

# **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: N/A
Policy Number: PHW.PDL.537	Effective Date: 01/01/2020 Revision Date: 07/2020
Policy Name: Antimigraine Agents, Other	•
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 when submitting policies for drug classes included on the selection.</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:	
Q3 2020 annual review: no changes.	
Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
Francis G. Grillo, MD	Francis Shym Stille M.D

### **CLINICAL POLICY**

Antimigraine Agents, Other



# **Clinical Policy: Antimigraine Agents, Other**

Reference Number: PHW.PDL.537

Effective Date: 01/01/2020 Last Review Date: 07/2020

**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 health plans affiliated with PA Health and Wellness® that Other Antimigraine Agents are **medically necessary** when the following criteria are met:

### I. Requirements for Prior Authorization of Antimigraine Agents, Other

A. Prescriptions That Require Prior Authorization

All prescriptions for Antimigraine Agents, Other must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antimigraine Agent, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

- 1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package insert OR a medically accepted indication; **AND**
- 2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- 4. Does not have a history of contraindication to the prescribed medication; **AND**
- 5. For a calcitonin gene-related peptide (CGRP) antagonist/inhibitor prescribed for the prevention of migraine, **all** of the following:
  - a. Is prescribed the CGRP antagonist/inhibitor 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),

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- 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 the rapeutic 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 history of contraindication or intolerance to all preventive medications from **all** 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),
- f. Will not be using the requested CGRP antagonist/inhibitor with another CGRP antagonist/inhibitor;

### AND

- 6. For a CGRP antagonist/inhibitor prescribed for a diagnosis of episodic cluster headache, all of the following:
  - a. Is prescribed the CGRP antagonist/inhibitor 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,
  - Has a diagnosis of episodic cluster headache confirmed according to the current International Headache Society Classification of Headache Disorders,
  - c. Has a history of therapeutic failure, contraindication, or intolerance of at least

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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),

d. Will not be using the requested CGRP antagonist/inhibitor with another CGRP antagonist/inhibitor;

### **AND**

- 7. For a non-preferred CGRP antagonist/inhibitor, has a history of therapeutic failure, contraindication, or intolerance to the preferred CGRP antagonists/inhibitors approved or medically accepted for the beneficiary's diagnosis.
- 8. For ergot alkaloids, **both** of the following:
  - a. Has a diagnosis of headache based on the current International Headache Society Classification of Headache Disorders
  - Has a history of trial and failure, contraindication, or intolerance to standard
    first-line abortive medications based on headache classification as
    recommended by current consensus guidelines (such as guidelines from the
    American Academy of Neurology, American Academy of Family Physicians,
    American Headache Society);

### **AND**

9. If a prescription for an Antimigraine Agent, Other 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 beneficiary 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 beneficiary, the request for prior authorization will be approved.

# FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN ANTIMIGRAINE AGENT, OTHER:

The determination of medical necessity of a request for renewal of a prior authorization for an Antimigraine Agent, Other that was previously approved will take into account whether the beneficiary:

- 1. Does not have a history of contraindication to the prescribed medication; **AND**
- 2. For a CGRP antagonists/inhibitor prescribed for the prevention of migraine, **all** of the following:

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- a. **One** of the following:
  - i. Has a reduction in the average number of migraine days or headache days per month from baseline
  - ii. Has experienced a decrease in severity or duration of migraines from baseline,
- b. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
- c. Is prescribed the CGRP antagonist/inhibitor 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;

#### AND

- 3. For a CGRP antagonist/inhibitor prescribed for a diagnosis of episodic cluster headache, **all** of the following:
  - a. Has documentation of a positive clinical response to the requested medication as evidenced by a reduction in cluster headache frequency from baseline,
  - b. Is prescribed a dose and duration of therapy that is consistent with FDA- approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
  - c. Is prescribed the CGRP antagonist/inhibitor 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;

### **AND**

- 4. For ergot alkaloids, **all** of the following:
  - a. Has experienced an improvement in headache pain control or duration
  - b. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

### **AND**

5. If a prescription for an Antimigraine Agent, Other 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

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Override.

NOTE: If the beneficiary 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 beneficiary, 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 an Antimigraine Agent, Other. 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 beneficiary.

# D. Dose and Duration of Therapy

Requests for prior authorization of Antimigraine Agents, Other will be approved as follows:

- 1. Initial requests for prior authorization of CGRP antagonists/inhibitors prescribed for the prevention of migraine will be approved for 6 months.
- 2. Renewals of requests for prior authorization of CGRP antagonists/inhibitors prescribed for the prevention of migraine will be approved for 12 months.
- 3. Initial requests for prior authorization of CGRP antagonists/inhibitors prescribed for a diagnosis of episodic cluster headache will be approved for 4 months.
- 4. Renewals of requests for prior authorization of CGRP antagonists/inhibitors prescribed for a diagnosis of episodic cluster headache will be approved for 6 months.

### E. References

- 1. Aimovig Package Insert. Thousand Oaks, CA: Amgen Inc.; March 2019.
- 2. Ajovy Package Insert. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2018.
- 3. American Headache Society. The American Headache Society position statement on integrating the new migraine treatments into clinical practice. Headache. 2019;59:1-18.
- 4. Bajwa Z, Smith J. Acute treatment of migraine in adults. Waltham, MA: UpToDate Inc. Updated July 31, 2019. Accessed August 2, 2019.
- 5. Bajwa Z, Smith J. Preventive treatment of migraine in adults. Waltham MA:

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- UpToDate Inc. Updated May 21, 2019. Accessed August 2, 2019.
- 6. Beck E, Sieber, WJ, Trejo R. Management of cluster headache. American Family Physician. 2005;71(4):717-724.
- 7. Botox Package Insert. Madison, NJ: Allergan. June 2019.
- 8. 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.
- 9. 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.
- 10. 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.
- 11. D.H.E. 45 Package Insert. Novartis. East Hanover, New Jersey. July 2002.
- 12. Emgality Package Insert. Indianapolis, IN: Eli Lilly and Company; June 2019
- 13. Garza I, Schwedt T. Chronic migraine. UpToDate. Accessed August 6, 2018.
- 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. Waltham MA: UpToDate Inc. Updated October 12, 2018. Accessed July 26, 2019.
- 18. May A. Cluster Headache: Treatment and Prognosis. Waltham MA: UpToDate Inc. Updated March 11, 2019. Accessed July 26, 2019.
- 19. Mayans L, Walling A. Acute migraine headache: treatment strategies. American Family Physician. 2018;97(4):243-251.
- 20. 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.
- 21. 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.

Reviews, Revisions, and Approvals	Date
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