<table>
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<tr>
<th><strong>Section:</strong></th>
<th>Prescription Drugs</th>
<th><strong>Effective Date:</strong></th>
<th>July 1, 2020</th>
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<tbody>
<tr>
<td><strong>Subsection:</strong></td>
<td>Analgesics and Anesthetics</td>
<td><strong>Original Policy Date:</strong></td>
<td>August 10, 2018</td>
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**Last Review Date:** June 18, 2020

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Migraine Calcitonin Gene-Related Peptide (CGRP) Antagonists SC

**Description**

Aimovig (erenumab-aooe), Ajovy* (fremanezumab-vfrm), Emgality (galcanezumab-gnim)

*Non-covered medications must go through prior authorization and the formulary exception process

**Background**

Aimovig, Ajovy, and Emgality are human immunoglobulin G2 (IgG2) monoclonal antibodies that have high affinity for binding to the calcitonin gene-related peptide (CGRP) receptor and act by antagonizing this receptor. Aimovig, Ajovy, and Emgality are indicated for the preventive treatment of migraine in adults. Emgality is also indicated for the treatment of episodic cluster headaches in adults. Other migraine prophylaxis options include antiepileptic drugs, antidepressants, and antihypertensive agents (1-4).

**Regulatory Status**

FDA approved indication: Aimovig, Ajovy, and Emgality are calcitonin gene-related peptide receptor antagonists indicated for the preventive treatment of migraine in adults (1-3).

Emgality is also indicated for the treatment of episodic cluster headache in adults (3).

The safety and effectiveness of Aimovig, Ajovy, and Emgality in pediatric patients have not been established (1-3).

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**Related policies**

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Amerge, Axert, Butalbital analgesics, Frova, Maxalt, Migraine CGRP Antagonists IV, Migraine CGRP Antagonists Oral, Migraine Powders, Migranal Nasal Spray, Relpax, Reyvow, Sumatriptan, Sumatriptan Injection, Vyepti, Zomig

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

CGRP antagonists SC may be considered **medically necessary** for patients 18 years and older for the prevention of migraines and if the conditions indicated below are met.

Emgality may be considered **medically necessary** for patients 18 years and older for the treatment of episodic cluster headaches and if the conditions indicated below are met.

CGRP antagonists SC may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Aimovig & Emgality (excluding Emgality 100 mg/mL):

Patients who have filled a 6 month trial of a single migraine prophylactic agent in the past 2 years are exempt from these Initial PA requirements. Migraine prophylactic agents include: Divalproex Sodium (Depakote, Depakote ER), Topiramate (Topamax), Amitriptyline (Elavil), Venlafaxine (Effexor), or Beta-Blockers such as: Atenolol/ Metoprolol/ Propranolol/ Timolol/ Nadolol.

Age 18 years of age or older

Diagnosis:

Patient must have the following:

Migraine
AND ALL of the following:
1. Used for the prevention of migraines
2. Patient has completed an adequate 6-month trial of at least ONE of the following prophylactic agents:
   a. Divalproex Sodium (Depakote, Depakote ER)
   b. Topiramate (Topamax)
   c. Amitriptyline (Elavil)
   d. Venlafaxine (Effexor)
   e. Beta-Blockers: Atenolol/Metoprolol/Propranolol/Timolol/Nadolol
3. Patient has completed an adequate 3-month trial OR patient has an intolerance or contraindication to at least ONE of the following treatment (Triptan) agents:
   a. Amerge (naratriptan)
   b. Axert (almotriptan)
   c. Frova (frovatriptan)
   d. Maxalt (rizatriptan)
   e. Relpax (eletriptan)
   f. Imitrex (sumatriptan)
   g. Zomig (zolmitriptan)
4. NO dual therapy with Botulinum toxin (Botox) or another CGRP antagonist (see Appendix 1)
5. Aimovig only: Prescriber agrees to monitor for severe constipation

Emgality 100 mg/mL ONLY

Age 18 years of age or older

Diagnosis:

Patient must have the following:

Episodic cluster headaches

AND ALL of the following:
1. Patient has completed an adequate 3-month trial OR patient has an intolerance or contraindication to at least ONE of the following:
a. Triptan agent  
b. Ergotamine tartrate  
c. Dihydroergotamine

2. **NO** dual therapy with another CGRP antagonist (see Appendix 1)

### Prior–Approval Renewal Requirements

**Age**  
18 years of age or older

**Diagnosis:**

Patient must have the following:

Migraine

**AND ALL** of the following:

1. Used for prevention of migraine  
2. Documented decrease in migraine days from baseline **OR** improvement in daily activities due to the reduction of debilitating migraine  
3. **NO** dual therapy with Botulinum toxin (Botox) or another CGRP antagonist (see Appendix 1)  
4. **NO** dual therapy with Triptan Agents at Prior Authorization quantities  
5. **Aimovig only:** Prescriber agrees to monitor for severe constipation

**Emgality 100 mg/mL ONLY**

**Age**  
18 years of age or older

**Diagnosis:**

Patient must have the following:

