Clinical Policy: Lidocaine Transdermal (Lidoderm, ZTlido)

Reference Number: ERX.NPA.82
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, 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 the relief of pain associated with post-herpetic neuralgia. ZTlido is indicated specifically for 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1,800 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) (amitriptyline, nortriptyline, desipramine), unless clinically significant adverse effects are experienced or all are contraindicated;
5. Member must use generic lidocaine transdermal patch, unless contraindicated or clinically significant adverse effects are experienced;
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. Request is for Lidoderm;
4. Member must use generic lidocaine transdermal patch, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1,800 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of a ≥ 30 day trial of a serotonin-norepinephrine reuptake inhibitor (duloxetine, extended-release venlafaxine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
7. 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 clinically significant adverse effects are experienced or all are contraindicated;
8. Request does not exceed 3 patches per day.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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†
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	150 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Post-herpetic Neuralgia** 75 mg to 150 mg PO daily	
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 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: 3,600 mg/day† Gralise: 1,800 mg/day† Horizant: 1,200 mg/day†
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

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 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%

Drug Name	Availability
lidocaine topical system (ZTlido)	Topical system: 1.8%

VII. References

1. Lidoderm Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; November 2018. Available at: http://www.endo.com/endopharma/our-products. Accessed May 12, 2021.
2. Ztlido Prescribing Information. San Diego, CA: Scilex Pharmaceuticals Inc.; April 2021. Available at www.ztlido.com. Accessed May 12, 2021.
3. 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 (reaffirmed in 2008). Neurology. 2004; 63(6): 969-965.
4. 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.
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6. 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.
7. 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.
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9. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 12, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from ERX.ST.19; created criteria for postherpetic neuralgia and diabetic neuropathy; references reviewed and updated.	04.10.18	08.18
3Q 2019 annual review: changes align with previously approved clinical guidance – added ZTlido to the policy; references reviewed and updated.	05.20.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.11.20	08.20
3Q 2021 annual review: no significant changes; replaced "Documentation of" language with "Member must use"; references reviewed and updated.	05.12.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.