Topical Lidocaine Prior Authorization with Quantity Limit Program Summary

This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace, Medicaid, FocusRx and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

FDA APPROVED INDICATIONS AND DOSAGE[1]

Agent	Indication	Dosage and Administration
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
lidocaine ointment 5%	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

CLINICAL RATIONALE[1-2]

Guidelines, Reviews

A meta-analysis (Lancet Neurol, 2015) on treatment of neuropathic pain (included 229 trials). Findings permitted a strong recommendation for use and proposal as first-line treatment in neuropathic pain for tricyclic antidepressants, serotonin-noradrenaline reuptake inhibitors, pregabalin, and gabapentin; a weak recommendation for use and proposal as second line for lidocaine patches, capsaicin high-concentration patches, and tramadol; and a weak recommendation for use and proposal as third line for strong opioids and botulinum toxin A. Topical agents and botulinum toxin A are recommended for peripheral neuropathic pain only.[3]

A review (N Engl J Med, 2014) on PHN states topical therapy alone is reasonable to consider as first-line treatment for mild pain, and is sometimes combined with systemic drugs for moderate or severe pain. Data are lacking from RCTs comparing combination topical and systemic therapy with either therapy alone. Evidence in support lidocaine patch efficacy is limited. A meta-analysis of small placebo-controlled trials suggested an NNT for one person to obtain > 50% pain relief from lidocaine patch is 2. A subsequent double-blind, placebo-

controlled trial, in which the primary end point was the time to study discontinuation owing to insufficient pain relief, showed no significant difference between lidocaine and placebo, although a per-protocol analysis suggested some potential benefit of lidocaine.[4]

A Cochrane Review (2014; 12 studies; N=508) evaluated topical lidocaine use in patients with PHN, and other mixed, neuropathic pain conditions, (e.g., trigeminal, postsurgical, post-traumatic neuralgias). Four different formulations were used: 5% medicated patch, 5% cream, 5% gel, and 8% spray. There was no evidence from good quality RCTs to support use of topical lidocaine to treat neuropathic pain, although individual studies indicated that it was effective for relief of pain. Clinical experience also supports efficacy in some patients.[5]

Other systematic reviews of the literature have concluded that the treatments shown to be more effective than placebo for post-herpetic neuralgia include tricyclic antidepressants, gabapentin, pregabalin, opioids, topical capsaicin, and topical lidocaine. The long-term benefits of most therapies are uncertain, and side effects are common. A 2004 practice parameter from the American Academy of Neurology similarly recommends tricyclic antidepressants, gabapentin, pregabalin, opioids, and topical lidocaine patches as first-line therapies for post-herpetic neuralgia.[2]

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.

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. Dubinsky RM et al. Practice parameter: treatment of post-herpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2004;63(6):959.
3. Finnerup N, Attal N, Haroutounian S, et al. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet Neurol 2015; 162–173.
4. Johnson, R, Rice A. Postherpetic neuralgia. N Engl J Med 2014;371:1526-1533.
5. Derry S, Wiffen P, Moore R, Quinlan J. Topical lidocaine for neuropathic pain in adults. Cochrane Data Syst Rev 2014;7:CD010958. DOI: 10.1002/14651858.CD010958.pub2.
6. National Comprehensive Cancer Netowrk (NCCN) Guidelines: Adult Cancer Pain Version 2.2017. Available at: www.NCCN.org. Accessed May 2017.
7. lidocaine ointment prescribing information. Solubiomix. January 2016.

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 ointment 5%[a]
Lidoderm® (lidocaine patch 5%)[a]
a – generic available

PROGRAM QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity per Day Limit
lidocaine ointment			
5%	90850060004210	M, N, O, or Y	20 grams
Lidoderm® (lidocaine patch)			
5%	90850060005930	M, N, O, or Y	3 patches

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
lidocaine ointment 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. Temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites
    OR
    d. Another FDA approved diagnosis

    AND
2. ONE of the following:
    a. The patient has tried and failed over-the-counter topical lidocaine
    OR
    b. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

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

    AND
4. 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) 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

Lidoderm (lidocaine patch) will be approved when ALL of the following are met:

1. The patient has at least ONE of the following diagnosis:
   A. Pain associated with post-herpetic neuralgia (PHN)
   OR
   B. Neuropathic pain associated with cancer
   OR
   C. Another FDA approved diagnosis

   AND
2. ONE of the following:
   A. The patient has tried and failed over-the-counter topical lidocaine
   OR
   B. The prescriber has provided documentation that over-the-counter topical lidocaine cannot be used

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

   AND
4. 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) 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

Step Therapy Supplement

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx formularies.

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. The patient's medication history include the required prerequisite/preferred agent(s) as indicated by:
    a. Evidence of a paid claim(s) within the past 999 days
    OR
    b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event

    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