UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2018 P 2146-3 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab) |
| P&T Approval Date | 6/2018, 10/2018, 11/2018 |
| Effective Date | 1/1/2019;<br>Oxford only: 1/1/2019 |

**1. Background:**

Aimovig, Ajovy and Emgality are calcitonin gene-related peptide receptor (CGRP) antagonists indicated for the preventive treatment of migraine in adults.

**2. Coverage Criteria [a]:**

**A. Episodic Migraines**

1. **Initial Therapy**

a. **Aimovig, Ajovy or Emgality** will be approved based upon **all** of the following criteria:

(1) Diagnosis of episodic migraines with **both** of the following:

(a) Less than 15 headache days per month
(b) Patient has 4 to 14 migraine days per month

**-AND-**

(2) Trial and failure (after a trial of at least two months[b]), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below:

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
(c) Divalproex sodium (Depakote/Depakote ER)
(d) Topiramate (Topamax)
(e) Venlafaxine (Effexor/Effexor XR)

**-AND-**

(3) Medication will not be used in combination with another CGRP antagonist or inhibitor

**Authorization will be issued for 3 months.**

2. **Reauthorization**

a. **Aimovig, Ajovy or Emgality** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with another CGRP antagonist or inhibitor

**Authorization will be issued for 12 months.**

**B. Chronic Migraines**

1. **Initial Therapy**

a. **Aimovig, Ajovy or Emgality** will be approved based upon **all** of the following criteria:

(1) Diagnosis of chronic migraines with **both** of the following:

(a) Greater than or equal to 15 headache days per month
(b) Greater than or equal to 8 migraine days per month

**-AND-**

(2) Trial and failure (after a trial of at least two months[b]), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below:

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
(c) Divalproex sodium (Depakote/Depakote ER)
(d) OnabotulinumtoxinA (Botox)
(e) Topiramate (Topamax)
(f) Venlafaxine (Effexor/Effexor XR)

**-AND-**

(3) Medication will not be used in combination with onabotulinumtoxinA

(Botox)

**-AND-**

(4) Medication will not be used in combination with another CGRP antagonist or inhibitor

**Authorization will be issued for 3 months.**

2. **Reauthorization**

a. **Aimovig, Ajovy or Emgality** will be approved based on **all** of the following criteria:

(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

**-AND-**

(2) Medication will not be used in combination with onabotulinumtoxinA (Botox)

**-AND-**

(3) Medication will not be used in combination with another CGRP antagonist or inhibitor

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] For Connecticut and Kentucky business, only a 30 day trial will be required.

## 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

## 4. References:

1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc; May 2018.

2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; September 2018.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2018.
4. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. *Cephalalgia* 2018; 38:1-211.
5. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012 Apr 24;78(17):1337-45.
6. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May 10;86(19):1818-26.
7. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed June 4, 2018. Accessed 5/22/18

| Program | Prior Authorization/Notification – CGRP antagonists |
|---|---|
| **Change Control** | |
| 6/2018 | New program. |
| 8/2018 | Administrative update. Documented CT and KY duration of trial regulation |
| 10/2018 | Added Ajovy and Emgality. Modified the trial and failure requirement and removed the documentation requirement. Updated references. |
| 11/2018 | Removed the prescriber requirement. |