Clinical Policy: Fremanezumab-vfrm (Ajovy)

Reference Number: CP.PHAR.403
Effective Date: 10.30.18
Last Review Date: 02.20
Line of Business: Medicaid

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 contraindicated or clinically significant adverse effects are experienced: 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 CGRP inhibitors (e.g., Aimovig™, Emgality™);
      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 CGRP inhibitors (e.g., Aimovig, Emgality);
      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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants such as:</td>
<td><strong>Migraine Prophylaxis</strong></td>
<td>Refer to prescribing information or Micromedex</td>
</tr>
<tr>
<td>divalproex (Depakote®),</td>
<td>Refer to prescribing information or Micromedex</td>
<td>Refer to prescribing information or Micromedex</td>
</tr>
<tr>
<td>topiramate (Topamax®),</td>
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<tr>
<td>valproate sodium</td>
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</tbody>
</table>
### Drug Name

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<tr>
<th>Beta-blockers such as: propranolol (Inderal®), metoprolol (Lopressor®)<em>, timolol, atenolol (Tenormin®)</em>, nadolol (Corgard®)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dosing Regimen</strong></td>
</tr>
<tr>
<td>Migraine Prophylaxis</td>
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<tr>
<td>Refer to prescribing information or Micromedex</td>
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<td><strong>Dose Limit/ Maximum Dose</strong></td>
</tr>
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<table>
<thead>
<tr>
<th>Antidepressants/tricyclic antidepressants* such as: amitriptyline (Elavil®), venlafaxine (Effexor®)</th>
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<tbody>
<tr>
<td><strong>Dosing Regimen</strong></td>
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*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

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### 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine prophylaxis</td>
<td>225 mg SC once monthly or 675 mg SC every three months</td>
<td>675 mg every 3 months</td>
</tr>
</tbody>
</table>

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### VI. Product Availability

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

### VII. References

**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.

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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.

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