Clinical Policy: Fremanezumab-vfrm (Ajovy)

Reference Number: CP.PHAR.403
Effective Date: 10.30.18
Last Review Date: 02.21
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Fremanezumab-vfrm (Ajovy®) is a calcitonin gene-related peptide (CGRP) receptor antagonist.

FDA Approved Indication(s)

Ajovy is indicated for the preventive treatment of migraine in adults.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ajovy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraine Prophylaxis (must meet all)**:**

1. Diagnosis of episodic or chronic migraine;
2. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Prescribed by or in consultation with a neurologist, headache, or pain specialist;
4. Age ≥ 18 years;
5. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless clinically significant adverse effects are experienced or all are contraindicated: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
6. Failure of Aimovig®, unless contraindicated or clinically significant adverse effects are experienced;
7. Ajovy is not prescribed concurrently with Botox® or other injectable and oral CGRP inhibitors (e.g., Aimovig®, Emgality®, Vyepti™, Nurtec®, Ubrelvy™);
8. Dose does not exceed one of the following (a or b):
   a. 225 mg (1 injection) once monthly;
   b. 675 mg (3 injections) every 3 months.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Migraine Prophylaxis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline;
3. Ajovy is not prescribed concurrently with Botox or other injectable and oral CGRP inhibitors (e.g., Aimovig, Emgality, Vyepti, Nurtec, Ubrelvy);*
   **This requirement does not apply to CA if member was previously approved via Centene benefit and is currently stable on therapy with both oral and injectable CGRP inhibitors*
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 225 mg (1 injection) once monthly;
   b. 675 mg (3 injections) every 3 months.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Cluster headaches.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration
ICHD: International Classification of Headache Disorder

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®),	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
topiramate (Topamax®), valproate sodium		
Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)*, timolol, atenolol (Tenormin®)*, nadolol (Corgard®)*	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)	**Migraine Prophylaxis** *Refer to prescribing information or Micromedex*	*Refer to prescribing information or Micromedex*
Aimovig™ (erenumab-aaoe)	**Migraine Prophylaxis** 70 mg SC once monthly Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly	140 mg/month

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label use*

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

Appendix D: General Information
- In clinical trials, a migraine day was defined as any calendar day in which the patient reported either a headache that lasted at least 2 consecutive hours and met International Classification of Headache Disorder (ICHD)-3 diagnostic criteria for migraine (with or without aura) or probable migraine (subtype in which only 1 migraine criterion is absent), or a day when a headache of any duration was treated with migraine-specific medications (triptans or ergots).
- The ENFORCE Phase III clinical trial program evaluating the efficacy of Ajovy in episodic and chronic cluster headache was discontinued after a pre-specified futility analysis revealed that the study's primary endpoints were unlikely to be met.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Migraine prophylaxis	225 mg SC once monthly or 675 mg SC every three months	675 mg every 3 months

VI. Product Availability

Single-dose prefilled syringe, autoinjector: 225 mg/1.5 mL

VII. References

1. Ajovy Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2020. Available at: www.ajovy.com. Accessed November 18, 2020.
2. Silberstein SD, Holland S, Freitag F, et al. American Academy of Neurology: Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78: 1337-45.
3. Digre KB. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache 2019; 59: 1-18.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3031	Injection, fremanezumab-vfrm, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.30.18	02.19
Added requirement that Ajovy is not prescribed concurrently with Botox or other injectable CGRP inhibitors; modified continuation of therapy to require maintenance of positive response.	01.15.19	05.19
1Q 2020 annual review: added cluster headaches to section III; references reviewed and updated.	11.04.19	02.20
Per SDC and prior clinical guidance, revised line of business to remove Commercial (separated to policy CP.PCH.xx); added redirection to Aimovig.	12.03.19	
RT4: added autoinjector formulation; references reviewed and updated.	02.13.20	
1Q 2021 annual review: no significant changes; added coding implications; references reviewed and updated.	11.18.20	02.21
Revised requirement on concurrent use with other CGRP inhibitors to include oral products with Nurtec and Ubrelvy listed as additional examples; added clarification in continuation of therapy to indicate requirement for concurrent use with other CGRP inhibitors does not apply to CA if member was previously approved via Centene benefit and is currently stable on therapy with both oral and injectable CGRP inhibitors.	06.28.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.