wellsense.org | 877-957-1300

**Pharmacy Policy**

# Pregabalin and Lyrica

**Policy Number:** 9.206
**Revision Number:** R0
**Version Effective Date:** 1/1/2021

| Product Applicability | ☐ **All Plan[+] Products** |
|---|---|
| **Well Sense Health Plan**<br>☒ New Hampshire Medicaid | **Boston Medical Center HealthNet Plan**<br>☐ MassHealth - MCO<br>☐ MassHealth - ACO<br>☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☐ Senior Care Options |

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

**Products Affected:**

- Pregabalin
- **Lyrica® (pregablain)**
- **Lyrica® CR (pregabalin extended-release)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

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| **Covered Use** | All FDA approved indications not otherwise excluded |
| **Required Medical Information** | **For Pregabalin:**<br><br>A diagnosis of one of the following: |

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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| | 1. Fibromyalgia; ***AND***<br>a. An inadequate response, intolerance, or contraindication to a trial of all of the following;<br>i. Tricyclic antidepressant; **AND**<br>ii. Duloxetine; **AND**<br>iii. Gabapentin **AND**<br><br>b. For brand Lyrica only: An inadequate response, intolerance, or contraindication to a trial of generic pregabalin<br><br>2. Neuropathic pain associated with diabetic neuropathy; ***AND***<br>a. An inadequate response, intolerance, or contraindication to a trial of all of the following;<br>i. Tricyclic antidepressant; **AND**<br>ii. Duloxetine; **AND**<br>iii. Gabapentin **AND**<br><br>b. For brand Lyrica and Lyrica CR only: An inadequate response, intolerance, or contraindication to a trial of generic pregabalin<br><br>3. Neuropathic pain associated with spinal cord injury; ***AND***<br>***a.*** Inadequate response, intolerance or contraindication to a trial of Gabapentin; ***AND***<br><br>b. For brand Lyrica only: An inadequate response, intolerance, or contraindication to a trial of generic pregabalin<br><br>4. Post-herpetic neuralgia***; AND***<br>a. An inadequate response, intolerance, or contraindication to a trial of both of the following;<br>i. Tricyclic antidepressant; AND<br>ii. Gabapentin **AND**<br><br>b. For brand Lyrica and Lyrica CR only : An inadequate response, intolerance, or contraindication to a trial of generic pregabalin.<br><br>5. Partial seizure disorder (adjunctive therapy); ***AND***<br>a. For Lyrica only: An inadequate response or intolerance to a trial of at least two preferred formulary anticonvulsants. (Appendix A) |
| **Prescriber** | Fibromyalgia: Prescribed by or in consultation with a rheumatologist, physiatrist, pain |

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| **Restriction** | management specialist or neurologist |
| **Coverage Duration** | Initial:<br>• Seizure Diagnosis: Lifetime<br>• All other diagnoses: 12 months<br>Reauthorization: 12 months |
| **Quantity Limit** | Pregabalin and Lyrica 25mg, 50mg, 75mg, 100mg, 150mg, 200mg: 3 per day<br>Pregabalin and Lyrica 225mg, 300mg: 2 per day<br>Pregabalin and Lyrica solution: 30mL per day<br>Lyrica® CR 82.5 mg, 165 mg, 330 mg extended-release: 1 capsule per day |
| **Other criteria** | *Lyrica CR is only indicated for use in Neuropathic pain associated with diabetic peripheral neuropathy AND Post-herpetic neuralgia. |

Appendix A:

| **Preferred Products: Anticonvulsants – Second Generation** | |
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| clobazam (generic for Onfi®) | pregabalin (generic for Lyrica®) (requires additional clinical PA) |
| gabapentin (generic for Neurontin®) | tiagabine (generic for Gabitril®) |
| Gabitril® | topiramate ER (generic for Qudexy XR®) |
| lamotrigine/ODT/XR (generic for Lamictal®/ODT/XR) | vigabatrin (generic for Sabril®) |
| levetiracetam/ER (generic for Keppra/XR®) | zonisamide (generic for Zonegran®) |

**Clinical Background Information and References**


1. Lyrica (pregabalin) [prescribing Information] New York, NY; Pfizer Inc.; December2016.
2. Lexi-Drugs Online: Pregabalin [cited May 26, 2015].
3. Blommel ML, Blommel AL. Pregabalin: an antiepileptic agent useful for neuropathic pain. Am J Health Syst Pharm. 2007;64(14):1475-1482.
4. Marcus D. Treatment of Nonmalignant Chronic Pain. Am Fam Physician 2000 Vol. 61:1331-8, 1345-6Bril V, England J, Franklin GM, et al, "Evidence-Based Guideline: Treatment of Painful Diabetic Neuropathy: Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation," Neurology, 2011, 76(20):1758-65.
5. Lyseng-Williamson KA, Siddiqui MA. Pregabalin: a review of its use in fibromyalgia. Drugs. 2008;68(15):2205-2223


| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|---|---|---|---|
| 9/10/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee, NH DHHS |

| Policy Revisions History | | | |
|---|---|---|---|
| **Review Date** | **Summary of Revisions** | **Revision Effective Date** | **Approved by** |
| 9/10/2020 | P&T annual review, Retired Policy 9.088 and created a separate policy for each applicable line of business. Addition of partial onset and adjunctive therapy to seizure indication. Addition of other criteria information to include specific indications for Lyrica CR product. Separate each covered drug based on NH PDL limitations. Added Pregabalin solution as preferred and removed all brand Lyrica formulations to NP. Added specific Lyrica CR FDA approved indications. | 1/1/2021 | P&T Committee, NH DHHS |

**Next Review Date**

2021

**Other Applicable Policies**

**Reference to Applicable Laws and Regulations, If Any**

**Disclaimer Information**

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated

on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.