PRIOR AUTHORIZATION GUIDE: ZTlido®

ZTlido® (lidocaine topical system) 1.8%

Medication Information	
Medication:	**Strength:**
Directions for use:	**Quantity:**
Medication Administered: ☐ Self-Administered ☐ Physician's Office ☐ Other: _____	

Clinical Information

What is the patient's diagnosis for the medication being requested? _____

PHN, or specify the diagnosis such as neuropathic pain associatied with PHN[1]

ICD-10 Code(s): _____

What medication(s) does the patient have a history of failure to? (*Please specify ALL medication(s)/strengths tried, directions, length of trial, and reason for discontinuation of each medication*)

List all OTC topical patches (i.e. lidocaine 4% patch), Rx lidocaine topical patches (i.e. lidocaine 5% patch), oral agents for neuropathic pain (i.e. Gabapentin/Pregabalin, SSRIs, TCAs, SNRIs, Opioids)

What medication(s) does the patient have a contraindication or intolerance to? (*Please specify ALL medication(s) with the associated contraindication to or specific issues resulting in intolerance to each medication.*

List intolerance or contraindications to oral agents for neuropathic pain (i.e. Gabapentin/Pregabalin, SSRIs, TCAs, SNRIs, Opioids)

Are there any supporting laboratory or test results related to the patient's diagnosis? (*Please specify or provide documentation*)

List tests/questionnaires, if any, supporting neuropathic pain diagnosis.

Additional information that may be important for this review

Provide rationale for ZTlido in this patient. State treatment goal.

Provide as much documentation as possible to support PA: patient notes, test results (including questionnaire results), supporting peer-reviewed publications below

EXAMPLES

ZTlido (lidocaine topical system) 1.8%
Apply to most painful area 12 hours on/12 hours off.
Apply 1, 2 or 3 patches daily (30/60/90 per month), based on size of the painful area. Use for initial trial of 6 months.

Diagnosis with appropriate code:
ICD Codes (not full list): B02.2x (PHN).

Patient has trialed OTC lidocaine 4% patch X 1 month with no relief. Gabapentin 900 mg per day X 30 days provided partial relief, but patient unable to tolerate further dose increase to minimum effective dose (1800 mg). Addition of lidocaine 5% patch to gabapentin provided additional pain relief, but patch did not adhere for full treatment period (detached within 2-3 hours). Patient tolerated lidocaine 5% patch well.

Patient did not tolerate gabapentin at doses above 900 mg/day (experienced dizziness and sedation). Recommended gabapentin dose is 1800-3600 mg/day for treatment of neuropathic pain.

Patient score on the PainDETECT questionnaire is highly suggestive of neuropathic pain.

Addition of lidocaine patch to gabapentin resulted in 48% reduction of pain intensity in clinical studies.[2] ZTlido has shown superior adhesion over lidocaine 5% patch in head-to-head clinical studies.[3] Uniform adhesion is required, per FDA, for lidocaine patch to work effectively. Patient has trialed ZTlido through sample program and demonstrated significant pain relief.

Treatment goal: improvement of function, and sleep within 1 year with this ZTlido opioid-sparing regimen.

1. Lawson E, Singla P, Adler J, Argoff CE, Bettinger JJ, Bhaskar A, Clarke H, Eidelman A, Hirani S, Hooten WM, Tishler J, Wallace MS, Barreveld AM. Topical analgesics for neuropathic pain: An Evidence-Informed guide for the practicing clinician. *Pain Med*. 2025 Sep 29:pnaf130. doi: 10.1093/pm/pnaf130. Epub ahead of print. PMID: 41017645.

2. Rehm S, Binder A, Baron R. Post-herpetic neuralgia: 5% lidocaine medicated plaster, pregabalin, or a combination of both? A randomized, open, clinical effectiveness study. *Curr Med Res Opin*. 2010;26(7):1607-1619. doi:10.1185/03007995.2010.483675.

3. Gudin J, Webster LR, Greuber E, Vought K, Patel K, Kuritzky L. Open-label adhesion performance studies of a new lidocaine topical system 1.8% versus lidocaine patches 5% and lidocaine medicated plaster 5% in healthy subjects. *J Pain Res*. 2021;14:513-526.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

ZTLIDO is indicated for relief of pain associated with post-herpetic neuralgia (PHN) in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ZTLIDO is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

Warnings and Precautions

Accidental exposure can occur even after a ZTLIDO patch has been used. Small children or pets could suffer serious adverse effects from chewing or ingesting a new or used ZTLIDO patch. Store and dispose of patches properly and keep out of reach of children and pets.

Excessive dosing or overexposure to lidocaine can occur. Longer duration of application, application of more than the recommended number of patches, smaller patients, or impaired elimination may all contribute to increased blood concentration levels of lidocaine. If lidocaine overdose is suspected, check drug blood concentration. Management of overdose includes close monitoring, supportive care, and symptomatic treatment.

Cases of methemoglobinemia have been reported with local anesthetic use, although patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, or concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. Signs and symptoms include cyanotic skin discoloration and/or abnormal coloration of the blood and may occur immediately or may be delayed after exposure. Methemoglobin levels may continue to rise leading to more serious central nervous system and cardiovascular adverse effects. Discontinue ZTLIDO and any other oxidizing agents. Depending on severity of the symptoms, patients may respond to supportive care or may require treatment with methylene blue, exchange transfusion, or hyperbaric oxygen.

Application site reactions can occur during or immediately after treatment with ZTLIDO. This may include development of blisters, bruising, burning sensation, depigmentation, dermatitis, discoloration, edema, erythema, exfoliation, irritation, papules, petechia, pruritus, vesicles, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours. If application site reactions occur while the topical system is being worn, advise the patient to remove ZTLIDO and not to reapply until skin reactions subside.

Hypersensitivity cross-reactions may be possible for patients allergic to PABA derivatives. Manage hypersensitivity reactions by conventional means.

Eye exposure with ZTLIDO should be avoided. If eye contact occurs, immediately wash out the eye with water or saline and protect the eye (eg, eye glasses/eye wear) until sensation returns.

Adverse Reactions

Side effects of ZTLIDO include application site reactions such as irritation, erythema, and pruritus. These are not all of the adverse reactions that may occur. Please see full Prescribing Information for more information.

Use in Specific Populations

Use of ZTLIDO during lactation should be used with caution as lidocaine is excreted into breast milk. The limited human data with lidocaine in pregnant women are not sufficient to inform drug-associated risk for major birth defects and miscarriage.

To report SUSPECTED ADVERSE REACTIONS, contact SCILEX Pharmaceuticals Inc. at 1-866-SCILEX3 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see ZTlido full Prescribing Information for additional safety information.

SCILEX® PHARMACEUTICALS