RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	fremanezumab-vfrm
Policy Number:	RxA.588
Drug(s) Applied:	Ajovy®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Fremanezumab-vfrm (Ajovy®) is a calcitonin gene-related peptide (CGRP) receptor antagonist. It is indicated for the preventive treatment of migraine in adults.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
fremanezumab-vfrm (Ajovy®)	Migraine prophylaxis	225 mg SC once monthly or 675 mg SC every three months	675 mg every 3 months

Dosage Forms

- Single-dose prefilled syringe and prefilled autoinjector: 225 mg/1.5 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Migraine Prophylaxis (must meet all)**:**

1. Diagnosis of episodic or chronic migraine;
2. Member experiences ≥ 4 migraine days per month for at least 3 months;
3. Age 18 years of age or older;
4. Failure of at least 2 of the following oral migraine preventative therapies, each for 8 weeks and from different therapeutic classes, unless contraindicated or clinically significant adverse effects are experienced: antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate), beta-blockers (e.g., metoprolol, propranolol, timolol), antidepressants (e.g., amitriptyline, venlafaxine);
5. Ajovy® is not prescribed concurrently with Botox® or other injectable CGRP inhibitors (e.g., Aimovig®, Emgality®);
6. Dose does not exceed one of the following (a or b):
   a. 225 mg (1 injection) once monthly;
   b. 675 mg (3 injections) every 3 months.

Approval Duration

Commercial: 3 months

Medicaid: 3 months

II. Continued Therapy Approval

A. Migraine Prophylaxis (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline;
3. Ajovy® is not prescribed concurrently with Botox® or other injectable CGRP inhibitors (e.g., Aimovig®, Emgality®);
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 225 mg (1 injection) once monthly;
   b. 675 mg (3 injections) every 3 months.

Approval Duration
Commercial: 12 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CGRP: calcitonin gene-related peptide
FDA: Food and Drug Administration
ICHD: International Classification of Headache Disorder

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anticonvulsants such as: divalproex (Depakote®), topiramate (Topamax®)	**Migraine Prophylaxis** Refer to prescribing information	Refer to prescribing information
Beta-blockers such as: Propranolol, metoprolol (Lopressor®)*, timolol	**Migraine Prophylaxis** Refer to prescribing information	Refer to prescribing information
Antidepressants/tricyclic antidepressants* such as: amitriptyline, venlafaxine	**Migraine Prophylaxis** Refer to prescribing information	Refer to prescribing information

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic. Brand name might be non-preferred when generic is preferred.
*Off-label use

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- In clinical trials, a migraine day was defined as any calendar day in which the patient reported either a headache that lasted at least 2 consecutive hours and met International Classification of Headache Disorder (ICHD)-3 diagnostic criteria for migraine (with or without aura) or probable migraine (subtype in which only 1 migraine criterion is absent), or a day when a headache of any duration was treated with migraine-specific medications (triptans or ergots).

References

1. Ajovy Prescribing Information. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2020. Available at: www.ajovy.com. Accessed October 06, 2020.
2. Silberstein SD, Holland S, Freitag F, et al. American Academy of Neurology: Evidence- based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78: 1337-45. Accessed October 06, 2020.
3. Digre KB. The American Headache Society Position Statement on Integrating New Migraine Treatments Into Clinical Practice. Headache 2019; 59: 1-18. Accessed October 06, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated as "fremanezumab-vfrm". 2. Line of business policy applies to all lines of business. 3. Initial and continued approval duration criteria was updated to add Medicaid approval duration. 4. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 5. Appendix B updated: removed brand Inderal, Elavil & Effexor as all were discontinued. 6. References were reviewed and updated. 7. Updated the Continued Therapy approval duration for commercial plan from 6 months to 12 months. 8. Removed the specialist requirement.	11/23/2020	12/07/2020