

## 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)**

**XYLOCAINE 4% TOPICAL SOLUTION  
(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 (lidocaine 2.5% and prilocaine 2.5% cream)**

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.

Lidocaine 2.5% and prilocaine 2.5% 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**

LDO Plus is indicated for the following:

Lidocaine, Topical, LidocainePrilocaine Post Limit

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- 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

**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.

**Xylocaine 4% Topical Solution (lidocaine 4% solution)**

4% Xylocaine (lidocaine HCl) topical solution is indicated for the production of topical anesthesia of accessible mucous membranes of 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
  - 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 (Xylocaine) 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.

**REFERENCES**

1. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Melville, NY: E. Fougera & CO.; January 2016.
2. Lidocaine 2% gel [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2016.
3. Astero [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
4. LDO Plus (Lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
5. Lidocaine 5% ointment [package insert]. Melville, NY: E. Fougera & CO.; October 2011.
6. Xylocaine 4% topical solution [package insert]. Schaumburg, IL: APP Pharmaceuticals, LLC; March 2009.
7. Pliaglis [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; May 2014.
8. Synera [package insert]. Souderton, PA: Galen US Inc.; March 2014.
9. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. September 2017.
10. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. September 2017.
11. Drug Information (Drugs@FDA). Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed September 2017.

**\*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.**

<b>Drug</b>	<b>Quantities to approve per 25 days*</b>
Emla 2.5%-2.5% cream 2.5-2.5% cream	Lidocaine-Prilocaine 60 gm
Lidocaine 2% gel	60 mL
Lidocaine 4% gel	60 mL
Lidocaine 5% ointment	100 gm
Xylocaine 4% topical solution Lidocaine 4% topical solution	100 mL
Pliaglis 7-7% cream (lidocaine-tetracaine 7-7% cream)	60 gm

Synera 70-70mg patch  
(lidocaine-tetracaine 70-70mg patch)

4 patches

*\* 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.***