Lidocaine Topicals

Description

Emla (lidocaine 2.5% and prilocaine 2.5%), Lidocaine Topical 5%, Pliaglis Cream (lidocaine 7% and tetracaine 7%), Tetravex Gel (tetracaine 2%)

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 (1-3).

Tetracaine is an ester local anesthetic that blocks both the initiation and conduction of nerve impulses by inhibiting sodium ion influx, inhibiting depolarization of the cells. Tetracaine is in Pliaglis Cream as well as Tetravex Gel (4-5).

Regulatory Status
FDA-approved indications:
1. Lidocaine ointment 5% 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).
2. Lidocaine and prilocaine 2.5%/2.5% (Emla) is indicated as a topical anesthetic for use on: normal intact skin for local analgesia or genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia (2).
3. Lidocaine and tetracaine Cream 7%/7% (Pliaglis) is a combination of lidocaine, an amide local anesthetic, and tetracaine, an ester local anesthetic, indicated for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal (3).

4. Tetracaine gel 2% (Tetravex) is indicated for the local management of painful skin wounds, including pressure ulcers, venus stasis ulcers, superficial wounds and scrapes, 1st and 2nd degree burns (5).

** Use of this medication for the treatment of pain associated with a cosmetic procedure is a non-covered benefit.

**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. 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 (1-3).

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).

**Related policies**
Anesthetic Powders, Lidocaine Injection, Lidocaine Patches

**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 5%, lidocaine and prilocaine 2.5%/2.5%, lidocaine and tetracaine 7%/7%, and tetracaine 2% topical may be considered **medically necessary** in patients with acute neuropathic pain; and if the conditions indicated below are met.

Lidocaine 5%, lidocaine and prilocaine 2.5%/2.5%, lidocaine and tetracaine 7%/7%, and tetracaine 2% topical may be considered **investigational** for all other diagnoses.

**Prior-Approval Requirements**

**Diagnosis**

Patient must have **ONE** of the following:

1. Local wound pain
2. Local analgesia

**AND** the following:

a. **NOT** for used for pain associated with cosmetic procedures

**Prior – Approval Renewal Requirements**

None

**Policy Guidelines**

**Pre - PA Allowance**

**Quantity**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity per 90 Days</th>
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<tbody>
<tr>
<td>Lidocaine ointment 5%</td>
<td>100 grams per 90 days</td>
</tr>
<tr>
<td>Lidocaine and prilocaine 2.5%/2.5% (Emla)</td>
<td>30 grams per 90 days</td>
</tr>
<tr>
<td>Tetracaine gel 2% (Tetravex)</td>
<td>30 grams per 90 days</td>
</tr>
</tbody>
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**Prior - Approval Limits**

**Quantity**
Summary
Lidocaine is an amide-type local anesthetic that blocks the initiation and conduction of impulses. Tetracaine is an ester local anesthetic that blocks both the initiation and conduction of nerve impulses by inhibiting sodium ion influx, inhibiting depolarization of the cells. 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 (1-3).

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

References
Section: Prescription Drugs  
Effective Date: July 1, 2019

Subsection: Topical Products  
Original Policy Date: April 29, 2016

Subject: Lidocaine Topicals  
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Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>April 2016</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2016</td>
<td>Annual review</td>
</tr>
<tr>
<td>August 2016</td>
<td>Change of SA to 100 gm per 90 days and PA limit to 600 gm and the addition of “acute” to neuropathic pain</td>
</tr>
<tr>
<td>March 2017</td>
<td>Annual Review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Addition of Lidocaine and prilocaine 2.5%/2.5% (Emla) and Lidocaine and Tetracaine Cream 7%/7% (Pliaglis) to criteria Change of PA limit for Lidocaine 5% from 600mg to 150mg</td>
</tr>
<tr>
<td>July 2018</td>
<td>Change in criteria from the diagnosis of Acute Neuropathic Pain to use for diagnosis of Local wound pain and Local analgesia Addition of Tetravax Gel to criteria</td>
</tr>
<tr>
<td>September 2018</td>
<td>Annual review</td>
</tr>
<tr>
<td>May 2019</td>
<td>Increased Emla PA quantity from 60 g/90 days to 180 g/90 days. Increased PA duration to 12 months for Emla patients on dialysis</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.