

## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Topical Anesthetics Drug Quantity Management Policy – Per Days

- lidocaine 2% jelly (generic only)
- lidocaine 5% ointment (generic only)
- lidocaine 2.5%/prilocaine 2.5% cream (generic only)
- Pliaglis® (lidocaine 7%/tetracaine 7% cream – Taro, generic)

**REVIEW DATE:** 12/02/2022

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### OVERVIEW

Lidocaine 2% jelly is indicated for the following uses:<sup>1</sup>

- **Prevention and control of pain** in procedures involving the male and female urethra.
- **Painful urethritis** as a topical treatment.
- **Anesthetic lubricant for endotracheal intubation** (oral and nasal).

Lidocaine 5% ointment is indicated for the following uses:<sup>2</sup>

- **Production of anesthesia of accessible mucous membranes** of the oropharynx.
- **Anesthetic lubricant for intubation.**
- **Temporary relief of pain** associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

Lidocaine 2.5%/prilocaine 2.5% cream is indicated as a topical anesthetic for use on:<sup>3</sup>

- **Local analgesia** on normal intact skin.
- **Genital mucous membranes** for superficial minor surgery and as pretreatment for infiltration anesthesia.

Lidocaine 7%/tetracaine 7% topical cream (Pliaglis, generic) is indicated to provide **topical local analgesia for superficial dermatological procedures** (e.g., dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, laser-assisted tattoo removal), in adults for use on intact skin.<sup>4</sup>

### Dosing/Availability

#### *Lidocaine 2% Jelly*

The dose of lidocaine 2% jelly varies depending on a variety of factors.<sup>1</sup> Providers should use the lowest dose needed to provide effective anesthesia. No more than 600 mg of lidocaine HCl (30 mL of lidocaine 2% jelly) should be administered in any 12 hour period for any of the listed indications. Recommended dosing of lidocaine 2% jelly is in Table 1. Lidocaine 2% jelly is supplied in 5 mL and 30 mL tubes.<sup>8</sup>

**Table 1. Lidocaine 2% Jelly Recommended Dosing.<sup>1</sup>**

Indication	Dosing
Surface Anesthesia of the Male Adult Urethra	<ul style="list-style-type: none"> <li>• Prior to cystoscopy: a total dose of 30 mL (600 mg) is usually required.</li> <li>• Prior to catheterization: volumes of 5 mL to 10 mL (100 mg to 200 mg) are usually adequate.</li> </ul>
Surface Anesthesia of the Female Adult Urethra	Instill 3 to 5 mL (60 to 100 mg of lidocaine HCl) of the jelly into the urethra.
Lubrication for Endotracheal Intubation	Apply a moderate amount of jelly to the external surface of the endotracheal tube.
Pediatric Dosing	Patients < 10 years of age: <sup>*</sup> maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark’s rule). <ul style="list-style-type: none"> <li>• The maximum amount of lidocaine administered should not exceed 4.5 mg/kg of body weight.</li> </ul>

<sup>\*</sup> For patients who have a normal lean body mass and a normal lean body development.

### *Lidocaine 5% Ointment*

For adults, a single application of lidocaine 5% ointment should not exceed 5 g (equivalent to approximately 300 mg of lidocaine HCl).<sup>2</sup> No more than one-half of a tube (approximately 17 g to 20 g of ointment) should be administered per day. In children, the dose of lidocaine 5% should be reduced; however, it is difficult to recommend a specific maximum dose. In patients < 10 years of age who have a normal lean body mass and a normal lean body development, the maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark’s rule). In any case, the maximum amount of lidocaine administered should not exceed 4.5 mg/kg of body weight. While there is no frequency of administration listed in the lidocaine 5% ointment Prescribing Information, medical literature reports typical administration of two times daily. Lidocaine 5% ointment is supplied in 35.44 g tubes and 50 g jars.

### *Lidocaine 2.5%/Prilocaine 2.5% Cream*

Recommended dosing of lidocaine 2.5%/prilocaine 2.5% cream in adults is in Table 2. Maximum dosing in pediatric patients varies based on the patient’s age and body weight.<sup>3</sup> Lidocaine 2.5%/prilocaine 2.5% cream is supplied as a 5 g tube and a 30 g tube.

**Table 2. Lidocaine 2.5% and Prilocaine 2.5% Cream Adult Dosing.<sup>3</sup>**

Indication	Dosing
Minor Dermal Procedures <sup>*a</sup>	Apply 2.5 grams over 20 to 25 cm <sup>2</sup> of the skin surface for at least 1 hour.
Major Dermal Procedures <sup>*†</sup>	Apply 2 grams of cream per 10 cm <sup>2</sup> of skin and allow to remain in contact with the skin for at least 2 hours.
Adult Male Genital Skin <sup>*β</sup>	Apply a thick layer of cream (1 g per 10 cm <sup>2</sup> ) to the skin surface for 15 minutes.
Adult Female External Genital Mucous Membranes <sup>Δ</sup>	Apply a thick layer of cream (5 to 10 g) for 5 to 10 minutes.

<sup>\*</sup> In adults with intact skin; <sup>a</sup> Minor procedures include intravenous cannulation and venipuncture; <sup>†</sup> Major procedures include split thickness skin graft harvesting; <sup>β</sup> As an adjunct prior to local anesthetic infiltration; <sup>Δ</sup> Minor procedures include the removal of condylomata cuminata.

