

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3113-10
Program	Step Therapy
Medication	Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab)
P&T Approval Date	6/2018, 10/2018, 2/2019, 7/2019, 7/2020, 7/2021, 3/2022, 5/2022, 5/2023, 3/2024
Effective Date	6/1/2024

1. Background:

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.

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

2. Coverage Criteria^a:

<p>A. Aimovig or Emgality (120 mg strength) will be approved based upon the following criterion:</p> <ol style="list-style-type: none"> 1. Failure (after a trial of at least two months^b), contraindication or intolerance to two of the following prophylactic therapies (document name and date tried): <ol style="list-style-type: none"> a. Amitriptyline (Elavil) b. A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol) c. Candesartan (Atacand) d. Divalproex sodium (Depakote/Depakote ER) e. OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements] f. Topiramate (Topamax) g. Venlafaxine (Effexor/Effexor XR) <p>B. Ajovy* will be approved based both of the following criteria:</p> <ol style="list-style-type: none"> 1. Failure (after a trial of at least two months^b), contraindication or intolerance to two of the following prophylactic therapies from the list below (document name and date tried): <ol style="list-style-type: none"> a. Amitriptyline (Elavil) b. A beta-blocker (i.e., atenolol, metoprolol, nadolol, propranolol, or timolol) c. Candesartan (Atacand) d. Divalproex sodium (Depakote/Depakote ER) e. OnabotulinumtoxinA (Botox) [Note: Coverage of onabotulinumtoxinA (Botox) may be subject to additional benefit and coverage review requirements] f. Topiramate (Topamax)
--

g. Venlafaxine (Effexor/Effexor XR)

-AND-

2. Failure (after a trial of at least three months^b) contraindication or intolerance to **both** of the following (document date tried):
 - a. Aimovig
 - b. Emgality (120 mg strength)

Authorization will be issued for 12 months

C. Emgality (100 mg strength)

1. **Emgality (100 mg strength) 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, Kentucky and Mississippi 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 2023.
2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; October 2022.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; March 2021.
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. AHS Consensus Statement. *Headache*. 2021; 61:1021-39.
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.
7/2020	Annual review. Added documentation language. Updated references.
7/2021	Annual review. Updated failure language to remove reference to trial. Combined episodic and chronic migraine sections. Updated references.
3/2022	Added candesartan as a preventive option. Updated mandate language. Added section for the 100 mg strength. Updated references.
5/2022	Updated the state mandate language to include Mississippi.
5/2023	Annual review. Updated references.
3/2024	Annual review. Updated state mandate language. Updated references.