Episodic cluster headaches

**AND ALL** of the following:

1. Patient has had a decrease in frequency of cluster headache attacks
2. **NO** dual therapy with another CGRP antagonist (see Appendix 1)

### Policy Guidelines

#### Pre–PA Allowance

None

#### Prior–Approval Limits

**Quantity**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aimovig syringe</td>
<td>3 injections per 90 days OR</td>
</tr>
<tr>
<td>Emgality prefilled pen 120 mg/mL</td>
<td>7 injections per 180 days OR</td>
</tr>
<tr>
<td>*for migraines only</td>
<td></td>
</tr>
<tr>
<td>Emgality prefilled syringe 120 mg/mL</td>
<td>7 injections per 180 days OR</td>
</tr>
<tr>
<td>*for migraines only</td>
<td></td>
</tr>
<tr>
<td>Emgality prefilled syringe 100 mg/mL</td>
<td>9 injections per 90 days</td>
</tr>
<tr>
<td>*for cluster headaches only</td>
<td></td>
</tr>
</tbody>
</table>

**OR**

<table>
<thead>
<tr>
<th>Drug: with approved MFE only</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ajovy</td>
<td>3 injections per 90 days</td>
</tr>
</tbody>
</table>

**Duration** 6 months

#### Prior–Approval Renewal Limits

**Quantity**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aimovig syringe</td>
<td>3 injections per 90 days OR</td>
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</tbody>
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Subsection: Analgesics and Anesthetics

Subject: Migraine CGRP Antagonists SC

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<table>
<thead>
<tr>
<th>Drug</th>
<th>With approved MFE only</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>Ajovy</td>
<td></td>
<td>3 injections per 90 days</td>
</tr>
</tbody>
</table>

Duration 12 months

Rationale

Summary
Aimovig, Ajovy, and Emgality are human immunoglobulin G2 (IgG2) monoclonal antibodies that have high affinity for binding to the calcitonin gene-related peptide receptor and acts by antagonizing this receptor. They are indicated for the preventive treatment of migraine in adults. Emgality is also used for the treatment of episode cluster headaches in adults. The safety and effectiveness of Aimovig, Ajovy, and Emgality in pediatric patients have not been established (1-4).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of CGRP antagonists SC while maintaining optimal therapeutic outcomes.

References
**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 2018</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td></td>
<td>Addition of renewal requirements of one of the following: decrease of ≥ 50% in migraine frequency from baseline, decrease in use of acute migraine medications, reduction of at least 6 migraines or more per month, added intolerance or contraindication to triptans per SME</td>
</tr>
<tr>
<td>November 2018</td>
<td>Annual review. Changed renewal requirements from 50% reduction in migraine frequency to 30% and reduction of at least 6 migraines per month to 3 migraines per SME</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review. Revised Aimovig quantity limits due to new 140 mg/mL availability</td>
</tr>
<tr>
<td>May 2019</td>
<td>Removal of gabapentin, verapamil/nimodipine and other oral migraine prophylactic therapy considered to be appropriate by the requesting physician</td>
</tr>
<tr>
<td></td>
<td>Removal of the requirement of baseline migraine frequency of at least 8 migraines per month</td>
</tr>
<tr>
<td></td>
<td>Change in the preventative trial of 3 months to 6 months</td>
</tr>
<tr>
<td></td>
<td>Ajovy was added to MFE</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review and reference update. Addition of cluster headache diagnosis to Emgality</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual editorial review and reference update. Addition of requirement to monitor for severe constipation for Aimovig</td>
</tr>
<tr>
<td>February 2020</td>
<td>Revised Emgality cluster headache initiation requirement to t/f a triptan, ergotamine, or dihydroergotamine and removed t/f preventative agent per FEP</td>
</tr>
<tr>
<td>March 2020</td>
<td>Annual review and reference update. Addition of Vyepti to policy and renamed policy Migraine CGRP Antagonists Injectable</td>
</tr>
<tr>
<td>April 2020</td>
<td>Addition of requirement of no dual therapy with another CGRP antagonist per FEP</td>
</tr>
<tr>
<td>June 2020</td>
<td>Annual review and reference update. Removed Vyepti to separate criteria. Renamed policy Migraine CGRP Antagonists SC. Revised renewal</td>
</tr>
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requirement to “documented decrease in migraine days from baseline OR improvement in daily activities due to the reduction of debilitating migraines” per SME

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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 18, 2020 and is effective on July 1, 2020.
### Appendix 1 - List of CGRP Antagonists

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>eptinezumab-jjmr</td>
<td>Vyepti</td>
</tr>
<tr>
<td>erenumab-aooe</td>
<td>Aimovig</td>
</tr>
<tr>
<td>fremanezumab-vfrm</td>
<td>Ajovy</td>
</tr>
<tr>
<td>galcanezumab-gnim</td>
<td>Emgality</td>
</tr>
<tr>
<td>rimegepant</td>
<td>Nurtec ODT</td>
</tr>
<tr>
<td>ubrogepant</td>
<td>Ubrelvy</td>
</tr>
</tbody>
</table>