

# Calcitonin Gene-Related Peptide Receptor Antagonists

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# Background

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- ▶ Chronic migraine can cause significant quality life disruptions in migraine sufferers
- ▶ Calcitonin gene-related peptide (CGRP) has demonstrated a role in migraine pain processing and vasodilation
- ▶ New class of migraine medications targeting the receptor or the peptide itself
- ▶ DERP CGRP review slides found in packet for clinical evidence

# HIT-6

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- ▶ Scale used to measure the quality of life impact on patients with migraines
- ▶ Maximum score is 78
- ▶ A clinically meaningful change for an individual patient has been defined by as a 5-point decrease
- ▶ A reduction of 6-7 points was achievable in both the CGRP and Botox studies for chronic migraine

# Medications

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Brand Name	Generic Name	Dosing
Aimovig™	erenumab-aooe	70 mg SQ monthly OR 140 mg SQ monthly
Ajovy™	fremanezumab-vrfm	225 mg SQ monthly OR 675 mg SQ quarterly
Emgality™	galcanezumab-gnlm	240 mg SQ loading dose AND 120 mg SQ monthly

# Criteria Summary

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## ▶ Seven initial criteria:

- 1) Diagnosis
- 2) Number of migraines per month
- 3) Prescribed by a specialist
- 4) Trial and failure of preferred therapies
- 5) Baseline migraine instrument measurement
- 6) Quantity limit
- 7) Previous Botox treatment

# Initial Request Criteria

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- ▶ Patient has diagnosis of migraine headache
- ▶ Patient is experiencing 4 or more migraines per month

# Initial Request Criteria (continued)

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- ▶ Patient has failed a 3-month trial of at least **ONE** agent from **EACH** of the following classes of preventative medications
  - ▶ Defined as an inability to reduce migraine headaches by 2 or more days per month
  - ▶ Documentation of adherence is required for each therapy (unless contraindicated or intolerance to treatment)
  - ▶ Anticonvulsants
  - ▶ Antidepressants
  - ▶ Beta blockers OR calcium channel blockers

# Preferred Therapies

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Drug Class	Drugs
Anticonvulsants	Topiramate or divalproex sodium
Antidepressants	Venlafaxine, amitriptyline, or nortriptyline
Beta-blockers	Propranolol, metoprolol, or atenolol
Calcium Channel Blockers	Verapamil

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# Initial Request Criteria (continued)

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- ▶ A baseline measurement from a standard migraine instrument (MIDAS or HIT6)
- ▶ Quantity Limit:
  - ▶ Aimovig: 140 mg per 28-days
  - ▶ Ajovy: 225 mg per 28-days
  - ▶ Emgality: 240mg one time, followed by 120mg once per 28-days
- ▶ Patient has not received Botox in the previous 12 weeks
- ▶ If **ALL** criteria are met, the medication will be approved for 3 months.

# Reauthorization Criteria

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- ▶ Migraine days reduced by at least 40% from baseline; **OR**
- ▶ Documentation of significant improvement in Quality of Life measures (eg, a 6-point reduction on the HIT-6 score)
- ▶ Quantity Limit:
  - ▶ Aimovig: 140mg per 28-days
  - ▶ Ajovy: 225mg per 28-days or 675mg per 84-days
  - ▶ Emgality: 120mg once per 28-days
  
- ▶ If criteria are met, the medication will be approved for 12 months.

# Stakeholder Comments

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# Motion

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- ▶ “I move that the Apple Health Medicaid Program implement the clinical criteria listed on slides 7-10 as recommended.”
  - ▶ Motion: Buccola
  - ▶ 2<sup>nd</sup>: Park

# References

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- ▶ Product Information: AIMOVIG™ subcutaneous injection, erenumab-aooe subcutaneous injection. Amgen Inc (per manufacturer), Thousand Oaks, CA, 2018
- ▶ Product Information: AJOVY™ subcutaneous injection, fremanezumab-vfrm subcutaneous injection. Teva Pharmaceuticals USA Inc (per FDA), North Wales, PA, 2018
- ▶ Product Information: EMGALITY™ subcutaneous injection, galcanezumab-gnlm subcutaneous injection. Eli Lilly and Company (per FDA), Indianapolis, IN, 2018
- ▶ Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/14/2018).