Clinical Policy: Lamotrigine (Lamcital XR, Lamictal ODT)

Reference Number: CP.CPA.97
Effective Date: 11.16.16
Last Review Date: 08.19
Line of Business: Commercial

Revision Log

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:
  - partial-onset seizures.
  - primary generalized tonic-clonic seizures.
  - 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 or evidence of coverage documents.

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
lamotrigine (Lamictal®), immediate-release	Dosing is based on concomitant medications, indication, and patient age. Refer to full prescribing information.	In seizure disorders, individualize to the patient's age, weight, indication, concurrent medication, and clinical response. In bipolar disorder, maximum monotherapy dosage is 200 mg/day PO; 100 mg/day PO if taking valproate; 400 mg/day PO if taking enzyme-inducing drugs.

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed warnings

- Contraindication(s): Hypersensitivity to the drug (e.g., rash, angioedema, acute urticaria, extensive pruritus, mucosal ulceration
- Boxed Warning(s): Serious Skin Rashes (Stevens-Johnson Syndrome)

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
lamotrigine ODT (Lamictal ODT)	Epilepsy	25 mg QOD to 500 mg QD, in divided doses Refer to full prescribing information for specific dosing recommendations depending upon concomitant AEDs or other concomitant medications, indication, and patient age.	500 mg/day
	Bipolar	25 mg QOD to 400 mg QD, in divided doses Refer to full prescribing information for specific dosing recommendations depending upon concomitant AEDs or other concomitant medications, indication, and patient age.	400 mg /day
Lamotrigine (Lamictal XR)	Epilepsy	25 mg QOD to 600 mg PO QD	600 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Refer to full prescribing information for specific dosing recommendations depending upon concomitant AEDs or other concomitant medications, indication, and patient age.	

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

1. Lamictal XR Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; July 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed May 31, 2019.
2. Lamictal tablets, Lamictal chewable dispersible tablets, Lamictal ODT [Prescribing Information] Research Triangle Park, NC: GlaxoSmithKline; July 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed May 31, 2019.
3. Micromedex Healthcare Series [Internet database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed May 31, 2019.
4. Lamictal. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed April 23, 2018.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	1.25.17	8.17
3Q 2018 annual review: no significant changes; references reviewed and updated.	04.23.18	08.18
3Q 2019 annual review: no significant changes; added contraindications; references reviewed and updated.	05.31.19	08.19

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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.