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| ISSUE DATE November 10, 2021 | EFFECTIVE DATE January 3, 2022 | 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 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 MCO.

BACKGROUND:

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| *01-21-34 | 09-21-33 | 27-21-25 | 33-21-33 |
| 02-21-21 | 11-21-23 | 30-21-28 | |
| 03-21-21 | 14-21-24 | 31-21-36 | |
| 08-21-36 | 24-21-31 | 32-21-21 | |

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>.

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 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 September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Migraine Prevention Agents:

- Addition of a guideline that refers to the prior authorization guidelines for Migraine Acute Treatment Agents for requests for a gepant when used for the acute treatment of migraine;
- Revision of the guideline for a contraindication or intolerance to preventive medications when the beneficiary is prescribed a Migraine Prevention Agent for the prevention of migraine;
- Revision of the guidelines regarding concomitant use of more than one Migraine Prevention Agent when prescribed for the preventive treatment of migraine or the treatment of episodic cluster headaches;
- Addition of a guideline regarding concomitant use of more than one gepant;
- Addition of guidelines that for Nurtec ODT for the prevention of migraine, the beneficiary has a documented history of therapeutic failure, contraindication, or intolerance to the preferred calcitonin gene-related peptide monoclonal antibodies approved or medically accepted for the beneficiary's indication; and
- Addition of a guideline to the requests for renewal of the prior authorization section that for a non-preferred Migraine Prevention Agent, the beneficiary 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 or 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 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 provider handbook pages in the SECTION II chapter 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 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 medical literature or national treatment guidelines;

AND

- 9. For a gepant, if currently using a different gepant, **one** of the following:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- 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 medical 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 beneficiary'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 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 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.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:
 - a. A neurologist
 - b. A headache specialist who is certified in headache medicine by the UCNS;

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 beneficiary'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 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**
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.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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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.; 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. Emgality Package Insert. Indianapolis, IN: Eli Lilly and Company; December 2019.
9. Garza I, Schwedt T. Chronic migraine. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated December 9. Accessed July 19, 2021.
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.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

13. 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.
14. 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.
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. Schwedt TJ, Garza I. Preventive treatment of episodic migraine in adults. Swanson JW, Goddeau Jr. RP, eds. Waltham MA: UpToDate Inc. Updated June 2, 2021. Accessed July 19, 2021.
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. Vyepiti Package Insert. Bothell, WA: Lundbeck Seattle BioPharmaceuticals, Inc.; February 2020.