UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 3113-4</th>
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</thead>
<tbody>
<tr>
<td>Program</td>
<td>Step Therapy</td>
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<tr>
<td>Medication</td>
<td>Aimovig (erenumab), Ajovy (fremanezumab)*, Emgality (galcanezumab)</td>
</tr>
<tr>
<td>P&amp;T Approval Date</td>
<td>6/2018, 10/2018, 2/2019, 7/2019</td>
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<tr>
<td>Effective Date</td>
<td>9/1/2019; Oxford only: N/A</td>
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1. **Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to a trial of lower cost migraine preventive medications before providing coverage for Aimovig, Ajovy* or Emgality.

Aimovig, Ajovy* and Emgality 120 mg are calcitonin gene-related peptide receptor (CGRP) antagonists indicated for the preventive treatment of migraine in adults. The 100 mg strength of Emgality is indicated for the treatment of episodic cluster headache in adults.

2. **Coverage Criteria:**

A. **Episodic Migraines**

   a. **Aimovig or Emgality 120 mg** will be approved based upon the following criterion:

      (1) Trial and failure (after a trial of at least two months\(^b\)), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below:

         (a) Amitriptyline (Elavil)
         (b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
         (c) Divalproex sodium (Depakote/Depakote ER)
         (d) Topiramate (Topamax)
         (e) Venlafaxine (Effexor/Effexor XR)

   b. **Ajovy*** will be approved based all of the following criteria:

      (1) Trial and failure (after a trial of at least two months\(^b\)), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below:

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(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
(c) Divalproex sodium (Depakote/Depakote ER)
(d) Topiramate (Topamax)
(e) Venlafaxine (Effexor/Effexor XR)

-AND-

(2) Trial and failure (after a trial of at least three months\(^b\)) contraindication, or intolerance both of the following:
(a) Aimovig
(b) Emgality 120 mg

Authorization will be issued for 12 months

B. **Chronic Migraines**

a. **Aimovig or Emgality 120 mg** will be approved based upon the following criterion:

(1) Trial and failure (after a trial of at least two months\(^b\)), contraindication, or intolerance to two of the following prophylactic therapies from the list below:

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
(c) Divalproex sodium (Depakote/Depakote ER)
(d) OnabotulinumtoxinA (Botox)
(e) Topiramate (Topamax)
(f) Venlafaxine (Effexor/Effexor XR)

b. **Ajovy**\(^a\) will be approved based all of the following criteria:

(1) Trial and failure (after a trial of at least two months\(^b\)), contraindication, or intolerance to two of the following prophylactic therapies from the list below:

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol
(c) Divalproex sodium (Depakote/Depakote ER)
(d) OnabotulinumtoxinA (Botox)
(e) Topiramate (Topamax)
(f) Venlafaxine (Effexor/Effexor XR)
(2) Trial and failure (after a trial of at least three months) contraindication, or intolerance both of the following:
   (a) Aimovig
   (b) Emgality 120 mg

C. Other Diagnoses

1. Aimovig, Ajovy* or Emgality (100 mg, 120 mg) will be approved

   Authorization will be issued for 12 months

a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
b For Connecticut and Kentucky business, only a 30 day trial will be required.

* Ajovy is typically excluded from benefit coverage.

3. Additional Clinical Rules:

   • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   • Supply limits and/or Notification may be in place.

4. References:


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<thead>
<tr>
<th>Program</th>
<th>Step Therapy – CGRP antagonists</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>6/2018</td>
<td>New program</td>
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<tr>
<td>10/2018</td>
<td>Added Ajovy and Emgality. Modified the trial and failure requirement and removed the documentation requirement. Updated references.</td>
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<tr>
<td>2/2019</td>
<td>Modified the criteria for Ajovy to require trial and failure of Aimovig and Emgality.</td>
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<tr>
<td>7/2019</td>
<td>Added the episodic cluster headache indication and included approvable strength for episodic and chronic migraine.</td>
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