Calcitonin Gene-Related Peptide Receptor Antagonists

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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

- 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

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aimovig™</td>
<td>erenumab-aooe</td>
<td>70 mg SQ monthly OR 140 mg SQ monthly</td>
</tr>
<tr>
<td>Ajovy™</td>
<td>fremanezumab-vrfm</td>
<td>225 mg SQ monthly OR 675 mg SQ quarterly</td>
</tr>
<tr>
<td>Emgality™</td>
<td>galcanezumab-gnlm</td>
<td>240 mg SQ loading dose AND 120 mg SQ monthly</td>
</tr>
</tbody>
</table>
Criteria Summary

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

- Patient has diagnosis of migraine headache
- Patient is experiencing 4 or more migraines per month
Initial Request Criteria (continued)

- 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

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants</td>
<td>Topiramate or divalproex sodium</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Venlafaxine, amitriptyline, or nortriptyline</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>Propranolol, metoprolol, or atenolol</td>
</tr>
<tr>
<td>Calcium Channel Blockers</td>
<td>Verapamil</td>
</tr>
</tbody>
</table>
Initial Request Criteria (continued)

- 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

- 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
Motion

“I move that the Apple Health Medicaid Program implement the clinical criteria listed on slides 7-10 as recommended.”

- Motion: Buccola
- 2nd: Park
References

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