



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: 12/15/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Lidocaine 2% jelly is indicated for the following uses:¹

- **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:²

- **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:³

- **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.⁴

Dosing/Availability

Lidocaine 2% Jelly

The dose of lidocaine 2% jelly varies depending on a variety of factors.¹ 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.⁸

Table 1. Lidocaine 2% Jelly Recommended Dosing.¹

Indication	Dosing
Surface Anesthesia of the Male Adult Urethra	<ul style="list-style-type: none"> • Prior to cystoscopy: a total dose of 30 mL (600 mg) is usually required. • Prior to catheterization: volumes of 5 mL to 10 mL (100 mg to 200 mg) are usually adequate.
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	<p>Patients < 10 years of age:* maximum dose may be determined by the application of one of the standard pediatric drug formulas (e.g., Clark's rule).</p> <ul style="list-style-type: none"> • The maximum amount of lidocaine administered should not exceed 4.5 mg/kg of body weight.

* 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).² 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 30 g tubes, 35.44 g tubes, 50 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.³ 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.³

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

* In adults with intact skin; ^a Minor procedures include intravenous cannulation and venipuncture; [†] Major procedures include split thickness skin graft harvesting; ^β As an adjunct prior to local anesthetic infiltration; ^Δ Minor procedures include the removal of condylomata acuminata.

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.⁴ 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 in² 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.

Drug Quantity Limits

Product	Package Size	Retail Maximum Quantity per 30 days	Home Delivery Maximum Quantity per 90 days
lidocaine 2% jelly (generic) [no longer available]	5 mL tube	60 mL	180 mL
	30 mL tube		
lidocaine 5% ointment (generic)	30 gram tube	50 grams*	150 grams*
	35.44 gram tube		
	50 gram jar		

	50 gram tube		
lidocaine 2.5% and prilocaine 2.5% cream (generic)	5 gram tube	30 grams [†]	90 grams [†]
	30 gram tube		
Pliaglis [®] (lidocaine 7% and tetracaine 7% cream, generic)	30 g tube	30 g (1 tube) [°]	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; [°] This is enough drug to allow for coverage of 250 square centimeter (38.7 square inch) area.

Topical Anesthetics Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

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 at retail or 450 grams per 90 days at home delivery.

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]. Hawthorne, NY: Taro; January 2019.
3. Lidocaine 2.5% and prilocaine 2.5% cream [prescribing information]. Ocean Springs, MS: Alvix; April 2018.
4. Pliaglis® cream [prescribing information]. Hawthorne, NY: Taro; January 2021.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. No criteria changes.	12/02/2022
Annual Revision	Lidocaine 5% ointment: Added 30 gram tube and 50 gram tube to the policy. Existing quantity limits of 50 grams per 30 days at retail or 150 grams per 90 days at home delivery apply. Existing clinical overrides apply.	12/15/2023

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