

## Prior Authorization Criteria

## Calcitonin Gene-Related Peptides (CGRP) Inhibitors PA Criteria

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

Calcitonin gene-related peptides (CGRP) are elevated during acute migraines and may be chronically elevated in chronic migraines. These drugs antagonize CGRP receptor function. Aimovig, Ajovy, Emgality, Nurtec ODT, and Qulipta are indicated for migraine *preventive*. Emgality 300mg is indicated for the treatment of *episodic cluster headache* in adults. Nurtec ODT, Ubrelvy, and Zavzpret nasal spray are indicated for *treatment of acute* migraine in adults.

Prior authorization is required for CGRP inhibitors. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation. Please also denote the indication (e.g., acute migraine treatment, episodic migraine prevention, chronic migraine prevention, episodic cluster headache treatment) for which the CGRP inhibitor is being requested for.

VYEPTI (eptinezumab-jjmr) – Please see separate criteria at <a href="https://medicaid.ms.gov/pharmacy-prior-authorization/">https://medicaid.ms.gov/pharmacy-prior-authorization/</a>

#### **Denial Criteria for any of the CGRP inhibitors:**

- Medication will not be used within 12 weeks of last Botox administration
- Currently pregnant or nursing
- Medication Overuse Headache or Tension-Type Headache

## A. Acute Migraine

#### 1. Initial Authorization: 6 months

Preferred Agent(s)

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

Criteria for Preferred Agents for Acute Migraine Treatment

- 1. Patient must be in the age range as recommended by FDA label; AND
- 2. Documented diagnosis of migraine; AND
- 3. Documented trial and failure of <u>two</u> chemically distinct triptans in the past 6 months *OR* intolerance *OR* contraindication\* to triptans as documented by historical diagnosis. Please provide documentation of contraindication (e.g., ICD-10 of contraindication); **AND**
- 4. No concurrent therapy with another oral CGRP agent; AND
- 5. No concurrent therapy with a strong CYP3A4 inhibitor.
- \* 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(s)

• Zavzpret single 10mg dose into one nostril once a day (limit 6 doses per 31 days)

Criteria for Non-Preferred Agents for Acute Migraine Treatment

- 1. Documented trial and failure of Nurtec ODT AND Ubrelvy in the past 6 months; having met the criteria above; **AND**
- 2. No concurrent therapy with an oral CGRP agent; AND
- 3. No concurrent therapy with a strong CYP3A4 inhibitor; AND
- 4. If unable to tolerate oral medications, documented trial of sumatriptan nasal spray in the past 6 months unless triptan use is contraindicated subject to the definition detailed in above section.

#### 2. Reauthorization Criteria: 12 months

- 1. Positive response to therapy demonstrated by a reduction in frequency or severity of migraines [documentation required]; **AND**
- 2. Patient has an overall improvement in function with therapy.

## **Initial Authorization - Episodic or Chronic Migraine:**

## **Preferred Agents**

- Aimovig 70mg/1ml subcutaneously 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)
- Emgality 240 mg/1ml subcutaneously once as loading dose\* (2 consecutive 120-mg injections) followed by Emgality 120 mg subcutaneously once monthly

## Non-Preferred Agents (must try and fail 2 preferred agents)

- Nurtec ODT 75mg every OTHER day (limit 16 tablets per 31 days)
- Qulipta 10, 30 or 60mg tablet once daily
- \* Please provide documented date of first administered dose in prescriber's office of requested medication if applicable.

## B. Episodic Migraine

#### 1. Initial Authorization: 12 weeks

- 1. Patient must be within the age range as recommended by the FDA label; AND
- 2. Documentation of at least 4, but no more than 14 migraine days per month; AND
- 3. Prescriber is a specialist or has consulted a specialist such as a neurologist; AND
- 4. Documentation of MIDAS or HIT-6 assessment at baseline <a href="https://headaches.org/resources/headache-tests/">https://headaches.org/resources/headache-tests/</a>; AND
- 5. 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.
  - (a) Antidepressants: amitriptyline (20-50mg qhs), nortriptyline (10-100 mg qhs), duloxetine (60-120mg daily), or venlafaxine (75-150mg daily)
  - (b) Anticonvulsants: divalproex sodium/valproate (500-1500mg daily) or topiramate (100mg daily)
  - (c) Beta-blockers: atenolol (25-100mg daily), metoprolol (50-200mg daily), nadolol (20-240mg daily), propranolol (40-160mg daily), or timolol (10-30mg daily)
  - (d) Angiotensin II Receptor Blockers: Candesartan (4 to 16 mg daily)

## C. Chronic Migraine

#### 1. Initial Authorization: 12 weeks

- 1. Patient must be within the age range as recommended by the FDA label; AND
- 2. Documentation of 15 or more headache days per month, of which at least 8 must be migraine days for at least 3 months; **AND**
- 3. Prescriber is a specialist or has consulted a specialist such as a neurologist; AND
- 4. Documentation of MIDAS or HIT-6 assessment at baseline <a href="https://headaches.org/resources/headache-tests/">https://headaches.org/resources/headache-tests/</a>; AND
- 5. Documented failure to a consecutive 8-week trial at an optimal therapeutic dose as evidenced by paid pharmacy claims for drugs "a-d" below, or a 12-week trial of "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. One trial must be within the past 12 months.
  - (a) Antidepressants: amitriptyline (20-50mg qhs), nortriptyline (10-100mg qhs), duloxetine (60-120mg daily), or venlafaxine (75-150mg daily)
  - (b) Anticonvulsants: divalproex sodium/valproate (500-1500mg daily) or topiramate (100mg daily)
  - (c) Beta-blockers: atenolol (25-100mg daily), metoprolol (50-200mg daily), nadolol (20-240mg daily), propranolol (40-160mg daily), or timolol (10-30mg daily)
  - (d) Angiotensin II Receptor Blockers: Candesartan (4 to 16 mg daily)
  - (e) Botulinum Toxin serotype A: *specifically* onabotulinumtoxinA (Botox®)

## 2. Reauthorization for Episodic or Chronic Migraine: 12 months

#### Reauthorization will be based on the following criteria:

- 1. 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
- 2. Patient has an overall improvement in function with therapy; AND
- 3. 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

**Requested Product:** 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 provide documented date of first administered dose in prescriber's office of requested medication.

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

- 1. Patient must be within the age range as recommended by the FDA label; AND
- 2. Diagnosis of episodic cluster headaches; AND
- 3. At least 2 cluster periods lasting from 7 days to  $\leq$  1 year each and separated by pain-free remission periods of  $\geq$  3 months; **AND**
- 4. Prescribed by or in consultation with a neurologist or headache specialist; AND
- 5. Failure of verapamil at a dose of 360 mg per day, unless contraindicated or clinically significant adverse effects are experienced; **AND**
- 6. Emgality is not prescribed concurrently with other injectable CGRP antagonists or inhibitors; **AND**
- 7. 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)

- 1. Positive response to therapy demonstrated by a reduction in cluster headache attack frequency; **AND**
- 2. Must meet one of the following:
  - a. Patient has not received more than 12 months of consecutive treatment; **OR**
  - It has been at least 3 months since the patient last received Emgality;
    AND
- 3. Emgality is not prescribed concurrently with other injectable CGRP antagonists or inhibitors; **AND**
- 4. Dose does not exceed 300 mg once monthly.