

Lidocaine Topical System

- Lidoderm (lidocaine) 5% Transdermal Patch
- Bondlido (lidocaine 10% topical system)

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.

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Summary

Lidocaine topical systems, including Lidoderm (Lidocaine 5% Transdermal Patch) and Bondlido (lidocaine 10% topical system) are FDA-approved for relief of pain associated with post-herpetic neuralgia. The main ingredient in the medication is lidocaine, a local anesthetic, which causes a loss of feeling in the

area around where the patch is applied. Lidocaine, when applied topically, can help manage pain, including nerve pain.

Definitions

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

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

“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).

“[s]” indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

lidocaine (Lidoderm) 5% Transdermal Patch

The Plan considers lidocaine (Lidoderm) 5% Transdermal Patch medically necessary when the member has ONE of the following diagnoses:

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

If the above prior authorization criteria are met, lidocaine (Lidoderm) 5% Transdermal Patch will be approved for up to 12 months.^[s]

Bondlido (lidocaine 10%) Topical System

The Plan considers Bondlido (lidocaine 10%) transdermal system medically necessary when the member meets ALL of the following:

1. The member is experiencing pain associated with postherpetic neuralgia; *AND*
2. The member is unable to use, or has tried and failed lidocaine 5% transdermal patch.^[s]

If the above prior authorization criteria are met, Bondlido (lidocaine) 10% topical system will be approved for up to 12 months.^[s]

Experimental or Investigational / Not Medically Necessary^[5]

Lidocaine topical systems (Lidocaine (Lidoderm) 5% Transdermal Patch or Bondlido [lidocaine] 10% topical system] for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Appendix A

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 an open-label study of lidocaine 5% transdermal patch, researchers found among consecutive pain participants, those who did not perceive a clinical

improvement in pain were more likely to experience low back pain at baseline. However, studies are mixed and have shown benefit in those with chronic low back pain and osteoarthritis.

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.

In two meta-analyses assessing the role of lidocaine 5% transdermal patch in acute pain and emergency department settings, they found no statistically significant benefit of lidocaine over other conventional therapy such as non-steroidal anti-inflammatory drugs (NSAIDs).

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.

Clinical Guideline Revision / History Information

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