PRIOR AUTHORIZATION CRITERIA

DRUG CLASS CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONISTS

INJECTABLE, INTRAVENOUS INFUSION

BRAND NAME (generic)

AIMOVIG

(erenumab-aooe injection)

AJOVY

(fremanezumab-vfrm injection)

EMGALITY

(galcanezumab-gnlm injection)

VYEPTI

(eptinezumab-jjmr injection, for intravenous use)

Status: CVS Caremark Criteria Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Aimovia

Aimovig is indicated for the preventive treatment of migraine in adults.

Ajovy

Ajovy is indicated for the preventive treatment of migraine in adults.

Emgality

Migraine

Emgality is indicated for the preventive treatment of migraine in adults

Cluster Headache

Emgality is indicated for the treatment of episodic cluster headache in adults

Vyepti

Vyepti is indicated for the preventive treatment of migraine in adults.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the preventive treatment of migraine in an adult patient AND
 - The patient received at least 3 months of treatment with the requested drug and had a reduction in migraine days per month from baseline

OR

The patient experienced an inadequate treatment response with an 8-week trial of any of the following: A)
Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Beta-adrenergic

CGRP Receptor Antagonists Inj, IV PA with Limit Policy 2581-C, REG 3160-C 07-2021.docx ©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)

OR

 The patient experienced an intolerance or has a contraindication that would prohibit an 8-week trial of any of the following: A) Antiepileptic drugs (AEDs) (e.g., divalproex sodium, topiramate, valproate sodium), B) Betaadrenergic blocking agents (e.g., metoprolol, propranolol, timolol, atenolol, nadolol), C) Antidepressants (e.g., amitriptyline, venlafaxine)

AND

- The requested drug will not be used concurrently with another CGRP receptor antagonist
- AND
- The request is for Aimovig, Ajovy, Emgality 120mg, or Vyepti

OR

- The request is for Emgality 100mg for treatment of episodic cluster headaches in an adult patient AND
 - The patient received at least 3 weeks treatment with the requested drug and had a reduction in weekly cluster headache attack frequency from baseline OR
 - The patient experienced an inadequate treatment response to any of the following: A) sumatriptan (subcutaneous or nasal), B) zolmitriptan (nasal or oral)
 - The patient experienced an intolerance or contraindication to any of the following: A) sumatriptan (subcutaneous or nasal), B) zolmitriptan (nasal or oral)

AND

o The requested drug will not be used concurrently with another CGRP receptor antagonist

Quantity limits apply.

REFERENCES

- 1. Aimovig [package insert]. Thousand Oaks, CA: Amgen Inc; February 2021.
- 2. Ajovy [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc. October 2020.
- 3. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; December 2019.
- 4. Vyepti [package insert]. Bothell, WA: Lundbeck Seattle Bio Pharmaceuticals, Inc; February 2020.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed June 4, 2021.
- 6. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed June 4, 2021.
- 7. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. *Neurology* 2012;78;1337-1346.
- 8. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. *Neurology* 2013;80;871
- 9. American Academy of Neurology. Update: Pharmacologic Treatments for Episodic Migraine Prevention in Adults. Available at: https://www.aan.com/Guidelines/Home/GetGuidelineContent/545. Accessed June 2021.
- 10. American Headache Society. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache 2019; 59:1-18.
- 11. Goadsby P, Reuter U, Hallström Y, et al. A Controlled Trial of Erenumab for Episodic Migraine. *N Engl J Med* 2017;377:2123-32.
- 12. Dodick D, Ashina M, Brandes J, et al. ARISE: A Phase 3 Randomized Trial of Erenumab for Episodic Migraine. *Cephalalgia* 2018; 38 (6): 1026-1037
- 13. Silberstein S, Dodick D, Bigal M, et al. Fremanezumab for the Preventive Treatment of Chronic Migraine. *N Engl J Med* 2017;377:2113-22.

CGRP Receptor Antagonists Inj, IV PA with Limit Policy 2581-C, REG 3160-C 07-2021.docx ©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

- 14. Dodick D, Silberstein S, Bigal M, et al. Effect of Fremanezumab Compared With Placebo for Prevention of Episodic Migraine: A Randomized Clinical Trial. *JAMA*. 2018 May 15;319(19):1999-2008.
- 15. Stauffer V, Dodick D, Zhang Q, et al. Evaluation of Galcanezumab for the Prevention of Episodic Migraine: The EVOLVE-1 Randomized Clinical Trial. *JAMA Neurol.* 2018 Sep 1;75(9):1080-1088.
- 16. Robbins M, et al. Treatment of Cluster Headache: The American Headache Society Evidence Based Guidelines. Headache 2016;56:1093-1106.
- 17. Weaver-Agostoni J. Cluster Headache. American Academy of Family Physicians. Am Fam Physician. 2013;88(2):122-128.
- 18. Francis G, et al. Acute and preventive pharmacologic treatment of cluster headache. American Academy of Neurology. Neurology 2010; 463-473.

Migraine:		
Drug	1 Month Limit*	3 Month Limit*
Aimovig 70mg (erenumab-aooe injection)	2mL (2 autoinjectors or syringes x 1mL each) / 25 days	6mL (6 autoinjectors or syringes x 1mL each) / 75 days
Aimovig 140mg (erenumab-aooe injection)	1mL (1 autoinjector or syringe x 1mL each) / 25 days	3mL (3 autoinjectors or syringes x 1mL each) / 75 days
Ajovy 225mg (fremanezumab-vfrm injection)	4.5mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days	4.5mL (3 autoinjectors or syringes x 1.5 mL each) / 75 days
Emgality 120mg (galcanezumab-gnlm injection)	1mL (1 syringe or pen x 1mL each) / 25 days	3mL (3 syringes or pens x 1mL each) / 75 days
Vyepti 100mg (eptinezumab-jjmr injection, for intravenous use)	3mL (3 single dose vials x 1mL each) / 75 days	3mL (3 single dose vials x 1mL each) / 75 days
Cluster Headache:		
Drug	1 Month Limit*	3 Month Limit*
Emgality 100mg (galcanezumab-gnlm injection)	3mL (3 syringes x 1mL each)/ 25 days	9mL (9 syringes x 1mL each)/ 75 days