

UnitedHealthcare Pharmacy
Clinical Pharmacy Program

Program Number	2024 P 1247-10
Program	Prior Authorization/Notification
Medication	Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab)
P&T Approval Date	6/2018, 10/2018, 7/2019, 7/2020, 11/2020, 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 (CGRP) receptor 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:

<p>A. Migraines</p> <p>1. Initial Therapy</p> <p>a. Aimovig, Ajovy* or Emgality (120 mg strength) will be approved based upon <u>all</u> of the following criteria:</p> <p>(1) Diagnosis of migraines</p> <p style="text-align: center;">-AND-</p> <p>(2) Used for the preventive treatment of migraines</p> <p style="text-align: center;">-AND-</p> <p>(3) 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*, Vyepi[^])</p> <p>Authorization will be issued for 12 months</p> <p>2. Reauthorization</p> <p>a. Aimovig, Ajovy* or Emgality (120 mg strength) will be approved based on <u>both</u> of the following criteria:</p> <p>(1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p> <p style="text-align: center;">-AND-</p>

- (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 for 12 months

2. Reauthorization

- a. **Emgality (100 mg strength)** will be approved based on **both** 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 migraine (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.

*Ajovy, and Qulipta are typically excluded from 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.
- Medical Necessity, 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. 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. Ailani, J, Burch, RC, Robbins, MS, et. al. AHS Consensus Statement: The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61:1021–39.

Program	Prior Authorization/Notification – CGRP antagonists
Change Control	
6/2018	New program
10/2018	Added Ajovy and Emgality. Updated references.
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.
11/2020	Updated to note not to be used in combination with another biologic CGRP. Added that Ajovy is typically excluded from coverage.
7/2021	Annual review. Added statement regarding concomitant therapy with other preventive CGRPs. Updated references.
3/2022	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	Combined the episodic and chronic migraine criteria and removed the migraine and headache days.
5/2023	Annual review. Added state mandate language. Updated references.
3/2024	Annual review. Increased the initial authorization to 12 months. Updated references.