

ISSUE DATE November 12, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below	
SUBJECT Prior Authorization of Migraine Prevention Agents (formerly Antimigraine Agents, Other) – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Migraine Prevention Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of Migraine Prevention Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Migraine Prevention Agents to the appropriate managed care organization.

*01-20-35	09-20-34	27-20-30	33-20-31
02-20-28	11-20-28	30-20-27	
03-20-28	14-20-29	31-20-35	
08-20-38	24-20-28	32-20-27	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the August 12, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Migraine Prevention Agents:

- Revision of the Statewide PDL class name from Antimigraine Agents, Other to Migraine Prevention Agents to more accurately reflect the agents in this PDL class;
- Deletion of the guidelines related to ergot alkaloids because these agents are now included in the Migraine Acute Treatment Agents PDL class; and
- Revision to the guideline for initial and renewal requests for prior authorization of a Migraine Prevention Agent that a beneficiary prescribed a Migraine Prevention Agent for the prevention of migraine or for a diagnosis of episodic cluster headache will not be using the requested Migraine Prevention Agent with another Migraine Prevention Agent or a small molecule calcitonin gene-related peptide receptor antagonist.

The revisions to the guidelines to determine medical necessity of Migraine Prevention Agents, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Migraine Prevention Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Migraine Prevention Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

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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 beneficiary:

1. 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**
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 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),

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- 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 Migraine Prevention Agent with another Migraine Prevention Agent or a small molecule CGRP receptor antagonist (gepant);

AND

6. 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),
 - d. Will not be using the requested Migraine Prevention Agent with another Migraine Prevention Agent or a gepant;

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 beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>; **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 the Quantity Limits Chapter. The list of drugs that

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are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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 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 beneficiary:

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. Will not be using the requested Migraine Prevention Agent with another Migraine Prevention Agent or a gepant; **AND**
7. 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

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into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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 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 beneficiary.

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. Aimovig Package Insert. Thousand Oaks, CA: Amgen Inc.; April 2020.
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.
4. Botox Package Insert. Madison, NJ: Allergan. June 2019.
5. 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.

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6. 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.
7. 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.
8. Emgality Package Insert. Indianapolis, IN: Eli Lilly and Company; December 2019.
9. Garza I, Schwedt T. Chronic migraine. Waltham MA: UpToDate Inc. Updated June 02, 2020. Accessed June 15, 2020.
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.
12. 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.
13. May A. Cluster headache: Epidemiology, clinical features, and diagnosis. Waltham MA: UpToDate Inc. Updated March 10, 2020. Accessed June 15, 2020.
14. May A. Cluster Headache: Treatment and Prognosis. Waltham MA: UpToDate Inc. Updated March 10, 2020. Accessed June 15, 2020.
15. 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.
16. 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.
17. Smith J. Preventive treatment of migraine in adults. Waltham MA: UpToDate Inc. Updated June 05, 2020. Accessed June 15, 2020.
18. Vyepti Package Insert. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.