

QUANTITY LIMIT 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: Quantity Limit

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 topical Lidocaine-Prilocaine Lidocaine-Tetracaine Limit Policy 1329-H 09-2017.doc

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Lidocaine 4% Gel

LDO Plus 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
- 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.

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 [available with subscription]. September 2017.
10. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. September 2017.

LIMIT CRITERIA

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	Lidocaine-Prilocaine	1 Month Limit and 3 Months Limit*
Emla 2.5%-2.5% cream 2.5-2.5% cream	Lidocaine-Prilocaine	30 gm / 25 days
Lidocaine 2% gel		30 mL / 25 days
Lidocaine 4% gel		30 mL / 25 days
Lidocaine 5% ointment		50 gm / 25 days
Xylocaine 4% topical solution		50 mL / 25 days
Lidocaine 4% topical solution		
Pliaglis 7-7% cream		30 gm / 25 days
Lidocaine-tetracaine 7-7% cream		
Synera 70-70mg patch		2 patches / 25 days
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.**