BlueCross BlueShield
Federal Employee Program

LIDOCAINE TOPICALS
Emla (lidocaine 2.5% and prilocaine 2.5%), Lidocaine Topical 5%, Tetravex Gel (tetracaine 2%)

RATIONALE FOR INCLUSION IN PA PROGRAM

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.

<u>Off-Label Uses:</u>

Compounded topical lidocaine preparations have not been shown to be superior to commercially available topical lidocaine preparations.

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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).

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.