Clinical Policy: Erenumab-aaoe (Aimovig)

Reference Number: ERX.SPA.246
Effective Date: 09.01.18
Last Review Date: 02.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 4 migraine days per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Age ≥ 18 years;
5. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
6. Aimovig is not prescribed concurrently with Botox® or other injectable and oral CGRP inhibitors (e.g., Ajovy®, Emgality®, Vyepti™, Nurtec®, Ubrelvy™);
7. Dose does not exceed one of the following (a or b):
   a. 70 mg (1 injection) once monthly;
   b. 140 mg (1 injection) once monthly if medical justification is provided.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline;
3. Aimovig is not prescribed concurrently with Botox or other injectable and oral CGRP inhibitors (e.g., Ajovy, Emgality, Vyepti, Nurtec, Ubrelvy);

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 (1 injection) 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®), valproate sodium	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol, atenolol (Tenormin®)*, nadolol (Corgard®)*	**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/Boxed Warnings

- Contraindication(s): serious hypersensitivity to erenumab-aooe or to any of the excipients
- Boxed warning(s): none reported

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 SC once monthly	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.; April 2020. Available at: www.aimovig.com. Accessed November 18, 2020.
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.
3. Digre KB. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache 2019; 59: 1-18.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.10.18	08.18
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.	01.15.19	05.19
Added new dosage form: 140 mg/mL syringe/autoinjector; modified max dosing criteria to reflect that only 1 injection is needed for the 140 mg dose.	04.10.19	
3Q 2019 annual review: no significant changes; references reviewed and updated.	06.19.19	08.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.04.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	11.18.20	02.21
Revised requirement on concurrent use with other CGRP inhibitors to include oral products with Nurtec and Ubrelvy listed as additional examples.	06.28.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.