolerate two prophylactic medications from the following groups:
    a. Beta-blockers (e.g., metoprolol, timolol, or propranolol);
    b. Calcium channel blockers (e.g., verapamil);
    c. Antidepressants (e.g., amitriptyline or venlafaxine);
    d. Anticonvulsant medications (e.g., topiramate or valproic acid);
    e. OnabotulinumtoxinA (Botox for migraine).
4. **Dosage allowed:** 70 mg subcutaneous injection once a month. Some patients may benefit from dosage of 140 mg once monthly. The 140 mg dose is administered once monthly as two consecutive injections of 70 mg each. Quantity Limit: 1 syringe or autoinjecter (70 mg/1 ml or 140 mg/1 ml) per 30 days.

Note: Aimovig is considered experimental and investigational as combination therapy with Botox, Vyepti, Ajovy or Emgality because the safety and effectiveness of these combinations has not been established.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member has improvement in prevention of migraines (e.g., reduced migraine frequency, reduced use of medication for acute migraines attacks).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Aimovig (erenumab-aooe) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
08/03/2018	New policy for Aimovig created.
03/05/2019	Criterion on pregnant or nursing females added. Initial authorization length increased to 6 months and reauthorization length increased to 12 months.
06/05/2020	Diagnosis of episodic migraine headache prophylaxis added. Definition of chronic migraine simplified to just frequency of migraine and headache days. No concurrent use with other CGRP agents added. Trial of Botox added as an additional option under chronic migraine prophylaxis. Criteria pregnancy, psychiatric issues, CV disease, cancer, infection were removed from excluded list. Length of prophylactic and abortive trials reduced to 2 months/trial.
05/05/2022	Transferred to new policy. Updated references. Removed prescriber specialty and abortive trials. Quantity Limit added
11/9/2022	Combined chronic and episodic criteria. Removed prescriber specialty requirement, contraindications. Reduced headache day requirement to at least 4 migraines per month. Reduced trials to two prophylactic medications.
03/06/2023	Removed chart note requirement from reauthorization criteria

References:

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc.; November 2021.
2. ClinicalTrials.gov. Identifier: NCT 03096834. A Study Evaluating the Effectiveness of AMG 334 Injection in Preventing Migraines in Adults Having Failed Other Therapies (LIBERTY). Available: https://clinicaltrials.gov/ct2/show/NCT03096834?term=NCT03096834&rank=1.
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4. ICHD-3 The International Classification of Headache Disorders. www.ichd-3.org.
5. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the Differences Between Episodic Migraine and Chronic Migraine. Current Pain and Headache Reports. 2012;16(1):86-92. doi:10.1007/s11916-011-0233-z.
6. ClinicalTrials.gov. Identifier: NCT 02066415. A Study to Evaluate the Efficacy and Safety of AMG 334 in Chronic Migraine Prevention. Available at: https://clinicaltrials.gov/ct2/show/NCT02066415?term=NCT+02066415&rank=1.
7. Tepper S, et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomized, double-blind, placebo-controlled phase 2 trial. The Lancet Neurology. 2017;16(6): 425-434.
8. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019;59: 1-18.
9. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology Apr 2012, 78 (17) 1337-1345.
10. Ailani J, Burch R, et al. Consensus Statement: The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.

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