Clinical Policy Title:	lidocaine transdermal
Policy Number:	RxA.405
Drug(s) Applied:	Lidoderm®, ZTlido®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Lidocaine (Lidoderm®, ZTlido®) is an amide-type local anaesthetic 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

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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 days 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 days 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: 6 months
Medicaid: 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 days 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 days 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 days 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: 6months
Medicaid: 6 months

II. Continued Therapy Approval

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

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
TCA: Tricyclic Antidepressant
PHN: Post-Herpetic Neuralgia

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
desipramine (Norpramin®)	**Diabetic Peripheral Neuropathy**** Initially 25 mg orally nightly at bedtime, then titrate as tolerated to	200 mg/day†

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	efficacy (usual range: 75 mg to 150 mg orally nightly at bedtime) **Postherpetic Neuralgia**** 10 to 25 mg orally nightly at bedtime and titrate to pain relief as tolerated (in one study, mean dose was 167 mg/day)	
nortriptyline (Pamelor®)	**Diabetic Peripheral Neuropathy**** 10 to 25 mg/day **Postherpetic Neuralgia**** 10 mg to 20 mg orally nightly at bedtime	100 mg/day 160 mg/day
duloxetine (Cymbalta®)	**Diabetic Peripheral Neuropathy** 60 mg orally once daily	60 mg/day
venlafaxine extended- release (Effexor XR®)	**Diabetic Peripheral Neuropathy**** 75 mg to 225 mg orally once daily	225 mg/day
gabapentin immediate- release: Neurontin®; extended-release: Horizant®, Gralise®)	**Diabetic Peripheral Neuropathy**** Immediate -release: 300 mg orally three times daily titrated based on clinical response **Postherpetic Neuralgia** Immediate-release: 300 mg orally once daily on day 1, 300 mg orally twice daily on day 2, 300 mg orally three times daily on day 3, then titrate as needed to 1,800 mg/day. Extended-release (Gralise): 300 mg orally 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. Extended-release (Horizant): 600 mg/day orally for 3 days, 600 mg orally twice daily.	Immediate release: 3600 mg/day† Gralise: 1,800 mg/day† Horizant: 1,200 mg/day†

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.*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

- Lidocaine toxicity can be expected at lidocaine blood concentrations above 5 mcg/mL. The blood concentration of lidocaine is determined by the rate and extent of lidocaine absorption and elimination. Longer duration of application, application of more than the recommended number of ZTlido®, smaller patients, or impaired elimination may all contribute to increasing the blood concentration of lidocaine.
- Cases of methemoglobinemia have been reported in association with local anesthetic use. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.
- Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure and are characterized by a cyanotic skin discoloration and/or abnormal coloration of the blood. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue ZTlido® and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. A more severe clinical presentation may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

References

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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
Policy was reviewed: 1. Drug(s) Applied has been updated from ZTlido™ to ZTlido® 2. Dosing Information was updated to remove off-label indication “Diabetic neuropathy…” 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Initial Approval Criteria and Continued Therapy Approval Criteria have been updated to remove HIM approval duration. 5. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 6. Appendix A was updated to include abbreviation PHN.	06/01/2021	09/14/2021

7. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 8. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 9. Appendix D: General information has been updated to include “Lidocaine toxicity can be expected at…”. 10. References were reviewed and updated.		