Drug Coverage Policy

Effective Date.....12/15/2025
Coverage Policy Number.....IP0709
Policy Title.....Lidocaine Patches

Lidocaine Patch Products

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

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Lidocaine 5% patch and ZTlido are indicated for the **relief of pain associated with postherpetic neuralgia** (PHN).[1-3] ZTlido is specifically indicated for use in adults. While the labeling for lidocaine 5% patch does not specify an age group, safety and efficacy have not been established in pediatric patients.

Lidocaine is an amide-type local anesthetic that exerts its effect by stabilizing neuronal membranes through the inhibition of sodium ion channels, thereby reducing the initiation and conduction of nerve impulses.[1-3] When applied transdermally, lidocaine provides localized analgesia without producing a complete sensory block.

Due to differences in formulation and bioavailability, the clinical efficacy of lidocaine topical systems does not directly correlate with the total drug content.[1-3] The total lidocaine content per patch is approximately 700 mg for lidocaine 5% patch, and 36 mg for ZTlido. Despite these differences, ZTlido has demonstrated bioequivalence to lidocaine 5% patch in terms of systemic exposure and peak plasma concentration in single-dose, crossover studies completed in healthy volunteers.

Other Uses with Supportive Evidence

Low Back Pain

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.[4-5,34] The American College of Physicians guidelines for treatment of nonradicular 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.

Neuropathic Pain

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.[7-15, 34] 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] 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 as first-line therapy.[16]

Osteoarthritis

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), 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.[21]

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of lidocaine patches. All approvals are provided for the duration noted below.

Lidoderm and ZTlido patches are considered medically necessary when ONE of the following criteria are met:

FDA-Approved Indication

1. **Postherpetic Neuralgia.** Approve for 1 year if the patient meets the following criteria:
   A. Preferred product criteria are met for the product(s) as listed in the below table.

Other Uses with Supportive Evidence

2. **Low Back Pain.** Approve for 1 year if the patient meets **ALL** of the following criteria:
   A. 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.

   B. Preferred product criteria are met for the product(s) as listed in the below table.

3. **Neuropathic Pain.** Approve for 1 year if the patient meets the following criteria:
   A. Preferred product criteria are met for the product(s) as listed in the below table.
   Note: For neuropathic pain due to radiculopathy or sciatica, please refer to the Conditions Not Covered section for Radiculopathy or Sciatica.

4. **Osteoarthritis.** Approve for 1 year if the patient meets **ALL** of the following criteria:
   A. 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, duloxetine, nonsteroidal anti-inflammatory drugs (oral and topical), intraarticular glucocorticoids, intraarticular hyaluronan, and topical capsaicin.[22] Examples of nonsteroidal anti-inflammatory drugs include celecoxib, salicylates, etodolac, meloxicam, and nabumetone.

   B. Preferred product criteria are met for the product(s) as listed in the below table.

Employer Plans:

Product	Criteria
Lidoderm (lidocaine 5% patch)	The patient has tried the bioequivalent generic product, lidocaine 5% patch, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result , per the prescriber, in a significant allergy or serious adverse reaction.

Individual and Family Plans:

Product	Criteria
Lidoderm (lidocaine 5% patch)	The patient has tried the bioequivalent generic product, lidocaine 5% patch, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result , per the prescriber, in a significant allergy or serious adverse reaction.
ZTlido (lidocaine topical system 1.8%)	The patient has tried lidocaine 5% patch (Lidoderm, generics).

Conditions Not Covered

Lidoderm and ZTlido patches for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Carpal Tunnel Syndrome.** Two open-label trials have investigated the lidocaine 5% patch for the relief of pain associated with carpal tunnel syndrome.[23,24] In an open-label, parallel-group, single-center, active-controlled trial, 40 patients with carpal tunnel syndrome were randomized to daily treatment with lidocaine 5% patch or an injection of lidocaine 1% plus methylprednisolone.[23] 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 in the Average Pain Intensity scores in 100 patients with carpal tunnel syndrome.[24] The 2024 American Academy of Orthopaedic Surgeons (AAOS) guidelines on carpal tunnel syndrome list topical treatments (such as lidocaine patches) among non-operative therapies that do not improve long-term outcomes.[25]

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] Existing studies show inconsistent outcomes and limited impact on opioid use. 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.

References

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Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	1/1/2025
Annual Revision	**Updated** policy title **from** "Ztlido for Individual and Family Plans" **to** "Lidocaine Patch Products." **Added** Lidoderm patches to policy. **Added** preferred product table **for** Employer Plans with criteria for Lidoderm patches. **Added** Lidoderm patches **to** preferred product table for Individual and Family Plans. **Osteoarthritis**: The note providing examples of different classes of pharmacologic therapies for osteoarthritis was updated to add duloxetine. It was also clarified that salicylates and celecoxib are examples of nonsteroidal anti-inflammatory drugs.	12/15/2025

The policy effective date is in force until updated or retired.