

Lidoderm (lidocaine) 5% Transdermal Patch

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Lidocaine 5% Transdermal Patch is the generic name for the U.S. Brand Name product Lidoderm, FDA-approved for relief of pain associated with post-herpetic neuralgia. The main ingredient in the medication is lidocaine, which causes a loss of feeling in the area around where the patch is applied. It helps treat pain, including nerve pain.

Definitions

"Post-herpetic Neuralgia" is a very bad pain that develops after a shingles infection (a condition where the body has painful rash on an area, typically the face or body torso).

"Neuropathic Pain" is pain in your body that is caused by an injury or disease to your central nervous system.

“**Chemotherapy**” is a treatment where drugs are used to kill cancer cells.

Medical Necessity Criteria for Initial Authorization

The Plan considers Lidocaine 5% Transdermal Patch medically necessary when the member has **ONE** of the following diagnoses:

1. pain associated with postherpetic neuralgia; **OR**
2. neuropathic pain (e.g., painful diabetic neuropathy, neuropathy associated with radiation treatment or chemotherapy).

If the above prior authorization criteria are met, Lidocaine 5% Transdermal Patch will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Lidocaine 5% Transdermal Patch for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. This is primarily due to a lack of robust evidence in the form of large-scale, well-designed, randomized controlled trials to conclusively establish its safety and effectiveness for other conditions.

Appendix

Lidocaine 5% Transdermal Patch for non-specified indications

There is potential for the Lidocaine 5% Transdermal Patch to relieve symptoms in off-label conditions such as low back pain and osteoarthritis. However, these applications are not officially approved. Despite suggestive preliminary findings and anecdotal clinical evidence, we need more robust data to endorse widespread use for these conditions.

In the context of low back pain and osteoarthritis, the Lidocaine 5% Transdermal Patch has been utilized as additional or alternative therapy when conventional treatments have proven ineffective or have not been tolerated. Yet, the evidence for its efficacy in these scenarios remains sparse and is primarily based on small-scale studies or individual case reports.

It's important to consider that these conditions encompass a variety of underlying causes and patients often have diverse responses to treatments. Therefore, robust and consistent evidence is needed before

changing standard treatment protocols. To conclusively establish the effectiveness of the Lidocaine 5% Transdermal Patch for these and other off-label uses, more research, particularly in the form of large-scale randomized controlled trials, is required. Until this evidence becomes available, use for these indications is categorized as experimental or investigational.

References

1. Cheng, Y. J. (2016). Lidocaine skin patch (Lidopat® 5%) is effective in the treatment of traumatic rib fractures: a prospective double-blinded and vehicle-controlled study. *Medical Principles and Practice*, 25(1), 36-39.
2. Derry S, Wiffen PJ, Moore RA, Quinlan J. Topical lidocaine for neuropathic pain in adults. *Cochrane Database Syst Rev* 2014; :CD010958.
3. Derry, S., Wiffen, P. J., Moore, R. A., & Quinlan, J. (2014). Topical lidocaine for neuropathic pain in adults. *Cochrane database of systematic reviews*, (7).
4. Dworkin RH, O'Connor AB, Audette J, et al. Recommendations for the pharmacological management of neuropathic pain: an overview and literature update. *Mayo Clin Proc* 2010; 85:S3.
5. Fleming, J. A., & O'Connor, B. D. (2009). Use of lidocaine patches for neuropathic pain in a comprehensive cancer centre. *Pain Research and Management*, 14(5), 381-388.
6. Garzón-Rodríguez C, Casals Merchan M, Calsina-Berna A, et al. Lidocaine 5 % patches as an effective short-term co-analgesic in cancer pain. Preliminary results. *Support Care Cancer* 2013; 21:3153.
7. Gilron I, Baron R, Jensen T. Neuropathic pain: principles of diagnosis and treatment. *Mayo Clin Proc* 2015; 90:532.
8. Gudín, J., Argoff, C., Fudin, J., Greuber, E., Vought, K., Patel, K., & Nalamachu, S. (2020). A randomized, open-label, bioequivalence study of lidocaine topical system 1.8% and lidocaine patch 5% in healthy subjects. *Journal of Pain Research*, 13, 1485.
9. Gudín, J., Webster, L. R., Greuber, E., Vought, K., Patel, K., & Kuritzky, L. (2021). Open-label adherence performance studies of a new lidocaine topical system 1.8% versus lidocaine patches 5% and lidocaine medicated plaster 5% in healthy subjects. *Journal of Pain Research*, 14, 513.
10. Hussain, N., Said, A. S., Javaid, F. A., Al Haddad, A. H. I., Anwar, M., Khan, Z., & Abu-Mellal, A. (2021). The efficacy and safety profile of capsaicin 8% patch versus 5% Lidocaine patch in patients with diabetic peripheral neuropathic pain: a randomized, placebo-controlled study of south Asian male patients. *Journal of Diabetes & Metabolic Disorders*, 20(1), 271-278.

11. Lidoderm (lidocaine patch 5%) [prescribing information]. Malvern, PA: Endo Pharmaceuticals; November 2018.
12. Ma, K., Jiang, W., Wang, Y. X., Wang, L., Lv, Y., Liu, J. F., ... & Liu, Y. Q. (2021). Expert consensus of the Chinese Association for the Study of Pain on pain treatment with the transdermal patch. *World journal of clinical cases*, 9(9), 2110.
13. Neurology, "Evidence-Based Guideline: Treatment of Painful Diabetic Neuropathy," April 2011
14. Voute, M., Morel, V., & Pickering, G. (2021). Topical Lidocaine for Chronic Pain Treatment. *Drug Design, Development and Therapy*, 15, 4091.
15. Yang, X. D., Fang, P. F., Xiang, D. X., & Yang, Y. Y. (2019). Topical treatments for diabetic neuropathic pain. *Experimental and therapeutic medicine*, 17(3), 1963-1976.
16. ZTlido (lidocaine) [prescribing information]. Palo Alto, CA: Scilex Pharmaceuticals Inc; April 2021.

Clinical Guideline Revision / History Information

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