

Post Limit Prior Authorization

Lidocaine, Lidocaine-Prilocaine, Lidocaine-Tetracaine

Dermatological Topical

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are included.

Brand Name	Generic Name	Dosage Form
lidocaine HCl 2% (all brands)	lidocaine HCl 2%	gel
lidocaine HCl-collagen-aloe vera 2% (all brands)	lidocaine HCl-collagen-aloe vera 2%	gel
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel
lidocaine HCl urethral/mucosal 2% (all brands)	lidocaine HCl urethral/mucosal 2%	gel prefilled syringe
lidocaine HCl 4% (all brands)	lidocaine HCl 4%	solution
lidocaine 5% (all brands)	lidocaine 5%	ointment
lidocaine 2.5% and prilocaine 2.5% (all brands)	lidocaine 2.5% and prilocaine 2.5%	cream
Plagiis	lidocaine and tetracaine 7-7%	cream
Synera	lidocaine and tetracaine 70-70 mg	patch

Indications

FDA-approved Indications

Lidocaine HCl 2% Gel

For the local management of skin wounds, including:

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

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 hydrochloride 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, 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, 2.5%/2.5% 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

Authorization may be granted for the requested product when it will NOT be used as part of a compound and ONE of the following criteria is met:

- Lidocaine-prilocaine 2.5-2.5 percent cream is being prescribed as a topical anesthetic for use on EITHER: normal intact skin for local analgesia OR genital mucous membranes for superficial minor surgery or as pretreatment for infiltration anesthesia
- Lidocaine 5 percent 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, or insect bites

- Lidocaine urethral/mucosal 2 percent 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 or nasal)
- Lidocaine-tetracaine 7-7 percent 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
- Lidocaine 4 percent 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
- Lidocaine-tetracaine 70-70 mg 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
- Lidocaine 2 percent gel OR Lidocaine-collagen-aloe vera 2 percent gel is being prescribed for the local management of painful skin wounds for ANY of the following: pressure ulcers, venous stasis ulcers, superficial wounds or scrapes, 1st or 2nd degree burns, AND the following criteria is met:
 - 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
- Lidocaine 4 percent 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 or second degree burns; post-surgical incisions, cuts or abrasions; AND the following criteria is met:
 - 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

Quantity Limits Apply

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.

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 intent is for prescriptions of the requested product to be filled one month at a time; there should be no 3 month supplies filled.

Product	1 Month Limit	3 Month Limit
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% (lidocaine-tetracaine cream)	60 gm / 25 days	Does Not Apply
Synera 70-70 mg (lidocaine-tetracaine patch)	10 patches / 25 days	Does Not Apply

Duration of Approval (DOA)

- 1330-J: DOA: 3 months

References

1. Astero (lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; May 2016.
2. Glydo (lidocaine 2% jelly urethral/mucosal prefilled syringe) [package insert]. Schaumburg, IL: Sagent Pharmaceuticals. March 2020.
3. Lidotrex (lidocaine-collagen-aloe 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.; September 2022.
6. Lidocaine HCl 4% topical solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.
7. Lidocaine 5% ointment [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; October 2023.
8. Lidocaine and prilocaine cream, 2.5%/2.5% [package insert]. Melville, NY: Fougera Pharmaceuticals Inc.; December 2018.
9. Pliaglis [package insert]. Hawthorne, NY: Taro Pharma; August 2020.
10. Proxivol (lidocaine 2% gel) [package insert]. Ripley, MS: Misemer Pharmaceutical; February 2022.
11. Synera [package insert]. Souderton, PA: Galen US Inc.; December 2020.

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13. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed September 9, 2024.
14. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 09/09/2024).
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Document History

Created: UM Development (CT) 01/2016

Revised: 01/2017; 09/2017 (operational update to denial reason); TM 09/2017, 09/2018, (removed brand Emla d/c), 02/2019 (add Lidotrex), 09/2019 (add q9, revised quantities), 10/2019 (updated urethral/mucosal, & qtys), 09/2020 (no clinical changes); PM 08/2021 (updated denial reasons); TM 08/2021 (no clinical changes), 09/2022 (no clinical changes); KMB 08/2023 (no clinical changes), 09/2024 (no clinical changes)

Reviewed: Medical Affairs WF 01/2016; AN 01/2017, AN 09/2017, AN 09/2018, AN 03/2019, CHART: 10/2019, 11/2019, CHART 09/24/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 03/2016, 04/2017, 02/2018, 02/2019, 04/2019 (FYI), 02/2020, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

