

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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; 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.