

Clinical Policy: Lidocaine Transdermal (Lidoderm, ZTlido)

Reference Number: CP.PMN.08

Effective Date: 09.01.06

Last Review Date: 08.20

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 and ZTlido are indicated for relief of pain associated with post-herpetic neuralgia.

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 \geq 18 years;
3. Failure of a \geq 30 day trial of gabapentin at doses \geq 1,800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. If member is \leq 64 years of age: Failure of a \geq 30 day trial of one tricyclic antidepressant (TCA) (e.g., amitriptyline, nortriptyline, desipramine), unless contraindicated or clinically significant adverse effects are experienced;
5. Documentation supports inability to use generic lidocaine transdermal patch (e.g., contraindications to the excipients in the generic product);
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 \geq 18 years;
3. Request is for Lidoderm;
4. Documentation supports inability to use generic lidocaine transdermal patch (e.g., contraindications to the excipients in the generic product);
5. Failure of a \geq 30 day trial of gabapentin at doses \geq 1,800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;

6. 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;
7. 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;
8. Request does not exceed 3 patches per day.

Approval duration: 6 months

C. 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, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 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, HIM.PHAR.21 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.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

B.

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
<i>TCA</i>s		
amitriptyline (Elavil [®])	Diabetic Peripheral Neuropathy** 25 mg to 100 mg PO QD Postherpetic Neuralgia** 25 mg to 137.5 mg (median: 75 mg) PO QHS	150 mg/day [†]
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) Postherpetic 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 Postherpetic Neuralgia** 75 mg to 150 mg PO daily	150 mg/day
<i>Serotonin/Norepinephrine Reuptake Inhibitors</i>		
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
<i>Miscellaneous</i>		
gabapentin (immediate-release: Neurontin [®] ;	Diabetic Peripheral Neuropathy** <i>Immediate</i> -release: 300 mg PO TID titrated based on clinical response	Immediate release: 3600 mg/day [†] Gralise: 1,800 mg/day [†]

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
extended-release: Horizant [®] , Gralise [®])	Postherpetic Neuralgia <i>Immediate-release:</i> 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 <i>Extended-release (Gralise):</i> 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 <i>Extended-release (Horizant):</i> 600 mg/day PO for 3 days, 600 mg PO BID on day 4 and thereafter	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
Postherpetic neuralgia	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
Diabetic neuropathy [†]	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 May 11, 2020.
2. Ztlido Prescribing Information. San Diego, CA: Scilex Pharmaceuticals Inc.; November 2018. Available at www.ztlido.com. Accessed May 11, 2020.
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.
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8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>.
9. DRUGDEX[®] System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 11, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Post-herpetic neuralgia: removed requirement for concurrent use of oral and topical agents; modified to require trial of one of the first line oral agents and topical agent within the last 6 months; added capsaicin cream/gel as an option for topical trial as it is indicated for use; removed requirement for failure of 2 topical agents in those who have contraindications to both oral agents as magnitude of benefit is low with capsaicin per American Academy of Neurology postherpetic neuralgia treatment guideline. Modified specific maximum quantity limit to generalized FDA maximum recommended dose/health plan approved daily quantity limit statement. Updated references to reflect current literature search.	05.16	08.16
Converted to new integrated template; Modified generalized FDA approved maximum recommended dose and health plan approved QL statement to 3 patches per day; Diabetic neuropathy: added a requirement related to failure of ≥ 30 day trial of gabapentin at doses ≥ 1800 mg/day, unless contraindicated or intolerant to gabapentin; Modified TCA or SNRI requirement by adding “at maximum	10.16	11.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
indicated doses” and removing the statement “within the last 6 months”; Updated references to reflect current literature search.		
Converted to new template. Post-herpetic neuralgia: Removed requirement related to failure of topical lidocaine gel/ointment or capsaicin-per AAN guidelines, magnitude of benefit for topical capsaicin is below the level that is considered clinically important in treatment of chronic pain/lower efficacy, or limited strength of evidence than lidocaine patch. Diabetic neuropathy (off-label): Modified criterion related to failure of either a TCA or SNRI to require both agents since level of recommendation for TCA and SNRI (level B) is higher than Lidoderm patch (level C) per AAN guidelines. Member ≥ 65 years exempted from TCA trial as this is a high risk medication in this age group. Re-auth: Added a requirement that member is responding positively to therapy. Increased approval duration from 6 to 12 months. Updated references.	08.17	11.17
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

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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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.

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