Clinical Policy: Erenumab-aaoe (Aimovig)

Reference Number: PA.CP.PHAR.128
Effective Date: 10.17.18
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Revision Log

Description
Erenumab-aaoe (Aimovig™) is a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)
Aimovig is indicated for the preventive treatment of migraine in adults.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Aimovig is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraine Prophylaxis (must meet all)**:**

1. Diagnosis of episodic or chronic migraine;
2. Member experiences an average of ≥ 4 migraine days per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Failure of an 8-week trial of at least 2 of the following oral migraine preventative therapies, each from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
5. Aimovig is not prescribed concurrently with Botox® or other injectable CGRP inhibitors (e.g., Ajovy™, Emgality™);
6. Dose does not exceed one of the following (a or b):
   a. 70 mg (1 injection) once monthly;
   b. 140 mg once monthly if medical justification is provided.

Approval duration: 4 months

B. Other diagnoses/indications:

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Migraine Prophylaxis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;

2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month, a reduction in the severity, or reduction in duration of migraines from baseline;
3. Aimovig is not prescribed concurrently with Botox or other injectable CGRP inhibitors (e.g., Ajovy, Emgality);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 70 mg (1 injection) once monthly;
   b. 140 mg once monthly if medical justification is provided.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CGRP: calcitonin gene-related peptide

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®)	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label use*

Appendix C: Contraindications
Not applicable

Appendix D: General Information
- In clinical trials, a migraine day was defined as any calendar day in which the patient experiences a qualified migraine headache (onset, continuation, or recurrence of the migraine headache). A qualified migraine headache is defined as a migraine with or without aura, lasting for ≥ 30 minutes, and meeting at least one of the following criteria (a and/or b):
  a) ≥ 2 of the following pain features: unilateral, throbbing, moderate to severe, exacerbated with exercise/physical activity;
  b) ≥ 1 of the following associated symptoms: nausea and/or vomiting, photophobia, and phonophobia.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraine prophylaxis	70 mg SC once monthly Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly, which is administered as two consecutive subcutaneous injections of 70 mg each	140 mg/month

VI. Product Availability
Single-dose prefilled SureClick® autoinjector or prefilled syringe: 70 mg/mL, 140 mg/mL

VII. References
1. Aimovig Prescribing Information. Thousand Oaks, CA: Amgen Inc.; May 2018. Available at: www.aimovig.com. Accessed June 6, 2018.
2. Silberstein SD, Holland S, Freitag F, et al. American Academy of Neurology: Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78: 1337-45.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10/18	
Added requirement that Aimovig is not prescribed concurrently with Botox or other injectable CGRP inhibitors; modified continuation of therapy to require maintenance of positive response; modified initial approval duration to match FFS bulletin	04/19	