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Section:	Prescription Drugs	**Effective Date:**	April 1, 2023
Subsection:	Analgesics and Anesthetics	**Original Policy Date:**	April 1, 2016
Subject:	Anesthetic Powders	**Page:**	1 of 5

Last Review Date: March 10, 2023

Anesthetic Powders

Description

Lidocaine Powder, Prilocaine Powder

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 antiesthetic. 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).

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).

Related policies
Lidocaine Injection, Lidoderm Patches, Lidocaine Topical

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 powder and prilocaine powder may be considered **medically necessary** for patients if the compounded products are being used for an FDA-approved indication supporting the use of the compounded ingredients for the diagnosis provided, the requested dosage form is for topical use; the requested dose/strength does not exceed the maximum FDA- approved dose/strength for the requested ingredients; and if the requested doses are not commercially available.

Lidocaine powder and prilocaine powder 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

Diagnoses

Patient must have the following:

FDA-approved indication supporting the use of the compounded ingredient for the diagnosis provided

AND ALL of the following:

1. The requested dosage form is for topical use
2. The requested dose/strength does **NOT** exceed the maximum FDA-approved dose/strength for the requested ingredient
3. The requested dose is **NOT** commercially available

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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

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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; August 2012.
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; September 2013.

Policy History

Date	Action
April 2016	Addition to PA
June 2016	Annual review
March 2017	Annual review
March 2018	Annual editorial review and reference update
June 2018	Change in policy name from “Lidocaine Powder” to “Anesthetic Powders” Addition of prilocaine powder to criteria
September 2018	Annual review
March 2019	Annual review
March 2020	Annual review
March 2021	Annual review
March 2022	Annual review

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March 2023	Annual review. Changed policy number to 5.70.049

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.