Clinical Policy Title:	erenumab-aooe, fremanezumab-vfrm, atogepant
Policy Number:	RxA.587
Drug(s) Applied:	Aimovig®, Ajovy®, Qulipta™
Original Policy Date:	03/06/2020
Last Review Date:	11/27/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of the following (must meet a or b):
   a. Episodic migraine: between 4 to 14 migraine days per month;
   b. Chronic migraine: more than 15 headache days per month for ≥ 3 months;
2. Trial of at least 2 months of two (2) of the following preventative therapies, unless contraindicated or adverse effects are experienced:
   a. Candesartan;
   b. antiepileptic drugs (e.g., divalproex sodium, sodium valproate, topiramate);
   c. beta-blockers (e.g., metoprolol, propranolol, timolol);
   d. antidepressants (e.g., amitriptyline, venlafaxine);
3. For members currently treated with Botox for migraine (must meet a, b, and c):
   a. Diagnosis of chronic migraine;
   b. Member has tried a minimum of 2 quarterly injections (6 months) of Botox;
   c. Member has experienced and maintained a positive response;
4. Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis*.

*Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.

CGRP monotherapy initial approval duration
All Lines of Business (except Medicare): 12 months

CGRP and Botox dual therapy initial approval duration
All Lines of Business (except Medicare): 3 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication, excluding manufacturer samples;
2. Members treated with Aimovig, Ajovy, or Qulipta™ AND Botox for chronic migraine prophylaxis, member has achieved > 50% reduction in the frequency of days with headache or migraine;
3. Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis*.

*Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/22529202/. Accessed July 11, 2023.
2. Digre KB. The American Headache Society Position Statement on Integrating New Migraine Treatments into Clinical Practice. Headache 2019; 59: 1-18. Available at: https://pubmed.ncbi.nlm.nih.gov/30536394/. Accessed July 11, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/25/2020	03/06/2020
Policy was reviewed. 1. Clinical Policy Title Table was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Dosage forms were updated. 5. APPENDIX A: Abbreviation/Acronym Key was updated to include SC. 6. APPENDIX B: Therapeutic Alternatives verbiage was updated to “Below are suggested therapeutic alternatives based on clinical guidance... ” 7. APPENDIX C was updated include detailed contraindications. 8. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 9. Initial Approval criteria: Medicaid approval duration was updated to 3 months. 10. Continued Approval criteria: Medicaid approval duration was updated to 6 months. References were updated.	09/28/2020	12/07/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Initial approval criteria I.A was updated to remove ”Prescribed by……pain specialist”. 3. Initial Approval Criteria I.A.7.a, and Continued Therapy Criteria II.A.4.a was updated to remove,” 70 mg (1 injection) once monthly”. 4. Initial Approval Criteria I.A.7.b, and Continued Therapy Criteria II.A.4.b was updated to remove “if medical justification	10/12/2021	12/07/2021

is provided". 5. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". Appendix B Therapeutic Alternative table was updated to include dosing regimen and maximum dose for divalproex (Depakote®), topiramate (Topamax®), propranolol (Inderal®), metoprolol (Lopressor®), timolol, amitriptyline (Elavil®), venlafaxine (Effexor®). 7. Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 6. References were reviewed and updated.		
Policy was reviewed: 1. Appendix B, Maximum Dose, metoprolol (Lopressor®): Updated maximum dose information from 400 mg/day to 450 mg/day. 2. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 3. References were reviewed and updated.	08/30/2022	10/19/2022
Policy was reviewed: 1. Clinical Policy Title, Drugs applied, Background, Dosing Information, Dosage forms and Appendix C: Contraindications Updated to include information regarding new drug fremanezumab-vfrm (Ajovy®) and atogepant (Qulipta™). 2. Clinical Policy Title, Lines of Business Policy Applies to: Updated from All line of Business to All lines of business (except Medicare). 3. Initial Approval Criteria, I.A.1: Updated diagnosis criteria from Diagnosis of episodic or chronic migraine to Diagnosis of the following (must meet a or b): a. Episodic migraine: between 4 to 14 migraine days per month; b. Chronic migraine: more than 15 headache days per month for ≥ 3 months. 4. Initial Approval Criteria, I.A.2: Updated to	07/11/2023	07/13/2023

remove prior criteria pertaining to indication Migraine Prophylaxis, "Member experiences ≥ 4 migraine days per month for at least 3 months".

5. Initial Approval Criteria, I.A.3: Updated to remove prior age criteria "Age 18 years of age or older".
6. Initial Approval Criteria, I.A.2: Rephrased prior trial and failure therapy criteria and included new therapy drug, Candesartan.
7. Initial Approval Criteria, I.A.3: Updated to include new combination therapy criteria For members currently treated with Botox for migraine (must meet a, b, and c):
   a. Diagnosis of chronic migraine;
   b. Member has tried a minimum of 2 quarterly injections (6 months) of Botox;
   c. Member has experienced and maintained a positive response.
8. Initial Approval Criteria, I.A.4: Updated combination therapy criteria from Aimovig® is not prescribed concurrently with Botox® or other injectable CGRP inhibitors (e.g., Ajovy®, Emgality®) to Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis*. *Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine treatment.
9. Initial Approval Criteria, I.A.6: Updated to remove prior dosing criteria "Dose does not exceed 140 mg (1 injection) once monthly".
10. Initial Approval Criteria, I.A: Updated CGRP monotherapy initial approval duration from 3 to 12 months for Commercial and Medicaid.
11. Initial Approval Criteria, I.A: Updated to include CGRP and Botox dual therapy initial approval duration for Commercial and Medicaid.
12. Continued Therapy Approval Criteria, II.A.1 was updated from Member is currently receiving medication that has been authorized by RxAdvance or the member has previously met initial approval criteria listed in this policy to Member is currently receiving medication, excluding manufacturer samples.

    Continued Therapy Approval Criteria, II.A.2: Updated response to therapy criteria from

Member has experienced and maintained positive response to therapy as evidenced by a reduction in migraine days per month from baseline to Member has experienced and maintained positive response to therapy. 14. Continued Therapy Approval Criteria, II.A.3: Updated to remove concurrently therapy criteria "Aimovig® is not prescribed concurrently with Botox or other injectable CGRP inhibitors (e.g., Ajovy, Emgality)". 15. Continued Therapy Approval Criteria, II.A.3: Updated to include new criteria pertaining to indication Migraine Prophylaxis Members who are treated with Aimovig®, Ajovy®, or Qulipta™ AND Botox for chronic migraine prophylaxis, member has achieved > 50% reduction in the frequency of days with headache or migraine. 16. Continued Therapy Approval Criteria, II.A.4: Updated to remove prior dosing criteria "If request is for a dose increase, new dose does not exceed 140 mg (1 injection) once monthly". 17. Continued Therapy Approval Criteria, II.A.4: Updated to include new combination therapy criteria "Medication is not prescribed in combination with other CGRP inhibitors used for migraine prophylaxis*. *Medication may be prescribed concurrently with other CGRP inhibitors used for acute migraine". 18. Continued Therapy Approval Criteria, II.A: Updated Approval duration from 6 to 12 months for Commercial and Medicaid. 19. Appendix A: Updated to include abbreviation ICHD. 20. Appendix D, General Information: Updated to include new information regarding clinical trial for drug fremanezumab-vfrm (Ajovy®). 13. References were reviewed and updated		
Policy was reviewed.	11/27/2023	11/27/2023