Pharmacy Medical Necessity Guidelines: Vimpat® (lacosamide)

Effective: July 11, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>✓</th>
<th>Type of Review – Care Management</th>
</tr>
</thead>
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<tr>
<td>Not Covered</td>
<td></td>
<td>Type of Review – Clinical Review ✓</td>
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<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RX</td>
<td>Department to Review RXUM</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 Direct – Health Connector
- ✓ Tufts Health Together – A MassHealth Plan
- ✓ Tufts Health RITogether – A RIte Care + Rhody Health Partners 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 Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

Vimpat (lacosamide) is available as both an oral and intravenous (IV) formulation as monotherapy or adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy. The availability of an IV formulation avoids the risks associated with switching to an alternative therapy when oral therapy is no longer feasible. Vimpat (lacosamide) has a novel dual mechanism of action, which results in controlled neuronal hyperexcitability and potentially decreases the neuronal loss.

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Vimpat (lacosamide) tablets and oral solution are indicated as monotherapy or adjunctive therapy in patients with partial-onset seizures. Vimpat (lacosamide) injection is indicated as short term replacement when oral administration is not feasible.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Vimpat (lacosamide) for Members when all of the following criteria are met:
1. Documented diagnosis of partial-onset seizures by a neurologist
   AND
2. One of the following:
   a. The member is stable on the medication
   OR
   b. The member has had an insufficient response or intolerance to at least two (2) other medications indicated for adjunct partial seizures (see examples) OR the provider indicates clinical inappropriateness of treatment with the alternative medications

Examples:
- felbamate
- tiagabine
- lamotrigine
- pregabalin
- levetiracetam
- gabapentin
- topiramate
- oxcarbazepine
- zonisamide

**LIMITATIONS**

1. The following quantity limitations apply:

<table>
<thead>
<tr>
<th>Vimpat (lacosamide) tablets</th>
<th>180 tablets per 90 days</th>
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<tr>
<td>Vimpat (lacosamide) oral solution</td>
<td>1,200 mLs per 30 days</td>
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2. Vimpat (lacosamide) injection for IV use is covered under the medical benefit without prior authorization.

CODES
None

REFERENCES

APPROVAL HISTORY
July 14, 2009: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
- July 13, 2010: No changes
- September 14, 2010: Added solution to the criteria title. Added "oral solution" to the FDA-Approved indications. Added the limitation for Vimpat oral solution to be 1200 mLs per 30 days for each dispense.
- September 13, 2011: No changes
- September 11, 2012: No changes
- July 9, 2013: No changes
- July 8, 2014: Changed criteria #2: The member is stable on the medication OR the member has had an insufficient response or intolerance to at least two (2) other medication indicated for adjunct partial seizures (see examples), or the provider indicates clinical inappropriateness of treatment with the alternative medications. Removed the brand names for the alternative medications.
- July 14, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- July 12, 2016: No changes
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- July 11, 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 CareLink℠ 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.