Lidocaine Topical 5%

Description

Lidocaine Topical 5%

Background
Lidocaine is an amide-type local anesthetic that inhibits the ionic fluxes required for the initiation and conduction of impulses. This stabilizes the neuronal membrane and affects local anesthetic action. Lidocaine is currently available as an external cream, intradermal injectable powder, external gel, ophthalmic gel, external jelly, external lotion, external ointment, external patch, injection solution, and topical solution (1).

Regulatory Status
FDA-approved indications:
1. Lidocaine ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx. It is also used as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites (1).

Off-Label Uses:
Compounded topical lidocaine preparations have not been shown to be superior to commercially available topical lidocaine preparations.

Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to any other component of the product (1). Seizures, cardiopulmonary arrest, and death in patients under the age of 3 have been reported with use of lidocaine hydrochloride oral topical solution, 2%, when not administered in strict adherence to the dosing and administration recommendations (1).
For lidocaine ointment a single adult application should not exceed 5 g of Lidocaine Ointment 5%, containing 250 mg of lidocaine base. This is roughly equivalent to squeezing a six (6) inch length of ointment from the tube. No more than one-half tube, approximately 17-20 g of ointment or 850-1000 mg lidocaine base, should be administered in any one day. Excessive dosage or short intervals between doses can result in high plasma levels and serious adverse effects (1).

Lidocaine criteria was created with dosing above FDA limits in order to help existing patients that have been taking doses above the FDA limits to safely taper down their doses to the FDA appropriate levels. This will allow physicians to time to work with their patients in creating a custom taper that is safe and provides adequate pain control.

Related policies
Lidocaine Injection, Lidocaine Patches, Lidocaine Powder

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lidocaine topical may be considered medically necessary in patients with neuropathic pain; physician agrees to taper patient’s dose to the maximum FDA allowable dose based on their daily dose and patients taking over 600 grams of topical lidocaine in 90 days be required to taper to 600 grams topical lidocaine within 90 days.

Lidocaine topical may be considered investigational in diagnoses that are off-label or in formulations that do not have a confirmed FDA approval of use.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

Neuropathic pain

AND the following:
1. Physician agrees to taper patient’s dose to the maximum FDA allowable dose based on their daily dose
**Section:** Prescription Drugs  
**Effective Date:** July 1, 2016  
**Subsection:** Topical Products  
**Original Policy Date:** April 29, 2016  
**Subject:** Lidocaine Topical 5%  
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a. Patients taking over 600 grams of topical lidocaine in 90 days be required to taper to 600 grams topical lidocaine within 90 days

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### Prior - Approval **Renewal Requirements**

None

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### Policy Guidelines

**Pre - PA Allowance**

| Quantity | 600 grams per 90days |

**Prior - Approval Limits**

| Quantity | 900 grams per 90days |
| Duration | 3 months |

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### Rationale

**Summary**

Lidocaine is an amide-type local anesthetic that blocks the initiation and conduction of impulses. Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to any other component of the product. Seizures, cardiopulmonary arrest, and death in patients under the age of 3 have been reported with use of lidocaine hydrochloride oral topical solution, 2%, when not administered in strict adherence to the dosing and administration recommendations (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of lidocaine topical while maintaining optimal therapeutic outcomes.

**References**


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### Policy History

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<td>April 2016</td>
<td>Addition to PA</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective on July 1, 2016.

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