

Clinical Policy: Erenumab-aaoc (Aimovig)

Reference Number: CP.PHAR.128

Effective Date: 07.10.18

Last Review Date: 02.21

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Erenumab-aaoc (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 Centene Corporation[®] 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., Ajoovy[®], 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraine Prophylaxis (must meet all):

1. Currently receiving medication via Centene benefit 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);*
**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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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.PMN.53 for Medicaid 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 <i>Refer to prescribing information or Micromedex</i>	<i>Refer to prescribing information or Micromedex</i>

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Beta-blockers such as: propranolol (Inderal [®]), metoprolol (Lopressor [®])*, timolol, atenolol (Tenormin [®])*, nadolol (Corgard [®])*	Migraine Prophylaxis <i>Refer to prescribing information or Micromedex</i>	<i>Refer to prescribing information or Micromedex</i>
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil [®]), venlafaxine (Effexor [®])	Migraine Prophylaxis <i>Refer to prescribing information or Micromedex</i>	<i>Refer to prescribing information or Micromedex</i>

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-aaoc 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):
 - ≥ 2 of the following pain features: unilateral, throbbing, moderate to severe, exacerbated with exercise/physical activity;
 - ≥ 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	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 member has not received Botox within the previous 12 weeks per clinical trial exclusion criteria and Botox dosing frequency.	08.15.18	11.18
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	
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.14.19	11.19
1Q 2020 annual review: no significant changes; references reviewed and updated. Added HIM line of business per SDC and prior clinical guidance.	02.01.20	02.20
HIM line of business removed per September SDC and prior clinical guidance.	09.10.20	
Commercial line of business removed per October SDC and prior clinical guidance.	11.17.20	
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 and is currently stable on therapy with both oral and injectable CGRP inhibitors.	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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

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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.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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