MEDICAL MUTUAL®

Drug Policy

Policy:	Lidocaine 5% patches	Annual Review Date: 05/16/2024 Last Revised Date: 05/16/2024

OVERVIEW

Lidocaine 5% patch is indicated for the relief of pain associated with postherpetic neuralgia (PHN). Lidocaine is an amide-type local anesthetic agent whose neuronal membrane stabilizing effect produces a local analgesic effect when applied transdermally. The lidocaine penetration into intact skin is adequate to produce an analgesic effect, but less than the amount needed to produce a complete sensory block.

POLICY STATEMENT

This policy involves the use of lidocaine patches. Prior authorization is recommended for pharmacy benefit coverage of lidocaine patches. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: When available, the ICD-10 codes for postherpetic polyneuropathy (B02.23) will be used as part of automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of lidocaine patches is recommended in those who meet the following criteria:

1. **Postherpetic Neuralgia (PHN)**
   Criteria. *Approve*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Other Uses with Supportive Evidence (lidocaine 5% patches only)

2. **Low Back Pain**

Criteria. *Approve after trying at least three pharmacologic therapies, each one from a different class of medication used to treat low back pain (e.g. acetaminophen, celecoxib, NSAIDs [e.g. etodolac, meloxicam, nabumetone], muscle relaxants [e.g. carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, orphenadrine], duloxetine, gabapentin)*

3. **Neuropathic Pain (not Sciatica)**
   Criteria. *Approve.* (Note: For neuropathic pain due to radiculopathy or sciatica, please refer to the Not Recommended for Approval section for Radiculopathy or Sciatica.)

4. **Osteoarthritis (OA)**
   Criteria. *Approve after trying at least three pharmacologic therapies with each one from a different class of medication used for the treatment of osteoarthritis (e.g. acetaminophen, celecoxib, NSAIDs [e.g. etodolac, meloxicam, nabumetone], salicylates, intra-articular glucocorticoids, intra-articular hyaluronan, topical capsaicin, and topical methylsalicylate).*

5. **Diabetic Peripheral Neuropathy (DPN)**
   Criteria. *Approve*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lidocaine patches have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Carpal Tunnel Syndrome.** Two open-label trials have investigated the lidocaine 5% patch for the relief of pain associated with carpal tunnel symdrome. In an open-label, parallel-group, single-center, active-controlled trial, 40 patients with carpal tunnel syndrome were randomized to daily treatment with lidocaine patch 5% or an injection of lidocaine 1% plus methylprednisolone. After 4 weeks of treatment, both groups reported statistically significant improvement in pain scores. A 6-week, randomized, parallel-group, open-label multicenter study found that lidocaine 5% patches given every 24 hours and naproxen 500 mg twice daily both led to significant reductions is the Average Pain Intensity scores in 100 patients with carpal tunnel syndrome. The 2016 American Academy of Orthopaedic Surgeons (AAOS) guidelines on carpal tunnel syndrome do not mention topical lidocaine in their recommendations for treatment. In addition, the AAOS guidelines have a supplemental evidence table that addresses the studies AAOS evaluated for their guidelines. This table states that the above-referenced articles were excluded from their guidelines because they used non-validated outcome measures.

2. **Fibromyalgia.** There are no data available on the use of lidocaine 5% patch in treating pain associated with fibromyalgia.

3. **Myofascial Pain as Adjunctive Therapy.** Published data are limited to small ($n \leq 60$ in each study) studies. Larger, controlled studies are needed to fully determine the place in therapy of lidocaine 5% patch for the treatment of myofascial pain.

4. **Pain Associated with Rib Fractures.** Lidocaine 5% patch did not significantly improve pain control in patients with traumatic rib fractures in one randomized, double-blind, placebo-controlled study. A retrospective chart analysis found lidocaine patches decreased pain scores in 29 patients with rib fractures vs. 29 matched controls, with no change in narcotic use and no difference in time to return to baseline activity. Larger, controlled studies are needed to fully determine the place in therapy of lidocaine 5% patch for the treatment of pain associated with rib fractures.

