Calcitonin Gene-Related Peptide (CGRP) Inhibitors
Aimovig (erenumab-aooe)
Ajovy (fremanezumab-vfrm)
Emgality (galcanezumab-gnlm)
Vyepti (eptinezumab-jjmr)
Effective 06/01/2021

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<tr>
<th>Plan</th>
<th>Program Type</th>
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<tbody>
<tr>
<td>☐ MassHealth</td>
<td>☑ Prior Authorization</td>
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<tr>
<td>☑ MassHealth (PUF)</td>
<td>☑ Quantity Limit</td>
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<tr>
<td>☐ Commercial/Exchange</td>
<td>☐ Step Therapy</td>
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<tr>
<th>Benefit</th>
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<tr>
<td>☑ Pharmacy Benefit</td>
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<td>☑ Medical Benefit (NLX)</td>
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| Specialty Limitations | N/A |

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<th>Contact Information</th>
<th>Specialty Medications</th>
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<tr>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
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<th>Non-Specialty Medications</th>
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<td>MassHealth</td>
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<tr>
<th>Commercial</th>
<th>Phone: 800-294-5979</th>
<th>Fax: 888-836-0730</th>
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<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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| Medical Specialty Medications (NLX) |
| All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |

| Exceptions |
| Vyepti is only available through Medical Benefit (MB). All other products are only available on the Pharmacy Benefit (PB). |

Overview
Aimovig, Ajovy, Emgality and Vyepti are calcitonin gene-related peptide receptor (CGRP) antagonists indicated for the prophylactic treatment of migraines in adults and episodic cluster headaches (Emgality only)

PA required
Aimovig® (erenumab-aooe for migraine prophylaxis)
Ajovy® (fremanezumab-vfrm for migraine prophylaxis)PD
Emgality® (galcanezumab-gnlm for migraine prophylaxis)
Emgality® (galcanezumab-gnlm for cluster headaches)PD
Vyepti® (eptinezumab-jjmr)^

PD = preferred drug. In general, Atrial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
^ This agent is available through the medical benefit only

Coverage Guidelines
Authorization requests will be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Prophylactic Treatment of Migraines
Authorizations may be granted for the prophylactic treatment of migraines when the following criteria are met:

1. The member is ≥ 18 years of age
2. The member has been experiencing at least 4 migraine days per month AND
3. The member has had an inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following*:
   a. atenolol
   b. metoprolol
   c. nadolol
   d. propranolol
   e. timolol
4. The member has had an inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following*:
   a. a tricyclic antidepressant
   b. topiramate
   c. valproic acid
   d. venlafaxine
5. The member has not been treated with Botox for migraines within the past 4 months AND
6. The member is not currently using any other CGRP or Botox for the treatment of migraines AND
7. Appropriate dose
8. For Aimovig® (erenumab-aooe), Emgality® (galcanezumab-gnlm) 120 mg/mL syringe, and Vyepti® (eptinezumab-jjmr) ONLY, the member has had inadequate response, adverse reaction, or contraindication to Ajovy®

Notes:
*If a prescriber specifically documents they wish to avoid a β blocker in a member due to a concurrent diagnosis of depression, this is acceptable rationale to bypass this trial. However, avoidance of a β blocker due to risk of depression in members without a documented diagnosis of depression is not adequate rationale to bypass this trial. In addition, the following conditions can be accepted as rationale for avoidance of β blockers: asthma (bronchospastic disease), COPD, peripheral vascular disease, Raynaud’s, baseline hypotension or bradycardia, and pheochromocytoma.

Previous prior authorizations for Botox®, for migraine prophylaxis, should be end-dated if member is approved for a CGRP Inhibitor. These should not be used concomitantly. Please call office to inform them of the above.

Episodic Cluster Headaches
Authorization for Emgality® (galcanezumab-gnlm) 100 mg/mL syringe for the treatment of episodic cluster headaches may be granted when the following criteria are met:

1. The member is ≥ 18 years of age
2. Prescriber is a neurologist or headache specialist, or the prescription is being written for the member in consultation with a neurologist or headache specialist
3. Appropriate dose
**Continuation of Therapy**
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

**For Cluster Headache:**
- Resubmission will need to document that member is still actively having a cluster headache and that member has been initiated on prophylactic therapy for the cluster headache (e.g., verapamil, topiramate, steroids, etc.) or rationale why this is not appropriate.

**Limitations**
1. Initial approvals will be granted for up to 3 months
2. Reauthorizations will be granted for 6 months
3. The following quantity limits apply

<table>
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<tr>
<th>Medicine</th>
<th>Limitation</th>
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<tr>
<td>Aimovig 70mg/mL</td>
<td>1 pen per 30 days</td>
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<tr>
<td>Aimovig 140mg/mL</td>
<td>1 pen per 30 days</td>
</tr>
<tr>
<td>Ajovy 225mg/1.5mL pre-filled syringe and Ajovy 225mg/1.5mL autoinjector</td>
<td>1 pen per 30 days or 3 pens (675mg) every 90 days</td>
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| Emgality                        | Migraines
2 pens (240mg) for initial month, then 1 pen per 30 days
Cluster headaches
Loading dose: 3x100mg (3 consecutive doses)
Maintenance dose: 300mg every 4 weeks

**Appendix**
Concomitant Therapy: Oral and Injectable
There is growing data showing efficacy and safety in using injectable CGRP inhibitors for prophylaxis therapy with oral CGRP inhibitors for acute treatment. As such, we will allow concomitant use.
- NCT04179474: Safety, Tolerability & Drug Interaction Study of Ubrogepant With Erenumab or Galcanezumab in Participants With Migraine.

**References**
1. Aimovig (erenumab-aooe) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2019
2. Ajovy (fremanezumab-vfrm) [prescribing information]. North Wales, PA: Teva Pharmaceuticals; September 2018
3. Emgality (galcanezumab-gnlm) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; June 2019
5. Botox (OnabotulinumtoxinA) [prescribing information]. Irvine, CA: Allergan; May 2011clusig (ponatinib) [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals Inc; October 2018


Review History
04/17/2019 – Reviewed
07/01/2019 – Implemented
09/18/2019 - Added cluster headaches indication to Emgality
10/06/2020 – Updated; Match Masshealth partial unified formulary requirements for implementation on 1/1/21
03/21/2021 – Reviewed and Updated; Notes were updated with acceptable diagnoses for bypassing the beta blocker for migraine prophylaxis for Ajovy, Aimovig, Emgality, and Vyepti per MH UPPL. Effective 06/01/2021.

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.