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| ISSUE DATE July 23, 2018 | EFFECTIVE DATE July 23, 2018 | NUMBER *See below |
| SUBJECT Prior Authorization of Neuropathic Pain 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:

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 under the MA managed care delivery system should address any questions related to Neuropathic Pain Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the following:

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| *01-18-16 | 09-18-17 | 27-18-15 | 33-18-16 |
| 02-18-11 | 11-18-11 | 30-18-11 | |
| 03-18-11 | 14-18-12 | 31-18-17 | |
| 08-18-18 | 24-18-12 | 32-18-11 | |

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 Web site at:

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

- 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 the PDL; and
- Guidelines to determine medical necessity.

DISCUSSION:

During the May 16, 2018, meeting, the P&T Committee recommended a change in the status of lidocaine 5% topical patch from non-preferred to preferred in order to provide an additional non-opioid alternative for the treatment of pain. DHS proposed to remove the guidelines related to a determination of medical necessity of lidocaine 5% topical patch as it will no longer require prior authorization. The proposed deletion was subject to public review and comment, and subsequently approved for implementation by DHS with updated handbook pages that reflect this change.

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. DHS 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

SECTION II
Neuropathic Pain Agents

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Neuropathic Pain Agents (Formerly Myalgia and Neuropathy Agents)

A. Prescriptions That Require Prior Authorization

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

1. Non-preferred Neuropathic Pain Agents, regardless of the quantity prescribed. See the most recent Preferred Drug List (PDL) for the list of preferred and non-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. See Quantity Limits for the list of drugs with quantity limits at:
http://www.dhs.pa.gov/cs/groups/webcontent/documents/document/s_002077.pdf

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 the following:

1. For Gralise (gabapentin extended release) whether the beneficiary:
 - a. Has a diagnosis of postherpetic neuralgia (PHN)

AND
 - b. Has a documented history of therapeutic failure, contraindication or intolerance to tricyclic antidepressants and regular release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)

AND
 - c. Does not have a creatinine clearance less than 30 mL/min

OR

2. For Horizant (gabapentin enacarbil), whether the beneficiary is being prescribed a dose of the requested medication that is appropriate for his/her renal function according to package labeling **AND**

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- a. Has a diagnosis of postherpetic neuralgia (PHN)

AND

- b. Has a documented history of therapeutic failure, intolerance, or contraindication to tricyclic antidepressants and therapeutic failure or intolerance to regular release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)

OR

- c. Has a diagnosis of moderate-to-severe primary Restless Leg Syndrome (RLS)

AND

- d. Has a documented history of therapeutic failure or intolerance to regular release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day) and therapeutic failure, contraindication or intolerance to pramipexole or ropinirole.

- 3. For all other non-preferred Neuropathic Pain Agents, whether the beneficiary has a documented history of therapeutic failure, contraindication or intolerance to the preferred Neuropathic Pain Agents with the same indication.
- 4. In addition, if a prescription for either a preferred or non-preferred 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 that are set forth in the Quantity Limits Chapter.

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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.

- 5. For requests for renewals of prior authorization of a non-preferred Neuropathic Pain Agent, whether the MA beneficiary has a documented clinical response showing symptom improvement or stabilization.

C. Clinical Review Process

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All requests for prior authorization of a Neuropathic Pain Agent will be automatically forwarded to a physician reviewer for a medical necessity determination.

The physician reviewer will prior authorize the prescription when:

1. The guidelines in Section B are met, **OR**
2. In the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

References:

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6. Wolfe F, Smythe HA, Yunus MB, et al. "The American College Of Rheumatology 1990 Cirteria For The Classification Of Fibromyalgia." *Arthritis and Rheumatism* 33.2 (1990): 160-72.
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