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5.90.020

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	April 29, 2016
Subject:	Lidocaine Topicals	**Page:**	1 of 5

Last Review Date: March 7, 2025

Lidocaine Topicals

Description

Emla (lidocaine 2.5% and prilocaine 2.5%), Lidocaine Topical 5%, 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 (1-2).

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 Tetravex Gel (3-4).

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. 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 (4).

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 (1-2).

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 topicals may be considered **medically necessary** if the conditions indicated below are met.

Lidocaine topicals may be considered **investigational** for all other indications.

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

Drug	Quantity
Lidocaine ointment 5%	100 grams per 90 days
Lidocaine and prilocaine 2.5%/2.5% (Emla)	30 grams per 90 days
Tetracaine gel 2% (Tetravex)	30 grams per 90 days

Prior - Approval Limits

Quantity

Drug	Quantity
Lidocaine ointment 5%	150 grams per 90 days
Lidocaine and prilocaine 2.5%/2.5% (Emla)*	180 grams per 90 days
Tetracaine gel 2% (Tetravex)	60 grams per 90 days

Duration 3 months
*12 months for patients requesting Emla who are also on dialysis (and every year is considered initiation)

Rationale

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 (1-2).

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

References

1. Lidocaine Ointment [package insert]. Melville, NY: Fourgera Pharmaceuticals Inc; August 2014.
2. Emla [package insert]. Wilmington, DE: AstraZeneca LP; April 2006.
3. Tetracaine Hydrochloride. Drug Facts and Comparisons. Accessed on April 14, 2023.
4. Tetravex gel [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; April 2018.

Policy History

Date	Action
April 2016	Addition to PA
June 2016	Annual review
August 2016	Change of SA to 100 gm per 90 days and PA limit to 600 gm and the addition of “acute” to neuropathic pain
March 2017	Annual Review
June 2018	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
July 2018	Change in criteria from the diagnosis of Acute Neuropathic Pain to use for diagnosis of Local wound pain and Local analgesia Addition of Tetravex Gel to criteria
September 2018	Annual review

May 2019	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
June 2019	Annual review
September 2020	Annual review
June 2021	Annual review
June 2022	Annual review and reference update
June 2023	Annual review and reference update. Changed policy number to 5.90.020
September 2023	Annual review
June 2024	Annual review
September 2024	Annual review
December 2024	Removal of Pliaglis cream
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.