


ISSUE DATE November 9, 2023	EFFECTIVE DATE January 8, 2024	NUMBER *See below
SUBJECT Prior Authorization of Migraine Prevention Agents – 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 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)

*01-23-46	09-23-45	27-23-36	33-23-43
02-23-34	11-23-34	30-23-37	
03-23-32	14-23-33	31-23-47	
08-23-49	24-23-42	32-23-32	

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>.

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).
- 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 13, 2023, meeting, the P&T Committee recommended revisions to the medical necessity guidelines for Migraine Prevention Agents to clarify that the guideline related to Nurtec ODT for the prevention of migraine applies to all preferred gepants.

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.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>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 guidelines 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 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:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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;

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 beneficiary'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 beneficiary's diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: <https://papdl.com/preferred-drug-list>; **AND**
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 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.

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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 beneficiary'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 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 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.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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. 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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. Vyepiti Package Insert. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; October 2022.