

**Pharmacy Policy**

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**Pregabalin**

**Policy Number:** 9.206

**Version Number:** 2.0

**Version Effective Date:** 6/01/2021

Product Applicability <input type="checkbox"/> <b>All Plan<sup>+</sup> Products</b>	
<b>Well Sense Health Plan</b>	<b>Boston Medical Center HealthNet Plan</b>
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth - MCO
	<input checked="" type="checkbox"/> MassHealth - ACO
	<input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

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

**Prior Authorization Policy**

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**Products Affected:**

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

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Required Medical Information</b>	A diagnosis of one of the following: <ol style="list-style-type: none"> <li>1. Fibromyalgia; <b>AND</b> <ol style="list-style-type: none"> <li>a. An inadequate response, intolerance, or contraindication to a trial of all of the following;               <ol style="list-style-type: none"> <li>i. Tricyclic antidepressant; <b>AND</b></li> <li>ii. Duloxetine; <b>AND</b></li> <li>iii. Gabapentin; <b>OR</b></li> </ol> </li> </ol> </li> </ol>

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	<p>2. Neuropathic pain associated with diabetic neuropathy; <b>AND</b></p> <p>a. An inadequate response, intolerance, or contraindication to a trial of all of the following;</p> <p>i. Tricyclic antidepressant; <b>AND</b></p> <p>ii. Duloxetine; <b>AND</b></p> <p>iii. Gabapentin; <b>OR</b></p> <p>3. Neuropathic pain associated with spinal cord injury; <b>AND</b></p> <p>a. Inadequate response, intolerance or contraindication to a trial of Gabapentin; <b>OR</b></p> <p>4. Post-herpetic neuralgia; <b>AND</b></p> <p>a. An inadequate response, intolerance, or contraindication to a trial of all of the following;</p> <p>i. Tricyclic antidepressant; <b>AND</b></p> <p>ii. Gabapentin; <b>OR</b></p> <p>5. Partial Seizure disorder (adjunctive therapy); <b>AND</b></p> <p>a. An inadequate response or intolerance to a trial of at least one formulary anticonvulsant</p>
<b>Prescriber Restriction</b>	Fibromyalgia: Prescribed by or in consultation with a rheumatologist, physiatrist, pain management specialist or neurologist
<b>Reauthorization Criteria:</b>	<p>1. Currently receiving medication via BMCHP benefit or member has previously met initial approval criteria. <b>AND</b></p> <p>2. Member has experienced a positive clinical response to therapy.</p>
<b>Coverage Duration</b>	<p>Seizure Diagnosis: Lifetime</p> <p>All other diagnoses: 12 months</p>
<b>Quantity Limit</b>	<p>Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg: 3 per day</p> <p>Pregabalin 225mg, 300mg: 2 per day</p> <p>Pregabalin solution: 30mL per day</p>

## Clinical Background Information and References

1. Lyrica (pregabalin) [prescribing information]. New York, NY: Parke-Davis, Division of Pfizer Inc; April 2020.
2. Lyrica CR (pregabalin) [prescribing information]. New York, NY: Parke-Davis, Division of Pfizer Inc; April 2020.
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, 1345-6 Brill 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

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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

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
9/10/2020	P&T annual review, Discontinue Policy 9.088. Created a separate policy for Pregabalin per each applicable line of business. Addition of criteria that Pregabalin will be used as an adjunctive therapy for members with a diagnosis of partial onset seizures.	1/1/2021	P&T Committee
2/11/2021	P & T annual review. Addition of reauthorization criteria to ensure appropriate continued use of this medication.	6/01/2021	P&T Committee

**Next review Date:**

February 2022

**Other Applicable Policies**

9.500 Pediatric Behavioral Health Initiative

**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

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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.

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