Clinical Policy: Lidocaine transdermal (Lidoderm)

Reference Number: PA.CP.PMN.08
Effective Date: 09/06
Last Review Date: 07/17/19

Coding Implications
Revision Log

Description
Lidocaine (Lidoderm®) patch is comprised of an adhesive material containing 5% lidocaine, an amide-type local anesthetic agent.

FDA approved indication
Lidoderm is indicated for

- Relief of pain associated with post-herpetic neuralgia

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

It is the policy of Pennsylvania Health and Wellness® 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. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1800 mg/day, unless member experiences clinically significant adverse effects or has contraindication(s) to gabapentin;
3. 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;
4. Request does not exceed 3 patches per day.

Approval duration: 6 months

B. Diabetic Neuropathy (must meet all):

1. Diagnosis of diabetic neuropathy;
2. Failure of a ≥ 30 day trial of gabapentin at doses ≥ 1800 mg/day, unless member experiences clinically significant adverse effects or has contraindication(s) to gabapentin;
3. 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;
4. Request does not exceed 3 patches per day.

Approval duration: 6 months

C. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

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 – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
PDL: preferred drug list
SNRI: serotonin-norepinephrine reuptake inhibitor
TCA: tricyclic antidepressant

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

Lidoderm is supplied as a 5% transdermal patch.

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	Approval Date
3Q 2018 annual review: removed timeframe of within the last 6 months for gabapentin or TCA trial; 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.	08/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	