Clinical Policy Title:	erenumab-aooe
Policy Number:	RxA.587
Drug(s) Applied:	Aimovig®
Original Policy Date:	03/06/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Erenumab-aaoe is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
erenumab-aaoe (Aimovig®)	Migraine prophylaxis	70 mg SC once monthly; some patients may benefit from a dosage of 140 mg once monthly	140 mg/month

Dosage Forms

- Single-dose prefilled SureClick® autoinjector: 70 mg/mL, 140 mg/mL
- Single-dose prefilled syringe: 70 mg/mL, 140 mg/mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of episodic or chronic migraine;
2. Member experiences 4 migraine days or more per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Member is 18 years of age or older;
5. Failure of an 8-week trial of at least two (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, valproate sodium, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), antidepressants (e.g., amitriptyline, venlafaxine);
6. Aimovig® is not prescribed concurrently with a botulinum product (e.g., Botox®) or other injectable CGRP inhibitors (e.g., Ajovy®, Emgality®);

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
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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 a botulinum product (e.g., 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 (1 injection) once monthly if medical justification is provided.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CGRP: Calcitonin Gene-Related Peptide
SC: Subcutaneous

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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, metoprolol, timolol, atenolol, nadolol	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Antidepressants/tricyclic antidepressants* such as: amitriptyline, venlafaxine	**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):
  - Patients with 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 or longer, and meeting at least one of the following criteria (a and/or b):
  a) 2 or more of the following pain features: unilateral, throbbing, moderate to severe, exacerbated with exercise/physical activity;
  b) 1 or more of the following associated symptoms: nausea and/or vomiting, photophobia, and phonophobia.
- Hypersensitivity reactions: If a serious hypersensitivity reaction occurs, discontinue administration of erenumab-aooe and initiate appropriate therapy. Hypersensitivity reactions can occur within hours to more than one week after administration.
- Constipation with serious complications: Serious complications of constipation may occur.
- Hypertension: New-onset or worsening of pre-existing hypertension may occur.

References

1. Aimovig® Prescribing Information. Thousand Oaks, CA: Amgen Inc.; February 2021. Available at: www.aimovig.com. Accessed April 30, 2021.
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. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. Neurology 2013; 80: 871
4. American Academy of Neurology. Update: Pharmacologic Treatments for Episodic Migraine Prevention in Adults. Available at: https://www.aan.com/Guidelines/Home/GetGuidelineContent/545. Accessed May 4, 2021.
5. Goadsby P, Reuter U, Hallström Y, et al. A Controlled Trial of Erenumab for Episodic Migraine. *N Engl J Med* 2017; 377: 2123-32.
6. Dodick D, Ashina M, Brandes J, et al. ARISE: A Phase 3 Randomized Trial of Erenumab for Episodic Migraine. Available at: journals.sagepub.com.
7. Robbins M, et al. Treatment of Cluster Headache: The American Headache Society Evidence Based Guidelines. Headache 2016; 56: 1093-1106.
8. Weaver-Agostoni J. Cluster Headache. American Academy of Family Physicians. Am Fam Physician. 2013;88(2):122-128.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/25/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosage forms were updated. 5. APPENDIX A: Abbreviation/Acronym Key was updated to include SC. 6. APPENDIX B: Therapeutic Alternatives verbiage was updated to “Below are suggested therapeutic alternatives based on clinical guidance....” 7. APPENDIX C was updated include detailed contraindications. 8. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 9. Initial Approval criteria: Medicaid approval duration was updated to 3 months. 10. Continued Approval criteria: Medicaid approval duration was updated to 6 months. 11. References were updated.	09/28/2020	12/07/2020
Policy was reviewed: 1. Policy title was updated. 2. Dosing information was updated. 3. Clinical policy - Verbiage added: ‘‘The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage” after “Provider must submit…” 4. Continued approval duration updated. 5. Appendix D was updated. 6. References were updated.	04/30/2021	06/10/2021