Clinical Policy: Lidocaine Transdermal (Lidoderm, ZTlido)

Reference Number: CP.PMN.08
Effective Date: 09.01.06
Last Review Date: 08.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

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

FDA Approved Indication(s)

Lidoderm is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to **intact skin**.

ZTlido is indicated for relief of pain associated with post-herpetic neuralgia in adults.

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 transdermal lidocaine is **medically necessary** when the following criteria are met:

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. For requests exceeding a 30 day supply (> 90 patches), member must meet both of the following (a and b):*
   **For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
   a. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1,800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
   b. If member is ≤ 64 years of age: Failure of a ≥ 30 day trial of one tricyclic antidepressant (TCA) (e.g., amitriptyline, nortriptyline, desipramine), unless contraindicated or clinically significant adverse effects are experienced;
4. Member must use generic lidocaine transdermal patch, unless contraindicated or clinically significant adverse effects are experienced;
5. 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. Request is for Lidoderm;

4. Member must use generic lidocaine transdermal patch, unless contraindicated or clinically significant adverse effects are experienced;
5. For requests exceeding a 30 day supply (> 90 patches), member must meet all of the following (a, b, and c):
   a. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1,800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
   b. If member is ≤ 64 years of age: 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;
   c. Failure of a ≥ 30 day trial of a serotonin-norepinephrine reuptake inhibitor (duloxetine, extended-release venlafaxine, desvenlafaxine) 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Member must use generic lidocaine transdermal patch, unless contraindicated or clinically significant adverse effects are experienced;

4. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

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

*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
Generic lidocaine transdermal patch 5% (Lidoderm)	Apply up to 3 patches to intact skin to cover the most painful area for up to 12 hours in a 24-hour period.	3 patches/day for a maximum of 12 hours
TCAs		
amitriptyline	Diabetic Peripheral Neuropathy** 25 mg to 100 mg PO daily Post-herpetic Neuralgia**	150 mg/day†

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	10 mg to 150 mg PO daily	
desipramine (Norpramin®)	Diabetic Peripheral Neuropathy** 12.5 mg to 150 mg PO daily Post-herpetic Neuralgia** 10 to 25 mg PO QHS and titrate to pain relief as tolerated (in one study, mean dose was 167 mg/day)	200 mg/day†
imipramine	Diabetic Peripheral Neuropathy** 50 mg to 150 mg PO QHS	150 mg/day
nortriptyline (Pamelor®)	Diabetic Peripheral Neuropathy** 50 mg to 75 mg PO daily Post-herpetic Neuralgia** 75 mg to 150 mg PO daily	150 mg/day
Serotonin/Norepinephrine Reuptake Inhibitors		
duloxetine (Cymbalta®)	Diabetic Peripheral Neuropathy 60 mg PO daily	60 mg/day
venlafaxine (extended-release) (Effexor XR®)	Diabetic Peripheral Neuropathy** 37.5 mg PO daily for 1 week, then 75 mg PO daily for 1 week, then 150 mg PO daily	225 mg/day
desvenlafaxine (Pristiq®)	Diabetic Peripheral Neuropathy** 200 mg PO daily	400 mg/day†
Miscellaneous		
gabapentin (immediate-release: Neurontin®; extended-release: Horizant®, Gralise®)	Diabetic Peripheral Neuropathy** *Immediate-release*: 300 mg PO TID titrated based on clinical response Post-herpetic Neuralgia *Immediate-release*: 300 mg PO daily on day 1, 300 mg PO BID on day 2, 300 mg PO TID on day 3, then titrate as needed to 1,800 mg/day *Extended-release (Gralise)*: 300 mg PO on day 1, 600 mg on day 2, 900 mg on days 3-6, 1,200 mg on days 7-10, 1,500 mg on days 11-14, and 1,800 mg on day 15 and thereafter	Immediate release: 3,600 mg/day† Gralise: 1,800 mg/day† Horizant: 1,200 mg/day†

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Extended-release (Horizant): 600 mg/day PO for 3 days, 600 mg PO BID on day 4 and thereafter	

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.
**Agents not included in this list may not have evidence supporting their use in the indications covered by this policy*
***Off-label use*
†Maximum dose for drug, not necessarily indication

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of sensitivity to local anesthetics of the amide type, or to any other component of the product
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Post-herpetic neuralgia	Apply up to 3 patches at once to intact skin to cover the most painful area for up to 12 hours in a 24-hour period.	3 patches/day for a maximum of 12 hours
Diabetic neuropathy† (Lidoderm only)	Apply up to 4 patches topically to the most painful area (Max recommended by manufacturer: 3 patches to the most painful area). Wear for up to 12 hours within a 24-hour period; however, some studies allowed patches to remain in place for up to 18 hours.	Optimal dosage has not been determined (max recommended by manufacturer: 3 patches/day for a maximum of 12 hours)

† *Off-label indication*

VI. Product Availability

Drug Name	Availability
lidocaine patch (Lidoderm)	Transdermal patch: 5%
lidocaine topical system (ZTlido)	Topical system: 1.8%

VII. References

1. Lidoderm Prescribing Information. San Jose, CA: TPU Pharma, Inc.; December 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=db0092f5-02a0-4076-ac32-969f075a6ab1. Accessed May 9, 2025.
2. ZTlido Prescribing Information. Palo Ato, CA: Scilex Pharmaceuticals Inc.; April 2021. Available at: https://www.ztlido.com. Accessed May 9, 2025.
3. Mallick-Searle T, Snodgrass B, Brant JM. Postherpetic neuralgia: epidemiology, pathophysiology, and pain management pharmacology. *Journal of Multidisciplinary Healthcare*. 2016;9:447-454. Doi:10.2147/JMDH.S106340.

4. Price R, Smith D, Franklin G, et al. Oral and topical treatment of painful diabetic polyneuropathy: practice guideline update summary: report of the AAN guideline subcommittee. *Neurology*. 2022 Jan;98(1):31-43. doi: 10.1212/WNL.0000000000013038.
5. Dworkin RH, O'Connor AB, Audette J, 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.
6. Saguil A, Kane S, Mercado M, Lauters R. Herpes Zoster and Postherpetic Neuralgia: Prevention and Management. *Am Fam Physician*. 2017 Nov 15;96(10):656-663.
7. American Diabetes Association Professional Practice Committee. 12. Retinopathy, Neuropathy, and Foot Care: Standards of Care in Diabetes-2025. *Diabetes Care*. 2025 Jan 1;48(Supplement_1):S252-S265. doi: 10.2337/dc25-S012.
8. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed May 9, 2025.
9. Merative™ Micromedex® Alternative Medicine (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2021 annual review: no significant changes; revised HIM.PHAR.21 to HIM.PA.154; replaced "Documentation of" language with "Member must use"; references reviewed and updated.	05.12.21	08.21
3Q 2022 annual review: revised initial criteria to clarify redirection to systemic therapy if request exceeds 30 day supply; references reviewed and updated.	08.12.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.19.22	
3Q 2023 annual review: no significant changes; updated desipramine and venlafaxine off-label dosing for diabetic neuropathy; references reviewed and updated.	05.02.23	08.23
3Q 2024 annual review: for diabetic neuropathy, added desvenlafaxine as an example SNRI per AAN and ADA guidelines; revised Lidoderm/ZTlido to generic transdermal lidocaine in Policy/Criteria; for continued therapy, added requirement of a trial of generic lidocaine patches; in Appendix B, removed commercially unavailable brand alternatives; references reviewed and updated.	05.28.24	08.24
3Q 2025 annual review: for postherpetic neuralgia, added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	05.09.25	08.25

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.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.