Clinical Policy: Lidocaine Transdermal (Lidoderm)

Reference Number: CP.PMN.08
Effective Date: 09.01.06
Last Review Date: 08.18
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®) is an amide-type local anesthetic agent.

FDA Approved Indication(s)

Lidoderm 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 health plans affiliated with Centene Corporation® that Lidoderm 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. Request does not exceed 3 patches per day.

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

B. Diabetic Neuropathy (off-label) (must meet all)**:**

1. Diagnosis of diabetic neuropathy;
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 TCA (amitriptyline, nortriptyline, desipramine, imipramine) at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;

5. 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;
6. Request does not exceed 3 patches per day.

Approval duration:
Medicaid/HIM – 6 months
Commercial – Length of Benefit

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:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

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.

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
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) 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
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	Immediate release: 3600 mg/day† Gralise: 1800 mg/day† Horizant: 1200 mg/day†

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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	

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
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
Transdermal patch: 5%

VII. References
1. Lidoderm Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; January 2015. Available at: https://dailymed.nlm.nih.gov/. Accessed April 9, 2018.

2. 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.
3. 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.
4. 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.
5. 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.
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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.
8. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 9, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Updated References. Added diabetic neuropathy as indication. Created criteria for diabetic neuropathy pain.	12.14	12.14
Converted to new template. Guideline converted to question and answer format. Added criteria for appropriate age of use per FDA labeling; Modified criteria for postherpetic neuralgia to require the use of gabapentin at a specific dose and for a specified time period; changed TCA requirement to use for at least 30 days; Removed other anticonvulsant from acceptable trial with the exception of gabapentin because first line PDL agents include gabapentin and TCAs only, other agents don't have a strong literature backing for efficacy; Modified required concomitant trial to include only lidocaine ointment/gel; Added requirement that capsaicin and lidocaine gel/or ointment must be used for patients with contraindication to TCAs and gabapentin; Modified criteria for diabetic neuropathy to include only TCAs and SNRI as acceptable first line trials; other agents currently required by the criteria are either second line or has weak literature backing for its use in diabetic neuropathy; Modified renewal and approval time to 6 months.	08.15	08.15
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	05.16	08.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
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 ≥ 1800mg/day, unless contraindicated or intolerant to gabapentin; Modified TCA or SNRI requirement by adding "at maximum indicated doses" and removing the statement "within the last 6 months"; Updated references to reflect current literature search.	10.16	11.16
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

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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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.

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.