Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky 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 **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.

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 ≥ 15 headache days per month for more than 3 months, of which ≥ 8 days were migraine days characterized as ≥ 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 30 days, 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 30 days (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.
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
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