Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Aimovig (erenumab-aooe)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Botox QUANTITY LIMIT— up to 140 mg per month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Aimovig (erenumab-aooe) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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. Member has documented history of ≥ 15 headache days per month for more than 3 months, of which ≥ 8 days were migraine days characterized as ≥ 5 attacks lasting 4-72 hours with **both** of the following:
   a) **Two** or more of the following:
      i) Aggravation by or causing avoidance of routine physical activity;
      ii) Moderate or severe pain intensity;
      iii) Pulsating quality;
      iv) Unilateral location;
   b) **One** or more of the following:
      i) Nausea or vomiting;
      ii) Photophobia and phonophobia; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Other prophylactic therapeutic options have been ineffective or not tolerated for trial of at least 3 months, as indicated by **two** or more of the following:
   a) Beta-blockers;
   b) Calcium channel blockers;
   c) Antidepressants such as amitriptyline, nortriptyline, doxepin, or protriptyline;
   d) Anticonvulsant medications such as topiramate or valproic acid; AND
5. Abortive therapeutic options (i.e., ergotamine, triptans, combination analgesics, or simple analgesics) have been ineffective or not tolerated for at least 3 months (for a minimum of 8 or more days per month); AND
6. Member has not received botulinum toxin injection for headache prophylaxis in the past 4 months; AND
7. Member does **not** have ANY of the following:
   a) Medication overuse headache;

b) Pregnant or nursing female;
c) History of cluster or hemiplegic headache;
d) Cardiac or hepatic disease;
e) Member was older than 50 years of age at migraine onset.

8. **Dosage allowed:** 70 mg subcutaneous injection once a month. Some patients may benefit from a dosage of 140 mg once monthly. The 140 mg dose is administered once monthly as two consecutive injections of 70 mg each.

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

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member has improvement in prevention of migraines documented in chart notes (e.g., reduced migraine frequency, reduced use of medication for acute migraines attacks); AND
2. Member has not received botulinum toxin injection for headache prophylaxis in the past 4 months.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Aimovig (erenumab-aooe) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Cluster or hemiplegic migraine headache

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.

References:

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc.; May 2018.
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.
3. ClinicalTrials.gov. Identifier: NCT 02456740. Study to Evaluate the Efficacy and Safety of AMG 334 in Migraine Prevention (STRIVE). Available at: https://clinicaltrials.gov/ct2/show/NCT02456740?term=NCT+02456740&rank=1.
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.

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