UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3113-4
Program	Step Therapy
Medication	Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab)
P&T Approval Date	6/2018, 10/2018, 2/2019, 7/2019
Effective Date	9/1/2019; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to a trial of lower cost migraine preventive medications before providing coverage for Aimovig, Ajovy* or Emgality.

Aimovig, Ajovy* and Emgality 120 mg are calcitonin gene-related peptide receptor (CGRP) antagonists indicated for the preventive treatment of migraine in adults. The 100 mg strength of Emgality is indicated for the treatment of episodic cluster headache in adults.

2. Coverage Criteria[a]:

A. **Episodic Migraines**

a. **Aimovig or Emgality 120 mg** will be approved based upon the following criterion:

(1) 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)

b. **Ajovy*** will be approved based all of the following criteria:

(1) 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-

(2) Trial and failure (after a trial of at least three months[b]) contraindication, or intolerance **both** of the following:
(a) Aimovig
(b) Emgality 120 mg

Authorization will be issued for 12 months

B. **Chronic Migraines**

a. **Aimovig or Emgality 120 mg** will be approved based upon the following criterion:

(1) 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)

b. **Ajovy*** will be approved based all of the following criteria:

(1) 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-

(2) Trial and failure (after a trial of at least three months[b]) contraindication, or intolerance **both** of the following:
(a) Aimovig
(b) Emgality 120 mg

C. Other Diagnoses

1. Aimovig, Ajovy* or Emgality (100 mg, 120 mg) will be approved

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.

* Ajovy is typically excluded from benefit coverage.

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 and/or Notification 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; June 2019.
4. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition. *Cephalalgia.* 2018; 38:1-211.
5. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019;59:1-18.
6. 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.
7. 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.

Program	Step Therapy – CGRP antagonists
Change Control	
6/2018	New program
10/2018	Added Ajovy and Emgality. Modified the trial and failure requirement and removed the documentation requirement. Updated references.
2/2019	Modified the criteria for Ajovy to require trial and failure of Aimovig and Emgality.
7/2019	Added the episodic cluster headache indication and included approvable strength for episodic and chronic migraine.