Topical Lidocaine Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date
1/1/2024

Date of Origin
10/1/2016

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
lidocaine topical jelly 2% Topical jelly*	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)	* generic available	7
lidocaine topical solution 4% Solution*	Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract	* generic available	6
lidocaine topical ointment 5% Ointment*	• Anesthesia of accessible mucous membranes of the oropharynx • Anesthetic lubricant for intubation • Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites	* generic available	3
Lidoderm® (lidocaine patch 5%) Transdermal patch*	Relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.	* generic available	1
Pliaglis® (lidocaine 7%/tetracaine 7% cream) Cream	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		9
Synera® (lidocaine 70 mg/tetracaine 70 mg patch) Topical patch	Use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication, and shave biopsy of skin lesions		5

Agent(s)	FDA Indication(s)	Notes	Ref#
ZTlido® (lidocaine topical system 1.8%) Transdermal system	Relief of pain associated with post-herpetic neuralgia (PHN)		4

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Clinical Rationale	Moderate to severe cancer pain is treated with opioids; however, opioids alone may not provide optimal analgesia. When a specific cancer pain syndrome is suspected or documented, additional interventions may be targeted to that pain syndrome. Cancer-related neuropathic pain is common and can be related to the cancer itself or the acute or chronic effects of cancer treatment. Adjuvant analgesics (e.g., antidepressants, anticonvulsants, corticosteroids, topical anesthetic agents) are particularly important in treating neuropathic pain. Topical local anesthetic agents can be useful in preventing procedural pain and in relieving some types of cancer-related neuropathic pain. They act locally and are also thought to have some central inhibitory effect on pain. They may be used in combination with an opioid, antidepressant, and/or an anticonvulsant. Both the gel and patch forms of lidocaine have been shown to reduce the pain of postherpetic neuropathy and cancer-related pain.(2) Certain treatments for cancer can cause pain in the mouth, pharynx, and esophagus. Therapeutic approaches include cryotherapy, gabapentin in combination with opioid or non-opioid analgesics, and oral care protocols such as good oral hygiene and prophylactic mouth rinses. Local anesthetics may be used to treat mucositis either as component of a mouth rinse or separately in a topical solution or topical gel formulation.(2,11) Topical lidocaine products for use as a topical anesthetic are available over-the-counter. The 95th percentile weight for adult females aged 20 and over is 119.6 kilograms (kg) (263.8 pounds (lbs)) and 130.3 kg (287.2 lbs) for adult males aged 20 and over.(10)
Safety	The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites.(1,3-7,9) When lidocaine patch is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations (additive effect) must be considered. All lidocaine topical products have a contraindication of known history of sensitivity to local anesthetics of the amide type, or to any other component of the product. Pliaglis and Synera have an additional contraindication of para-aminobenzoic acid (PABA) hypersensitivity.(1,3-7,9)

REFERENCES

Number	Reference
1	Lidoderm prescribing information. Endo Pharmaceuticals Inc. January 2020.
2	National Comprehensive Cancer Network (NCCN) Guidelines in Oncology: Adult Cancer Pain Version 2.2021.

