UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2146-12
Program	Prior Authorization/Medical Necessity
Medication	Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab)
P&T Approval Date	6/2018, 10/2018, 11/2018, 2/2019, 6/2019, 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.

2. Coverage Criteria[a]:

A. Migraines

1. Initial Therapy

a. **Aimovig or Emgality (120 mg strength)** will be approved based upon **all** of the following criteria:

1) Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

-AND-

2) **One** of the following:

a) 4 to 7 migraine days per month and at least **one** of the following:

(1) Less than 15 headache days per month

-OR-

(2) Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

-OR-

b) Greater than or equal to 8 migraine days per month

-AND-

3) 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):

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-

4) Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines [e.g. Ajovy*, Nurtec ODT, Qulipta*, Vyepti (eptinezumab-jjmr)^]

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

1) Diagnosis of migraine consistent with The International Classification of Headache Disorders, 3rd edition

-AND-

2) **One** of the following:

a) 4 to 7 migraine days per month and at least one of the following:

(1) Less than 15 headache days per month

-OR-

(2) Provider attests this is the member's predominant headache diagnosis (i.e., primary driver of headaches is not a different, non-migrainous condition)

-OR-

b) Greater than or equal to 8 migraine days per month

-AND-

3) 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):

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-

4) 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)

-AND-

5) Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Emgality, Nurtec ODT, Qulipta*, Vyepti^)

Authorization will be issued for 12 months.

1. **Reauthorization**

a. **Aimovig, Ajovy* or Emgality (120 mg strength)** 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 used for the preventive treatment of migraines (e.g., Nurtec ODT, Qulipta*, Vyepti^)

Authorization will be issued for 12 months.

B. Episodic Cluster Headache

1. **Initial Therapy**

a. **Emgality (100 mg strength)** will be approved based upon **all** of the following criteria:

(1) Diagnosis of episodic cluster headache

-AND-

(2) Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.

-AND-

(3) Medication will not be used in combination with another CGRP antagonist or inhibitor used for the preventive treatment of migraines (e.g., Aimovig, Ajovy*, Nurtec ODT, Qulipta*, Vyepti^)

Authorization will be issued for12 months.

2. **Reauthorization**

a. **Emgality (100 mg strength)** 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 used for the preventive treatment of migraines (e.g., Aimovig, Ajovy*, Nurtec ODT, Qulipta*, Vyepti^)

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, and Qulipta are typically excluded from benefit coverage.
^Vyepti may be subject to additional benefit and coverage review requirements.

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.
- Notification, Step Therapy and Supply limits 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	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.
2/2019	Modified the step therapy requirements for Ajovy.
6/2019	Removed - Medication will not be used in combination with onabotulinumtoxinA (Botox) requirement.
7/2019	Added the episodic cluster headache indication and included approvable strength for episodic and chronic migraine.
7/2020	Annual review. Updated initial authorization duration. Added documentation requirement. Modified concomitant CGRP use to allow non-biologic CGRPs.
7/2021	Annual review. Updated the criteria for episodic migraines. Combined the criteria for episodic and chronic migraines. Added statement regarding concomitant therapy with other preventive CGRPs. Updated references.
3/2022	Added candesartan as a preventive option. Updated mandate language. Added Qulipta as CGRP to not be used in combination with. Updated the products typically excluded from coverage. Added note for Vyetpi regarding additional benefit and coverage review requirements. Updated references.
5/2022	Updated the migraine diagnostic criteria. Added Mississippi to state mandate language.
5/2023	Annual review. Updated references.
3/2024	Annual review. Updated initial authorization to 12 months. Added episodic to cluster headaches in section header. Updated mandate language. Updated references.