Clinical Policy: Lidocaine Transdermal (Lidoderm, ZTlido)

Reference Number: CP.PMN.08
Effective Date: 09.01.06
Last Review Date: 08.22
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.

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 Lidoderm and ZTlido are **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):
   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) 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. 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 (Elavil®)	Diabetic Peripheral Neuropathy** 25 mg to 100 mg PO QD Post-herpetic Neuralgia** 25 mg to 137.5 mg (median: 75 mg) PO QHS	150 mg/day†

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
desipramine (Norpramin®)	Diabetic Peripheral Neuropathy** Initially 25 mg PO QHS, then titrate as tolerated to efficacy (usual range: 75 mg to 150 mg PO QHS) 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 (Tofranil®, Tofranil PM®)	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 QD	60 mg/day
venlafaxine (extended-release) (Effexor XR®)	Diabetic Peripheral Neuropathy** 75 mg to 225 mg PO QD	225 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 QD 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 *Extended-release (Horizant)*: 600 mg/day PO for 3 days, 600 mg PO BID on day 4 and thereafter	Immediate release: 3600 mg/day† Gralise: 1,800 mg/day† Horizant: 1,200 mg/day†

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. Malvern, PA: Endo Pharmaceuticals Inc.; November 2018. Available at: https://dailymed.nlm.nih.gov/. Accessed April 21, 2022.
2. ZTlido Prescribing Information. San Diego, CA: Scilex Pharmaceuticals Inc.; April 2021. Available at www.ztlido.com. Accessed April 21, 2022,.
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. 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.
5. 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.

6. 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.
7. 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.
8. Clinical Pharmacology [database online]. Elsevier; 2022. Available at: https://www.clinicalkey.com/pharmacology/.
9. Micromedex [database online]. Greenwood Village, CO: Truven Health Analytics.; 2022. Available at: http://micromedex.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policies combined for Centene Medicaid, HIM, and Commercial lines of business; Medicaid/HIM: removed timeframe of within the last 6 months for gabapentin or TCA trial; Commercial: added age requirement; for post-herpetic neuralgia, modified dosage of gabapentin from 1200 mg/day to 1800 mg/day and added duration of trial of 30 days, added TCA trial for members ≤ 64 years of age; for diabetic neuropathy, added requirements related to trial of gabapentin and a TCA; references reviewed and updated.	04.10.18	08.18
Changes align with previously approved clinical guidance: added ZTlido to policy per SDC requiring use of generic Lidoderm.	02.01.19	
3Q 2019 annual review: no significant clinical changes; added requirement of a trial of generic lidocaine patches prior to brand name patches as generic patches are the formulary preferred product; references reviewed and updated.	05.20.19	08.19
3Q 2020 annual review: amended Commercial initial and continued approval durations from length of benefit to 6 months and 12 months, respectively; removed all mention of redirecting to HIM.PA.103 for ZTlido; references reviewed and updated.	05.11.20	08.20
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	

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.

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.