CareSource

PHARMACY POLICY STATEMENT **Indiana 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) 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.

CHRONIC 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 migraine, defined as **both** of the following and must be documented in chart notes:
   a) ≥ 15 headache days per month for at least 3 months;
   b) ≥ 8 migraine days per month for at least 3 months; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Member has tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
5. Member has tried and failed or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
   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); AND
6. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month); AND
7. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Emgality, Ajovy, or Vyepti); AND
8. 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.
9. **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, Vyepti, 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).

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

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 prevention of episodic migraine, defined as **both** of the following and must be documented in chart notes:
   a) ≤ 14 headache days per month for at least 3 months;
   b) 4 or more migraine days per month for at least 3 months that cause significant impairment to quality of life (i.e. requiring bed rest, missed school/work); AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Member has tried and failed or unable to tolerate **three** prophylactic medications from the following groups for 2 months per trial:
   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); AND
5. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month); AND
6. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Emgality, Ajovy, or Vyepti); 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, Vyepti, 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).

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.
06/05/2020	Diagnosis of episodic migraine headache prophylaxis added. Definition of chronic migraine simplified to just frequency of migraine and headache days. Requirement of no botox in the past 4 months removed. No concurrent use with Botox and other CGRP agents added. Trial of Botox added as an additional option under chronic migraine prophylaxis. Length of prophylactic and abortive trials reduced to 2 months/trial.

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.
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.

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