

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	LIDOCAINE, LIDOCAINE-PRILOCAINE, LIDOCAINE-TETRACAINE DERMATOLOGICAL TOPICAL
BRAND NAME (generic)	(lidocaine HCl 2% gel) (lidocaine HCl-collagen-aloe vera 2% gel) (lidocaine HCl 4% gel) (lidocaine HCl urethral/mucosal 2% gel) (lidocaine HCl urethral/mucosal 2% gel prefilled syringe) (lidocaine HCl 4% solution) (lidocaine 5% ointment) (lidocaine 2.5% and prilocaine 2.5% cream) 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

Lidocaine HCl 2% Gel

Lidocaine HCl 2% gel is intended to be used under the supervision of a healthcare professional to be used as local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

Lidocaine HCl-Collagen-Aloe Vera 2% Gel

Lidocaine-collagen-aloe vera 2% gel is indicated for the local management of painful skin wounds, including:

- Pressure ulcers
- Venous stasis ulcers
- Superficial wounds and scrapes
- 1st and 2nd degree burns

Lidocaine HCl 4% Gel

Lidocaine 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
- Post-surgical incisions, cuts and abrasions

Lidocaine HCl Urethral/Mucosal 2% Gel

Lidocaine HCl 2% jelly 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 HCl Urethral/Mucosal 2% Gel Prefilled Syringe

Lidocaine HCl jelly USP, 2% 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 HCl 4% Topical Solution

Lidocaine HCl 4% 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.

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 2.5% and Prilocaine 2.5% Cream

Lidocaine and Prilocaine cream USP, 2.5%/2.5% (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 and prilocaine 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.

Pliaglis (lidocaine and tetracaine 7-7% cream)

Pliaglis 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 (lidocaine and tetracaine 70-70mg patch)

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 product will be covered with prior authorization when the following criteria are met:

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

OR

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

OR

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

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, or laser-assisted tattoo removal

OR

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

OR

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

OR

- Lidocaine 2% gel or Lidocaine-collagen-aloe vera 2% gel is being prescribed for the local management of painful skin wounds for any of the following:
 - A) Pressure ulcers
 - B) Venous stasis ulcers
 - C) Superficial wounds or scrapes
 - D) 1st or 2nd degree burns

AND

- The patient experienced an inadequate treatment response, intolerance, or contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for their medical condition

OR

- Lidocaine 4% gel is being prescribed for any of the following:
 - A) Stage I - IV pressure ulcers
 - B) Venous stasis ulcers
 - C) Ulcerations caused by mixed vascular etiologies
 - D) Diabetic skin ulcers
 - E) First or second degree burns
 - F) Post-surgical incisions, cuts or abrasions

AND

- The patient experienced an inadequate treatment response, intolerance, or contraindication to all available FDA-approved drugs and over-the-counter (OTC) products for their medical condition

AND

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

POST LIMIT QUANTITY

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Product	<u>1 Month Limit</u> *	<u>3 Month Limit</u>*
Lidocaine HCl 2% gel	85 gm or mL / 25 days	Does Not Apply*
Lidocaine HCl-collagen-aloe vera 2% gel	85 gm or mL / 25 days	Does Not Apply*
Lidocaine HCl 4% gel	90 mL / 25 days	Does Not Apply*
Lidocaine HCl urethral/mucosal 2% gel	125 mL / 25 days	Does Not Apply*

Lidocaine HCl urethral/mucosal 2% gel prefilled syringe	125 mL / 25 days	Does Not Apply*
Lidocaine HCl 4% topical solution	100 mL / 25 days	Does Not Apply*
Lidocaine 5% ointment	100 gm / 25 days	Does Not Apply*
Lidocaine-Prilocaine 2.5-2.5% cream	60 gm / 25 days	Does Not Apply*
Pliaglis 7-7% cream Lidocaine-tetracaine 7-7% cream	60 gm / 25 days	Does Not Apply*
Synera 70-70mg patch Lidocaine-tetracaine 70-70mg patch	10 patches / 25 days	Does Not Apply*

* The duration of 25 days is used for a 30-day fill period to allow time for refill processing.
* These products are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested product to be filled one month at a time, even if at mail order; there should be no 3 month supplies filled.

REFERENCES

1. 7T Lido (lidocaine 2% gel) [package insert]. Los Angeles, CA: 7T Pharma, LLC; October 2018.
2. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
3. Lidotrex (lidocaine-collagen-alo vera 2% gel) [package insert]. Ripley, MS: Sterling-Knight Pharmaceuticals, LLC; March 2018.
4. LDO Plus (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.
5. Lidocaine urethral/mucosal 2% gel [package insert]. Lake Forest, IL: Akorn, Inc.; February 2020.
6. Lidocaine HCl 4% topical solution [package insert]. Buena, NJ: Teligent Pharma, Inc; November 2019.
7. Lidocaine 5% ointment [package insert]. Bridgewater, NJ: Alembic Pharmaceuticals, Inc.; October 2019.
8. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Parsippany, NJ: Actavis Pharma, Inc; July 2019.
9. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; April 2019.
10. Synera [package insert]. Souderton, PA: Galen US Inc.; November 2018.
11. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed September 2020.
12. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed September 2020.
13. Drug Information (Drugs@FDA). Available at: <http://www.fda.gov/Drugs/default.htm>. Accessed September 2020.
14. Resources for You (Medical Devices). Available at: <https://www.fda.gov/MedicalDevices/ResourcesforYou/default.htm>. Accessed September 2020.