PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

LIDODERM
(lidocaine patch 5%)

ZTLIDO
(lidocaine topical system)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 125-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Lidoderm
Lidoderm is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to **intact skin**.

ZTLido
ZTLido (lidocaine topical system) 1.8% is indicated for relief of pain associated with post-herpetic neuralgia (PHN) in adults.

Compendial Uses
Pain associated with diabetic neuropathy[4,5,8]
Pain associated with cancer-related neuropathy[4,6,7]

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for any of the following: A) Pain associated with post-herpetic neuralgia, B) Pain associated with diabetic neuropathy, C) Pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy])

Quantity Limits apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Lidoderm (lidocaine patch 5%) is indicated for relief of pain associated with post-herpetic neuralgia (PHN).[1] ZTLido (lidocaine topical system) 1.8% is indicated for relief of pain associated with post-herpetic neuralgia (PHN) in adults.[2]

Because of the difference in bioavailability of ZTLido compared with Lidoderm (lidocaine 5% patch), a different dosage strength is required to be administered to the patient. One ZTLido (lidocaine topical system) 1.8% provides equivalent lidocaine exposure to one Lidoderm (lidocaine patch 5%). In a single-dose, crossover study conducted in 53 healthy volunteers, ZTLido (lidocaine topical system) 1.8% demonstrated equivalent exposure (AUC) and peak concentration (C_{max}) of lidocaine to Lidoderm (lidocaine patch 5%).[2]

Lidocaine 5% patches were well tolerated and reduced pain in patients with diabetic neuropathy in an open-label, flexible-dosing, 3-week study with a 5-week extension. The study included 56 patients with clinically defined painful diabetic polyneuropathy of longer than a 3 months' duration. Results determined that 5% lidocaine patches for up to 18 hours per day are well tolerated in patients with painful diabetic polyneuropathy, significantly improve pain and quality-of-life ratings, and may allow tapering of concomitant analgesic therapy.[5] Additionally, the American Academy of Neurology recommends that the Lidoderm patch may be considered for the treatment of painful diabetic neuropathy.[8] Because ZTLido patches provide an equivalent dose of lidocaine as Lidoderm patches, coverage is available for Lidoderm (lidocaine patches) 5% and ZTLido (lidocaine topical system) 1.8% for pain associated with diabetic neuropathy.

Neuropathic cancer pain (NCP) may be cancer-related, namely resulting from nervous system tumor invasion, surgical nerve damage during tumor removal, radiation-induced nerve damage and chemotherapy-related neuropathy, or may be of benign origin, unrelated to cancer.[7] Additional analgesic medications or therapies may be necessary in patients with cancer-related pain, particularly when opioid analgesics are ineffective or produce inadequate pain relief. According to the National Comprehensive Cancer Network (NCCN) guidelines for adult cancer pain, a topical agent such as lidocaine can be used as an adjunctive treatment for neuropathic pain.[4,6]

Lidoderm or ZTLido should be applied to intact skin to cover the most painful area. Apply the prescribed number of patches (maximum of 3), only once for up to 12 hours within a 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner. Excessive dosing by applying more than the recommended quantity of the requested drug or applying for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects. Therefore, the quantity limit is set to 90 patches per month.[1-4]

REFERENCES

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2. ZTLido [package insert]. Palo Alto, CA: Scilex Pharmaceuticals Inc.; April 2021.
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4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed September 2, 2021.
5. Barbano RL, Herrmann DN, Hart-Gouleau S, et al: Effectiveness, tolerability, and impact on quality of life of the 5% lidocaine patch in diabetic polyneuropathy. *Arch Neurol.* 2004; 61:914-918.
6. National Comprehensive Cancer Network (NCCN) Guidelines: Adult Cancer Pain V2.2021. National Comprehensive Cancer Network. Available from URL: http://www.nccn.org/professionals/physician_gls/PDF/pain.pdf. Accessed September 2021.
7. Vadalouca A, Raptis E, Moka E, et al. Pharmacological Treatment of Neuropathic Cancer Pain: A Comprehensive Review of the Current Literature. World Institute of Pain. *Pain Practice.* 2011; 12(3):219-251.
8. Bril V., England J., Franklin G.M., et al. Evidence-based guideline: Treatment of painful diabetic neuropathy. *Neurology.* 2011;76;1758-1765. Available at www.neurology.org. Accessed September 2021.
9. Derry S, Wiffen PJ, Moore RA, et al. Topical lidocaine for neuropathic pain in adults (Review). *Cochrane Database Syst Rev* 2014. doi: 10.1002/14651858.CD010958.

Written by:	UM Development (JG)
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CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for any of the following: A) Pain associated with post-herpetic neuralgia, B) Pain associated with diabetic neuropathy, C) Pain associated with cancer-related neuropathy (including treatment-related neuropathy [e.g., neuropathy associated with radiation treatment or chemotherapy])? [If no, then no further questions.]	Yes	No
2	Does the patient require more than the plan allowance of 90 patches per month? [RPh Note: If yes, then deny and enter a partial approval for 90 patches / 25 days or 270 patches / 75 days of Lidoderm or ZTLido.]	Yes	No

Mapping Instructions				
	Yes	**No**	**DENIAL REASONS (Non-Medicaid, Non-Medicare Part D)**	**DENIAL REASONS (Medicaid)**
1.	Go to 2	Deny	Coverage for this medication is denied for the following reason(s). We reviewed the information we received about your condition and circumstances. We used the policy (INSERT CRITERIA NAME) when making this decision. The policy states that this medication may be approved when being used for any of the following: -Pain associated with post-herpetic neuralgia -Pain associated with diabetic neuropathy -Pain associated with cancer-related neuropathy (including cancer treatment-related neuropathy) Based on the policy and the information we have, the request is denied. The information provided to us indicates that the requested medication will not be used for one of the uses listed above. [Short Description: Diagnosis]	You do not meet the requirements of your plan. Your plan covers this drug when you have any of the following: - Pain associated with post-herpetic neuralgia - Pain associated with diabetic neuropathy - Pain associated with cancer-related neuropathy (including treatment-related neuropathy) Your request has been denied based on the information we have. [Short description: No approvable diagnosis]
2.	Deny	Approve, 36 months, 90 patches/ 25 days* or 270 patches/ 75 days*	You do not meet the requirements of your plan. You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 90 patches/month of the requested drug. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 36 months. Your request for additional	You do not meet the requirements of your plan. You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 90 patches/month of the requested drug. Your request has been partially approved. You have been approved for the maximum quantity that your plan covers for a duration of 36 months. Your request for additional

			quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]	quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*