

QUANTITY LIMIT CRITERIA

BRAND NAME*
(generic)

LIDODERM
(lidocaine patch 5%)

ZTLIDO
(lidocaine topical system)

Status: CVS Caremark Criteria

Type: Quantity Limit

Ref # 2971-H

* 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 the relief of pain associated with post-herpetic neuralgia (PHN).

Compendial Uses

Pain associated with diabetic neuropathy

Pain associated with cancer-related neuropathy

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

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

In addition, Lidocaine patches 5% 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 with 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

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.⁸ 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 National Comprehensive Cancer Network (NCCN) guidelines for adult cancer pain, topical agents such as Lidocaine can be used as an adjunctive treatment option in neuropathic pain.^{4,7}

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 the requested drug for longer than the recommended wearing time could result in increased absorption of lidocaine and high blood concentrations, leading to serious adverse effects.¹⁻⁴

If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that quantity limits are exceeded.

REFERENCES

1. Lidoderm [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Inc.; November 2018.
2. ZTLido [package insert]. San Diego, CA: Scilex Pharmaceuticals Inc.; November 2018
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed September 2018.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed September 2018.
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. Dworkin RH, O'Connor AB, Backonja M, et al. Pharmacologic Management of Neuropathic Pain: Evidence-based Recommendations. *Pain* 2007; 132(3):237-251.
7. National Comprehensive Cancer Network: Adult Cancer Pain V.1.2018. National Comprehensive Cancer Network. Fort Washington, PA. 2008. Available from URL: http://www.nccn.org/professionals/physician_gls/PDF/pain.pdf. Accessed September 2018.
8. Vadalouca A, Raptis E, Moka E, et al. Pharmacological Treatment of Neuropathic Cancer Pain: A Comprehensive Review of Current Literature. *World Institute of Pain Pain Practice* 2011; 12(3):219-251.
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.

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LIMIT CRITERIA

Drug	1 Month Limit*	3 Month Limit*
Lidoderm 5% (lidocaine patch 5%)	90 patches/25 days	270 patches/75 days
ZTLido 1.8% (lidocaine patch 1.8%)	90 patches/25 days	270 patches/75 days

*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.