Clinical Policy: Lamotrigine (Lamictal XR, Lamictal ODT)
Reference Number: CP.CPA.97
Effective Date: 11.16.16
Last Review Date: 08.18
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Lamotrigine (Lamictal XR®, Lamictal ODT®) is an anticonvulsant.

FDA Approved Indication(s)
Lamictal XR is indicated:
• As adjunctive therapy for primary generalized tonic-clonic seizures and partial-onset seizures with or without secondary generalization in patients ages 13 years and older
• For conversion to monotherapy in patients 13 years and older with partial-onset seizures who are receiving treatment with a single antiepileptic drug (AED)

Limitation(s) of use: Safety and effectiveness in patients younger than 13 years have not been established.

Lamictal ODT is indicated for:
• Epilepsy—adjunctive therapy in patients aged 2 years and older:
  o partial-onset seizures.
  o primary generalized tonic-clonic seizures.
  o generalized seizures of Lennox-Gastaut syndrome.
• Epilepsy—monotherapy in patients aged 16 years and older: Conversion to monotherapy in patients with partial-onset seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single AED.
• Bipolar disorder: Maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes (depression, mania, hypomania, mixed episodes) in patients treated for acute mood episodes with standard therapy.

Limitation(s) of use: Treatment of acute manic or mixed episodes is not recommended. Effectiveness of Lamictal in the acute treatment of mood episodes has not been established.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Lamictal XR and Lamictal ODT are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Epilepsy, Bipolar Disorder (must meet all):
1. For Lamictal XR ONLY: Failure of immediate-release lamotrigine unless contraindicated or clinically significant adverse effects are experienced;
2. For Lamictal ODT ONLY: Documentation supports inability to swallow tablets or capsules or member has a documented swallowing disorder.

**Approval duration: Length of Benefit**

**B. Other diagnoses/indications**
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**II. Continued Therapy**

**A. Epilepsy, Bipolar disorder (must meet all):**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

**Approval duration: Length of Benefit**

**B. Other diagnoses/indications (must meet 1 or 2):**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial.**

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*
- AED: antiepileptic drug
- FDA: Food and Drug Administration
- ODT: orally disintegrating tablet
- XR: extended release

*Appendix B: Therapeutic Alternatives*
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.
**Dosing Regimen**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamotrigine (Lamictal®)</td>
<td>Epilepsy</td>
<td>25 mg QOD to 500 mg QD, in divided doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refer to full prescribing information for specific dosing recommendations depending upon concomitant AEDs or other concomitant medications, indication, and patient age.</td>
</tr>
<tr>
<td>Lamotrigine ODT (Lamictal ODT)</td>
<td>Bipolar</td>
<td>25 mg QOD to 400 mg QD, in divided doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Refer to full prescribing information for specific dosing recommendations depending upon concomitant AEDs or other concomitant medications, indication, and patient age.</td>
</tr>
<tr>
<td>Lamotrigine (Lamictal XR)</td>
<td>Epilepsy</td>
<td>25 mg QOD to 600 mg PO QD</td>
</tr>
</tbody>
</table>

**Maximum Dose**

- 500 mg/day
- 400 mg/day
- 600 mg/day

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**Appendix C: Contraindications**

Not applicable
<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Refer to full prescribing information for specific dosing recommendations depending upon concomitant AEDs or other concomitant medications, indication, and patient age.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VI. Product Availability

- Extended release tablets: 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg
- ODT Tablets: 25 mg, 50 mg, 100 mg, and 200 mg

VII. References


Reviews, Revisions, and Approvals

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<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<td>1.25.17</td>
<td>8.17</td>
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<td>04.23.18</td>
<td>08.18</td>
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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