

# Migraine Products : Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

Medical policy no. 67.70.20

Effective Date: April 1, 2019

**Note:**

- For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO\* preferred agents.  
\*If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed
- If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria

**Background:**

Calcitonin gene-related peptide (CGRP) mediates trigeminovascular pain from intracranial vessels to the central nervous system. Stimulation of the trigeminal ganglion induces the release of CGRP, and CGRP infusion can trigger a migraine attack in migraineurs.

**Medical necessity:**

Drug	Medical Necessity
erenumab-aooe ( <b>Aimovig</b> ) fremanezumab-vfrm ( <b>Ajovy</b> ) galcanezumab-gnlm ( <b>Emgality</b> )	Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist may be considered medically necessary when:  Used for prevention of migraine headaches which continue to occur 4 or more times per month following failure of at least 3 other prophylactic options

**Clinical policy:**

Drug	Clinical Criteria (Initial Approval)
erenumab-aooe ( <b>Aimovig</b> ) fremanezumab-vfrm ( <b>Ajovy</b> ) galcanezumab-gnlm ( <b>Emgality</b> )	<ol style="list-style-type: none"> <li>Patient has diagnosis of migraine headache. Documentation of prescriber ruling out medication overuse headache is required; <b>AND</b></li> <li>Patient is experiencing 4 or more migraines per month; <b>AND</b></li> <li>Patient has failed (<i>defined as an inability to reduce migraine headaches by 2 or more days per month</i>) a 3-month trial of at least ONE agent from <b>EACH</b> of the following classes of preventative medications (specific medications listed in the <b>Preferred therapies</b> section below). Documentation of adherence is required for each therapy (<i>unless contraindicated or intolerance to treatment</i>):               <ol style="list-style-type: none"> <li>Anticonvulsants; <b>AND</b></li> <li>Antidepressants; <b>AND</b></li> <li>Beta blockers OR calcium channel blockers; <b>AND</b></li> </ol> </li> <li>A baseline measurement from a standard migraine instrument (MIDAS or HIT6); <b>AND</b></li> </ol>

	<p>5. Quantity Limit:</p> <ul style="list-style-type: none"> <li>a. Aimovig: 140 mg per 28-days</li> <li>b. Ajovy: 225 mg per 28-days</li> <li>c. Emgality: 240mg one time, followed by 120mg once per 28-days; <b>AND</b></li> </ul> <p>6. Patient has not received Botox in the previous 12 weeks</p> <p><b>Approve for 3 months</b></p>
	<b>Criteria (Reauthorization)</b>
	<ul style="list-style-type: none"> <li>1. Migraine days reduced by at least 40% from baseline; <b>OR</b></li> <li>2. Documentation of significant improvement in Quality of Life measures (eg, a 6-point reduction on the HIT-6 score); <b>AND</b></li> <li>3. Quantity Limit: <ul style="list-style-type: none"> <li>a. Aimovig: 140mg per 28-days</li> <li>b. Ajovy: 225mg per 28-days or 675mg per 84-days</li> <li>c. Emgality: 120mg once per 28-days; <b>AND</b></li> </ul> </li> <li>4. Patient has not received Botox in the previous 12 weeks</li> </ul> <p><b>Approve for 12 months</b></p>

### Preferred therapies:

Drug Name	Preferred For:
Anticonvulsants Antidepressants Beta-blockers Calcium Channel blockers	<p><b>Anticonvulsants:</b> Topiramate or divalproex sodium</p> <p><b>Antidepressants:</b> Venlafaxine, amitriptyline, or nortriptyline</p> <p><b>Beta-blockers:</b> Propranolol, metoprolol, or atenolol</p> <p><b>Calcium Channel Blockers:</b> Verapamil</p>

### Dosage and quantity limits:

Drug Name	Dose and Quantity Limits
erenumab-aooe ( <b>Aimovig</b> )	140mg per 28-days
fremanezumab-vfrm ( <b>Ajovy</b> )	225mg per 28-days or 675mg per 84-days
galcanezumab-gnlm ( <b>Emgality</b> )	Loading Dose: 240mg one time Maintenance Dose: 120mg per 28-days

### Definitions:

Term	Description
CGRP	Calcitonin gene-related peptide

### References

1. Product Information: AIMOVIG™ subcutaneous injection, erenumab-aooe subcutaneous injection. Amgen Inc (per manufacturer), Thousand Oaks, CA, 2018
2. Product Information: AJOVY™ subcutaneous injection, fremanezumab-vfrm subcutaneous injection. Teva Pharmaceuticals USA Inc (per FDA), North Wales, PA, 2018

3. Product Information: EMGALITY™ subcutaneous injection, galcanezumab-gnlm subcutaneous injection. Eli Lilly and Company (per FDA), Indianapolis, IN, 2018
4. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/14/2018).
5. International Headache Society (IHS); Headache Classification Committee. The International Classification of Headache Disorders, 3rd edition (beta version). Cephalalgia. 2013; 33: 629-808.

## History

Date	Action and Summary of Changes
02.27.2019	New Policy