Clinical Policy: Erenumab-aooe (Aimovig)

Reference Number: CP.CPA.349
Effective Date: 12.01.20
Last Review Date: 11.24
Line of Business: Commercial*

Coding Implications
Revision Log

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

Description

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

**These criteria do NOT apply to California Exchange Plans. Requests for California Exchange Plans should be reviewed using HIM.PA.SP65.*

FDA Approved Indication(s)

Aimovig is indicated for the preventive treatment of migraine in adults.

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Aimovig is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

**These criteria do NOT apply to California Exchange Plans. Requests for California Exchange Plans should be reviewed using HIM.PA.SP65.*

1. Diagnosis of episodic or chronic migraine;
2. Provider's attestation that member experiences ≥ 4 migraine days per month for at least 3 months;
3. Age ≥ 18 years;
4. 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);
5. Failure of Ajovy®* and Emgality®*, unless clinically significant adverse effects are experienced or both are contraindicated;
   **Prior authorization may be required.*
6. If currently receiving treatment with Botox® for migraine prophylaxis and request is for concurrent use of Botox and Aimovig (i.e., not switching from one agent to another), all of the following (a, b, and c):
   a. Sufficient evidence is provided from at least two high-quality*, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (i – iv):
      **Case studies or chart reviews are not considered high-quality evidence*
      i. Adequate representation of the member's clinical characteristics, age, and diagnosis;

ii. Adequate representation of the prescribed drug regimen;
iii. Clinically meaningful outcomes such as a reduction in monthly migraine or headache days;
iv. Appropriate experimental design and method to address research questions (*see Appendix E for additional information*);

b. Member has experienced and maintained positive response to Botox monotherapy as evidenced by a ≥ 30% reduction in migraine days per month from baseline following at least 2 quarterly injection (6 months) of Botox monotherapy;
c. Despite Botox monotherapy, member continues to experience ≥ 4 migraine days per month and/or severe migraine headaches that result in disability and functional impairment;

7. Aimovig is not prescribed concurrently with other CGRP inhibitors (e.g., Ajovy®, Emgality®, Nurtec® ODT, Qulipta™, Ubrelvy™, Vyepti™, Zavzpret™);
8. 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member has experienced and maintained positive response to therapy as evidenced by provider's attestation of a reduction in migraine days per month from baseline;
3. Aimovig is not prescribed concurrently with other CGRP inhibitors (e.g., Ajovy, Emgality, Nurtec ODT, Qulipta, Ubrelvy, Vyepti, Zavzpret);*

**This requirement does not apply to CA if member was previously approved via Centene benefit and is currently stable on therapy with both oral and injectable CGRP inhibitors*

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

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 – CP.CPA.09 for commercial 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®), 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,	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
atenolol (Tenormin®)*, nadolol (Corgard®)*		
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Ajovy® (fremanezumab-vfrm)	**Migraine Prophylaxis** 225 mg SC once monthly or 675 mg SC every three months	675 mg every 3 months
Emgality® (galcanezumab-gnlm)	**Migraine Prophylaxis** Loading dose: 240 mg SC once Maintenance dose: 120 mg SC once monthly	120 mg/month

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
- 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.

Appendix E: Appropriate Experimental Design Methods
- Randomized, prospective controlled trials are generally considered the gold standard; however:
  - In some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos, or crossover.
  - Non-randomized prospective clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- Case reports and chart reviews are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

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	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 2023. Available at: www.aimovig.com. Accessed July 15, 2024.
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.
4. Charles AC, Digre KB, Goadsby PJ, et al. The American Headache Society: Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024; 64: 333–341.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adapted from CP.PHAR.128) per October SDC and prior clinical guidance; removed prescriber requirements; clarified provider attestation is required to confirm migraine day requirements.	10.07.20	11.20
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; added clarification in continuation of therapy to indicate requirement for concurrent use with other CGRP inhibitors does not apply to CA if member was previously approved via Centene benefit	06.28.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
and is currently stable on therapy with both oral and injectable CGRP inhibitors.		
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.14.21	02.22
Clarified the following "…not prescribed concurrently with Botox or other injectable **or** oral CGRP inhibitors."	05.31.22	
4Q 2022 annual review: Added criteria for concurrent use with Botox requiring supportive evidence from published studies or clinical practice guidelines, positive response with Botox monotherapy, and continued migraine burden; added unclassified drugs HCPCS code; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.19.22	11.22
4Q 2023 annual review: no significant changes; add HCPCS code C9399 for unclassified drugs or biologicals; references reviewed and updated.	06.29.23	11.23
Per September SDC and prior clinical guidance, added redirection to Ajovy and Emgality; added the following clarification under the description and initial approval criteria sections: These criteria do NOT apply to California Commercial Exchange Plans. Requests for California Commercial Exchange Plans should be reviewed using HIM.PA.SP65.	09.21.23	12.23
4Q 2024 annual review: Clarified that "California Commercial Exchange Plans" refers to "California Exchange Plans"; added Zavzpret to list of CGRP inhibitors that should not be prescribed concurrently with Aimovig, removed references to "injectable or oral CGRP" as Zavzpret is a nasal product; updated HCPCS code J3490 to J3590 for unclassified biologics; references reviewed and updated.	07.15.24	11.24

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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