# Clinical Policy: Neuropathic Pain Agents

Reference Number: PHW.PDL.232
Effective Date: 01/01/2020
Last Review Date: 11/2023

Revision Log

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health and Wellness® that Neuropathic Pain Agents are **medically necessary** when the following criteria are met:

**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.

2. A Neuropathic Pain Agent with a prescribed quantity that exceeds the quantity limit.

3. A prescription for a gabapentinoid (e.g., gabapentin, pregabalin) when there is a record of a recent paid claim for another gabapentinoid (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 historyof 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
      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 (RLS), 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 (CSA) (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 PA.CP.PMN.59 Quantity Limit Override.

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 tolerability and a positive clinical response to the medication; **AND**

2. For a Neuropathic Pain Agent that is subject to the U.S. Drug Enforcement Agency (DEA) Controlled Substances Act (CSA) (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**

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 PA.CP.PMN.59 Quantity Limit Override.

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. **Approval Duration:**
- **New Request: 6 months**
- **Renewal Request: 12 months**

E. References

1. Mease, P. J. Further strategies for treating fibromyalgia: the role of serotonin and norepinephrine reuptake inhibitors. Am J Med 122.12 (2009): S44-55. PubMed.gov. U.S. National Library of Medicine.
2. Savella [package insert]. Allergan USA, Inc. Irvine, CA. November 2017.
3. Cymbalta [package insert]. USA, LLC. Indianapolis, IN. December 2017.
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5. National Guideline Clearinghouse. Fibromyalgia Treatment Guideline. 2009.
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.
7. National Guideline Clearinghouse. Guideline for the management of fibromyalgia syndrome pain in adults and children. 2009.
8. Goldenberg, DL et.al. Differential diagnosis of fibromyalgia. UpToDate. Accessed October 28, 2011.
9. Bajwa ZH et.al. Postherpetic neuralgia. UpToDate. Accessed October 28, 2011.
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11. R. M. Dubinsky et al. Practice Parameter: Treatment of postherpetic neuralgia: An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2004;63;959
12. UpToDate, Postherpetic neuralgia. Accessed October 18, 2012
13. UpToDate, Restless leg syndrome. Accessed October 18, 2012.
14. Gralise [package insert]. Depomed, Inc. Newark, CA. September 2015.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 01/01/2020 |
| Q3 2020 annual review: no changes. | 07/2020 |
| Q1 2021 annual review: no changes. | 01/2021 |
| Q1 2022 annual review: no changes. | 11/2021 |
| Q1 2023 annual review: no changes. | 11/2022 |
| Q1 2024 annual review: no changes. | 11/2023 |