Topical Lidocaine Prior Authorization with Quantity Limit Program Summary

This program applies to MN Medicaid.

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

Program specific denial language for prerequisite step therapy component does not apply. Instead, supplemental program denial language will apply.

FDA APPROVED INDICATIONS AND DOSAGE[1,3-9]

Agent	Indication	Dosage and Administration
lidocaine topical jelly 2%[a]	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)	Surface anesthesia of the male adult urethra: Slowly instill approximately 15 mL (300 mg of lidocaine hcl) into the urethra or until the patient has a feeling of tension. An additional dose of not more than 15 mL (300 mg) can be instilled for adequate anesthesia. Prior to sounding or cystoscopy, a penile clamp should be applied for 5 to 10 minutes to obtain adequate anesthesia. A total dose of 30 mL (600 mg) is usually required to fill and dilate the male urethra. Prior to catheterization, smaller volumes of 5-10 mL (100-200 mg) are usually adequate for lubrication. Surface anesthesia of the female adult uretha: Slowly instill 3–5 mL (60–100 mg of lidocaine HCl) of the jelly into the urethra Lubrication for endotracheal intubation: Apply a moderate amount of jelly to the external surface of the endotracheal tube shortly before use. No more than 600 mg of lidocaine hcl should be given in any 12 hour period

Agent	Indication	Dosage and Administration
lidocaine topical ointment 5%[a]	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	Administer 5 grams per application for up to 20 grams per day
lidocaine topical solution 4%[a]	Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract	1-5 mL (40-200mg of lidocaine hcl), i.e., 0.6 – 3.0 mg/kg or 0.3-1.5 mg/lb of body weight Maximum dose should not exceed 4.5 mg/kg (2mg/lb) of body weight
Lidoderm® (lidocaine patch 5%)	Relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin	The recommended dosage is up to three patches topically, only once for up to 12 hours within a 24-hour period. Patches may be cut into smaller sizes with scissors prior to removal of the release liner
ZTlido™ (lidocaine topical system 1.8%)	Relief of pain associated with post-herpetic neuralgia (PHN)	Apply up to three topical systems only once for up to 12 hours in a 24-hour period.

Agent	Indication	Dosage and Administration
lidocaine 2.5% and prilocaine 2.5% cream[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	Intact skin for adult patients: Thick layer of cream applied to intact skin and covered with an occlusive dressing Minor dermal procedure: Apply 2.5 grams of cream over 20 to 25 cm^2 of skin surface for at least 1 hour Major dermal procedure: Apply 2 grams of cream per 10 cm^2 of skin and allow to remain in contact with the skin for at least 2 hours Adult Male Genital Skin: Adjunct prior to local anesthetic infiltration, apply a thick layer of cream (1 g/10 cm^2) to the skin surface for 15 minutes. Local anesthetic infiltration should be performed immediately after removal of cream Adult Female Patients Genital Mucous Membranes: Apply a thick layer (5-10 grams) of cream for 5 to 10 minutes Pediatric Patients Intact Skin: application areas and application times for cream based on child's age and weight. For infants 0-3 months or <5 kg – 1 gram with 1 hour application time. For infants 3-12 months and >5kg – 2 gram with 4 hour application time. For children 1-6 years and >10kg – 10 grams with 4 hour application time. For children 7-12 years and >20kg – 20 grams with 4 hour application time

Agent	Indication	Dosage and Administration
Pliaglis® (lidocaine 7% and tetracaine 7% 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.	For superficial dermatological procedures, such as dermal filler injection, non-ablative laser facial resurfacing, or pulsed-dye laser therapy, apply Pliaglis to intact skin for 20 to 30 minutes prior to the procedure. For superficial dermatological procedures, such as laser-assisted tattoo removal, apply Pliaglis to intact skin for 60 minutes prior to the procedure. Up to 53 grams of Pliaglis may be administered depending on treatment surface size.
Synera® (lidocaine 70 mg/tetracaine 70 mg patch)	For 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.	Synera should only be applied to intact skin. Apply Synera for 20 to 30 minutes prior to venipuncture or intravenous cannulation and for 30 minutes prior to superficial dermatological procedures. Simultaneous or sequential application of multiple Synera patches is not recommended. However, application of one additional patch at a new location to facilitate venous access is acceptable after a failed attempt.