Guidelines for Approval

Sets 1 – 4

Duration of Approval 3 Months

Quantity for Approval

See Post Limit Quantity Chart

Set 1 – Lidocaine-prilocaine 2.5-2.5 percent cream

Yes to question(s)	No to question(s)
1	12, 13

Set 2 – Lidocaine 5 percent ointment

Yes to question(s)	No to question(s)
2	1, 12, 13

Set 3 – Lidocaine urethral/mucosal 2 percent gel

Yes to question(s)	No to question(s)
3	1, 2, 12, 13

Set 4 – Lidocaine-tetracaine 7-7 percent cream (Pliaglis)

Yes to question(s)	No to question(s)
4	1, 2, 3, 12, 13

Sets 5 – 8

Duration of Approval 3 Months

Quantity for Approval

See Post Limit Quantity Chart

Set 5 - Lidocaine 4 percent topical solution

Yes to question(s)	No to question(s)
5	1, 2, 3, 4, 12, 13

Set 6 - Lidocaine-tetracaine 70-70mg patch (Synera)

Yes to question(s)	No to question(s)
6	1, 2, 3, 4, 5, 12, 13

Set 7 - Lidocaine 2 percent gel or Lidocaine-collagen-aloe vera 2 percent gel

Yes to question(s)	No to question(s)
7, 9	1, 2, 3, 4, 5, 6, 12, 13

Set 8 - Lidocaine 4 percent gel

Yes to question(s)	No to question(s)
8, 9	1, 2, 3, 4, 5, 6, 7, 12, 13

Sets 9 – 12

Duration of Approval 3 Months

Quantity for Approval

See Post Limit Quantity Chart

Set 9 - Lidocaine 2 percent gel or Lidocaine-collagen-aloe vera 2 percent gel

Yes to question(s)	No to question(s)
7, 10	1, 2, 3, 4, 5, 6, 9, 12, 13

Set 10 - Lidocaine 4 percent gel

Yes to question(s)	No to question(s)
8, 10	1, 2, 3, 4, 5, 6, 7, 9, 12, 13

Set 11 - Lidocaine 2 percent gel or Lidocaine-collagen-aloe vera 2 percent gel

Yes to question(s)	No to question(s)
7, 11	1, 2, 3, 4, 5, 6, 9, 10, 12, 13

Set 12 - Lidocaine 4 percent gel

Yes to question(s)	No to question(s)
8, 11	1, 2, 3, 4, 5, 6, 7, 9, 10, 12, 13

CRITERIA FOR APPROVAL

- | | | | |
|---|---|-----|----|
| 1 | Is this request for lidocaine-prilocaine 2.5-2.5 percent cream 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?
[If Yes, then go to 12. If No, then go to 2.] | Yes | No |
| 2 | Is this request for lidocaine 5 percent ointment 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? | Yes | No |

[If Yes, then go to 12. If No, then go to 3.]

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|---|--|-----|----|
| 3 | Is this request for lidocaine urethral/mucosal 2 percent gel 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)?
[If Yes, then go to 12. If No, then go to 4.] | Yes | No |
| 4 | Is this request for lidocaine-tetracaine 7-7 percent cream (Pliaglis) 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?
[If Yes, then go to 12. If No, then go to 5.] | Yes | No |
| 5 | Is this request for lidocaine 4 percent topical solution being prescribed for production of topical anesthesia of accessible mucous membranes of the oral or nasal cavities or proximal portions of the digestive tract?
[If Yes, then go to 12. If No, then go to 6.] | Yes | No |
| 6 | Is this request for lidocaine-tetracaine 70-70mg patch (Synera) 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?
[If Yes, then go to 12. If No, then go to 7.] | Yes | No |
| 7 | Is this request for lidocaine 2 percent gel OR lidocaine-collagen-aloe vera 2 percent gel 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) first or second degree burns?
[If Yes, then go to 9. If No, then go to 8.] | Yes | No |
| 8 | Is this request for lidocaine 4 percent gel 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?
[If Yes, then go to 9. If No, then no further questions.] | Yes | No |
| 9 | Has the patient experienced an inadequate treatment response to ALL available FDA-approved drugs and over-the counter (OTC) products for their medical condition?
[If Yes, then go to 12. If No, then go to 10.] | Yes | No |

10	Has the patient experienced an intolerance to ALL available FDA-approved drugs and over-the counter (OTC) products for their medical condition? [If Yes, then go to 12. If No, then go to 11.]	Yes	No
11	Does the patient have a contraindication that would prohibit a trial of ALL available FDA-approved drugs and over-the counter (OTC) products for their medical condition? [If Yes, then go to 12. If No, then no further questions.]	Yes	No
12	Will the requested product be used as part of a compound? [If Yes, then no further questions. If No, then go to 13.]	Yes	No
13	Does the patient require MORE than the plan allowance of ANY of the following per month: A) 100 gm or mL of lidocaine ointment or lidocaine solution, B) 125 mL of lidocaine urethral/mucosal gel, C) 60 gm of lidocaine-prilocaine cream or lidocaine-tetracaine cream (Pliaglis), D) 10 patches of lidocaine-tetracaine patch (Synera), E) 85 gm or mL of lidocaine HCl 2 percent gel or lidocaine-collagen-aloe vera 2 percent gel, F) 90 mL of lidocaine HCl 4 percent gel? [No further questions]	Yes	No

[RPh Note: If yes, then deny and enter a partial approval per Post Limit Quantity Chart.]

