Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Calcitonin Gene Related Peptides (CGRP) inhibitors PA Criteria

- **AIMOVIG™(erenumab-aooe)**
- **AJOVY™ (fremanezumab-vfrm)**
- **EMGALITY™ (galcanezumab-gnlm)**
- **NURTEC ODT(rimegepant)**
- **QULIPTA (atogepant)**
- **UBRELVY (ubrogepant)**

Calcitonin gene-related peptides (CGRP) are elevated during acute migraine and may be chronically elevated in chronic migraineurs. These drugs antagonize CGRP receptor function. Aimovig, Ajovy, Emgality, Nurtec ODT, and Qulipta are indicated for migraine *preventive*. Emgality 300mg is indicated for treatment of *episodic cluster headache* in adults. Nurtec ODT and Ubrelvy are indicated for *treatment of acute* migraine 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 within 12 weeks of date of last Botox® administration
- Currently pregnant or nursing
- Medication Overuse Headache, Hemiplegic Migraine or Tension-Type Headache

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A. Acute Migraine

Preferred Agent

□ Nurtec ODT 75mg once a day prn (limit 8 tablets per 31 days)

1. Initial Authorization: 6 months

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

AND

□ Documented diagnosis of migraine

AND

□ Documented trial and failure of two chemically distinct triptans in the past 6 months *OR* intolerance *OR* contraindication* to triptans as documented by historical diagnosis. ICD-10 of contraindication: _____

* Contraindication to triptans defined as follows:

1. History of ischemic heart disease: angina pectoris, Prinzmetal's angina, or previous myocardial infarction

2. Uncontrolled hypertension: documented diagnosis, claims history of current, ongoing multi-antihypertensive treatment
3. History of cerebrovascular disease: CVA (stroke), TIA, carotid stenosis, vertebral stenosis, intracranial stenosis, aneurysm, vascular malformation, peripheral vascular disease, ischemic bowel disease.

Non-Preferred Agent
□ Ubrelvy 50 or 100mg tablets once a day prn; may repeat once in 2 or more hours after first dose(limit 16 tablets per 31 days)

□ Documented trial and failure of Nurtec ODT in the past 6 months; having met the criteria above.

AND

□ No concurrent therapy with another oral CGRP agent.

AND

□ No concurrent therapy with a strong CYP3A4 inhibitor

2. **<u>Reauthorization Criteria</u>: 12 months**

□ 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

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<u>Initial Authorization-Episodic or Chronic migraine</u>: ***Select product requested***

<u>Preferred Agents</u>

□ Aimovig 70mg/1ml subcutaneous once monthly

□ Aimovig 140mg/2ml subcutaneously once monthly

□ Ajovy 225mg/1.5ml subcutaneously once monthly

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

<u>Non-preferred Agents (must try and fail 2 preferred agents)</u>

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

□ Nurtec ODT 75mg every OTHER day (limit 16 tablets per 31 days)

□ Qulipta 10, 30 or 60mg tablet once daily

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

B. <u>Episodic Migraine</u>

1. <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, but no more than 14 migraine days per month
AND
□ Prescriber is a specialist or has consulted a specialist such as a neurologist
AND
□ Documentation of MIDAS or HIT-6 assessment at baseline
https://headaches.org/resources/headache-tests/
AND
□ Documented failure of a consecutive 8-week trial at the optimal therapeutic dose as evidenced by paid pharmacy claims, *OR* intolerance *OR* contraindication, of at least ONE therapy, from any TWO of the following different therapeutic classes. One trial must be within the past 12 months. Please circle trial:

(a) Antidepressants: amitriptyline (20-50mg qhs) or venlafaxine (75-150mg qd)
(b) Anticonvulsants: divalproex sodium/valproate (500-1500mg qd) or topiramate (100mg qd)
(c) Beta-blockers: atenolol (25-100mg qd), metoprolol (50-200mg qd), nadolol (20-240mg qd), propranolol (40-160mg qd), or timolol (10-30mg qd)

C. <u>Chronic Migraine</u>

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

□ Patient must be within the age range as recommended by the FDA label
AND
□ Documentation of 15 or more headache days per month, of which at least 8 must be migraine days for at least 3 months.
AND
□ Prescriber is a specialist or has consulted a specialist such as a neurologist
AND

□ Documentation of MIDAS or HIT-6 assessment at baseline
https://headaches.org/resources/headache-tests/
AND
□ Documented failure to a consecutive 8-week trial at a optimal therapeutic dose as evidenced by paid pharmacy claims for drugs "*a-c"* below, or a 12-week trial of "d", onabotulinumtoxindA, 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. Doses are found above in section B.1. One trial must be within the past 12 months. Please circle trial:

(a) Antidepressants: amitriptyline (20-50mg qhs) or venlafaxine (75-150mg qd)
(b) Anticonvulsants: divalproex sodium/valproate (500-1500mg qd) or topiramate (100mg qd)
(c) Beta-blockers: atenolol (25-100mg qd), metoprolol (50-200mg qd), nadolol (20-240mg qd), propranolol (40-160mg qd), or timolol (10-30mg qd)
(d) Botulinum Toxin serotype A: *specifically* onabotulinumtoxin A (Botox®)

Reauthorization for Episodic or Chronic Migraine: 12 months

Reauthorization will be based on the following criteria:

□ Positive response to therapy demonstrated by a reduction in frequency or severity of migraines [documentation required] ie. overall symptom severity (as measured by MIDAS or HIT-6) compared to baseline

https://headaches.org/resources/headache-tests/

AND

□ Patient has an overall improvement in function with therapy

AND

□ Verified pharmacy prescription claims history of previously approved agent and demonstrated adherence to monthly or quarterly fills per FDA approved dosing.

D. Episodic Cluster Headache

Select product requested:

□ Emgality 300 mg subcutaneously once monthly (*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. _____

1. 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

2. 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