CLINICAL RATIONALE[1-2]

Guidelines, Reviews

The National Comprehensive Cancer Network (NCCN) recommends topical local anesthetic agents as adjuvant analgesic for neuropathy pain. Topical local anesthetic agents are useful in preventing procedural pain and in relieving neuropathic pain. Local anesthetic agents act locally and are also thought to have some central inhibitory effect on the pain. They may be used as an analgesic in combination with an opioid, antidepressant, and/or an anticonvulsant. Topical agents include lidocaine or diclofenac patch. Both the gel and patch forms of lidocaine have been shown to reduce the pain of postherpetic neuropathy and cancer-related pain.[6]

Topical lidocaine products for use as a topical anesthetic are available over-the-counter.

The 95th percentile weight for adults per the Center for Disease Control and Prevention is 116.5 kg (256.3 lbs).[10]

Safety[1,2]

Lidocaine transdermal patch is contraindicated in patients with known history of sensitivity to

local anesthetics of the amide type, or to any other component of the product.

Lidocaine ointment 5% is contraindicated in patients with known history of hypersensitivity to local anesthetics of the amide type or to other components of Lidocaine Ointment USP 5%.

When lidocaine patch is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered.

For additional clinical information see the Prime Therapeutics Formulary Chapters 14.5z.

REFERENCES

1. Lidoderm prescribing information. Endo Pharmaceuticals Inc. January 2015.
2. National Comprehensive Cancer Netowrk (NCCN) Guidelines: Adult Cancer Pain Version 1.2018.
3. lidocaine 5% ointment prescribing information. Solubiomix. January 2016.
4. ZTlido prescribing information. Scilex Pharmaceuticals Inc. August 2018.
5. Synera prescribing information. Galen US Incorporated. June 2016.
6. lidocaine 4% solution prescribing information. Morton Grove Pharmaceuticals, Inc. October 2014.
7. lidocaine 2% jelly prescribing information. Akorn, Inc. November 2017.
8. lidocaine 2.5%/prilocaine 2.5% prescribing information. Sterling-knight Pharmaceuticals, LLC. October 2016.
9. Pliaglis prescribing information. Galderma Laboratories, LP. May 2014.
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.

Topical Lidocaine Prior Authorization with Quantity Limit

OBJECTIVE

The intent of the Topical Lidocaine Prior Authorization (PA) criteria is to promote appropriate use for patients based on product labeling and/or clinical practice guidelines. The program will approve topical lidocaine agents for doses within the set limit. Doses above the set limit will be approved if the requested quantity is above the FDA limit and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis. Approval will not be granted to patients who have contraindication(s) to the requested agent. Requests for lidocaine patch 5% will be reviewed when patient-specific documentation is provided.

TARGET AGENTS

Lidocaine topical jelly[a]
lidocaine topical ointment 5%[a]
lidocaine topical solution 4%[a]
Lidoderm® (lidocaine patch 5%)[a]
ZTlido™ (lidocaine topical system 1.8%)
lidocaine 2.5% and prilocaine 2.5% cream[a]
Pliaglis® (lidocaine 7%/tetracaine 7% cream)
Synera® (lidocaine 70 mg/tetracaine 70 mg patch)

a – generic available

PROGRAM QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity per Day Limit
lidocaine topical jelly			
2%	90850060104005	M, N, O, or Y	30 mL
2%	90850060104006	M, N, O, or Y	30 mL
2%	9085006010E420	M, N, O, or Y	30 mL
lidocaine topical ointment			
5%	90850060004210	M, N, O, or Y	20 grams
lidocaine topical solution[a]			
4%	90850060102015	M, N, O, or Y	13.334 mL
Lidoderm® (lidocaine patch)			
5%	90850060005930	M, N, O, or Y	3 patches
ZTlido™ (lidocaine topical system)			
1.8%	90850060005910	M, N, O, or Y	3 systems
lidocaine/prilocaine cream			
2.5%/2.5%	90859902903710	M, N, O, or Y	2 grams
Pliaglis® (lidocaine/tetracaine cream)			
7%/7%	90859902843730	M, N, O, or Y	4 grams
Synera® (lidocaine/tetracaine patch)			
70 mg/70 mg	90859902845920	M, N, O, or Y	0.1334 patch

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

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:
    a. Prevention and control of pain in procedures involving the male and female urethra
    OR
    b. Topical treatment of painful urethritis
    OR

c. Anesthetic lubricant for endotracheal intubation (oral and nasal)
OR
d. BOTH of the following:
i. ONE of the following:
1. Neuropathic pain associated with cancer pain or cancer treatment
OR
2. Another FDA approved indication
OR
3. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence for the requested agent and route of administration
AND
ii. ONE of the following:
1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
OR
2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

AND

2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent
AND
3. ONE of the following:
a. The requested quantity (dose) does not exceed the program quantity limit
OR
b. ALL of the following:
i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
AND
iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
OR
c. ALL of the following:
i. The requested quantity (dose) is greater than the program quantity limit
AND
ii. The requested quantity (dose) is greater than the maximum FDA labeled dose (for the requested indication)
AND
iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

lidocaine topical ointment 5% will be approved when ALL of the following are met:

