Clinical Pharmacy Program Guidelines for CGRP Antagonists- ARIZONA

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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</thead>
<tbody>
<tr>
<td>Medication</td>
<td>Aimovig (erenumab), Ajovy (fremanezumab), Emgality (galcanezumab)</td>
</tr>
<tr>
<td>Markets in Scope</td>
<td>Arizona</td>
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</tbody>
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1. **Background:**

Aimovig, Ajovy, and Emgality 120mg are calcitonin gene-related peptide (CGRP) receptor 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 Migraine**

1. **Initial Therapy**

   a. **Ajovy or Emgality 120mg** 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), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below (document name and date tried):

      (a) Amitriptyline (Elavil)
      (b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
      (c) Divalproex sodium (Depakote/Depakote ER)
      (d) Topiramate (Topamax)
      (e) Venlafaxine (Effexor/Effexor XR)
(3) Medication will not be used in combination with another biologic CGRP antagonist or inhibitor [e.g. Aimovig, Vyepti (eptinezumab-jjmr)]

**Authorization will be issued for 6 months.**

b. **Aimovig** 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), contraindication, or intolerance to **two** of the following prophylactic therapies from the list below (document name and date tried):

(a) Amitriptyline (Elavil)
(b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
(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 biologic CGRP antagonist or inhibitor (e.g. Ajovy, Emgality, Vyepti)

-AND-

(4) The patient has a history of failure, contraindication, or intolerance to both of the following (document date tried):
- Ajovy
- Emgality 120mg

**Authorization will be issued for 6 months.**

2. **Reauthorization**

a. **Aimovig, Ajovy, or Emgality 120mg** 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 biologic CGRP antagonist or inhibitor (e.g. Vyepti)

Authorization will be issued for 12 months.

B. Chronic Migraine

1. Initial Therapy

   a. Ajovy or Emgality 120mg 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 months), contraindication, or intolerance to two of the following prophylactic therapies from the list below (document name and date tried):

          (a) Amitriptyline (Elavil)
          (b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
          (c) Divalproex sodium (Depakote/Depakote ER)
          (d) OnabotulinumtoxinA (Botox) ***NOTE*** This is a medical benefit, should not be included in denial to provider
          (e) Topiramate (Topamax)
          (f) Venlafaxine (Effexor/Effexor XR)

         -AND-

      (3) Medication will not be used in combination with another biologic CGRP antagonist or inhibitor (e.g., Aimovig, Vyepti)
Authorization will be issued for 6 months.

b. Aimovig 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 months), contraindication, or intolerance to two of the following prophylactic therapies from the list below(document name and date tried):

   (a) Amitriptyline (Elavil)
   (b) One of the following beta-blockers: atenolol, metoprolol, nadolol, propranolol, or timolol ***NOTE*** Nadolol and timolol are non-preferred and should not be included in denial to provider
   (c) Divalproex sodium (Depakote/Depakote ER)
   (d) OnabotulinumtoxinA (Botox) ***NOTE*** This is a medical benefit, should not be included in denial to provider
   (e) Topiramate (Topamax)
   (f) Venlafaxine (Effexor/Effexor XR)

-AND-

(3) Medication will not be used in combination with another biologic CGRP antagonist or inhibitor (e.g., Ajovy Emgality, Vyepti)

-AND-

(5) The patient has a history of failure, contraindication, or intolerance to both of the following (document date tried):
   • Ajovy
   • Emgality 120mg

Authorization will be issued for 6 months.

2. Reauthorization

   a. Aimovig, Ajovy, or Emgality 120mg will be approved based on both 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 biologic CGRP antagonist or inhibitor (e.g., Vyepti)

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-

      (1) Medication will not be used in combination with another biologic CGRP antagonist or inhibitor. (e.g., Aimovig, Ajovy, Vyepti).

Authorization will be issued for 63 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 biologic CGRP antagonist or inhibitor (e.g., Aimovig, Ajovy, Vyepti)

Authorization will be issued for 12 months.
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.

3. **References:**

8.  

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<thead>
<tr>
<th>Program</th>
<th>Prior Authorization –CGRP Antagonists- ARIZONA</th>
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</thead>
<tbody>
<tr>
<td>Change Control</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>6/2018</td>
<td>New Program</td>
</tr>
<tr>
<td>10/2018</td>
<td>Added Ajovy and Emgality to the program and changed program</td>
</tr>
</tbody>
</table>
name to CGRP. Modified trial/failure requirement and removed documentation requirement. Defined headache specialist. Updated background and references.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>11/2018</td>
<td>Removed prescriber requirement.</td>
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<tr>
<td>1/2019</td>
<td>Added step through Aimovig and Emgality for Ajovy for 4/1/19 PDL update.</td>
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<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 for Emgality and included approvable strength for episodic and chronic migraine.</td>
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<tr>
<td>8/2020</td>
<td>AZ specific policy created. Preferred products are Ajovy and Emgality. Aimovig moved to NP.</td>
</tr>
<tr>
<td>10/2020</td>
<td>Annual review. Updated initial authorization duration. Added documentation requirement. Modified concomitant CGRP use to allow non-biologic CGRPs.</td>
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