# Clinical Policy: Lidocaine Transdermal (Lidoderm)

Reference Number: HIM.PA.126
Effective Date: 12.01.17
Last Review Date:
Line of Business: Health Insurance Marketplace

Revision Log

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

## Description

Lidocaine (Lidoderm®) is an amide-type local anesthetic agent.

## FDA Approved Indication(s)

Lidoderm is indicated for relief of pain associated with post-herpetic neuralgia.

## Policy/Criteria

*Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria*

**I. Initial Approval Criteria**

**A. Post-herpetic Neuralgia Secondary to Herpes Zoster** (must meet all)**:**

1. Diagnosis of post-herpetic neuralgia secondary to herpes zoster;
2. Age ≥ 18 years;
3. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of a ≥ 30 day trial of one tricyclic antidepressant (TCA) (amitriptyline, nortriptyline, desipramine), unless contraindicated or clinically significant adverse effects are experienced;
5. Either gabapentin or a TCA must have been used within the last 6 months, unless both are contraindicated;
6. Request does not exceed 3 patches per day.

**Approval duration: 6 months**

**B. Diabetic Neuropathy (off-label)** (must meet all)**:**

1. Diagnosis of diabetic neuropathy;
2. Age ≥ 18 years;
3. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of a ≥ 30 day trial of one TCA (amitriptyline, nortriptyline, desipramine, imipramine) at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
5. Failure of a ≥ 30 day trial of a serotonin-norepinephrine reuptake inhibitor (duloxetine, extended-release venlafaxine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Request does not exceed 3 patches per day.

**Approval duration: 6 months**

**C. Other diagnoses/indications**

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## II. Continued Therapy

**A. All Indications in Section I** (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;
3. If request is for a dose increase, new dose does not exceed 3 patches per day.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## 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 policy – HIM.PHAR.21 or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
TCA: tricyclic antidepressant

## V. References

1. Lidoderm Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; January 2015. Available at: https://dailymed.nlm.nih.gov/. Accessed August 21, 2017.
2. Bril V, England J, Franklin GM, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology 2011; 76:1758-1765.
3. Dworkin RH, O'Connor AB, Audette J, Baron R, Gourlay GK, Haanpaa ML, et al. Recommendations for the Pharmacologic Management of Neuropathic Pain: An Overview and Literature Update. Mayo Clin Proc. 2010 Mar; 85(3 Suppl): S3-S14.
4. Dubinsky RM, Kabbani H, El-Chami Z, Boutwell C, Ali H. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology September 28, 2004 vol. 63 no. 6 959-965.

5. Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic neuropathy: A position statement by the American Diabetes Association. Diabetes Care. 2017;40(1):136-154.
6. Lidocaine Drug Monograph. Clinical Pharmacology. Accessed August 2017. http://www.clinicalpharmacology-ip.com.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 08.31.17 | 11.17 |

**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.