CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Ajovy (fremanezumab-vfrm)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ajovy (fremanezumab-vfrm) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 tried and failed 2 quarterly injections (6 months) of onabotulinumtoxinA (Botox); OR
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. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month); 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).

Note: Ajovy is considered experimental and investigational as combination therapy with Botox, Vyepti, Aimovig or Emgality because the safety and effectiveness of these combinations has not been established.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, 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 tried and failed or unable to tolerate **three** 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
4. Member has tried and failed or unable to tolerate **two** of the following abortive therapeutic options: ergotamine, triptans, combination analgesics, or simple analgesics (at least one trial must be a triptan drug) for 2 months per trial (for at least 8 days per month); 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).

Note: Ajovy is considered experimental and investigational as combination therapy with Botox, Vyepti, Aimovig or Emgality because the safety and effectiveness of these combinations has not been established.

If member meets all the requirements listed above, 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ajovy (fremanezumab-vfrm) not medically necessary for the treatment of the diseases that are not listed in this document.

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. No concurrent

	use with other CGRP agents added. Trial of Botox added as an additional option under chronic migraine prophylaxis. Criteria pregnancy, psychiatric issues, CV disease, cancer, infection were removed from excluded list. Length of prophylactic and abortive trials reduced to 2 months/trial.
07/20/2020	Prescriber requirement removed per state mandate.

References:

1. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; January 2019.
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

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