

ISSUE DATE November 12, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below	
SUBJECT Prior Authorization of Migraine Acute Treatment Agents (formerly Antimigraine Agents, Triptans) – 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 Acute Treatment 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 Acute Treatment 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 Acute Treatment Agents to the appropriate managed care organization.

*01-20-34	09-20-33	27-20-29	33-20-30
02-20-27	11-20-27	30-20-26	
03-20-27	14-20-28	31-20-34	
08-20-37	24-20-27	32-20-26	

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 Acute Treatment Agents:

- Revision of the PDL class name from Antimigraine Agents, Triptans to Migraine Acute Treatment Agents to reflect new agents in this PDL class;
- Addition of small molecule calcitonin gene-related peptide receptor antagonists (gepants), serotonin 1F receptor agonists (ditans), and ergot alkaloids to Prescriptions That Require Prior Authorization;
- Addition of a guideline that treatment of the beneficiary's diagnosis with and the prescribed dose of the requested Migraine Acute Treatment Agent are consistent with U.S. Food and Drug Administration (FDA)-approved package labeling or medical literature;
- Addition of a guideline that the beneficiary is of an appropriate age to receive treatment with the requested Migraine Acute Treatment Agent based on FDA-approved package labeling or medical literature;
- Addition of a guideline that the beneficiary does not have a history of a contraindication to the prescribed Migraine Acute Treatment Agent;
- Addition of initial and renewal guidelines for gepants;
- Addition of initial and renewal guidelines for ditans;
- Addition of initial and renewal guidelines for ergot alkaloids;
- Revision of the non-preferred guidelines to address non-preferred triptans separately from other non-preferred Migraine Acute Treatment Agents;
- Revision of the guidelines to determine medical necessity of initial requests for prescriptions for Migraine Acute Treatment Agents that exceed the quantity limits;
- Addition of a guideline to determine that the beneficiary is being prescribed the Migraine Acute Treatment Agent by an appropriate specialist;

- Addition of a guideline for the acute treatment of migraine and documentation of an evaluation for the overuse of abortive medications, including opioids; and
- Addition of guidelines to determine medical necessity of renewal of requests for prior authorization of prescriptions for Migraine Acute Treatment Agents.

The revisions to the guidelines to determine medical necessity of Migraine Acute Treatment 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 Acute Treatment 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 Acute Treatment 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 Acute Treatment Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Migraine Acute Treatment Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant).
2. A prescription for a serotonin (5-HT) 1F receptor agonist (ditan).
3. A prescription for an ergot alkaloid.
4. A non-preferred Migraine Acute Treatment Agent. See the Preferred Drug List (PDL) for the list of preferred Migraine Acute Treatment Agents at: <https://papdl.com/preferred-drug-list>.
5. A Migraine Acute Treatment Agent with a prescribed quantity that exceeds the quantity limit. 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>.
6. A Migraine Acute Treatment Agent when there is a record of a recent paid claim for another Migraine Acute Treatment Agent in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

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

1. **Both** of the following:
 - a. 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
 - b. Has a diagnosis confirmed according to the current International Headache Society Classification of Headache Disorders;

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**

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

4. Does not have a history of contraindication to the prescribed medication; **AND**
5. For a gepant, **both** of the following:
 - a. **One** of the following:
 - i. Has a history of therapeutic failure of at least two (5-HT_{1B/1D}) receptor agonists (triptans)
 - ii. Has a history of contraindication or intolerance to the preferred triptans,
 - b. Will not be using the requested gepant with another gepant or a CGRP monoclonal antibody;

AND

6. For a ditan, has a history of trial and failure, contraindication, or intolerance to the preferred triptans; **AND**
7. For ergot alkaloids, 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**
8. For a non-preferred Migraine Acute Treatment Agent, **one** of the following:
 - a. For a non-preferred triptan, has a history of therapeutic failure, contraindication, or intolerance to the preferred triptans
 - b. For all other non-preferred Migraine Acute Treatment Agents, has a history of therapeutic failure, contraindication, or intolerance to the preferred Migraine Acute Treatment Agents approved or medically accepted for the beneficiary's diagnosis;

AND

9. For therapeutic duplication, **one** of the following:
 - a. Is being titrated to or tapered from another drug in the same class
 - b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

10. If a prescription for a Migraine Acute Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account **all** of the following:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- a. The guidelines set forth in the Quantity Limits Chapter,
- b. Whether the beneficiary is prescribed the requested medication by **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS,
- c. For the acute treatment of migraine, **both** of the following:
 - i. **One** of the following:
 - a) The beneficiary is using the requested medication in addition to at least one medication for migraine prevention (e.g., beta-blocker, anticonvulsant, antidepressant, CGRP monoclonal antibody)
 - b) The beneficiary has a history of therapeutic failure, contraindication, or intolerance to all preventive migraine medications recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society),
 - ii. Has documentation of an evaluation for the overuse of abortive medications, including opioids.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment 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 ACUTE TREATMENT AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Migraine Acute Treatment 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. For a gepant, will not be using the requested gepant with another gepant or CGRP monoclonal antibody; **AND**
4. Has documentation of improvement in headache pain, symptoms, or duration; **AND**
5. If a prescription for a Migraine Acute Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account **all** of the following:

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- a. The guidelines set forth in the Quantity Limits Chapter,
- b. Whether the beneficiary is prescribed the requested medication by **one** of the following:
 - i. A neurologist
 - ii. A headache specialist who is certified in headache medicine by the UCNS,
- c. For the acute treatment of migraine, **both** of the following:
 - i. **One** of the following:
 - a) The beneficiary is using the requested medication in addition to at least one medication for migraine prevention (e.g., beta-blocker, anticonvulsant, antidepressant, CGRP monoclonal antibody)
 - b) The beneficiary has a history of therapeutic failure, contraindication, or intolerance to all preventive migraine medications recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society),
 - ii. Has documentation of an evaluation for the overuse of abortive medications, including opioids.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment 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.

B. 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 Acute Treatment 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.

C. References

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4. Frova Package Insert. Malvern, PA: Endo Pharmaceuticals Inc.; August 2018.

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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