CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ajovy (fremanezumab-vfrm)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Ajovy is a calcitonin gene-related peptide receptor antagonist initially approved by the FDA in 2018. It is indicated for the preventive treatment of migraine in adults. It is indicated for the preventive treatment of chronic migraine and episodic migraine in adults. Efficacy was shown in two phase III, multinational, randomized, double-blind, placebo-controlled, 12-week trials. Ajovy reduced monthly migraine days (MMD) by 1.3 days to 1.5 days for episodic migraines and 1.7 days to 2.1 days for chronic migraines.

Ajovy (fremanezumab-vfrm) will be considered for coverage when the following criteria are met:

Chronic Migraine Headache Prophylaxis

For **initial** authorization:

1. Member is 18 years of age or older with a history of migraine attacks with or without aura; AND
2. Medication is being prescribed for the prevention of chronic migraine, defined as **both** of the following and must be documented in chart notes:
   a) ≥ 15 headache days per month for at least 3 months;
   b) ≥ 8 migraine days per month for at least 3 months; AND
3. Member has trialed and failed Emgality or Aimovig; AND
4. Member has tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
5. Member has tried and failed or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
   a) Beta-blockers (e.g., metoprolol, timolol, or propranolol);
   b) Calcium channel blockers (e.g., verapamil);
   c) Antidepressants (e.g., amitriptyline or venlafaxine);
   d) Anticonvulsant medications (e.g., topiramate or valproic acid); AND
6. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Emgality, Aimovig, or Vyepti); AND
7. Member does **not** have ANY of the following:
   a) Medication overuse headache;
   b) Member was older than 50 years of age at migraine onset.
8. **Dosage allowed:** Subcutaneously 225 mg monthly, or 675 mg every 3 months (quarterly). Quantity limit: 1 syringe or autoinjector (225mg/1.5mL) per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member has improvement in prevention of migraines documented in chart notes (e.g., reduced migraine frequency, reduced use of medication for acute migraines attacks).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Episodic Migraine Headache Prophylaxis

For **initial** authorization:
1. Member is 18 years of age or older with a history of migraine attacks with or without aura; AND
2. Medication is being prescribed for prevention of episodic migraine, defined as **both** of the following and must be documented in chart notes:
   a) ≤ 14 headache days per month for at least 3 months;
   b) 4 or more migraine days per month for at least 3 months that cause significant impairment to quality of life (i.e. requiring bed rest, missed school/work); AND
3. Member has trialed and failed Emgality or Aimovig; AND
4. Member has tried and failed or unable to tolerate **two** prophylactic medications from the following groups for 2 months per trial:
   a) Beta-blockers (e.g., metoprolol, timolol, or propranolol);
   b) Calcium channel blockers (e.g., verapamil);
   c) Antidepressants (e.g., amitriptyline or venlafaxine);
   d) Anticonvulsant medications (e.g., topiramate or valproic acid); AND
5. Medication is not being used in combination with botulinum toxin therapy or any other prophylactic CGRP product (e.g. Emgality, Aimovig or Vyepti); AND
6. Member does **not** have ANY of the following:
   a) Medication overuse headache;
   b) Member was older than 50 years of age at migraine onset.
7. **Dosage allowed:** Subcutaneously 225 mg monthly, or 675 mg every 3 months (quarterly). Quantity limit: 1 syringe or autoinjector (225mg/1.5mL) per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member has improvement in prevention of migraines documented in chart notes (e.g., reduced migraine frequency, reduced use of medication for acute migraines attacks).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ajovy (fremanezumab-vfrm) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/05/2019	New policy for Ajovy created.
06/05/2020	Diagnosis of episodic migraine headache prophylaxis added. Definition of chronic migraine simplified to just frequency of migraine and headache days. Requirement of no botox in the past 4 months removed. No concurrent use with Botox and other CGRP agents added. Trial of Botox added as an additional option under chronic migraine prophylaxis. Length of prophylactic and abortive trials reduced to 2 months/trial.

05/05/2022	Transferred to new policy. Updated references. Removed prescriber specialty and abortive trials. Added Quantity Limit.
12/21/2022	Added trial and failure of Emgality or Aimovig.

References:

1. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; September 2021.
2. ICHD-3 The International Classification of Headache Disorders. www.ichd-3.org.
3. Katsarava Z, Buse DC, Manack AN, Lipton RB. Defining the Differences Between Episodic Migraine and Chronic Migraine. Current Pain and Headache Reports. 2012;16(1):86-92. doi:10.1007/s11916-011-0233-z.
4. ClinicalTrials.gov. Identifier: NCT 02621931. Comparing Efficacy and Safety of 2 Dose Regimens of Subcutaneous Administration of TEV-48125 Versus Placebo for the Preventive Treatment of Chronic Migraine. Available at: https://clinicaltrials.gov/ct2/show/NCT02621931?term=02621931&rank=1.
5. ClinicalTrials.gov. Identifier: NCT02629861. Efficacy and Safety of 2 Dose Regimens of TEV-48125 Versus Placebo for the Preventive Treatment of Episodic Migraine. Available at: https://clinicaltrials.gov/ct2/show/NCT02629861?term=02629861&rank=1.
6. 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.
7. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology Apr 2012, 78 (17) 1337-1345.
8. Oakes TM, Kovacs R, Rosen N, et al. Evaluation of Cardiovascular Outcomes in Adult Patients With Episodic or Chronic Migraine Treated With Galcanezumab: Data From Three Phase 3, Randomized, Double-Blind, Placebo-Controlled EVOLVE-1, EVOLVE-2, and REGAIN Studies. Headache. 2020;60(1):110-123. doi:10.1111/head.13684
9. Ailani J, Burch R, et al. Consensus Statement: The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039.

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