

<b>ISSUE DATE</b>  October 28, 2019	<b>EFFECTIVE DATE</b>  January 1, 2020	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Neuropathic Pain Agents – Pharmacy Services		<b>BY</b>   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:  
[http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**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 and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Neuropathic Pain Agents to the appropriate managed care organization.

**BACKGROUND/DISCUSSION:**

The Department of Human Services' (Department) Drug Utilization Review Board previously identified potential health and safety risks when two or more drugs within the same therapeutic class are used concurrently (therapeutic duplication). The board recommended

*01-19-73	09-19-69	27-19-67	33-19-69
02-19-67	11-19-66	30-19-65	
03-19-66	14-19-65	31-19-72	
08-19-75	24-19-67	32-19-65	

<p><b>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</b></p> <p>The appropriate toll-free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at  <a href="http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm">http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm</a></p>
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that the Department require prior authorization of these drugs when the Department's online claims adjudication system determines that there is a record of a recent paid claim for a different drug within the same therapeutic class. The Department is updating the prior authorization guidelines for Neuropathic Pain Agents to include a requirement for prior authorization of prescriptions for gabapentinoids (e.g., gabapentin, pregabalin) that may represent a therapeutic duplication.

Additional updates to the medical necessity guidelines for Neuropathic Pain Agents made by the Department include:

- Addition of a guideline that the prescriber or the prescriber's delegate conduct a search of the Pennsylvania Prescription Drug Monitoring Program for the beneficiary's controlled substance prescription history when prescribing a Neuropathic Pain Agent that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance) and
- Addition of a guideline that treatment of the beneficiary's diagnosis with and the prescribed dose of the requested Neuropathic Pain Agent are consistent with FDA-approved labeling or medical literature.

The revisions to the guidelines to determine medical necessity of Neuropathic Pain Agents 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 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

<http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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: <http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm>.
3. A prescription for a gabapentinoid when there is a record of a recent paid claim for another gabapentinoid in the Department of Human Services' 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 Gralise (gabapentin extended-release), has a history of therapeutic failure, contraindication, or intolerance to **both** of the following:
  - a. Tricyclic antidepressants
  - b. Regular-release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day);

**AND**

4. For Horizant (gabapentin enacarbil), **one** of the following:
  - a. For a diagnosis of postherpetic neuralgia, has a documented history of therapeutic failure, intolerance, or contraindication to **both** of the following:
    - i. Tricyclic antidepressants

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- ii. Regular-release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)
- b. For a diagnosis of moderate-to-severe primary restless leg syndrome, has a documented history of therapeutic failure, intolerance, or contraindication to **both** of the following:
  - i. Regular-release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)
  - ii. **One** of the following:
    - a) Pramipexole
    - b) Ropinirole;

**AND**

- 5. For all other non-preferred Neuropathic Pain Agents, has a history of therapeutic failure, contraindication, or intolerance of the preferred Neuropathic Pain Agents approved or medically accepted for the beneficiary's diagnosis; **AND**
- 6. For a Neuropathic Pain Agent that is subject to the U.S. Drug Enforcement Agency (DEA) Controlled Substances Act (i.e., controlled substance), has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history; **AND**
- 7. 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 medications that is supported by peer-reviewed literature or national treatment guidelines;

**AND**

- 8. 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

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Neuropathic Pain Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; **AND**
2. For a Neuropathic Pain Agent that is subject to the DEA Controlled Substances Act (i.e., controlled substance), has documentation that the prescriber or the prescriber's delegate conducted a search of the PDMP for the beneficiary's controlled substance prescription history; **AND**
3. 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

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