

Utilization Management and Clinical Medical Policy

Policy Name: Erenumab- <i>aooe</i> (Aimovig®), Fremanezumab- <i>vfrm</i> (Ajovy®), Galcanezumab- <i>gnlm</i> (Emgality®)	Policy Number: MP-RX-FP-17-23	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 11/30/2023 Last Review Date: 08/19/2026	Effective Date: 08/19/2026 Frequently Revision: Annual
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Service Category:

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| ☐ Anesthesia | ☐ Medicine Services and Procedures |
| ☐ Surgery | ☐ Evaluation and Management Services |
| ☐ Radiology Procedures | ☐ DME/Prosthetics or Supplies |
| ☐ Pathology and Laboratory Procedures | ☒ Other: Part B Drugs |

Service Description:

This document addresses the use of **Erenumab-*aooe* (Aimovig®)**, **Fremanezumab-*vfrm* (Ajovy®)**, **Galcanezumab-*gnlm* (Emgality®)**, a calcitonin-gene related peptide antagonist approved by the Food and Drug Administration (FDA) for the treatment of migraine prophylaxis, episodic cluster headache (Emgality only), and preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more (Ajovy only).

Background Information:

Migraine is a common episodic disorder, the hallmark of which is a disabling headache generally associated with nausea and/or light and sound sensitivity.

The abortive (symptomatic) therapy of migraine ranges from the use of simple analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen to triptans, antiemetics, calcitonin gene-related peptide (CGRP) antagonists, lasmiditan, and dihydroergotamine. The selection of a specific agent depends on patient-specific factors including the severity and character of symptoms, comorbid conditions, and prior response to treatment.

Abortive treatments are usually more effective if they are given early in the course of the headache; a large single dose tends to work better than repetitive small doses. For some patients, oral agents are less effective because of poor absorption secondary to migraine-induced gastric stasis and vomiting.

The early use of migraine-specific medications for severe attacks provided the best outcomes in a randomized controlled trial of 835 adults with migraine that compared these strategies. One group (step care within attacks) received aspirin (800 to 1000 mg) plus metoclopramide (20 mg) as initial therapy for all attacks; patients not responding to treatment after two hours in each attack escalated treatment to zolmitriptan (2.5 mg). A second group (step care across attacks) received initial treatment with aspirin (800 to 1000 mg) plus metoclopramide (10 mg); patients not responding in at least two of the first three attacks switched to zolmitriptan (2.5 mg) for the next three attacks. In a third group (stratified care), patients with mild headaches were treated with aspirin plus metoclopramide, while those with more severe headaches were treated with zolmitriptan. The latter two groups had significantly better outcomes than the first group as measured by headache response and disability time, although patients in the stratified group had the greatest number of adverse events.

The pharmacologic approach to migraine is directed mainly by the severity of the attacks, the presence of associated nausea and vomiting, the treatment setting (outpatient or medical care facility), and patient-specific factors, such as the presence of vascular risk factors and drug preference.

Approved Indications

- A. Migraine prophylaxis in adults

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- B. Episodic cluster headache (Emgality only)
- C. Preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more (Ajovy only)

Other Uses

- A. None.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

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A. Criteria For Initial Approval

Initial requests for Aimovig, Ajovy, and Emgality may be approved if the following criteria are met:

- i. Individual has a diagnosis of *migraine*; **AND**
 - A. The requested medication will be used as a preventative treatment; **AND**
 - B. Individual has at least 4 migraine headache days per month (before starting a preventative medication); **AND**
 - C. Individual has tried and failed at least 2 standard prevention therapies, each from a different drug class (anticonvulsant, beta-blocker, or antidepressant); **AND**
 - D. Individual meets *one* of the following criteria:
 1. Inadequate efficacy for both standard prophylactic drug therapies, according to the prescribing physician; **OR**
 2. Experienced adverse events sufficiently severe enough to warrant discontinuation of both standard preventive therapies, according to the prescribing physician; **OR**
 3. Inadequate efficacy with one standard preventive therapy and has experienced an adverse event severe enough to warrant discontinuation of another standard preventive therapy, according to the prescribing physician;
- OR**
- ii. Individual is a pediatric patient with diagnosis of episodic migraine (*Ajovy* only); **AND**
 - A. Individual is 6-17 years of age and weighs at least 45 kg; **AND**
 - B. Individual is using for preventive treatment.
- OR**
- iii. Individual has a diagnosis of *episodic cluster headache (Emgality only)*; **AND**
 - A. Individual has had at least 5 cluster headache attacks; **AND**
 - B. Individual has tried and failed at least one triptan (sumatriptan or zolmitriptan); **AND**
 - C. Individual meets *one* of the following criteria:
 1. Inadequate efficacy with at least one triptan; **OR**
 2. Experienced adverse events severe enough to justify discontinuation of triptan therapy.

