PRIOR AUTHORIZATION POLICY

POLICY: Lidocaine Patch Products Prior Authorization Policy
- Lidoderm® (lidocaine 5% patch – Endo, generic)
- ZTlido® (lidocaine 1.8% topical system – Scilex)

REVIEW DATE: 10/02/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Lidocaine 5% patch and ZTlido are indicated for the **relief of pain associated with postherpetic neuralgia** (PHN).[1,2]

Lidocaine is an amide-type local anesthetic agent that is suggested to stabilize neuronal membranes by inhibiting sodium ion channels and the ionic fluxes required for the initiation and conduction of neuronal impulses producing a local analgesic effect when applied transdermally.[1,2] 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. In a single-dose, crossover study in healthy volunteers, ZTlido demonstrated equivalent exposure and peak concentration of lidocaine to lidocaine patch 5% (Lidoderm, generics).[2]

Other Uses with Supportive Evidence

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 nonsteroidal anti-inflammatory drugs (NSAIDs), cyclooxygenase-2 (COX-2) inhibitors, gabapentin, tramadol, or opioids.[3-5] The guidelines for treatment of low back pain (2017) do not address the use of topical

lidocaine; however, various other agents are used for pain associated with low back pain.[6] In patients with acute or subacute low back pain, the guidelines recommend NSAIDs or skeletal muscle relaxants as pharmacologic treatment options (strong recommendation; moderate-quality evidence). In patients with chronic low back pain who have had an inadequate response to nonpharmacologic therapy, the guidelines recommend consideration of pharmacologic treatment with NSAIDs as first-line therapy or tramadol or duloxetine as second-line therapy. Of note, tramadol is a narcotic and, like other opioids, is associated with the risk for abuse. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients (weak recommendation; moderate-quality evidence). Moderate-quality evidence showed no difference in pain between tricyclic antidepressants (TCAs) or selective serotonin reuptake inhibitors vs. placebo, and low-quality evidence showed no differences in function for antidepressants. Moderate-quality evidence showed that duloxetine was associated with a small improvement in pain intensity and function vs. placebo.

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.[3,7-14] 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.[12] 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.[15] 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.[16]
Several open-label trials have shown lidocaine 5% patches to be effective in treating pain associated with osteoarthritis 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 osteoarthritis with lidocaine 5% patches (1-⅓ patches applied every 24 hours) resulted in comparable reductions in pain intensity scores as celecoxib 200 mg/day.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of lidocaine patches. All approvals are provided for the duration noted below.

- **Lidoderm® (lidocaine 5% patch (Endo, generic)**
- **ZTlido® (lidocaine 1.8% topical system – Scilex)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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

Other Uses with Supportive Evidence

2. **Low Back Pain.** Approve for 1 year after trying at least three pharmacologic therapies with each one from a different class of medication used to treat low back pain.
   Note: Examples of different classes of pharmacologic therapies for low back pain include acetaminophen, nonsteroidal anti-inflammatory drugs, muscle relaxants, celecoxib, duloxetine, gabapentin. Examples of nonsteroidal anti-inflammatory drugs include etodolac, meloxicam, and nabumetone. Examples of muscle relaxants include carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, and orphenadrine.

3. **Neuropathic Pain.** Approve for 1 year.
   Note: For neuropathic pain due to radiculopathy or sciatica, please refer to the Conditions Not Covered

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   is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):
   section for Radiculopathy or Sciatica.

4. **Osteoarthritis.** Approve for 1 year after trying at least three pharmacologic therapies with each one from a different class of medication used for the treatment of osteoarthritis.
   Note: Examples of different classes of pharmacologic therapies for osteoarthritis include acetaminophen, celecoxib, nonsteroidal anti-inflammatory drugs, salicylates, intraarticular glucocorticoids, intraarticular hyaluronan, topical capsaicin, and topical methylsalicylate.[22] Examples of nonsteroidal anti-inflammatory drugs include etodolac, meloxicam, and nabumetone.

CONDITIONS NOT COVERED

1. **Carpal Tunnel Syndrome.** Two open-label trials have investigated the lidocaine 5% patch for the relief of pain associated with carpal tunnel symdrome.[23,24] In an open-label, parallel-group, single-center, active-controlled trial,[23] 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[24] 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.[25] 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 patches 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 of lidocaine 5% patches.[26-29] Larger, controlled studies are needed to fully determine the place in therapy of lidocaine patches 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.[30] 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.[31] A small ($n = 44$) double-blind, placebo-controlled study in hospitalized patients with traumatic rib fracture in Taiwan found that lidocaine 5% patch decreased pain scores after Day 5 of therapy vs. placebo, with no difference in oral opioid use but decreased meperidine injection use.[32] 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.[11,33] 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 patches in treating pain associated with RA.

7. Sciatica. There are no data available on the use of lidocaine patches in treating pain associated with sciatica.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. Title of Policy was updated to from "Lidocaine Patch" to "Lidocaine Patch Products".	09/27/2023
Annual Revision	No criteria changes.	10/02/2024

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