



BlueCross BlueShield  
of Kansas City

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## Lidoderm (lidocaine 5% patch)

**Policy Number:** 5.01.562  
**Origination:** 06/2014

**Last Review:** 07/2014  
**Next Review:** 07/2015

### **Policy**

BCBSKC will provide coverage for Lidoderm when it is determined to be medically necessary because the following criteria are met.

### **When Policy Topic is covered:**

Coverage of lidocaine 5% patch is recommended in those who meet the following criteria:

#### **Food and Drug Administration (FDA)-Approved Indication(s)**

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

Lidocaine 5% patch is indicated for the treatment of PHN.<sup>1</sup>

#### **Other Uses with Supportive Evidence**

2. **Low Back Pain.** Approve after trying at least three pharmacologic therapies commonly used to treat low back pain (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, opioids, cyclooxygenase-2 [COX-2] inhibitors, tramadol, gabapentin, tricyclic antidepressants [TCAs] {e.g., amitriptyline}).

Lidocaine 5% patches have been shown to be effective in treating low back pain in open-label studies in patients not achieving adequate pain relief despite as needed or stable doses of non-selective NSAIDs, COX-2 inhibitors, gabapentin, tramadol, or opioids.<sup>2-4</sup> The guidelines for treatment of low back pain (2007) do not address the use of topical lidocaine; however, various other agents are used for pain associated with low back pain.<sup>5</sup>

3. **Neuropathic Pain (any form or etiology).** Approve.

Lidocaine 5% patch has been shown to be effective in treating neuropathic pain of various forms and etiologies as monotherapy and, more commonly, as adjunctive therapy to a stable analgesic regimen.<sup>2,6-13</sup> There is evidence to suggest that lidocaine 5% patch, along with several other analgesics (i.e., opioids, tramadol, TCAs), can be effective as first-line therapy in the management of neuropathic pain.<sup>11</sup> The 2011 evidence-based guideline on treatment of painful diabetic neuropathy, published by the American Academy of Neurology (AAN), indicates the lidocaine 5% patch may be considered for the treatment of painful diabetic neuropathy.<sup>14</sup> Recommendations for the pharmacological management of neuropathic pain, published by the Mayo Foundation, indicate that lidocaine 5% patch has shown efficacy in patients with varying types of neuropathic pain, and are considered a first-line therapy.<sup>15</sup>

4. **Osteoarthritis (OA).** Approve after trying at least three other pharmacologic therapies recommended by the American College of Rheumatology (ACR) for the treatment of OA of the hand, hip, and knee (i.e., acetaminophen, COX-2 inhibitors, NSAIDs, salicylates, tramadol, opioids,

intraarticular glucocorticoids, intraarticular hyaluronan, topical capsaicin, and topical methylsalicylate).<sup>16</sup>

The 2012 ACR guidelines for OA of the hand, hip, and knee do not address the use of topical lidocaine.<sup>16</sup> However, several open-label trials have shown lidocaine 5% patches to be effective in treating pain associated with OA of the knee both as monotherapy and in combination with other analgesics (e.g., NSAIDs, COX-2 inhibitors, opioids, tramadol, acetaminophen).<sup>17-20</sup> In one open-label comparative trial (prematurely terminated before enrollment goals were achieved due to safety concerns surrounding the entire COX-2 class),<sup>21</sup> treatment of knee OA with lidocaine 5% patches (1 ½ patches applied every 24 hours) resulted in comparable reductions in pain intensity scores as celecoxib 200 mg/day.

### **When Policy Topic is not covered:**

Coverage of lidocaine 5% patch is recommended in circumstances that are listed in the Recommended Authorization Criteria (FDA-Approved Indications and Other Uses with Supportive Evidence). The following provides rationale for specific Exclusions. This is not an exhaustive list of Exclusions.

