

Clinical Policy: Migraine Prevention Agents

Reference Number: PHW.PDL.537

Effective Date: 01/05/2021

Last Review Date: 11/2023

[Revision Log](#)

Policy/Criteria

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

It is the policy of PA Health and Wellness® that Migraine Prevention Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Migraine Prevention Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Migraine Prevention Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Migraine Prevention Agent, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) for the acute treatment of migraine, see **PHW.PDL.021 Migraine Acute Treatment Agents**; **OR**
2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**
3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
5. Does not have a contraindication to the prescribed medication; **AND**
6. For a Migraine Prevention Agent prescribed for the prevention of migraine, **all** of the following:
 - a. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:

- i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS),
- b. Has documentation of baseline average number of migraine days and headache days per month,
- c. Has averaged four or more migraine days per month over the previous three months,
- d. Has a diagnosis of migraine with or without aura confirmed according to the current International Headache Society Classification of Headache Disorders,
- e. **One** of the following:
- i. Has a history of therapeutic failure of at least **one** preventive medication from **two** of the following three classes:
 - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
 - b) Antidepressants (e.g., amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex)
 - ii. Has a contraindication or an intolerance that prohibits a trial of at least **one** preventive medication from **two** of the following three classes:
 - a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
 - b) Antidepressants (e.g., amitriptyline, venlafaxine),
 - c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex);

AND

7. For a Migraine Prevention Agent prescribed for a diagnosis of episodic cluster headache, **all** of the following:
- a. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS,
 - b. Has a diagnosis of episodic cluster headache confirmed according to the current International Headache Society Classification of Headache Disorders,
 - c. Has a documented history of therapeutic failure of or a contraindication or an intolerance to at least one other preventive medication recommended by current consensus guidelines for episodic cluster headache (such as guidelines from the

American Academy of Neurology, American Academy of Family Physicians, American Headache Society);

AND

8. If currently using a Migraine Prevention Agent for the preventive treatment of migraine or the treatment of episodic cluster headaches, **one** of the following:
 - a. Will discontinue use of that Migraine Prevention Agent prior to starting the requested Migraine Prevention Agent
 - b. Has a medical reason for concomitant use of both Migraine Prevention Agents that is supported by peer-reviewed literature or national treatment guidelines;

AND

9. For a gepant, if currently using a different gepant, **one** of the following:
 - a. Will discontinue use of that gepant prior to starting the requested gepant
 - b. Has a medical reason for concomitant use of both gepants that is supported by peer-reviewed literature or national treatment guidelines;

AND

10. For a preferred gepant for the prevention of migraine, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred CGRP monoclonal antibodies (mAbs) approved or medically accepted for the member's indication; **AND**
11. For a non-preferred Migraine Prevention Agent, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the member's diagnosis or indication; **AND**
See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>;
12. If a prescription for a Migraine Prevention Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override

NOTE: If the member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A MIGRAINE

PREVENTION AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Migraine Prevention Agent that was previously approved will take into account whether the member:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
2. Does not have a contraindication to the prescribed medication; **AND**
3. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:
 - a. A neurologist
 - b. A headache specialist who is certified in headache medicine by the UCNS;

AND

4. For a Migraine Prevention Agent prescribed for the prevention of migraine, **one** of the following:
 - a. Has a reduction in the average number of migraine days or headache days per month from baseline
 - b. Experienced a decrease in severity or duration of migraines from baseline;

AND

5. For a Migraine Prevention Agent prescribed for a diagnosis of episodic cluster headache, has documentation of a positive clinical response to the requested medication as evidenced by a reduction in cluster headache frequency from baseline; **AND**
6. For a preferred gepant for the prevention of migraine, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred CGRP mAbs approved or medically accepted for the member's indication; **AND**
7. For a non-preferred Migraine Prevention Agent, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the member's diagnosis or indication; **AND**

See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>;

8. If a prescription for a Migraine Prevention Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary

will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Migraine Prevention Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. Dose and Duration of Therapy

Requests for prior authorization of Migraine Prevention Agents will be approved as follows:

1. Initial requests for prior authorization of Migraine Prevention Agents prescribed for the prevention of migraine will be approved for up to 6 months.
2. Renewals of requests for prior authorization of Migraine Prevention Agents prescribed for the prevention of migraine will be approved for up to 12 months.
3. Initial requests for prior authorization of Migraine Prevention Agents prescribed for a diagnosis of episodic cluster headache will be approved for up to 4 months.
4. Renewals of requests for prior authorization of Migraine Prevention Agents prescribed for a diagnosis of episodic cluster headache will be approved for up to 6 months.