1. The patient has at least ONE of the following diagnosis:
a. Anesthesia of accessible mucous membranes of the oropharynx
OR
b. Anesthetic lubricant for intubation
OR
c. BOTH of the following:
i. ONE of the following:

1. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites
   OR
2. Another FDA approved diagnosis
   OR
3. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence) for the requested agent and route of administration

AND

ii. ONE of the following:
   1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
      OR
   2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

AND

2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent
   AND
3. ONE of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the FDA labeled dose
         AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

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:
   a. Topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract
      OR
   b. BOTH of the following:
      i. ONE of the following:
         1. Another FDA approved indication
            OR

2. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence) for the requested agent and route of administration

AND

ii. ONE of the following:
1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
OR
2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

AND

2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent

AND

3. ONE of the following:
   a. The requested quantity (dose) does not exceed the program quantity limit
   OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose (for the requested indication)
      AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Lidoderm (lidocaine patch 5%) and ZTlido (lidocaine topical system 1.8%) will be approved when ALL of the following are met:

1. The patient has at least ONE of the following diagnosis:
   a. BOTH of the following
      i. ONE of the following:
         1. Pain associated with post-herpetic neuralgia (PHN)
         OR
         2. Neuropathic pain associated with cancer or cancer treatment
         OR
         3. Another FDA approved diagnosis
         OR
         4. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence) for the requested agent and route of administration

      AND

      ii. ONE of the following:

1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
   OR
2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

AND

2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested medication
   AND

3. ONE of the following:
   a. The requested quantity (dose) is NOT greater than the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the FDA labeled dose
         AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis (must be reviewed by the Clinical Review pharmacist)

Length of Approval: 12 months

lidocaine 2.5%/prilocaine 2.5% cream will be approved when ALL of the following are met:

1. The requested agent will be used for ONE of the following:
   a. Genital mucous membranes for superficial minor surgery
      OR
   b. Pretreatment for infiltration anesthesia
      OR
   c. BOTH of the following:
      i. ONE of the following:
         1. Normal intact skin for local analgesia
            OR
         2. Another FDA approved indication
            OR
         3. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence) for the requested agent and route of administration
      AND
      ii. ONE of the following:

1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
   OR
2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

AND

2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent
   AND
3. ONE of the following:
   a. The requested quantity (dose) does not exceed the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose (for the requested indication)
         AND
   d. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

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:
   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:
      i. ONE of the following:
         1. Another FDA approved indication
            OR
         2. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence) for the requested agent and route of administration
      AND
      ii. ONE of the following:
         1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
            OR
         2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

AND

2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent
   AND
3. ONE of the following:
   a. The requested quantity (dose) does not exceed the program quantity limit
      OR
   b. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
      OR
   c. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose (for the requested indication)
         AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Synera (lidocaine 70 mg/tetracaine 70 mg patch) will be approved when ALL of the following are met:

1. The requested agent will be used for ONE of the following:
   a. Local dermal analgesia for superficial venous access
      OR
   b. Superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions
      OR
   c. BOTH of the following:
      i. ONE of the following:
         1. Another FDA approved indication
            OR
         2. Another indication that is supported in compendia (AHFS, or DrugDex 1 or 2a, NCCN 1 or 2a level of evidence) for the requested agent and route of administration
      AND
      ii. ONE of the following:
         1. The patient has tried and received inadequate response to over-the-counter topical lidocaine
            OR
         2. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used
   AND
2. The patient does NOT have any FDA labeled contraindication(s) to therapy with the requested agent
   AND

3. ONE of the following:
    a. The requested quantity (dose) does not exceed the program quantity limit
    OR
    b. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does not exceed the maximum FDA labeled dose (for the requested indication)
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    c. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose (for the requested indication)
        AND
        iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

Step Therapy Supplement Program Summary

This program applies to Medicaid.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT
OBJECTIVE
The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL
The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    a. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    c. The prescriber states that a change in therapy is expected to be ineffective or cause harm

    OR
2. BOTH of the following
    a. The patient's medication history includes the required prerequisite/preferred agent(s) or a drug in the same pharmacological class with the same mechanism of action as indicated by ONE of the following:
        i. Evidence of a paid claim(s) within the past 999 days
        OR
        ii. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days

    AND
    b. ONE of the following:
        i. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event
        OR
        ii. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s)

    OR
3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) 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

Length of Approval: As per program specific criteria