- 1. Carpal Tunnel Syndrome.** Two open-label trials have investigated the lidocaine 5% patch for the relief of pain associated with carpal tunnel syndrome.<sup>22-23</sup> In an open-label, parallel-group, single-center, active-controlled trial,<sup>22</sup> 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<sup>23</sup> found that lidocaine 5% patches given every 24 hours and naproxen 500 mg twice daily both led to significant reductions in the Average Pain Intensity scores in 100 patients with carpal tunnel syndrome. The 2008 American Academy of Orthopaedic Surgeons (AAOS) guidelines on carpal tunnel syndrome do not mention topical lidocaine in their recommendations for treatment.<sup>24</sup> 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 two small (n = 60 in each study) controlled studies, one small (n = 27) open-label study, and one case report (that appears to be one of the patients in the open-label study).<sup>25-28</sup> 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.<sup>29</sup>
- 5. Rheumatoid Arthritis (RA).** There are no data available on the use of lidocaine 5% patch in treating pain associated with RA.
- 6.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### **Considerations**

Lidocaine patches require prior authorization through the pharmacy services department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug

Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

### **Description of Procedure or Service**

Lidocaine 5% patch is indicated for the relief of pain associated with postherpetic neuralgia (PHN).<sup>1</sup> 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.

### **References:**

1. Lidoderm<sup>®</sup> patches [prescribing information]. Chadds Ford, PA: Endo Pharmaceuticals, Inc.; January 2013.
2. 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.
3. 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.
4. 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.
5. Chou R, Qaseem A, Snow V, et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. *Ann Intern Med*. 2007;147:478-491.
6. 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):914-8.
7. DRUGDEX<sup>®</sup> System. Thomson Reuters (Healthcare) Inc. Available at: <http://www.thomsonhc.com>. Accessed on June 12, 2013. Search terms: lidocaine.
8. 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):151-8.
9. 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.
10. Devers A, Galer BS. Topical lidocaine patch relieves a variety of neuropathic pain conditions: an open-label study. *Clin J Pain*. 2000;16:205-8.
11. Dworkin RH, Backonja M, Rowbotham MC, et al. Advances in neuropathic pain: diagnosis, mechanisms, and treatment recommendations. *Arch Neurol*. 2003;60(11):1524-34.
12. 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.
13. Fleming JA, O'Connor BD. Use of lidocaine patches for neuropathic pain in a comprehensive cancer centre. *Pain Res Manage*. 2009;14:381-388.
14. 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*. Epub ahead of print April 11, 2011.
15. 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.
16. 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. Available at:

<http://www.rheumatology.org/practice/clinical/guidelines/osteoarthritis.asp>. Accessed on June 12, 2013.

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):1455-8.
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):S13-9.
19. Burch F, Coddling C, Patel N, Sheldon E. Lidocaine patch 5% improves pain, stiffness, and physical function in osteoarthritis pain patients. *Osteoarthritis Cartilage*. 2004;12(3):253-5.
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. 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.
23. 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.
24. American Academy of Orthopaedic Surgeons. Clinical practice guideline on the treatment of carpal tunnel syndrome. September 2008. Available at: <http://www.aaos.org/research/guidelines/CTStreatmentguide.asp>. Accessed on: June 12, 2013.
25. Dalpiaz AS, Lordon SP, Lipman AG. Topical lidocaine patch therapy for myofascial pain. *J Pain Palliat Care Pharmacother*. 2004;18(3):15-34.
26. Dalpiaz AS, Dodds TA. Myofascial pain response to topical lidocaine patch therapy: case report. *J Pain Palliat Care Pharmacother*. 2002;16(1):99-104.
27. 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.
28. 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.
29. 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.

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#### **Billing Coding/Physician Documentation Information**

NA

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#### **Additional Policy Key Words**

Policy Number: 5.01.562

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#### **Related Topics**

N/A

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#### **Policy Implementation/Update Information**

06/2014 New Policy titled Lidoderm (lidocaine 5% patch)

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This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue

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