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 12	Go to 2	
2.	Go to 12	Go to 3	
3.	Go to 12	Go to 4	
4.	Go to 12	Go to 5	
5.	Go to 12	Go to 6	
6.	Go to 12	Go to 7	
7.	Go to 9	Go to 8	

8.	Go to 9	[Please select the appropriate denial close option. For the denial verbiage, only include the requested product. Remove all the other products from the verbiage.]. Deny	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to: A) 30 grams per month of lidocaine-prilocaine 2.5-2.5 percent cream, B) 60 mL per month of lidocaine HCl urethral/mucosal 2 percent gel, C) 50 grams per month of lidocaine 5 percent ointment, D) 50 mL per month of lidocaine HCl 4 percent solution, E) 30 grams per month of lidocaine-tetracaine 7-7 percent cream (Pliaglis), F) 2 patches per month of lidocaine-tetracaine 70-70mg patch (Synera), G) 30 gm or mL per month of lidocaine HCl 2 percent gel, H) 30 gm or mL per month of lidocaine-collagen-aloe vera 2 percent gel, I) 30 mL per month of lidocaine HCl 4 percent gel. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Post limit criteria not met]</p>
9.	Go to 12	Go to 10	
10.	Go to 12	Go to 11	
11.	Go to 12	[Please select the appropriate denial close option. For the denial verbiage, only include the requested product. Remove all the other products from the verbiage.].	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to: A) 30 grams per month of lidocaine-prilocaine 2.5-2.5 percent cream, B) 60 mL per month of lidocaine HCl urethral/mucosal 2 percent gel, C) 50 grams per month of lidocaine 5 percent ointment, D) 50 mL per month of lidocaine HCl 4 percent solution, E) 30 grams per month of lidocaine-tetracaine 7-7 percent cream (Pliaglis), F) 2 patches per month of lidocaine-tetracaine 70-70mg patch (Synera), G) 30 gm or mL per month of lidocaine HCl 2 percent gel, H) 30 gm or mL per month of lidocaine-collagen-aloe vera 2 percent gel, I) 30 mL per month of lidocaine HCl 4 percent gel. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can</p>

		Deny	<p>request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Post limit criteria not met]</p>
12.	[Please select the appropriate denial close option. For the denial verbiage, only include the requested product. Remove all the other products from the verbiage.]. Deny	Go to 13	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). Your plan only covers more of this drug (additional quantities) when you meet the criteria for additional quantities. Your plan covers up to: A) 30 grams per month of lidocaine-prilocaine 2.5-2.5 percent cream, B) 60 mL per month of lidocaine HCl urethral/mucosal 2 percent gel, C) 50 grams per month of lidocaine 5 percent ointment, D) 50 mL per month of lidocaine HCl 4 percent solution, E) 30 grams per month of lidocaine-tetracaine 7-7 percent cream (Pliaglis), F) 2 patches per month of lidocaine-tetracaine 70-70mg patch (Synera), G) 30 gm or mL per month of lidocaine HCl 2 percent gel, H) 30 gm or mL per month of lidocaine-collagen-aloe vera 2 percent gel, I) 30 mL per month of lidocaine HCl 4 percent gel. We reviewed the information we had. Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Post limit criteria not met]</p>
13.	[Please select the appropriate denial close option. For the denial verbiage, only include the requested product. Remove all the other products	[PA Approved for 3 months. See Post Limit Quantity Chart]. Approve, 3 Months	<p>We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers. [A) 60 grams per month of lidocaine-prilocaine 2.5-2.5 percent cream, B) 125 mL per month of lidocaine HCl urethral/mucosal 2 percent gel, C) 100 grams per month of lidocaine 5 percent ointment, D) 100 mL per month of lidocaine HCl 4 percent solution, E) 60 grams per month of lidocaine-tetracaine 7-7 percent cream (Pliaglis), F) 10 patches per month of lidocaine-tetracaine 70-70mg patch (Synera), G) 85 gm or mL per month of lidocaine HCl 2 percent gel, H) 85 gm or mL per month of lidocaine-collagen-aloe vera 2 percent gel, I) 90 mL per month of lidocaine HCl 4 percent gel.] Your request for more drug has been denied. Your doctor can send us any new or missing</p>

Reference number(s)
1330-J

	from the verbiage.]. Deny		<p>information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Quantity, Exceeds max limit, Partial denial]</p>
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