Prior Authorization Criteria

Injectable Calcitonin Gene Related Peptides (CGRP) inhibitors PA Criteria

- **AIMOVIG™(erenumab-aooe)**
- **AJOVY™ (fremanezumab-vfrm)**
- **EMGALITY™ (galcanezumab-gnlm)**

AIMOVIG, AJOVY and EMGALITY impact calcitonin gene-related peptides, which have been observed to increase during a migraine. These drugs are indicated for the *preventive* treatment of migraine.
Emgality 300mg is indicated for the treatment of episodic cluster headache in adults.

VYEPTI™ (eptinezumab-jjmr) – Please see separate criteria at https://medicaid.ms.gov /manual-prior-authorization -criteria/

Denial Criteria for any of the CGRP inhibitors: Medication will not be used in combination with another (CGRP) inhibitor

- Medication will not be used within 12 weeks of date of last Botox® administration
- History of myocardial infarction, stroke, unstable angina, and coronary bypass surgery or other revascularization procedures within the past 12 months, vascular ischemia, deep vein thrombosis, pulmonary embolism or thrombotic events
- Currently pregnant or nursing
- Medication Overuse Headache, Hemiplegic Migraine or Tension-Type Headache

Required Medical Information:

- Diagnosis of Episodic or Chronic Migraine
- Chart notes (documentation required upon request)
- Previous therapies tried/failed

Initial Authorization-Episodic or Chronic migraine: *Select product requested*

Preferred Agents

□ Aimovig 70mg/1ml subcutaneous once monthly

□ Aimovig 140mg/2ml subcutaneously once monthly *(2 consecutive 70 mg-SC injections)*

□ Ajovy 225mg/1.5ml subcutaneously once monthly

□ Ajovy 675mg/4.5ml subcutaneously once quarterly (*3 consecutive 225mg-SC injections*)

Non-preferred Agents (must try and fail 2 preferred agents or provide evidence as to why that is unreasonable)

□ Emgality 240 mg/1ml subcutaneously ***once as loading dose**** (*2 consecutive 120-mg injections*) ***followed by*** Emgality 120 mg subcutaneously once monthly

* Please document date of first administered dose in prescriber's office of requested medication. _____

A. <u>Episodic Migraine</u>

<u>Initial Authorization</u>: 12 weeks

□ Patient must be within the age range as recommended by the FDA label
AND

□ Documentation of at least 4 to 14 migraine days per month, but no more than 14 headaches per month
AND
□ Documented failure to a consecutive 8-week trial as evidenced by paid pharmacy claims, *OR* intolerance *OR* contraindication, of at least ONE therapy, from any TWO of the following different therapeutic classes:

(a) Antidepressants: amitriptyline or venlafaxine
(b) Antiepileptics: divalproex sodium, sodium valproate, or topiramate
(c) Beta-blockers: metoprolol, propranolol, timolol, atenolol, nadolol

B. <u>Chronic Migraine</u>

<u>Initial Authorization:</u> 12 weeks

□ Patient must be within the age range as recommended by the FDA label
AND

□ Documentation of greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months.
AND

□ Documented failure to a consecutive 8-week trial as evidenced by paid pharmacy claims for drugs "*a-d"* below, or a 12-week trial for "e", onabotulinumtoxinA, as documented by physician attestation and/ or paid medical claims *OR* intolerance *OR* contraindication of at least ONE therapy , from any TWO of the following different therapeutic classes:

(a) Antidepressants: amitriptyline or venlafaxine
(b) Antiepileptics: divalproex sodium, valproate sodium, or topiramate

(c) Beta-blockers: metoprolol, propranolol, timolol, atenolol, nadolol,
(d) Botulinum Toxin serotype A: *specifically* onabotulinumtoxinA (Botox®)

<u>Reauthorization for Episodic or Chronic Migraine:</u> 12 months

Select product requested:

□ Aimovig 70mg subcutaneous once monthly

□ Aimovig 140mg subcutaneously once monthly (*2 consecutive injections of 70mg*)

□ Ajovy 225mg subcutaneously once monthly

□ Ajovy 675mg subcutaneously once quarterly (*3 consecutive injections of 225 mg*)

□ Emgality 120 mg subcutaneously once monthly

Reauthorization will be based on the following criteria:

□ Positive response to therapy demonstrated by a reduction in frequency or severity of migraines [documentation required]; ***AND***

□ Patient has an overall improvement in function with therapy; ***AND***

□ Verified pharmacy prescription claims history of Aimovig, Ajovy or Emgality and demonstrated adherence to monthly or quarterly fills per FDA approved dosing.

<u>C. Episodic Cluster Headache</u>

<u>Select product requested:</u>

□ Emgality 300 mg subcutaneously once quarterly (*3 consecutive injections of 100 mg*)

Required Medical Information:

- Diagnosis of Episodic Cluster Headache
- Chart notes (documentation required upon request)
- Previous therapies tried/failed

Initial Authorization: Episodic Cluster Headache

Emgality 300 mg* *(3 consecutive injections of 100 mg)* at the onset of the cluster period, and then monthly until the end of the cluster period

* Please document date of first administered dose in prescriber's office of

requested medication. _____

Episodic Cluster Headaches -Initial Therapy (Emgality only: 12 weeks)

☐ Yes ☐ No Patient must be within the age range as recommended by the FDA label;
AND
☐ Yes ☐ No Diagnosis of episodic cluster headaches;
AND
☐ Yes ☐ No At least 2 cluster periods lasting from 7 days to ≤ 1 year each and separated by pain-free remission periods of ≥ 3 months;
AND
☐ Yes ☐ No Prescribed by or in consultation with a neurologist or headache specialist;
AND
☐ Yes ☐ No Failure of verapamil at a dose of 360 mg per day, unless contraindicated or clinically significant adverse effects are experienced;
AND
☐ Yes ☐ No Emgality is not prescribed concurrently with other injectable CGRP antagonists or inhibitors;
AND
☐ Yes ☐ No Dose does not exceed 300 mg once monthly.

Episodic Cluster Headaches Reauthorization (Emgality only: up to a total of 12 months supply per cluster period)

☐ Yes ☐ No Positive response to therapy demonstrated by a reduction in cluster headache attack frequency;
AND
☐ Yes ☐ No Must meet one of the following:
a. Patient has not received more than 12 months of consecutive treatment;
OR
b. It has been at least 3 months since the patient last received Emgality;
AND
☐ Yes ☐ No Emgality is not prescribed concurrently with other injectable CGRP antagonist antagonists or inhibitors;
AND
☐ Yes ☐ No Dose does not exceed 300 mg once monthly.