CRITERIA FOR PRIOR AUTHORIZATION

Calcitonin Gene-Related Peptide (CGRP) Antagonists

BILLING CODE TYPE: For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES: Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

- Erenumab-aooe (Aimovig™)
- Fremanezumab-vfrm (Ajovy™)
- Galcanezumab-gnlm (Emgality™)

CRITERIA FOR INITIAL APPROVAL: (must meet all of the following)
- Patient has a diagnosis of chronic or episodic migraine
  - Chronic migraine: 15 or more headache days per month, for more than three months, which, on at least 8 days/month, has the features of migraine headache.¹
  - Episodic migraine: 4 to 14 migraine days per month.⁵,⁷
- Patient must have experienced an inadequate response after a trial of at least one agent from each medication class listed in Table 2 at a maximum tolerated dose, OR have a documented intolerance or contraindication to all preventive therapies.²
- Patient must have experienced an inadequate response to a trial of a botulinum toxin indicated for chronic migraines (trial of at least 180 days), OR have a documented intolerance or contraindication to treatment with botulinum toxins.²
  - Treatment with a botulinum toxin for chronic migraines must be discontinued prior to initiation with a CGRP antagonist.
    ▪ At least 90 days must have elapsed after last treatment with botulinum toxin.
- Prescriber must provide documentation of all previous medication trials. Documentation must include the medication name(s), trial date(s) and outcome(s) of the trial (i.e. inadequate response, intolerance or contraindication).
- Prescriber must attest that all medication-specific safety criteria, as defined in Table 1, is met.

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL:
- Prescriber must attest that all medication-specific safety criteria continues to be met.
- The patient must meet one of the following:
  - The patient has experienced a reduction in the number of monthly headache days compared to baseline (prior to starting treatment with the requested agent)
  - Re-initiation for chronic migraines, if reverting from other step therapies, must meet all of the following:
    ▪ Must not have had a botulinum toxin treatment for chronic migraine in the past 90 days.
    ▪ Must discontinue topiramate extended release for at least 30 days (90 days from last dispensing if a 90-day supply was used).

LENGTH OF APPROVAL (RENEWAL): 12 months
APPROVED PA Criteria

For drugs that have a current PA requirement, but not for the newly approved indications, for other FDA-approved indications, and for changes to age requirements not listed within the PA criteria:

- The PA request will be reviewed based upon the following package insert information: Indication, Age, Dose, and any pre-requisite treatment requirements for that indication.

Length of Approval (Initial and Renewal): 12 months

Table 1. Medication-Specific Criteria.5-7

<table>
<thead>
<tr>
<th>Agents</th>
<th>Indication(s)</th>
<th>Age</th>
<th>Dosing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ajovy™ (fremanezumab-vfrm)</td>
<td>Migraine prevention</td>
<td>≥18</td>
<td>Dose must not exceed either 225 mg (1.5 mL/1 syringe) per month OR 675 mg (4.5 mL/3 syringes) every 3 months</td>
</tr>
<tr>
<td>Aimovig™ (erenumab-aooe)</td>
<td>Migraine prevention</td>
<td>≥18</td>
<td>70mg to 140mg subcutaneously once monthly. If using 140mg, must use the package labeled specifically for 140mg/mL.</td>
</tr>
<tr>
<td>Emgality™ (galcanezumab-gnml)</td>
<td>Migraine prevention</td>
<td>≥18</td>
<td>Dose must not exceed 240 mg (2 mL/2 syringes) for initial dose and 120 mg (1 mL/1 syringe) for maintenance dosing</td>
</tr>
<tr>
<td>Episodic cluster headache</td>
<td>≥18</td>
<td></td>
<td>300mg subcutaneously every month</td>
</tr>
</tbody>
</table>

Table 2. Prior Preventative Migraine Therapies.3

<table>
<thead>
<tr>
<th>Beta-Blocking Agents</th>
<th>Antiepileptic Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propranolol</td>
<td>Topiramate</td>
</tr>
<tr>
<td>Metoprolol</td>
<td>Valproic acid</td>
</tr>
<tr>
<td>Timolol</td>
<td>Divalproex</td>
</tr>
</tbody>
</table>

References

APPROVED PA Criteria

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

DATE

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE