

## Pharmacy Medical Necessity Guidelines: Lyrica® (pregabalin)

Effective: July 20, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans</li> <li>• CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)</li> <li><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans</li> <li><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan</li> </ul>		<p><b>Fax Numbers:</b> RXUM: 617.673.0988</p>	

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### **FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Lyrica (pregabalin) is indicated for:

- Management of neuropathic pain associated with diabetic peripheral neuropathy
- Management of postherpetic neuralgia
- Adjunctive therapy for adult patients with partial onset seizures
- Management of fibromyalgia
- Management of neuropathic pain associated with spinal cord injury

### COVERAGE GUIDELINES

**Note:** Prescriptions that meet the initial step therapy requirements, will adjudicate at the point of service. If the member does not meet the initial step therapy criteria, then the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to the plan using the Universal Pharmacy Medical Review Request Form for members who do not meet the step therapy criteria at the point of service.

**Please refer to the table below for formularies and medications subject to this policy:**

Drug	Tufts Health Plan Large Groups	Tufts Health Plan Small Groups and Individual Plans
<b>Step-1</b>		
gabapentin	Covered	Covered
<b>Step-2</b>		
pregabalin	Requires prior use of a drug on Step-1 or Step-2	Requires prior use of a drug on Step-1 or Step-2

#### **Automated Step Therapy Coverage Criteria**

The following stepped approach applies to coverage of the Step-2 medications by the plan:

**Step 1:** Medications on Step-1 are covered without prior authorization

**Step 2:** The plan may cover pregabalin if the following criteria are met:

1. The Member has had a trial of gabapentin within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan.

**Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale**

The following stepped approach applies to pregabalin:

**Step 2:** The plan may cover Step-2 medications if the following criteria are met:

1. The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use.

**OR**

2. The Member has a physician documented contraindication or intolerance to all Step-1 medication

**Note:** The plan may authorize coverage of pregabalin for Members, when any of the following criteria below are met:

1. **Partial onset seizures:**
  - a. Diagnosis of partial onset seizures.

**LIMITATIONS**

- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.
- The brand-name Lyrica is not covered as of January 1, 2020 for all Tufts Health Plan Commercial formularies. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs with Suggested Alternatives.

**CODES**

None

**REFERENCES**

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3. Dworkin RH, Backonja M, Rowbotham MC, et al. Advances in neuropathic pain: diagnosis, mechanisms, and treatment recommendations. *Arch Neurol.* 2003 Nov;60(11):1524-34.
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6. Levendoglu F, Ogun CO, Ozerbil O, et al. Gabapentin is a first line drug for the treatment of neuropathic pain in spinal cord injury. *Spine.* 2004 Apr 16;29(7):743-51.
7. Lyrica (pregabalin) [package insert]. New York, NY: Pfizer Pharmaceuticals LLC; May 2019.
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12. Tai Q, Kirshblum S, Chen B, et al. Gabapentin in the treatment of neuropathic pain after spinal cord injury: a prospective, randomized, double-blind, crossover trial. *Journal of Spinal Cord Medicine.* 2002;25(2):100-5.
13. Teasell RW, Mehta S, Aubut JA, et al. A systematic review of pharmacologic treatments of pain after spinal cord injury. *Arch Phys Med & Rehab.* 2010 May;91(5):816-31.

**APPROVAL HISTORY**

December 13, 2005: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2006: Added coverage criteria for partial onset seizures. For Diabetic peripheral neuropathy criteria, changed "amitriptyline" to "tri-cyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine, etc.) Added criteria for the treatment of neuropathic pain
- March 13, 2007: Added initial step therapy criteria. Added clarification for when to apply clinical coverage criteria: The Step Therapy edits do not find that the Member has had a previous paid claim for a 30-day supply of gabapentin under the prescription benefit administered by Tufts Health Plan within the previous 180 days. The Member has failed a trial of gabapentin more than 180 days ago. The Member is a new Member to Tufts Health Plan. Removed failure of a tricyclic antidepressant from criteria. Removed the age limitation for the diagnoses of DPN or PHN. Removed requirement that the diagnosis be made by "a pain specialist" from criteria for other neuropathic pain conditions
- September 11, 2007: Added coverage criteria for fibromyalgia
- September 9, 2008: Added restriction that the use of samples is excluded from evidence of a trial of gabapentin. Added limitation that previous use of samples or vouchers/coupons for Lyrica (pregabalin) will not be considered for authorization.
- September 8, 2009: Moved Tufts Health Plan Medicare Preferred MA-PD and PDP formularies to step therapy table
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- September 14, 2010: No changes
- September 13, 2011: No changes
- September 9, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drug
- June 12, 2012: Administrative update: removed historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs. Clarified step criteria to reflect that Step-2 drugs are prerequisites for drugs on Step-2
- August 14, 2012: Added neuropathic pain associated with spinal cord injury indication to clinical coverage criteria
- June 11, 2013: No changes
- October 8, 2013: Administrative update: Removed requirement of 30-day trial and replaced with just a previous trial of the medication.
- April 1, 2014: Administrative Update: Removed language pertaining to the Generic Focused Formulary and added the EHB MA/RI formulary.
- June 10, 2014: No changes
- June 9, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- May 10, 2016: No changes
- May 9, 2017: No changes; Administrative update, Adding Tufts Health RITogether to the template
- October 16, 2018: No changes
- August 13, 2019: Effective January 1, 2020, moved Lyrica to non-covered status for all Commercial formularies, due to launch of the generic. Updated step therapy criteria to require trial and failure with, or contraindication to lower step medications and updated require to list diagnosis of partial onset seizures as an indication not requiring trial and failure with gabapentin.
- July 14, 2020: Removed sample exclusion language from coverage criteria and updated sample limitation to the following: Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.