Migraine Calcitonin Gene-Related Peptide (CGRP) Antagonists

Description

Aimovig (erenumab-aooe) injection, Ajovy* (fremanezumab-vfrm) injection, 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, and Emgality is 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 recommended dosage of Aimovig is 70 mg injected subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly (1).
Ajovy can be dosed as 225 mg once monthly, or 675 mg every 3 months (quarterly), which is administered as three consecutive subcutaneous injections of 225 mg each (2).

The recommended dosage of Emgality is 240 mg (two consecutive subcutaneous injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg injected subcutaneously (3).

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

**Related policies**

Amerge, Axert, Butalbital analgesics, Frova, Maxalt, Migraine Powders, Migranal Nasal Spray, Relpax, Sumatriptan, Sumatriptan Injection, 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.*

Calcitonin gene-related peptide antagonists 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.

Calcitonin gene-related peptide antagonists 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: Divalproex Sodium (Depakote, Depakote ER), Topiramate (Topamax), Amitriptyline (Elavil), Venlafaxine (Effexor), or Beta-Blockers*
such as: Atenolol/Metoprolol/Propranolol/Timolol/Nadolol)) in the past 2 years are exempt from these Initial PA requirements.

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 for the prevention of migraines

Emgality ONLY
### Prescription Drugs

**Section:** Prescription Drugs  
**Effective Date:** July 1, 2019  
**Subsection:** Analgesics and Anesthetics  
**Original Policy Date:** August 10, 2018  
**Subject:** Migraine Calcitonin Gene-Related Peptide (CGRP) Antagonists  
**Page:** 4 of 8

<table>
<thead>
<tr>
<th>Age</th>
<th>18 years of age or older</th>
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</table>

**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 Imitrex (sumatriptan) injection
2. Patient has completed an adequate 3-month trial OR patient has an intolerance or contraindication to at least one preventative agent
3. **NO** dual therapy with another CGRP antagonist

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### Prior–Approval *Renewal* Requirements

<table>
<thead>
<tr>
<th>Age</th>
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**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
3. **NO** dual therapy with Botulinum toxin (Botox) or another CGRP for the prevention of migraines
4. **NO** dual therapy with Triptan Agents at Prior Authorization quantities

**Emgality ONLY**

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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

Policy Guidelines

Pre–PA Allowance
None

Prior–Approval Limits

Quantity

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

OR

<table>
<thead>
<tr>
<th>Drug: with approved MFE only</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>Ajovy</td>
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Duration 6 months

Prior–Approval *Renewal Limits*

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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 Calcitonin gene-related peptide antagonists 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>
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<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>
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<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>
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<td>Removal of the requirement of baseline migraine frequency of at least 8 migraines per month</td>
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<td>Change in the preventative trial of 3 months to 6 months</td>
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<td></td>
<td>Ajovy was added to MFE</td>
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June 2019 | Annual review and reference update. Addition of cluster headache diagnosis to Emgality

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.