1. Background:

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 Criteriaa:

A. Episodic Migraines

1. Initial Therapy

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

      (1) Diagnosis of episodic migraines with both of the following:

          (a) Less than 15 headache days per month
          (b) Patient has 4 to 14 migraine days per month

        -AND-

      (2) Trial and failure (after a trial of at least two monthsb), 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)

        -AND-
(3) Medication will not be used in combination with another CGRP antagonist or inhibitor

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

   (1) Diagnosis of episodic migraines with **both** of the following:

   (a) Less than 15 headache days per month
   (b) Patient has 4 to 14 migraine days per month

   **-AND-**

   (2) 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)

   **-AND-**

   (3) Trial and failure (after a trial of at least three months\(^b\), contraindication, or intolerance to **both** of the following:

   (a) Aimovig
   (b) Emgality 120 mg

   **-AND-**

   (4) Medication will not be used in combination with another CGRP antagonist or inhibitor

**Authorization will be issued for 3 months.**

2. **Reauthorization**

   a. **Aimovig, Ajovy*** or **Emgality 120 mg** will be approved based on **all** of the following criteria:

   (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity
-AND-

(2) Medication will not be used in combination with another CGRP antagonist or inhibitor

Authorization will be issued for 12 months.

B. Chronic Migraines

1. Initial Therapy

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

      (1) Diagnosis of chronic migraines with both of the following:

         (a) Greater than or equal to 15 headache days per month
         (b) Greater than or equal to 8 migraine days per month

     -AND-

      (2) Trial and failure (after a trial of at least two monthsb), 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)

     -AND-

      (3) Medication will not be used in combination with another CGRP antagonist or inhibitor

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

      (1) Diagnosis of chronic migraines with both of the following:

         (a) Greater than or equal to 15 headache days per month
         (b) Greater than or equal to 8 migraine days per month
(2) 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)

(3) Trial and failure (after a trial of at least three months\(^b\)), contraindication, or intolerance to **both** of the following:

(a) Aimovig
(b) Emgality 120 mg

(4) Medication will not be used in combination with another CGRP antagonist or inhibitor

Authorization will be issued for 3 months.

2. **Reauthorization**

   a. **Aimovig, Ajovy**\(^*\) or **Emgality 120 mg** will be approved based on **all** of the following criteria:

      (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

      -AND-

      (2) Medication will not be used in combination with another CGRP antagonist or inhibitor

Authorization will be issued for 12 months.

C. **Episodic Cluster Headache**
1. **Initial Therapy**
   a. **Emgality 100 mg** will be approved based upon all of the following criteria:
      
      (1) Diagnosis of episodic cluster headache
      
      -AND-
      
      (2) Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months.
      
      -AND-
      
      (3) Medication will not be used in combination with another CGRP antagonist or inhibitor.

      **Authorization will be issued for 3 months.**

2. **Reauthorization**
   a. **Emgality 100 mg** will be approved based on all of the following criteria:
      
      (1) Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity
      
      -AND-
      
      (2) Medication will not be used in combination with another CGRP antagonist or inhibitor

      **Authorization will be issued for 12 months.**

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*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 may be in place.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Change Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/2018</td>
<td>New program.</td>
</tr>
<tr>
<td>8/2018</td>
<td>Administrative update. Documented CT and KY duration of trial regulation</td>
</tr>
<tr>
<td>10/2018</td>
<td>Added Ajovy and Emgality. Modified the trial and failure requirement and removed the documentation requirement. Updated references.</td>
</tr>
<tr>
<td>11/2018</td>
<td>Removed the prescriber requirement.</td>
</tr>
<tr>
<td>2/2019</td>
<td>Modified the step therapy requirements for Ajovy.</td>
</tr>
<tr>
<td>6/2019</td>
<td>Removed - Medication will not be used in combination with onabotulinumtoxinA (Botox) requirement.</td>
</tr>
<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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</tbody>
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