Number	Reference
3	lidocaine 5% ointment prescribing information. Teligent Pharma, Inc. October 2018.
4	ZTlido prescribing information. Scilex Pharmaceuticals Inc. April 2021.
5	Synera prescribing information. Galen US Inc. November 2018.
6	lidocaine 4% solution prescribing information. Teligent Pharma, Inc. December 2019.
7	lidocaine 2% jelly prescribing information. Akorn, Inc. October 2020.
8	lidocaine 2.5%/prilocaine 2.5% prescribing information. Actavis Pharma, Inc. August 2020.
9	Pliaglis prescribing information. Taro Pharmaceuticals USA, Inc. January 2020.
10	Anthropometric Reference Data for Children and Adults: United States, 2011–2014. Vital Health Statistics Series 39, August 2016. US Department of Health and Human Services – Centers for Disease Control and Prevention.
11	Bensinger W, Schubert M, Ang KK, et al. National Comprehensive Cancer Network (NCCN) Task Force Report: Prevention and Management of Mucositis in Cancer Care. J Natl Compr Canc Ne 2008;6(1):S1-S21. https://doi.org/10.6004/jnccn.2008.2001.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
7t lido gel ; Proxivol ; Regenecare ha ; Xeroburn	Lidocaine HCl Gel 2%	2 %	M ; N ; O ; Y	Y		
	Lidocaine HCl Soln 4%	4 %	M ; N ; O ; Y	Y		
	Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	M ; N ; O ; Y	N		
Glydo	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	M ; N ; O ; Y	Y		
Premium lidocaine	Lidocaine Oint 5%	5 ; 5 %	M ; N ; O ; Y	Y		
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	M ; N ; O ; Y	N		
Lidocan ; Lidoderm	Lidocaine Patch 5%	5 ; 5 %	M ; N ; O ; Y	O ; Y		
	Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	M ; N ; O ; Y	Y		
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	M ; N ; O ; Y	M		
Synera	Lidocaine-Tetracaine Topical Patch 70-70 MG	70-70 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Lidocaine HCl Soln 4%	4 %	150	mLs	30	DAYS			
	Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	150	mLs	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	60	Grams	30	DAYS			
7t lido gel ; Proxivol ; Regenecare ha ; Xeroburn	Lidocaine HCl Gel 2%	2 %	150	mLs	30	DAYS			
Glydo	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	150	mLs	30	DAYS			
Lidocan ; Lidoderm	Lidocaine Patch 5%	5 ; 5 %	90	Patches	30	DAYS			
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	120	Grams	30	DAYS			
Premium lidocaine	Lidocaine Oint 5%	5 ; 5 %	100	Grams	30	DAYS			
Synera	Lidocaine-Tetracaine Topical Patch 70-70 MG	70-70 MG	4	Patches	30	DAYS			
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	90	Systems	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Lidocaine HCl Soln 4%	4 %	Medicaid
	Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	Medicaid
	Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	Medicaid
7t lido gel ; Proxivol ; Regenecare ha ; Xeroburn	Lidocaine HCl Gel 2%	2 %	Medicaid
Glydo	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	Medicaid
Lidocan ; Lidoderm	Lidocaine Patch 5%	5 ; 5 %	Medicaid
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	Medicaid
Premium lidocaine	Lidocaine Oint 5%	5 ; 5 %	Medicaid
Synera	Lidocaine-Tetracaine Topical Patch 70-70 MG	70-70 MG	Medicaid
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Lidocaine HCl Soln 4%	4 %	Medicaid
	Lidocaine HCl Urethral/Mucosal Gel 2%	2 %	Medicaid
	Lidocaine-Prilocaine Cream 2.5-2.5%	2.5-2.5 %	Medicaid
7t lido gel ; Proxivol ; Regenecare ha ; Xeroburn	Lidocaine HCl Gel 2%	2 %	Medicaid
Glydo	Lidocaine HCl Urethral/Mucosal Gel Prefilled Syringe 2%	2 %	Medicaid
Lidocan ; Lidoderm	Lidocaine Patch 5%	5 ; 5 %	Medicaid
Pliaglis	Lidocaine-Tetracaine Cream 7-7%	7-7 %	Medicaid
Premium lidocaine	Lidocaine Oint 5%	5 ; 5 %	Medicaid
Synera	Lidocaine-Tetracaine Topical Patch 70-70 MG	70-70 MG	Medicaid
Ztlido	Lidocaine Patch 1.8% (36 MG)	1.8 %	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
lidocaine topical jelly 2%	**lidocaine topical jelly 2%** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Prevention and control of pain in procedures involving the urethra **OR** B. Topical treatment of painful urethritis **OR** C. Anesthetic lubricant for endotracheal intubation (oral and nasal) **OR** D. Mucositis associated with cancer treatment **OR** E. BOTH of the following: 1. The patient has ONE of the following: A. Neuropathic pain associated with cancer pain or cancer treatment **OR** B. Another FDA approved indication for the requested agent and route of administration **OR** C. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
lidocaine topical ointment 5%	**lidocaine topical ointment 5%** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Anesthesia of accessible mucous membranes of the oropharynx **OR** B. Anesthetic lubricant for intubation **OR** C. BOTH of the following: 1. The patient has ONE of the following:

Module	Clinical Criteria for Approval
	A. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites **OR** B. Another FDA approved indication for the requested agent and route of administration **OR** C. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
lidocaine topical solution 4%	**lidocaine topical solution 4%** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract **OR** B. Mucositis associated with cancer treatment **OR** C. BOTH of the following: 1. The patient has ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)	**Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%)** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Pain associated with post-herpetic neuralgia (PHN) **OR** B. Neuropathic pain associated with cancer or cancer treatment **OR** C. Another FDA approved indication for the requested agent and route of administration **OR** D. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

Module	Clinical Criteria for Approval
	3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Pliaglis (lidocaine 7%/tetracaine cream 7%)	**Pliaglis (lidocaine 7%/tetracaine cream 7%)** will be approved when ALL of the following are met: 1. The requested agent will be used for ONE of the following indications: A. Analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal **OR** B. BOTH of the following: 1. ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Synera (lidocaine 70	**Synera (lidocaine 70 mg/tetracaine 70 mg patch)** will be approved when ALL of the following are met:

Module	Clinical Criteria for Approval
mg/tetracaine 70 mg patch)	1. The requested agent will be used for ONE of the following indications: A. Local dermal analgesia for superficial venous access **OR** B. Local dermal analgesia for superficial dermatological procedures such as excision, electrodessication, and shave biopsy of skin lesions **OR** C. BOTH of the following: 1. ONE of the following: A. Another FDA approved indication for the requested agent and route of administration **OR** B. Another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The patient has ONE of the following: A. The patient's medication history over-the-counter topical lidocaine AND ONE of the following: 1. The patient has had an inadequate response to over-the-counter topical lidocaine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL over-the-counter topical lidocaine **OR** B. The prescriber has provided information that indicates over-the-counter topical lidocaine is not clinically appropriate **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**

Module	Clinical Criteria for Approval
	C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months