



Lidoderm (lidocaine 5% patch)

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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.¹

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.²⁻⁴ 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.⁵

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.^{2,6-13} 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.¹¹ 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.¹⁴ 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.¹⁵

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).¹⁶

The 2012 ACR guidelines for OA of the hand, hip, and knee do not address the use of topical lidocaine.¹⁶ 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).¹⁷⁻²⁰ In one open-label comparative trial (prematurely terminated before enrollment goals were achieved due to safety concerns surrounding the entire COX-2 class),²¹ treatment of knee OA with lidocaine 5% patches (1 1/3 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.²²⁻²³ In an open-label, parallel-group, single-center, active-controlled trial,²² 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 study²³ 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.²⁴ 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).²⁵⁻²⁸ 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.²⁹
- 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).¹ 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:

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Billing Coding/Physician Documentation Information

NA

Additional Policy Key Words

Policy Number: 5.01.562

Related Topics

N/A

Policy Implementation/Update Information

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

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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