B. Criteria For Continuation of Therapy

Continuation requests for *Aimovig, Ajovy, and Emgality* may be approved if the following criteria are met:

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- i. Progress notes or clinical documentation from the prescriber confirms that the patient requires continued treatment and has demonstrated stabilization and/or improvement in disease activity, such as reduction in monthly migraine days or reduction in frequency of episodic cluster headache attacks, as applicable; **AND**
- ii. There is no evidence of treatment-limiting adverse effects associated with *Aimovig*, *Ajovy*, and *Emgality*.

C. Authorization Duration

- i. Initial Approval Duration: 1 year
- ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Requests for *Aimovig*, *Ajovy*, and *Emgality* may not be approved when the criteria above (section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
- Erenumab-<i>aooe</i>, (Aimovig®) 70 mg/mL, 140 mg/mL SD prefilled SureClick autoinjector 70 mg/mL, 140 mg/mL SD prefilled syringe	70mg sc once monthly - Some patients may benefit from a dosage of 140 mg sc once monthly.
- Fremanezumab-<i>vfrm</i>, (Ajovy®) 225 mg/1.5 mL SD prefilled autoinjector 225 mg/1.5 mL SD prefilled syringe	- Adults: 225 mg sc monthly; OR 675 mg sc every 3 months (quarterly)* - Pediatric dosing: 225 mg monthly.
- Galcanezumab-<i>gnml</i>, (Emgality®) 120 mg/mL SD prefilled pen 100 mg/mL, 120 mg/mL SD prefilled syringe	<i>Migraine prophylaxis:</i> 240 mg sc (2 consecutive 120-mg doses) once as a loading dose, followed by 120 mg once monthly. <i>Episodic cluster headache:</i> 300 mg subQ (3 consecutive sc injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.
Exceptions	
*The 675 mg quarterly dosage is administered as three consecutive injection of 225 mg each.	

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
G43.0	Migraine without aura
G43.1	Migraine with aura
G43.4	Hemiplegic migraine
G43.5	Persistent migraine aura without cerebral infarction
G43.6	Persistent migraine aura with cerebral infarction
G43.7	Chronic migraine without aura
G43.8	Other migraine
G43.9	Migraine, unspecified
G43.E	Chronic migraine with aura
G44.01	Episodic cluster headache

HCPCS Codes:

Codes	Description
J3590	Injection, CGRP antagonists
J3031	Injection, fremanezumab- <i>vfrm</i> , 1 mg (Ajovy) (code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

CPT Codes:

Codes	Description

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Reference Information:

1. Amgen Inc. (2025). Aimovig® (erenumab-*aooe*) injection, for subcutaneous use: Prescribing information. Retrieved June 19, 2026.
2. Teva Pharmaceuticals USA, Inc. (2026). Ajovy® (fremanezumab-*vfrm*) injection, for subcutaneous use: Prescribing information. Retrieved June 19, 2026.
3. Eli Lilly and Company. (2026). Emgality® (galcanezumab-*gnlm*) injection, for subcutaneous use: Prescribing information. Retrieved June 19, 2026.
4. Centers for Medicare & Medicaid Services. Medicare Coverage Database, Self-Administered Drug Exclusion Articles/Reports. Accessed June 19, 2026.
5. Charles, A. C., Digre, K. B., Goadsby, P. J., Robbins, M. S., & Hershey, A. (2024). Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*, 64(4), 333–341. <https://doi.org/10.1111/head.14692>. Retrieved June 19, 2026.
6. ICD10Data.com. FY 2026 ICD-10-CM code set, migraine and cluster headache code families. Accessed June 19, 2026.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated Service Description and Approved uses to add FDA approved indication for Ajovy for preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more. Edited recommended initial dosage for Aimovig. Coding reviewed: removed ICD10 codes G43.91 and G44.019; added ICD10 codes G43.0, G43.1, G43.4, G43.5, G43.6, G43.7, G43.8, G43.9, G43.E; clarified that J3031 code may be used for medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered. Updated reference information. Wording and formatting changes. Incorporated new policy template.	8/14/2026	8/19/2026
Annual Review	Addition of clinical criteria for pediatric indication of episodic migraine for Ajovy. Addition of pediatric dosing for Ajovy in quantity limits table.	9/5/2025	9/16/2025
Annual Review	Add criteria for continuation of therapy and conditions not covered. Update generic drug names to include the suffix of each drug name. Review and update dosage table to include dosage forms and add additional information for clarification. Wording and formatting changes. Coding Reviewed; add G44.01 and G44.019 for cluster headache.	2/18/2025	3/6/2025
Policy Inception	9/27/2023 Policy reviewed and approved by P&T Committee.	10/30/2023	11/30/2023