RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	lidocaine transdermal
Policy Number:	RxA.405
Drug(s) Applied:	Lidoderm®, ZTlido™
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Lidocaine Transdermal (Lidoderm®, ZTlido™)	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*

Dosage Forms

- lidocaine patch (Lidoderm®) : Transdermal patch: 5%.
- lidocaine topical system (ZTlido™) : Topical system: 1.8%.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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) (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
Commercial: 12 months
Medicaid: 6 months.
HIM: 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. Documentation supports inability to use generic lidocaine transdermal patch (e.g., contraindications to the excipients in the generic product);
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. 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
Commercial: 12 months
Medicaid: 6 months
HIM: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months
HIM: 12 months

III. Appendices

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
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
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†
nortriptyline (Pamelor®)	Diabetic Peripheral Neuropathy**10 to 25 mg/day Postherpetic Neuralgia** 10 mg to 20 mg PO QHS	100 mg/day 160 mg/day
duloxetine (Cymbalta®)	Diabetic Peripheral Neuropathy 60 mg PO once daily	60 mg/day
venlafaxine (extended- release) (Effexor XR®)	Diabetic Peripheral Neuropathy** 75 mg to 225 mg PO once daily	225 mg/day
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 once 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, take once daily with the evening meal.	Immediate release: 3600 mg/day† Gralise: 1,800 mg/day† Horizant: 1,200 mg/day†

	Extended-release (Horizant): 600 mg/day PO for 3 days, 600 mg PO BID.	

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

Appendix D: General Information

- Not applicable

References

1. Lidoderm Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; November 2018. Available at: https://dailymed.nlm.nih.gov/. Accessed June 18, 2020.
2. Ztlido Prescribing Information. San Diego, CA: Scilex Pharmaceuticals Inc.; November 2018. Available at www.ztlido.com. Accessed June 18, 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.
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]. 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 June 18, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Approval duration for Commercial was updated to 12 months and added HIM approval duration. 4. Continued therapy criteria II.A.1.was rephrased to "Currently receiving medication that has been authorized by RxAdvance….". 5. Amitripyline and imipramine removed from Appendix B. 6. References were reviewed and updated.	06/18/2020	09/14/2020