CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Ajovy (fremanezumab-vfrm)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ajovy, approved by the FDA in 2018, is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of 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 at least 18 years of age; AND
2. Medication is being prescribed for the prevention of chronic migraine with or without aura, defined as ≥ 15 headache days per month, at least 8 of which are migraine days, for >3 months; AND
3. Member has tried and failed at least 1 of the following prophylactic medications for 8 weeks:
   a) Beta blocker (e.g., metoprolol, timolol, or propranolol)
   b) Calcium channel blocker (e.g., verapamil)
   c) Antidepressant (e.g., amitriptyline or venlafaxine)
   d) Anticonvulsant (e.g., topiramate or valproic acid)
   e) Candesartan; AND
4. Member has tried and failed Emgality or Aimovig; 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).
6. **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 migraine 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 at least 18 years of age; AND
2. Medication is being prescribed for prevention of episodic migraine with or without aura, defined as 4-

14 migraine days per month with at least moderate disability; AND
3. Member has tried and failed at least 1 of the following prophylactic medications for 8 weeks:
   a) Beta blocker (e.g., metoprolol, timolol, or propranolol)
   b) Calcium channel blocker (e.g., verapamil)
   c) Antidepressant (e.g., amitriptyline or venlafaxine)
   d) Anticonvulsant (e.g., topiramate or valproic acid)
   e) Candesartan; AND
4. Member has tried and failed Emgality or Aimovig; 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).
6. **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 migraine 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.
12/13/2022	Added trial and failure of Emgality and Aimovig.
04/29/2024	Updated references. Changed from 2 prior prophylactic trials to 1 and added candesartan to list of trial options (per AHS 2024 statement). Changed “significant impairment to quality of life” to “at least moderate disability.” Changed episodic definition from 4 or more days to 4-14 days. Removed >3 months from episodic definition (ICHD3). Removed botulinum toxin trial from chronic section. Removed exclusions for onset over age 50 and med overuse headache.

References:

1. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; 2022.
2. Silberstein SD, Dodick DW, Bigal ME, et al. Fremanezumab for the Preventive Treatment of Chronic Migraine. *N Engl J Med*. 2017;377(22):2113-2122. doi:10.1056/NEJMoa1709038
3. Dodick DW, Silberstein SD, Bigal ME, et al. Effect of Fremanezumab Compared With Placebo for Prevention of Episodic Migraine: A Randomized Clinical Trial. *JAMA*. 2018;319(19):1999-2008. doi:10.1001/jama.2018.4853

4. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38(1):1-211. doi:10.1177/0333102417738202
5. 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.
6. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024;64(4):333-341. doi:10.1111/head.14692

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