

## PHARMACY POLICY STATEMENT

### Ohio 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) Alternative preferred product includes Botox QUANTITY LIMIT— see <b>Dosage allowed</b> below
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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.

### 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. Member has documented history of  $\geq 15$  headache days per month for more than 3 months, of which  $\geq 8$  days were migraine days characterized as  $\geq 5$  attacks lasting 4-72 hours with **both** of the following:
  - a) **Two** or more of the following:
    - i) Aggravation by or causing avoidance of routine physical activity;
    - ii) Moderate or severe pain intensity;
    - iii) Pulsating quality;
    - iv) Unilateral location;
  - b) **One** or more of the following:
    - i) Nausea or vomiting;
    - ii) Photophobia and phonophobia; AND
3. Medication must be prescribed by neurologist or a headache specialist; AND
4. Other prophylactic therapeutic options have been ineffective or not tolerated for trial of at least 3 months, as indicated by **two** or more of the following:
  - a) Beta-blockers;
  - b) Calcium channel blockers;
  - c) Antidepressants such as amitriptyline, nortriptyline, doxepin, or protriptyline;
  - d) Anticonvulsant medications such as topiramate or valproic acid; AND
5. Abortive therapeutic options (i.e., ergotamine, triptans, combination analgesics, or simple analgesics) have been ineffective or not tolerated for at least 3 months (for a minimum of 8 or more days per month); AND
6. Medication is not being used in combination with botulinum toxin therapy; AND
7. Member does **not** have ANY of the following:
  - a) Medication overuse headache;
  - b) Pregnant or nursing female;
  - c) Evidence or medical history of clinically significant psychiatric issues, including any suicide attempt in the past, or suicidal ideation with a specific plan in the past 2 years;

- d) History of clinically significant cardiovascular disease or vascular ischemia, deep vein thrombosis, or pulmonary embolism;
  - e) Known infection or history of human immunodeficiency virus, tuberculosis, or chronic hepatitis B or C infection;
  - f) Past or current history of cancer in the last 5 years, except for appropriately treated non-melanoma skin carcinoma;
  - g) 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, 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.

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](http://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>.

Effective date: 07/01/2019

Revised date: 03/05/2019