

Document ID#: 2140004
Subject: Lidoderm (lidocaine patch 5%)
Effective Date: November 15, 2011

Clinical Documentation and Prior Authorization Required	√	Type of Review — Case Management	
Not Covered		Type of Review — Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Administrative Process (Internal Use Only)	LPN

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

Overview

FDA-Approved Indications

Lidoderm (lidocaine patch 5%) is indicated for relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.

Pharmacy Coverage Guidelines

Tufts Health Plan may authorize coverage of **Lidoderm** (lidocaine patch 5%) for Members, when the following criteria is met:

1. Neuropathic pain (e.g. Post Herpetic Neuralgia)
 - a. Failure, adverse reaction, or contraindication to gabapentin.

OR

2. Chronic (greater than 3 months) non-neuropathic pain
 - a. Documented failure of a trial of **at least two** of the following drug categories being used for the treatment of non-neuropathic pain: tricyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAIDs or COXII and/or opioid analgesics.

Note: A trial consists of at least 30 days of each medication at therapeutic doses.

OR

3. Member is new to plan and pain is currently well controlled on Lidoderm.

Limitations

1. Coverage of Lidoderm (lidocaine patch 5%) will be limited to 30 patches per 30 days.
2. Initial authorization for Chronic (greater than 3 months) non-neuropathic pain will be for a period of up to 3 months. Subsequent authorization for up to **one** (1) year will require documentation from the provider of sustained clinical effectiveness.

Codes

None.

References

1. Lidoderm (lidocaine patch 5%) prescribing information. Chadds Ford, PA: Endo Pharmaceuticals Inc.; 2008 February.
2. Lidoderm (lidocaine patch 5%) prescribing information. Chadds Ford, PA: Endo Pharmaceuticals Inc.; 2010 March.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee on September 8, 2009.

Subsequent Endorsement Date(s) and Changes Made:

1. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
2. July 13, 2010:
 - a. Removal of, "Tufts Health Plan will not authorize the use of Lidoderm (lidocaine patch 5%) for conditions other than those listed above without clinical justification." And "Documented diagnosis of pain associated with post-herpetic neuralgia".
 - b. Added: Neuropathic pain: failure, adverse reaction, or contraindication to gabapentin; OR Non-neuropathic pain: failure, adverse reaction, or contraindication to two prescription analgesics (including a narcotic); OR Member is new to plan and pain is currently well controlled on Lidoderm.
3. July 12, 2011: No changes.
4. November 15, 2011:
 - Removed the criteria for non-neuropathic pain which required failure, adverse reaction, or contraindication to two prescription analgesics (including a narcotic); and replaced it with Chronic (greater than 3 months) non-neuropathic pain "Documented failure of a trial of **at least two** of the following drug categories being used for the treatment of non-neuropathic pain: tricyclic antidepressants, SSRI's, SNRI's, anticonvulsants, NSAIDs or COXII and/or opioid analgesics"
 - Added a note: A trial consists of at least 30 days of each medication at therapeutic doses.
 - Added limitation: Initial authorization for non-neuropathic pain will be for a period of up to 3 months. Subsequent authorization for up to **one** (1) year will require documentation from the provider of sustained clinical effectiveness.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health Plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the Pharmacy section of our Web site at <http://www.tuftshealthplan.com/providers> to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline,

Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Medicare Preferred, please refer to Tufts Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.