




Medical Assistance BULLETIN

ISSUE DATE November 6, 2024	EFFECTIVE DATE January 6, 2025	NUMBER *See below
SUBJECT Prior Authorization of Migraine Prevention Agents – Pharmacy Services		BY  Sally 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.pa.gov/en/agencies/dhs/resources/providers/provider-enrollment-information/provider-enrollment-documents.html>.

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 and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Migraine Prevention Agents to the appropriate managed care organization.

BACKGROUND:

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

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-19	09-25-19	27-25-19	33-25-19
02-25-19	11-25-19	30-25-19	
03-25-19	14-25-19	31-25-19	
08-25-20	24-25-19	32-25-19	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
<https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html>

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Migraine Prevention Agents:

- Revision of the guidelines that the beneficiary has a history of therapeutic failure of at least one preventive drug from one of the following three classes: beta-blockers, antidepressants, or anticonvulsants or has a contraindication or intolerance that prohibits a trial of at least one preventive drug from one of the three classes.
- Deletion of the guidelines related to concomitant use of more than one gepant.
- Revision of the guidelines that for a gepant for the prevention of migraine, the beneficiary has a documented history of therapeutic failure of at least two preferred calcitonin gene-related peptide (CGRP) monoclonal antibodies (mAbs) approved or medically accepted for the beneficiary's indication or has a contraindication or intolerance to the preferred CGRP mAbs.
- Addition of a guideline that for a non-preferred gepant for the prevention of migraine, the beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants approved or medically accepted for the beneficiary's indication.

The revisions to the guidelines to determine medical necessity of prescriptions for Migraine Prevention Agents submitted for prior authorization, 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 and products 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II

Pharmacy Prior Authorization Guidelines

<https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html>

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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. For a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) for the acute treatment of migraine, see the prior authorization guideline related to 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 drug; **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:

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- i. Has a history of therapeutic failure of at least one preventive drug from **one** 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 drug from **one** 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 history of therapeutic failure of or a contraindication or an intolerance to at least one other preventive drug 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 medical literature or national treatment guidelines;

AND

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9. For a gepant for the prevention of migraine, **both** of the following:
- a. Has a history of therapeutic failure of or a contraindication or an intolerance to at least two preferred CGRP monoclonal antibodies (mAbs) approved or medically accepted for the beneficiary's indication. See the Preferred Drug List (PDL) for the list of preferred CGRP mAbs at: <https://papdl.com/preferred-drug-list>.
 - b. For a non-preferred gepant for the prevention of migraine, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants approved or medically accepted for the beneficiary's indication. See the PDL for the list of preferred gepants at: <https://papdl.com/preferred-drug-list>;

AND

10. For all other non-preferred Migraine Prevention Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the PDL for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>; **AND**
11. 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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

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 contraindication to the prescribed drug; **AND**
3. Is prescribed the Migraine Prevention Agent by or in consultation with **one** of the following:

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- 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 drug as evidenced by a reduction in cluster headache frequency from baseline; **AND**
- 6. For a gepant for the prevention of migraine, **both** of the following:
 - a. Has a documented history of therapeutic failure of or a contraindication or an intolerance to at least two preferred CGRP mAbs approved or medically accepted for the beneficiary's indication. See the PDL for the list of preferred CGRP mAbs at: <https://papdl.com/preferred-drug-list>.
 - b. For a non-preferred gepant for the prevention of migraine, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred gepants approved or medically accepted for the beneficiary's indication. See the PDL for the list of preferred gepants at: <https://papdl.com/preferred-drug-list>;

AND

- 7. For all other non-preferred Migraine Prevention Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the beneficiary's diagnosis or indication. See the 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 are subject to quantity limits, with accompanying quantity limits, is available at: <https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html>.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the

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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 six 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 four 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 six months.

E. References

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