Clinical Policy: Lidocaine Transdermal (Lidoderm)
Reference Number: ERX.ST.19
Effective Date: 06.01.15
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] 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
Lidoderm is indicated for the relief of pain associated with post-herpetic neuralgia.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Lidoderm is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. Step Therapy for Lidoderm (must meet all)**:**
1. Age ≥ 18 years;
2. Previous use of one of the following (a, b, or c) in the past 6 months, unless all are contraindicated or clinically significant adverse effects are experienced:
   a. ≥ 3 months of gabapentin;
   b. ≥ 30 days of gabapentin at ≥ 1800 mg/day;
   c. ≥ 30 days of a tricyclic antidepressant;
3. Request does not exceed 3 patches/day.

Approval duration: 12 months

II. Continued Therapy
A. Step Therapy for Lidoderm (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. If request is for a dose increase, request does not exceed 3 patches/day.

Approval duration: 12 months

III. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Gabapentin (immediate release: Neurontin®; extended release: Horizant®, Gralise®)	Postherpetic Neuralgia Immediate release: 300 mg PO as a single dose on day 1, then 600 mg/day (300 mg PO twice daily) on day 2, and 900 mg/day (300 mg PO three times per day) on day 3. Dose may be titrated as needed for pain relief (range: 1800 to	Immediate release: 3600 mg/day Gralise: 1800 mg/day Horizant: 1200 mg/day

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
	3600 mg/day in divided doses, daily doses > 1800 mg do not generally show greater benefit) Extended release (Gralise): 300 mg PO with evening meal on day 1, then titrate once daily dosage as follows: 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 PO in the morning for 3 days, 600 mg twice daily on day 4 and thereafter	
Lyrica (pregabalin®)	Postherpetic Neuralgia Initially, 150 mg/day PO given in 2 or 3 divided doses; may increase to 300 mg/day, given in 2 or 3 divided doses, within 1 week based on efficacy and tolerability. If pain relief is not sufficient after 2-4 weeks but the drug is well tolerated, dose may be increased up to 600 mg/day given in 2 or 3 divided doses	600 mg/day
Tricyclic Antidepressants		
Amitriptyline (Elavil®)	Postherpetic Neuralgia† 25 mg to 137.5 mg PO QHS (median dose: 75 mg/day)	150 mg/day*
Desipramine (Norpramin®)	Postherpetic Neuralgia† 10 mg to 25 mg PO QHS, and titrate to pain relief as tolerated. In one study, the mean dose of desipramine after 6 weeks of treatment was 167 mg/day	200 mg/day*
Nortriptyline (Pamelor®)	Postherpetic Neuralgia† Initially, 10-25 mg PO at HS; Increase by 10-25 mg every 3-7 days as tolerated to a target dose of 75-150 mg/day. The average effective dose in clinical trials was 122 mg/day	150 mg/day*

†*Off-label indication*
**Maximum dose for drug, not indication specific*

IV. 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

V. Product Availability

Transdermal patch: 5%

VI. References

1. Lidoderm Prescribing Information. Malvern, PA: Endo Pharmaceuticals Inc.; January 2015. Available at: http://www.endo.com/endopharma/our-products. Accessed July 13, 2017.

2. 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.
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. O'Connor AB, Dworkin RH. Treatment of neuropathic pain: an overview of recent guidelines. Am J Med. 2009; 122(10): S22-S32.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	06/15	06/15
Updated to new template (converted algorithm to bulleted criteria, added background and references). Removed option for trial/failure of SNRIs as those are not used to manage post-herpetic neuralgia (rather, they are commonly used for diabetic peripheral neuropathic pain).	07/16	09/16
Converted to new template. Removed option for trial/failure of pregabalin since it is available brand only, while Lidoderm is available generically. Modified general FDA max dose requirement to specific max dose of drug. Updated references.	07/17	08/17

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.