



## Drug Coverage Policy

Effective Date.....1/1/2025  
Coverage Policy Number.....IP0709  
Policy Title.....ZTlido for Individual and Family Plans

# ZTlido for Individual and Family Plans

- 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 and have discretion in making individual coverage determinations. 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.*

## Cigna Healthcare Coverage Policy

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

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.<sup>1,2</sup> 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).<sup>2</sup>

### **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.<sup>3-5</sup> 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.<sup>6</sup> 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.<sup>3,7-14</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>12</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>15</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>16</sup>

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).<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 osteoarthritis with lidocaine 5% patches (1-½ patches applied every 24 hours) resulted in comparable reductions in pain intensity scores as celecoxib 200 mg/day.

## **Medical Necessity Criteria**

**ZTlido is considered medically necessary when ONE of the following criteria are met:**

### **FDA-Approved Indication**

- 1. Postherpetic Neuralgia (PHN).** 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, celecoxib, nonsteroidal anti-inflammatory drugs, salicylates, intraarticular glucocorticoids, intraarticular hyaluronan, topical capsaicin, and topical methylsalicylate.<sup>22</sup> Examples of nonsteroidal anti-inflammatory drugs include etodolac, meloxicam, and nabumetone.

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

### Individual and Family Plans:

Product	Criteria
<b>ZTlido</b> (lidocaine topical system 1.8%)	The patient has tried lidocaine 5% patch (Lidoderm, generics).

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, 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.<sup>23,24</sup> In an open-label, parallel-group, single-center, active-controlled trial,<sup>23</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>24</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 2016 American Academy of Orthopaedic Surgeons (AAOS) guidelines on carpal tunnel syndrome do not mention topical lidocaine in their recommendations for treatment.<sup>25</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 patches in treating pain associated with fibromyalgia.
3. **Myofascial Pain as Adjunctive Therapy.** Published data are limited to small ( $n < 60$  in each study) studies of lidocaine 5% patches.<sup>26-29</sup> 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.<sup>30</sup> 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.<sup>31</sup> 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.<sup>32</sup> 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.<sup>11,33</sup> 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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## Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	1/1/2025

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

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