5. **Radiculopathy.** Published data on the use of lidocaine patches in treating pain associated with radiculopathy is limited. Larger controlled studies are needed to fully determine the place in therapy of lidocaine patches for the treatment of radiculopathy.

6. **Rheumatoid Arthritis (RA).** There are no data available on the use of lidocaine 5% patch in treating pain associated with RA.

7. **Sciatica.** There are no data available on the use of lidocaine 5% patch in treating pain associated with sciatica.

8. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lidoderm® patches [prescribing information]. Malvern, PA: Endo Pharmaceuticals, Inc.; November 2018.
2. ZTlido™ transdermal system [prescribing information]. San Diego, CA: Scilex Pharmaceuticals Inc.; November 2018.

3. White WT, Patel N, Drass M, Nalamachu S. Lidocaine patch 5% with systemic analgesics such as gabapentin: a rational polypharmacy approach for the treatment of chronic pain. *Pain Med.* 2003;4(4):321-30.
4. Galer BS, Gammaitoni AR, Oleka N, Jensen MP, Argoff CE. Use of the lidocaine patch 5% in reducing intensity of various pain qualities reported by patients with low-back pain. *Curr Med Res Opin*. 2004;20(Suppl 2):S5-12.
5. Gimbel J, Linn R, Hale M, Nicholson B. Lidocaine patch treatment in patients with low back pain: results of an open-label, nonrandomized pilot study. *Am J Ther*. 2005;12:311-319.
6. Qaseem A, Wilt TJ, McLean RM, et al. Noninvasive treatments for acute, subacute, and chronic low back pain: a clinical practice guideline from the American College of Physicians. *Ann Intern Med.* 2017;166(7):514-530.
7. Barbano RL, Herrmann DN, Hart-Gouleau S, Pennella-Vaughan J, Lodewick PA, Dworkin RH. Effectiveness, tolerability, and impact on quality of life of the 5% lidocaine patch in diabetic polyneuropathy. *Arch Neurol*. 2004;61(6):914-918.
8. Micromedex® Solutions. Truven Health Analytics Inc. Available at: http://www.micromedexsolutions.com/home/dispatch. Accessed on July 30, 2019. Search terms: lidocaine.
9. Meier T, Wasner G, Faust M, et al. Efficacy of lidocaine patch 5% in the treatment of focal peripheral neuropathic pain syndromes: a randomized, double-blind, placebo-controlled study. *Pain.* 2003;106(1-2):151-158.
10. Galer BS, Jensen MP, Ma T, et al. The lidocaine patch 5% effectively treats all neuropathic pain qualities: results of a randomized, double-blind, vehicle-controlled, three-week efficacy study with use of the neuropathic pain scale. *Clin J Pain.* 2002;18:297-301.
11. Devers A, Galer BS. Topical lidocaine patch relieves a variety of neuropathic pain conditions: an open-label study. *Clin J Pain.* 2000;16:205-208.
12. Dworkin RH, Backonja M, Rowbotham MC, et al. Advances in neuropathic pain: diagnosis, mechanisms, and treatment recommendations. *Arch Neurol*. 2003;60(11):1524-1534.
13. Herrmann DN, Barbano RL, Hart-Gouleau S, et al. An open-label study of the lidocaine patch 5% in painful idiopathic sensory polyneuropathy. *Am Acad Pain Med.* 2005;6(5):379-384.
14. Fleming JA, O'Connor BD. Use of lidocaine patches for neuropathic pain in a comprehensive cancer centre. *Pain Res Manage.* 2009;14:381-388.
15. 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(20):1758-1765.
16. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. *Mayo Clin Proc.* 2010;85:S3-S14.
17. Galer BS, Sheldon E, Patel N, et al. Topical lidocaine patch 5% may target a novel underlying pain mechanism in osteoarthritis. *Curr Med Res Opin.* 2004;20(9):1455-1458.
18. Gammaitoni AR, Galer BS, Onawala R, et al. Lidocaine patch 5% and its positive impact on pain qualities in osteoarthritis: results of a pilot 2-week, open-label study using the Neuropathic Pain Scale. *Curr Med Res Opin.* 2004;20(Suppl 2):S13-19.
19. Burch F, Codding C, Patel N, Sheldon E. Lidocaine patch 5% improves pain, stiffness, and physical function in osteoarthritis pain patients. *Osteoarthritis Cartilage*. 2004;12(3):253-255.
20. Stitik TP, Altschuler E, Foye PM. Pharmacotherapy of osteoarthritis. *Am J Phys Med Rehabil*. 2006;85(11 Suppl):S15-S28.
21. Kivitz A, Fairfax M, Sheldon EA, et al. Comparison of the effectiveness and tolerability of lidocaine patch 5% versus celecoxib for osteoarthritis-related knee pain: post hoc analysis of a 12-week, prospective, randomized, active-controlled, open-label, parallel-group trial in adults. *Clin Ther*. 2008;30:2366-2377.
22. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res.* 2012;64:465-474.
23. Nalamachu S, Crockett RS, Mathur D. Lidocaine patch 5 for carpal tunnel syndrome: how it compared with injections: a pilot study. *J Fam Pract*. 2006;55(3):209-214.
24. Nalamachu S, Crockett RS, Gammaitoni AR, Gould EM. A comparison of the lidocaine patch 5% vs. naproxen 500 mg twice daily for the relief of pain associated with carpal tunnel syndrome: a 6-week, randomized, parallel-group study. *MedGenMed.* 2006;8(3):33.
25. American Academy of Orthopaedic Surgeons. Management of Carpal Tunnel Syndrome Evidence-Based Clinical Practice Guideline. Available at: www.aaos.org/ctsguideline. Published February 29, 2016. Accessed on July 30, 2019.
26. Dalpiaz AS, Lordon SP, Lipman AG. Topical lidocaine patch therapy for myofascial pain. *J Pain Palliat Care Pharmacother*. 2004;18(3):15-34.
27. Firmani M, Miralles R, Casassus R. Effect of lidocaine patches on upper trapezius EMG activity and pain intensity in patients with myofascial trigger points: a randomized clinical study. *Acta Odontol Scand.* 2015;73(3):210-218.

