

PRIOR AUTHORIZATION CRITERIA

**BRAND NAME
(generic)**

**EMLA
(lidocaine 2.5% and prilocaine 2.5% cream)**

(lidocaine hcl 2% gel)

(lidocaine hcl 4% gel)

(lidocaine 5% ointment)

(lidocaine hcl 4% solution)

**PLIAGLIS
(lidocaine and tetracaine 7-7% cream)**

**SYNERA
(lidocaine and tetracaine 70-70mg patch)**

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

EMLA

EMLA cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on:

- normal intact skin for local analgesia.
- genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

EMLA cream is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies.

Lidocaine 2% gel

Lidocaine hcl 2% gel 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).

Lidocaine 4% Gel

Lidocaine hcl 4% gel is indicated for the following:

- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns

Lidocaine Post Limit Policy 1330-J 01-2017

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- Post-surgical incisions, cuts and abrasions

Lidocaine 5% Ointment

Lidocaine 5% ointment is indicated for 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.

Lidocaine 4% Solution

Lidocaine hcl 4% topical solution is indicated for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract.

Pliaglis

Pliaglis cream is a combination of lidocaine, an amide local anesthetic, and tetracaine, an ester local anesthetic, and is indicated for 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.

Synera

Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodesiccation and shave biopsy of skin lesions.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- Lidocaine 5% ointment is being prescribed for any of the following:
 - Production of anesthesia of accessible mucous membranes of the oropharynx
 - As an anesthetic lubricant for intubation
 - For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites

OR

- Lidocaine-prilocaine 2.5-2.5% cream (Emla) is being prescribed as a topical anesthetic for use on either
 - Normal intact skin for local analgesia
 - Genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia

OR

- Lidocaine hcl 2% gel is being prescribed for any of the following:
 - Prevention and control of pain in procedures involving the urethra
 - Topical treatment of painful urethritis
 - As an anesthetic lubricant for endotracheal intubation (oral and nasal)

OR

- Lidocaine hcl 4% gel is being prescribed for any of the following:
 - Stage I - IV pressure ulcers
 - Venous stasis ulcers
 - Ulcerations caused by mixed vascular etiologies
 - Diabetic skin ulcers
 - First and second degree burns
 - Post-surgical incisions, cuts and abrasions

OR

- Lidocaine hcl 4% topical solution is being prescribed for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract

OR

- Lidocaine-tetracaine 7-7% cream (Pliaglis) is being prescribed for 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

OR

- Lidocaine-tetracaine 70-70mg patch (Synera) is being prescribed for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodesiccation and shave biopsy of skin lesions

AND

The requested drug will not be used as part of a compounded product.

Quantity Limits apply.

***POST LIMIT QUANTITY**

This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

Drug	<u>Quantities to approve per 25 days*</u>
EMLA 2.5%-2.5% cream	60 gm
lidocaine -prilocaine 2.5-2.5% cream	
Lidocaine 2% gel	60 gm
Lidocaine 4% gel	60 gm
Lidocaine 5% ointment	100 gm
Lidocaine 4% solution	100 mL
Pliaglis 7-7% cream	60 gm
Lidocaine-tetracaine 7-7% cream	
Synera 70-70mg patch	4 patches
Lidocaine-tetracaine 70-70mg patch	

** The duration of 25 days is used for a 30-day fill period to allow time for refill processing.*

**** These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit.***

REFERENCES

1. EMLA [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; December 2014.
2. Lidocaine 2% gel [package insert]. Parsippany, NJ: Watson Pharma, Inc; October 2014.
3. LDO Plus (Lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
4. Lidocaine 5% ointment [package insert]. Amityville, NY: Hi-Tech Pharmacal Co., Inc.; September 2011.
5. Lidocaine 4% topical solution [package insert]. Columbus, OH: Roxane Laboratories, Inc.; August 2012.
6. Pliaglis [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; May 2014.
7. Synera [package insert]. Souderton, PA: Galen US Inc.; March 2014.
8. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. January 2017.
9. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. January 2017.
10. Drug Information (Drugs@FDA). Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed January 2017.