Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope	
CGRP Antagonists: Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (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 (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality) a drug 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.

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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 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.

B vs D Criteria: All CGRP's included in this protocol are subject to B vs D evaluation. Medication is eligible to be evaluated through part B if furnished "incident to" physician service provided. If not, medication must be evaluated through part D.

Erenumab (Aimovig), Fremanezumab (Ajovy), Galcanezumab (Emgality)

A. Criteria For Initial Approval

1. Diagnosis of one of the following:
1. Migraine and the medication will be used as a preventative treatment.
a) At least 4 migraine headache days per month (before starting a preventative medication tomigraine), AND tried and failed at least 2 standard prevention therapies, each of a class different drug (anticonvulsant, beta-blocker, or antidepressant), AND meets one of the following criteria:
i) the patient had inadequate efficacy for both standard prophylactic drug therapies,
according to the prescribing physician, OR
ii) the patient experienced adverse events sufficiently
severe enough to warrant discontinuation of both standard prophylactic therapies, according to the physician prescribing, OR
iii) the patient has had inadequate efficacy with prophylactic drug therapy
standard and has experienced an adverse event severe enough to warrant discontinuation of other standard prophylactic drug therapy, depending on the prescribing physician.
2. Episodic cluster headache (only emgality),
as treatment AND the patient tried and failed at least one triptan (sumatriptan or zolmitriptan), AND the Physician's certificate includes any of the following:
(A) Patient had inadequate efficacy with at least
least one triptan OR
(B) Patient has experienced adverse events severe enough to warrant
justify discontinuation of triptan therapy.

B. Authorization Duration

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

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Limits or Restrictions

A. 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, (Aimovig)	140mg subQ monthly
Frenamezumab, (Ajovy)	225 mg subQ monthly or 675 mg subQ every 3 months
Galcanezumab, (Emgality)	240 mg subQ (2 consecutive 120-mg doses) once as a loading dose, followed by 120 mg once monthly for migraine prophylaxis or 300 mg subQ (3 consecutive subQ injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period

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Reference Information

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Policy reviewed and approved by P&T Committee.	10/30/2023	11/30/2023

Rev. 09/27/2023