Policy: Lidocaine Transdermal (Lidoderm, ZTlido)

Reference Number: OR.CP.PMN.08
Effective Date: 10.01.21
Last Review Date: 07.22
Line of Business: Medicaid – Trillium Oregon Health Plan 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 is 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 Trillium Community Health Plan 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. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
4. 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;
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. 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.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:
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Trillium Oregon 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 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.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.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 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)	200 mg/day†

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Postherpetic Neuralgia** 10 to 25 mg PO QHS and titrate to pain relief as tolerated (in one study, mean dose was 167 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
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 Postherpetic 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 1800 mg/day *Extended-release (Gralise)*: 300 mg PO on day 1, 600 mg on day 2, 900 mg on days 3-6, 1200 mg on days 7-10, 1500 mg on days 11-14, and 1800 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: 1800 mg/day† Horizant: 1200 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
Not applicable

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

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.
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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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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.1805 Lidocaine Transdermal (Lidoderm, ZTlido)	06.15.21	07.15.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	06.15.22	07.07.22

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.

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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.

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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.