OVERVIEW
Lidocaine 5% patch and ZTlido are indicated for the relief of pain associated with postherpetic neuralgia (PHN). 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.

POLICY STATEMENT
This policy involves the use of Lidoderm, lidocaine patches, and ZTlido. Prior authorization is recommended for pharmacy benefit coverage of Lidoderm, lidocaine patches, and ZTlido. Approval is recommended for those who meet the conditions of coverage in the Criteria and Initial/Extended Approval for the diagnosis provided. Conditions Not Recommended for Approval are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Lidoderm, lidocaine patches, and ZTlido as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Lidoderm, lidocaine patches, and ZTlido be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Lidoderm, lidocaine patches, and ZTlido is recommended in those who meet the following criteria:

1. Postherpetic Neuralgia (PHN)
   Criteria. Approve

   Initial Approval/ Extended Approval.
   A) Initial Approval: 1 year
   B) Extended Approval: 1 year

   Other Uses with Supportive Evidence (Lidoderm and lidocaine 5% patches only)

2. Low Back Pain
Drug Policy

Criteria. Approve after trying at least three pharmacologic therapies, each one from a different class of medication used for the treatment of low back pain (e.g. acetaminophen, celecoxib, NSAIDs [e.g. etodolac, meloxicam, nabumeton], muscle relaxants [e.g. carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, orphenadrine], duloxetine, tramadol, gabapentin)

3. Neuropathic Pain (not Sciatica)
Criteria. Approve.

4. Osteoarthritis (OA)
Criteria. Approve after trying at least three pharmacologic therapies with each one from a different class of medication used for the treatment of OA of the hand, hip, and knee (e.g. acetaminophen, celecoxib, NSAIDs [e.g. etodolac, meloxicam, nabumeton], salicylates, intra-articular glucocorticoids, intra-articular hyaluronan, topical capsaicin, and topical methylsalicylate).

5. Diabetic Peripheral Neuropathy (DPN)
Criteria. Approve

Initial Approval/ Extended Approval.
A) Initial Approval: 1 year
B) Extended Approval: 1 year

Conditions Not Recommended for Approval
Lidoderm, lidocaine patches, and ZTildo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Carpal Tunnel Syndrome. Two open-label trials have investigated the lidocaine 5% patch for the relief of pain associated with carpal tunnel syndrome. In an open-label, parallel-group, single-center, active-controlled trial, 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 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. 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 small (n ≤ 60 in each study) studies. 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. 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. 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. **Rheumatoid Arthritis (RA).** There are no data available on the use of lidocaine 5% patch in treating pain associated with RA.

6. **Sciatica.** There are no data available on the use of lidocaine 5% patch in treating pain associated with sciatica.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**REFERENCES**

2. ZTlido topical system [prescribing information]. San Diego, CA: Scilex Pharmaceuticals; February 2018.