E. References

1. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021 Jul;61(7):1021-1039. doi: [10.1111/head.14153](https://doi.org/10.1111/head.14153). Epub 2021 Jun 23. PMID: 34160823.
2. Aimovig Package Insert. Thousand Oaks, CA: Amgen Inc.; September 2022.
3. Ajovy Package Insert. North Wales, PA: Teva Pharmaceuticals USA, Inc.; October 2022.

4. Beck E, Sieber, WJ, Trejo R. Management of cluster headache. *American Family Physician*. 2005;71(4):717-724.
5. ClinicalTrials.gov. 12-Week Placebo-controlled Study of Atogepant for the Preventive Treatment of Migraine in Participants With Episodic Migraine. <https://classic.clinicaltrials.gov/ct2/show/NCT03777059>. Accessed August 21, 2023.
6. ClinicalTrials.gov. A study to evaluate the efficacy and safety of erenumab (AMG 334) in chronic migraine prevention. <https://clinicaltrials.gov/ct2/show/NCT02066415>. Accessed July 30, 2018.
7. ClinicalTrials.gov. Efficacy, Safety, and Tolerability of Atogepant for the Prevention of Chronic Migraine. <https://classic.clinicaltrials.gov/ct2/show/NCT03855137>. Accessed August 21, 2023.
8. ClinicalTrials.gov. Study to evaluate the efficacy and safety of erenumab (AMG 334) compared to placebo in migraine prevention (ARISE). <https://clinicaltrials.gov/ct2/show/NCT02483585>. Accessed July 30, 2018.
9. ClinicalTrials.gov. Study to evaluate the efficacy and safety of erenumab (AMG 334) in migraine prevention (STRIVE). <https://clinicaltrials.gov/ct2/show/NCT02456740>. Accessed July 30, 2018.
10. Cohen F, Yuan H, Silberstein SD. Calcitonin Gene-Related Peptide (CGRP)-Targeted Monoclonal Antibodies and Antagonists in Migraine: Current Evidence and Rationale. *BioDrugs*. 2022 May;36(3):341-358. doi: [10.1007/s40259-022-00530-0](https://doi.org/10.1007/s40259-022-00530-0). Epub 2022 Apr 27. PMID: 35476215; PMCID: PMC9043885.
11. Croop R, Lipton RB, Kudrow D, Stock DA, Kamen L, Conway CM, Stock EG, Coric V, Goadsby PJ. Oral rimegepant for preventive treatment of migraine: a phase 2/3, randomised, double-blind, placebo-controlled trial. *Lancet*. 2021 Jan 2;397(10268):51-60. doi: [10.1016/S0140-6736\(20\)32544-7](https://doi.org/10.1016/S0140-6736(20)32544-7). Epub 2020 Dec 15. PMID: 33338437.
12. Emgality Package Insert. Indianapolis, IN: Eli Lilly and Company; March 2021.
13. Garza I, Schwedt T. Chronic migraine. Swanson JW, Robertson CE, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated June 08, 2023. Accessed August 21, 2023.
14. Goadsby PJ, Dodick DW, et al. Trial of galcanezumab in prevention of episodic cluster headache. *N Engl J Med* 2019; 381:132-141. DOI: 10.1056/NEJMoa1813440.
15. Institute for Clinical Systems Improvement. Diagnosis and treatment of headache. eleventh edition. January 2013.
16. International Headache Society. Headache Classification Committee of the International Headache Society (IHS): the international classification of headache disorders, 3rd edition. *Cephalalgia*. 2018; Vol. 38(1):1-211.
17. May A. Cluster headache: Epidemiology, clinical features, and diagnosis. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated June 06, 2023. Accessed August 21, 2023.
18. May A. Cluster Headache: Treatment and Prognosis. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated January 23, 2023. Accessed August 21, 2023.
19. Pringsheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012;39(Suppl 2):S1-S59.
20. Qulipta Package Insert. North Chicago, IL: AbbVie Inc.; June 2023.

21. Schwedt TJ, Garza I. Preventive treatment of episodic migraine in adults. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated June 22, 2023. Accessed August 21, 2023.
22. Silberstein SD, Holland S, Freitag F, et al. 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. *Neurology*. 2012;78:1337-45. Erratum in *Neurology* 2013;80:871.
23. Vyepeti Package Insert. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2022.

Reviews, Revisions, and Approvals	Date
Q1 2021: policy created according to DHS effective 01/05/2021	11/2020
Q1 2022: policy created according to DHS effective 01/03/2022	10/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024: policy created according to DHS effective 01/08/2024	11/2023