



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

<b>Plan</b>	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	Vyepeti is only available through Medical Benefit (MB). All other products are only available on the Pharmacy Benefit (PB).		

**Overview**

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

<b>PA required</b>
Aimovig <sup>®</sup> (erenumab-aooe for migraine prophylaxis)
Ajovy <sup>®</sup> (fremanezumab-vfrm for migraine prophylaxis) <sup>PD</sup>
Emgality <sup>®</sup> (galcanezumab-gnlm for migraine prophylaxis)
Emgality <sup>®</sup> (galcanezumab-gnlm for cluster headaches) <sup>PD</sup>
Vyepeti <sup>®</sup> (eptinezumab-jjmr) <sup>^</sup>

PD = preferred drug. In general, Atrial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

<sup>^</sup> This agent is available through the medical benefit only

**Coverage Guidelines**

Authorizations 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  $\geq 18$  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<sup>®</sup> (erenumab-aooe), Emgality<sup>®</sup> (galcanezumab-gnlm) 120 mg/mL syringe, and Vyepti<sup>®</sup> (eptinezumab-jjmr) ONLY**, the member has had inadequate response, adverse reaction, or contraindication to Ajovy<sup>®</sup>

Notes:

\*If a prescriber specifically documents they wish to avoid a  $\beta$  blocker in a member due to a concurrent diagnosis of depression, this is acceptable rationale to bypass this trial. However, avoidance of a  $\beta$  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  $\beta$  blockers: asthma (bronchospastic disease), COPD, peripheral vascular disease, Raynaud's, baseline hypotension or bradycardia, and pheochromocytoma.

Previous prior authorizations for Botox<sup>®</sup>, 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<sup>®</sup> (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  $\geq 18$  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 to 3 months
2. Reauthorizations will be granted for 6 months
3. The following quantity limits apply

Aimovig 70mg/mL	1 pen per 30 days
Aimovig 140mg/mL	1 pen per 30 days
Ajovy 225mg/1.5mL pre-filled syringe and Ajovy 225mg/1.5mL autoinjector	1 pen per 30 days or 3 pens (675mg) every 90 days
Emagility	<u>Migraines</u> 2 pens (240mg) for initial month, then 1 pen per 30 days  <u>Cluster headaches</u> 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.

- Mullin K, et al. Acute Treatment Benefit from Oral CGRP Receptor Antagonist and Monoclonal Antibody Combination: Rimegepant 75 mg for Acute Treatment of Attacks During Preventive Therapy With Erenumab. Biohaven Pharmaceuticals presentation. Diamond Headache Clinic Research & Educational Foundation Headache Update. July 25-28, 2019. Lake Buena Vista, FL.
- Mullin K, et al. 2020. Potential for Treatment Benefit of Small Molecule CGRP Receptor Antagonist Plus Monoclonal Antibody in Migraine Therapy. *Neurology*. 2020; 00: 1-5.
- NCT04179474: Safety, Tolerability & Drug Interaction Study of Ubrogapant 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
4. Tepper SJ. History and review of anti-calcitonin gene-related peptide (CGRP) therapies: from translational research to treatment. *Headache*. 2018;58(suppl 3):238-275. doi: 10.1111/head.13379
5. Botox (OnabotulinumtoxinA) [prescribing information]. Irvine, CA: Allergan; May 2011  
 Iclusig (ponatinib) [prescribing information]. Cambridge, MA: Ariad Pharmaceuticals Inc; October 2018

6. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society Guideline Developer(s): 2000 Sep (revised 2012 Apr 24)
7. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38:1
8. Koppen H, Stolwijk J, Wilms EB, et al. Cardiac monitoring of high-dose verapamil in cluster headache: An international Delphi study. Cephalalgia 2016; 36:1385
9. Cittadini E, May A, Straube A, et al. Effectiveness of intranasal zolmitriptan in acute cluster headache: a randomized, placebo-controlled, double-blind crossover study. Arch Neurol 2006; 63:1537
10. Ekbom K, Monstad I, Prusinski A, et al. Subcutaneous sumatriptan in the acute treatment of cluster headache: a dose comparison study. The Sumatriptan Cluster Headache Study Group. Acta Neurol Scand 1993; 88:63
11. Magnoux E, Zlotnik G. Outpatient intravenous dihydroergotamine for refractory cluster headache. Headache 2004; 44:249
12. Matharu M. Cluster headache. BMJ Clin Evid 2010; 2010
13. Ekbom K, Hardebo JE. Cluster headache: aetiology, diagnosis and management. Drugs 2002; 62:61.
14. Dodick DW, Capobianco DJ. Treatment and management of cluster headache. Curr Pain Headache Rep 2001; 5:83
15. Neurol Sci. 2017 May;38(Suppl 1):45-50. doi: 10.1007/s10072-017-2924-7.
16. Cluster headache: present and future therapy: PubMed
17. Dtsch Med Wochenschr. 2017 Mar;142(6):418-426. doi: 10.1055/s-0042-121336. Epub 2017 Mar 22.[Headache Treatment].:PubMed

### Review History

04/17/2019 – Reviewed

07/01/2019 – Implemented

09/18/2019 - Added cluster headaches indication to Emgality

07/22/2020 – added new formulation of Ajovy autoinjector to criteria. Effective 8/1/20.

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 Vypti 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.