Medical Policy

Healthcare Services Department

mePolicy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA	☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ 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 and episodic cluster headache (Emgality 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.

Medical Policy

Healthcare Services Department

mePolicy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA	☒ MMM Multihealth

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

B. Episodic cluster headache (Emgality only)

Applicable Codes

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.

HCPCS	Description
J3590	Injection, CGRP antagonists

ICD-10	Description
G43.91	Other migraine, intractable
G44.01	Cluster headache, intractable
G44.019	Cluster headache, not intractable

Medical Policy

Healthcare Services Department

mePolicy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA	☒ MMM Multihealth

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria

Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)

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 has a diagnosis of *epidosic 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.

mePolicy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA	☒ MMM Multihealth

B. Criteria for Continuation of Therapy

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

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; **AND**
ii. There is no evidence of treatment-limiting adverse effects associated with *Aimovig, Ajovy, and Emgality.*

C. 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.

D. Authorization Duration

i. Approval authorization
    a. Initial Approval Duration: 1 year
    b. Reauthorization Approval Duration: 1 year

mePolicy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA	☒ MMM Multihealth

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-aooe, (Aimovig®) – 70 mg/mL, 140 mg/mL SD prefilled SureClick autoinjector – 70 mg/mL, 140 mg/mL SD prefilled syringe	• 140mg sc once monthly ○ Some patients may benefit from a dosage of 140 mg sc once monthly.
▪ Frenamezumab-vfrm, (Ajovy®) – 225 mg/1.5 mL SD prefilled autoinjector – 225 mg/1.5 mL SD prefilled syringe	• 225 mg sc monthly; **OR** • 675 mg sc every 3 months (quarterly)*
– Galcanezumab-gnml, (Emgality®) – 120 mg/mL SD prefilled pen – 100 mg/mL, 120 mg/mL SD prefilled syringe	• *Migraine prophylaxis:* ○ 240 mg sc (2 consecutive 120-mg doses) once as a loading dose, followed by 120 mg once monthly. • *Episodic cluster headache:* ○ 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.	

Medical Policy

Healthcare Services Department

mePolicy Name	Policy Number	Scope
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA ☒ MMM Multihealth

Reference Information

1. Drug Formulary- Medicare & Mucho Más. Accessed July 11, 2023. https://mmm-pr.com/frontend/web/uploads/documentos/MMMPHIFormESP2022_633c37225d0f6.pdf.
2. DailyMed - emgality- galcanezumab-GNLM injection, solution. U.S. National Library of Medicine. Accessed July 11, 2023. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=33a147be-233a-40e8-a55e-e40936e28db0.
3. DailyMed - emgality- galcanezumab-GNLM injection, solution. U.S. National Library of Medicine. Accessed July 11, 2023. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=33a147be-233a-40e8-a55e-e40936e28db0.
4. DailyMed - Aimovig- erenumab-Aooe Injection aimovig- erenumab-aooe injection, solution. U.S. National Library of Medicine. Accessed July 11, 2023. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b998ed05-94b0-47fd-b28f-cddd1e128fd8.
5. Micromedex products: Please Login. Accessed July 11, 2023. https://www.micromedexsolutions.com/micromedex2/librarian/CS/49F9E2/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/267713/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/pf.HomePage?navitem=topHome&isToolPage=true.

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Choose an item.			
Annual Review 9/27/2024	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

Medical Policy

Healthcare Services Department

mePolicy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab-aooe (Aimovig®), Fremanezumab-vfrm (Ajovy®), Galcanezumab-gnlm (Emgality®)	MP-RX-FP-17-23	☒ MMM MA	☒ MMM Multihealth