Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 7, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Neuropathic Pain Agents – Pharmacy Services

BY

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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/for-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 Neuropathic Pain 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 Neuropathic Pain 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 Neuropathic Pain 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).

*01-25-22	09-25-22	27-25-22	33-25-22
02-25-22	11-25-22	30-25-22	
03-25-22	14-25-22	31-25-22	
08-25-23	24-25-22	32-25-22	

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 Neuropathic Pain Agents:

- Clarification of the guidelines for the treatment of postherpetic neuralgia related to therapeutic failure of or a contraindication or an intolerance to tricyclic antidepressants and immediate-release gabapentin.
- Clarification of the guideline for the treatment of restless legs syndrome related to therapeutic failure of or a contraindication or an intolerance to immediate-release gabapentin.
- Deletion of the guideline for the treatment of restless legs syndrome related to therapeutic failure of or a contraindication or an intolerance to pramipexole or ropinirole.
- Deletion of the guidelines related to documentation that the prescriber or prescriber's delegate conducted a search of the Prescription Drug Monitoring Program.
- Addition of a guideline for the determination of medical necessity of a request for renewal of the prior authorization of a prescription for a non-preferred Neuropathic Pain Agent except gabapentin extended-release and gabapentin enacarbil extended-release.
- Specification that requests for renewal of the prior authorization of prescriptions that represent a therapeutic duplication require prior authorization.

The revisions to the guidelines to determine medical necessity of prescriptions for Neuropathic Pain 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 Neuropathic Pain 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 Neuropathic Pain 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

I. Requirements for Prior Authorization of Neuropathic Pain Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Neuropathic Pain Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Neuropathic Pain Agent. See the Preferred Drug List (PDL) for the list of preferred Neuropathic Pain Agents at: https://papdl.com/preferred-drug-list.

2. A Neuropathic Pain 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

3. A prescription for a gabapentinoid when there is a record of a recent paid claim for another gabapentinoid 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 Neuropathic Pain 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 prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. For gabapentin extended-release for the treatment of postherpetic neuralgia, has a history of **both** of the following:

   a. Therapeutic failure of the maximum tolerated dose of a tricyclic antidepressant or a contraindication or an intolerance to tricyclic antidepressants
   b. Therapeutic failure of the maximum tolerated dose of immediate-release gabapentin or a contraindication or an intolerance to immediate-release gabapentin that would not be expected to occur with the requested drug;

   AND

4. For gabapentin enacarbil extended-release, **one** of the following:

   a. For the treatment of postherpetic neuralgia, has a history of **both** of the following:

i. Therapeutic failure of the maximum tolerated dose of a tricyclic antidepressant or a contraindication or an intolerance to tricyclic antidepressants
ii. Therapeutic failure of the maximum tolerated dose of immediate-release gabapentin or a contraindication or an intolerance to immediate-release gabapentin that would not be expected to occur with the requested drug

b. For the treatment of moderate to severe primary restless legs syndrome, has a history of therapeutic failure of the maximum tolerated dose of immediate-release gabapentin or a contraindication or an intolerance to immediate-release gabapentin that would not be expected to occur with the requested drug;

AND

5. For all other non-preferred Neuropathic Pain Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Neuropathic Pain Agents approved or medically accepted for the beneficiary's diagnosis; **AND**

6. For therapeutic duplication of a gabapentinoid, **one** of the following:

a. Is being titrated to or tapered from another gabapentinoid
b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

7. If a prescription for a Neuropathic Pain 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.

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 NEUROPATHIC PAIN AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Neuropathic Pain Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the requested drug; **AND**

2. For a non-preferred Neuropathic Pain Agent except gabapentin extended-release and gabapentin enacarbil extended-release, has a history of therapeutic failure of or a

contraindication or an intolerance to the preferred Neuropathic Pain Agents approved or medically accepted for the beneficiary's diagnosis; **AND**

3. For therapeutic duplication of a gabapentinoid, **one** of the following:

   a. Is being titrated to or tapered from another gabapentinoid
   b. Has a medical reason for concomitant use of the requested drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

4. If a prescription for a Neuropathic Pain 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.

   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.

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 Neuropathic Pain 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. References

1. Gralise [package insert]. Morristown, NJ: Almatica Pharma LLC; April 2023.
2. Horizant [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; April 2020.
3. Shefner JM. Postherpetic neuralgia. In: UpToDate [internet database]. Swanson JW, Goddeau RP, eds. Waltham, MA: UpToDate Inc. Updated August 2, 2024. Accessed August 16, 2024.
4. Silber MH. Management of restless legs syndrome and periodic limb movement disorder in adults. In: UpToDate [internet database]. Hurtig HI, Avidan AY, Eichler AF, eds. Waltham, MA: UpToDate Inc. Updated June 14, 2024. Accessed August 16, 2024.