

# **Prior Authorization Review Panel**

#### **CHC-MCO** Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	Submission Date: 11/2021	
Policy Number: PHW.PDL.537	Effective Date: 01/05/2021 Revision Date: 10/2021	
Policy Name: Migraine Prevention Agents		
Type of Submission – <u>Check all that apply</u> : 		
<ul> <li>□ New Policy</li> <li>✓ Revised Policy*</li> </ul>		
<ul> <li>Annual Review - No Revisions</li> <li>Statewide PDL - Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</li> </ul>		
*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.		
Please provide any changes or clarifying information for the policy below:		
Q1 2022: policy created according to DHS effective 01/03/2022		
Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:	
Venkateswara R. Davuluri, MD	- Raulun	



# **Clinical Policy: Migraine Prevention Agents**

Reference Number: PHW.PDL.537 Effective Date: 01/05/2021 Last Review Date: 10/2021

# **Policy/Criteria**

**Revision Log** 

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 health plans affiliated with PA Health and Wellness<sup>®</sup> 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 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, contraindication, or intolerance of 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 Nurtec ODT for the prevention of migraine, has a documented history of therapeutic failure, contraindication, or 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, contraindication, or intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the member's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: <u>https://papdl.com/preferred-drug-list;</u> **AND**
- 12. If a prescription for a Migraine Prevention Agent is in 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 history of 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 Nurtec ODT for the prevention of migraine, has a documented history of therapeutic failure, contraindication, or 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, contraindication, or intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the member's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: <u>https://papdl.com/preferred-drug-list;</u> AND
- 8. If a prescription for a Migraine Prevention Agent is in 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. <u>References</u>
  - 1. Aimovig Package Insert. Thousand Oaks, CA: Amgen Inc.; May 2021.
  - 2. Ajovy Package Insert. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2020.
  - 3. Beck E, Sieber, WJ, Trejo R. Management of cluster headache. American Family Physician. 2005;71(4):717-724.
  - ClinicalTrials.gov. A study to evaluate the efficacy and safety of erenumab (AMG 334) in chronic migraine prevention. <u>https://clinicaltrials.gov/ct2/show/NCT02066415.</u> Accessed July 30, 2018.

# CLINICAL POLICY

Migraine Prevention Agents



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- 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: <u>10.1016/S0140-6736(20)32544-7</u>. Epub 2020 Dec 15. PMID: 33338437.
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- 10. 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.
- 11. Institute for Clinical Systems Improvement. Diagnosis and treatment of headache. eleventh edition. January 2013.
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- May A. Cluster headache: Epidemiology, clinical features, and diagnosis. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated July 27, 2020. Accessed July 19, 2021.
- May A. Cluster Headache: Treatment and Prognosis. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated February 21, 2021. Accessed July 19, 2021.
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- 17. 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.
- 18. Vyepti Package Insert. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.

Reviews, Revisions, and Approvals	Date
Q1 2021: policy created according to DHS effective 01/05/2021	11/2020
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