Pharmacy Policy Bulletin: J-0760 Topical Lidocaine Products – Commercial and Healthcare Reform	
Number: J-0760	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1., 2., or 3.):** **1.** Rx Mgmt Performance = Deterrent/Patent Extenders **2.** Rx Mgmt Performance = Deterrent/Patent Extenders + Guideline **3.** Rx Mgmt Performance = MRXC = Yes **Quantity Limits (1., 2., 3., or 4.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **3.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRxC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0760-012	**Original Date:** 05/02/2018
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Lidocaine 5% ointment • Pliaglis (lidocaine and tetracaine) cream

FDA-Approved Indication(s):	• **Lidocaine 5% ointment**
	  ○ Production of anesthesia of accessible mucous membranes of the oropharynx. It is also useful 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.
	• **Pliaglis (lidocaine and tetracaine)**
	  ○ Use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.

Background:	• Lidocaine produces its analgesic effects by blocking both the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to sodium ions, which results in inhibition of depolarization with resultant blockade of conduction.
	• Tetracaine is an ester local anesthetic that blocks both the initiation and conduction of nerve impulses by inhibiting sodium ion influx and inhibiting depolarization of the cells.
	• Prilocaine is a local anesthetic of the amide class. The combination of lidocaine 2.5% and prilocaine 2.5% provides 2 amide local anesthetics for topical anesthesia.
	• Lidocaine is available in numerous dosage forms in varying percentages that are available both over-the-counter and as prescription products.
	• Claims for quantities of lidocaine 5% ointment that exceed 50 g per one month will reject at point of sale (if benefit allows). Patient Level Authorization will be needed for authorization for quantities exceeding lidocaine 5% ointment 50 g per month.
	• Excessive dosage or short intervals between doses can result in high plasma levels and serious adverse effects.
	• Prescribing Considerations:
	  ○ Lidocaine and Pliaglis (lidocaine and tetracaine), and lidocaine-prilocaine are contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type, ester type, or any other component in the individual product.
	  ○ Excessive dosage, or short intervals between doses, can result in high plasma levels and serious side effects. Patients should be instructed to strictly adhere to the recommended dosage and administration instructions.
	  ○ When topical anesthetics are used in the mouth, swallowing may be impaired, and patient is at risk for aspiration and unintentional biting trauma. Food should not be ingested for 60 minutes following the use of local anesthetic preparations in the mouth or throat area.
	  ○ A single topical application of the 5% ointment should not exceed 5 g of ointment (250 mg of lidocaine base); in addition, do not exceed 17-20 g of ointment (850-1,000 mg of lidocaine base) per day.

Approval Criteria

I. Approval Criteria

A. Lidocaine 5% ointment

When a benefit, coverage of lidocaine 5% ointment may be approved when one (1) of the following criteria is met **(1., 2., or 3.):**

1. The member is using the product for anesthesia (ICD-10 R20.0) of accessible mucous membranes of the oropharynx.

2. The member is using the product for an anesthetic lubricant for intubation (no ICD-10 code).

3. The member is using the product for temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites (no ICD-10 code).

B. Pliaglis (lidocaine and tetracaine) cream

When a benefit, coverage of Pliaglis (lidocaine and tetracaine) may be approved when all of the following criteria are met **(1., 2., and 3.):**

1. The member is 18 years of age or older.

2. The member is using the product on intact skin to provide topical local analgesia (no ICD-10 code) for one (1) of the following superficial dermatological procedures **(a. through d.)**:

a. Dermal filler injection

b. Pulsed dye laser therapy
c. Facial laser resurfacing
d. Laser-assisted tattoo removal

3. The member has experienced therapeutic failure or intolerance to plan-preferred, generic, lidocaine-prilocaine 2.5%-2.5% topical cream.

II. Quantity Level Limits for lidocaine 5% ointment:
When a benefit, coverage of an additional quantity of lidocaine 5% ointment may be approved when all of the following criteria are met **(A. and B.):**

A. The member has already received a prior authorization for the use of lidocaine ointment 5% within the past 30 days.
B. The prescriber attests that an additional quantity is needed for affected body surface area.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial and HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 3 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Lidocaine Ointment [package insert].Hawthorn, New York:Taro Pharmaceuticals U.S.A. Inc.; October 2018.
2. Pliaglis [package insert]. Hawthorne, NY: Taro Pharmaceuticals, Inc.; August 2020.
3. Lidocaine and Prilocaine [package insert]. Melville, NY: E. Fougera & Co., a division of Fougera Pharmaceuticals; January 2024.
4. Clinical Pharmacology On-Line, Tampa, FL: Elsevier 2022. Accessed July 8, 2022.