28. Affaitati G, Fabrizio A, Savini A, et al. A randomized, controlled study comparing a lidocaine patch, a placebo patch, and anesthetic injection for treatment of trigger points in patients with myofascial pain syndrome: evaluation of pain and somatic pain thresholds. *Clin Ther*. 2009;31:705-720.
29. Lin YC, Kuan TS, Hsieh PC, et al. Therapeutic effects of lidocaine patch on myofascial pain syndrome of the upper trapezius: a randomized, double-blind, placebo-controlled study. *Am J Phys Med Rehabil*. 2012;91:871-882.
30. Ingalls NK, Horton ZA, Bettendorf M, et al. Randomized, double-blind, placebo-controlled trial using lidocaine patch 5% in traumatic rib fractures. *J Am Coll Surg*. 2010;210:205-209.
31. Zink KA, Mayberry JC, Peck EG, et al. Lidocaine patches reduce pain in trauma patients with rib fractures. *Am Surg*. 2011;77(4):438-442.
32. Cheng YJ. Lidocaine skin patch (Lidopat® 5%) is effective in the treatment of traumatic rib fractures: a prospective double-blinded and vehicle-controlled study. *Med Princ Pract*. 2016;25(1):36-39.
33. Martini A, Del Balzo G, Schweiger V, et al. Efficacy of lidocaine 5% medicated plaster (VERSATIS®) in patients with localized neuropathic pain poorly responsive to pharmacological therapy. *Minerva Med*. 2018;109(5):344-351.