Pharmacy Medical Necessity Guidelines: Lyrica® (pregabalin)

Effective: May 9, 2017

Prior Authorization Required

<table>
<thead>
<tr>
<th>Pharmacy (RX) or Medical (MED) Benefit</th>
<th>Type of Review – Care Management</th>
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<td>√</td>
<td>Type of Review – Clinical Review</td>
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<tr>
<th>Not Covered</th>
<th>√ Type of Review – Care Management</th>
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<th>Pharmacy (RX) or Medical (MED) Benefit</th>
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<td>RX</td>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Together – A MassHealth Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

**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:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Tufts Health Plan Large Groups</th>
<th>Tufts Health Plan Small Groups and Individual Plans</th>
</tr>
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<tbody>
<tr>
<td><strong>Step-1</strong></td>
<td></td>
<td></td>
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<tr>
<td>gabapentin</td>
<td>Covered</td>
<td>Covered</td>
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<tr>
<td><strong>Step-2</strong></td>
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<tr>
<td>Lyrica (pregabalin)</td>
<td>Requires prior use of a drug on Step-1 or Step-2</td>
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**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 Lyrica (pregabalin) if the following criteria are met:
- 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 Lyrica (pregabalin):
Step 2: The plan may cover Step-2 medications if the following criteria are met:
- The Member has had a trial of a Step-1 or Step-2 medication as evidenced by physician documented use, excluding the use of samples.

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

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

2. **For Diabetic Peripheral Neuropathy (DPN) and Postherpetic Neuralgia (PHN):**
   a. Documented inadequate response to an appropriate trial with gabapentin

3. **For other neuropathic pain conditions:**
   a. Documented diagnosis of neuropathic pain

   AND

   b. The Member has failed standard medication treatment and/or pain management, including gabapentin

4. **For fibromyalgia**
   a. The Member has a documented diagnosis of fibromyalgia

   AND

   b. The Member has failed standard medication treatment and/or pain management, including gabapentin

5. **For neuropathic pain associated with spinal cord injury**
   a. Documented diagnosis of neuropathic pain associated with spinal cord injury

   AND

   b. The Member has failed standard medication treatment and/or pain management, including gabapentin

**LIMITATIONS**
1. Previous use of samples or vouchers/coupons for Lyrica (pregabalin) will not be considered for authorization.

**CODES**
None

**REFERENCES**

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 “tricyclic 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.

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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.
This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.