### *Lidocaine 7%/Tetracaine 7% Cream (Pliaglis, generic)*

For superficial dermatological procedures, lidocaine 7%/tetracaine 7% (Pliaglis, generic) should be applied to intact skin between 20 and 60 minutes prior to the procedure.<sup>4</sup> The amount of product to be applied depends on the size of the area to be treated, with up to 53 grams being a sufficient quantity to treat a 62 in<sup>2</sup> treatment site. Lidocaine 7% and tetracaine 7% cream (Pliaglis, generic) is supplied in 30 g tubes.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse, and/or overuse of the topical anesthetics. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

**Automation:** None.

## Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 30 days	Home Delivery Maximum Quantity per 90 days
lidocaine 2% jelly (generic)	5 mL tube	60 mL (12 tubes)	180 mL (36 tubes)
	30 mL tube	60 mL (2 tubes)	180 mL (6 tubes)
lidocaine 5% ointment (generic)	35.44 g tube	35.44 g (1 tube)*	106.32 g (3 tubes)*
	50 g jar	50 g (1 jar)*	150 g (3 jars)*
lidocaine 2.5% and prilocaine 2.5% cream (generic)	5 g tube	30 g (6 tubes)†	90 g (18 tubes)
	30 g tube	30 g (1 tube)†	90 g (3 tubes)
Pliaglis® (lidocaine 7% and tetracaine 7% cream, generic)	30 g tube	30 g (1 tube) <sup>a</sup>	90 g (3 tubes)

\* This is enough drug to cover approximately 2% of the body surface area when applying two times daily for a 1 month supply at retail or a 3 month supply at home delivery; † This is enough drug to allow for six (retail) or 18 (home delivery) separate dermal procedures utilizing 5 g of cream each or 12 (retail) or 36 (home delivery) separate dermal procedures utilizing 2.5 g of cream each;

<sup>a</sup> This is enough drug to allow for coverage of 250 square centimeter (38.7 square inch) area.

## CRITERIA

### Lidocaine 2% jelly

1. If the patient is performing self-catheterization on a routine basis, approve the requested quantity, not to exceed 1,800 mL per 30 days at retail or 5,400 mL per 90 days at home delivery.

### Lidocaine 5% ointment

1. If the patient needs anesthesia of accessible mucous membranes of the oropharynx > 2% of body surface area, approve the requested quantity, not to exceed 150 grams per 30 days or 450 grams per 90 days.
2. If the patient needs to administer lidocaine 5% ointment more frequently than twice per day, approve the requested quantity, not to exceed 150 grams per 30 days or 450 grams per 90 days.

### Lidocaine 2.5% and prilocaine 2.5% cream

1. If the patient needs topical anesthesia for > 12 separate dermal procedures (i.e., intravenous cannulation and venipuncture) utilizing 2.5 grams of cream each, approve 30 grams for each additional 12 minor dermal procedures (i.e., intravenous cannulation and venipuncture) utilizing 2.5 grams of cream per 30 days at retail or per 90 days at home delivery.
2. If the patient needs topical anesthesia for > 6 separate dermal procedures (intravenous cannulation and venipuncture) utilizing 5 grams of cream each, approve 30 grams for each additional 6 minor dermal procedures (intravenous cannulation and venipuncture) utilizing 2.5 grams of cream per 30 days at retail or per 90 days at home delivery.

Lidocaine 7%/Tetracaine 7% cream (Pliaglis, generic)

1. If the patient needs topical anesthesia for greater than a 250 square centimeter (38.7 square inch) area, approve a one-time override of 30 grams for each additional 250 square centimeter (38.7 square inch) area needing topical anesthesia per 30 days at retail or per 90 days at home delivery.
2. If the patient needs topical anesthesia of a 250 square centimeter (38.7 square inch) area greater than once per 30 days, approve a one-time override for 30 grams for each additional dermal procedure of a 250 square centimeter (38.7 square inch) area needing topical anesthesia per 30 days at retail or per 90 days at home delivery.

**EXCLUSIONS**

Approval of additional quantities of lidocaine 2% jelly, lidocaine 5% ointment, lidocaine 2.5%/prilocaine 2.5% cream, and lidocaine 7%/tetracaine 7% topical cream (Pliaglis, generic) is not recommended in the following situations:

1. No overrides are recommended for use in any compounded formulations.
2. No overrides are recommended for cosmetic uses or indications.  
Note: Examples of cosmetic uses or indications include dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.
3. No overrides are recommended for the treatment of peripheral or post-herpetic neuralgia, post-traumatic peripheral neuropathy, or peripheral diabetic neuropathy.

**REFERENCES**

1. Lidocaine 2% jelly [prescribing information]. Lake Forest, IL: Akorn; September 2022.
2. Lidocaine 5% ointment [prescribing information]. Baton Rouge, LA: Sola; January 2021.
3. Lidocaine 2.5% and prilocaine 2.5% cream [prescribing information]. Ocean Springs, MS: Alvix; May 2019.
4. Pliaglis® cream [prescribing information]. Hawthorne, NY: Taro; December 2018.
5. Derry S, Wiffen PJ, Moore RA et al. Topical lidocaine for neuropathic pain in adults. *Cochrane Database of Syst Rev.* 2014;(7):1-41.