UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for CGRP Antagonists

Program	Prior Authorization
Medication	Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab)
Markets in Scope	California, Florida-CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania- CHIP, Rhode Island
Issue Date	6/2018
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	1/2021

1. Background:

Aimovig, Ajovy, and Emgality 120mg 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. Episodic Migraine

1. Initial Therapy

a. **Aimovig or Emgality 120mg** 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), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below (document name and date tried):

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
(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 biologic CGRP antagonist or inhibitor [e.g. Ajovy, Vyepti (eptinezumab-jjmr)]

Authorization will be issued for 6 months.

b. **Ajovy** 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), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below (document name and date tried):

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
(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 biologic CGRP antagonist or inhibitor (e.g. Aimovig, Emgality, Vyepti)

-AND-

(4) The patient has a history of failure, contraindication, or intolerance to both of the following (document date tried):

- Aimovig
- Emgality 120mg

Authorization will be issued for 6 months.

2. Reauthorization

a. **Aimovig, Ajovy, or Emgality 120mg** 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 biologic CGRP antagonist or inhibitor (e.g. Vyepti)

Authorization will be issued for 12 months.

B. Chronic Migraine

1. Initial Therapy

a. **Aimovig or Emgality 120mg** 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), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below (document name and date tried):

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
(c) Divalproex sodium (Depakote/Depakote ER)
(d) OnabotulinumtoxinA (Botox) ***NOTE*** This is a medical benefit, should not be included in denial to provider

(e) Topiramate (Topamax)
(f) Venlafaxine (Effexor/Effexor XR)

-AND-

(3) Medication will not be used in combination with another biologic CGRP antagonist or inhibitor (e.g., Ajovy, Vyepti)

Authorization will be issued for 6 months.

b. **Ajovy** 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), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below (document name and date tried):

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
(c) Divalproex sodium (Depakote/Depakote ER)
(d) OnabotulinumtoxinA (Botox) ***NOTE*** This is a medical benefit, should not be included in denial to provider
(e) Topiramate (Topamax)
(f) Venlafaxine (Effexor/Effexor XR)

-AND-

(3) Medication will not be used in combination with another biologic CGRP antagonist or inhibitor (e.g., Aimovig, Emgality, Vyepti)

-AND-

(5) The patient has a history of failure, contraindication, or intolerance to both of the following (document date tried):

- Aimovig
- Emglaity 120mg

Authorization will be issued for 6 months.

2. Reauthorization

a. **Aimovig, Ajovy, or Emgality 120mg** 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 biologic CGRP antagonist or inhibitor (e.g., Vyepti)

Authorization will be issued for 12 months.

C. Episodic Cluster Headache

1. **Initial Therapy**

a. **Emgality 100 mg** 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 biologic CGRP antagonist or inhibitor (e.g., Aimovig, Ajovy, Vyepti).

Authorization will be issued for 6 months.

2. Reauthorization

a. **Emgality 100 mg** 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 biologic CGRP antagonist or inhibitor (e.g., Aimovig, Ajovy, Vyepti)

Authorization will be issued for 12 months.

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.; April 2020.
2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; January 2020.
3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2019.
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. 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.
8.

Program	Prior Authorization –CGRP Antagonists
Change Control	
Date	Change
6/2018	New Program
10/2018	Added Ajovy and Emgality to the program and changed program name to CGRP. Modified trial/failure requirement and removed

	documentation requirement. Defined headache specialist. Updated background and references.
11/2018	Removed prescriber requirement.
1/2019	Added step through Aimovig and Emgality for Ajovy for 4/1/19 PDL update.
6/2019	Removed - Medication will not be used in combination with onabotulinumtoxinA (Botox) requirement.
7/2019	Added the episodic cluster headache indication for Emgality and included approvable strength for episodic and chronic migraine.
10/2020	Annual review. Updated initial authorization duration. Added documentation requirement. Modified concomitant CGRP use to allow non-biologic CGRPs.