



**BlueCross
BlueShield**

Federal Employee Program.

ANESTHETIC POWDERS

(Lidocaine Powder, Prilocaine Powder)

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 available in various topical, injectable, ophthalmic gel, and oral formulations (1).

Prilocaine is also an amide type anesthetic and is used for dental procedures for local anesthetic by either nerve block or infiltration techniques. Topically, prilocaine is combined with lidocaine as a cream called Emla cream and is used for local anesthetic. Additionally, prilocaine and lidocaine are combined together as a gel for dental procedures called Oraqix (2-4).

Regulatory Status

FDA-approved indications:

1. Lidocaine ointment is indicated for production of anesthesia of accessible mucous membranes of the oropharynx (5).
2. Lidocaine hydrochloride injection is indicated for production of local or regional anesthesia by infiltration techniques such as percutaneous injection and by peripheral nerve block techniques such as brachial plexus and intercostal and by central neural techniques such as lumbar and caudal epidural blocks, when the accepted procedures for these techniques as described in standard textbooks are observed (6).
3. Lidocaine HCL 2% jelly is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal) (7).
4. Lidocaine ophthalmic gel (Akten) is FDA approved as an ophthalmic gel for ocular surface anesthesia during ophthalmologic procedures (8).
5. Lidocaine and prilocaine 2.5%/2.5% cream (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).
6. Lidocaine and prilocaine 2.5%/2.5% gel (Oraqix) is indicated as a topical anesthetic for use in periodontal pockets during scaling and/or root planing procedures (3).

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Off-Label Uses:

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

For lidocaine ointment a single application should not exceed 5 grams of lidocaine ointment 5%, containing 250 mg of lidocaine base. This is roughly equivalent to squeezing a six inch length of ointment from the tube. No more than one-half tube, approximately 17 to 20 grams of ointment or 850 to 1000 mg of lidocaine base, should be administered in any one day (5).

Summary

Lidocaine and prilocaine are amide-type local anesthetics that block the initiation and conduction of impulses. Compounded lidocaine and prilocaine drug products may be considered medically necessary if the compounded product is being used for an FDA-approved indication, the formulation requested is an FDA-approved formulation; the strength requested is not available commercially; and the strength does not exceed the maximum FDA-approved strength of the product (1-8).

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

References

1. Lidocaine drug monograph. Clinical pharmacology website. Accessed on 11-24-2017. <https://www.clinicalpharmacologyip.com/Forms/drugoptions.aspx?cpnum=348&n=Lidocaine&t=0>.
2. Prilocaine drug monograph. Drug facts and comparisons website. Accessed on 5-24-18. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5549409
3. Emla Cream [package insert]. Parsippany, NJ: Actavis Pharma; December 2014.
4. Oraqix [package insert]. York, PA: Dentsply Corporate; November 2018.
5. Lidocaine ointment [package insert]. Melville, New York: Fougera Pharmaceuticals Inc; October 2011.
6. Lidocaine hydrochloride injection [package insert]. Schaumburg, IL: APP Pharmaceuticals LLC; February 2010.
7. Lidocaine hydrochloride jelly [package insert]. Lake Forest, IL: Akorn, Inc; June 2016.
8. Akten [package insert]. Lake Forest, IL: Akorn, Inc; February 2022.