Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Topical Lidocaine Products***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***July 2008 (as adopted from UPMC Health Plan***

Last P & T Committee Approval Date: *September 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for lidocaine patch 5%, lidocaine ointment 5%, lidocaine solution 4%, and lidocaine-prilocaine cream 2.5-2.5%.

Lidocaine patch 5% is indicated for relief of pain associated with post-herpetic neuralgia.

Lidocaine ointment 5% 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 solution 4% 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-prilocaine cream 2.5-2.5% is indicated for use on normal intact skin to provide local analgesia; for use on genital mucous membranes for superficial minor surgery; and as pretreatment for infiltration anesthesia

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DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs lidocaine patch 5%, lidocaine ointment 5%, lidocaine solution 4%, and lidocaine-prilocaine cream 2.5-2.5% are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For lidocaine 5% patch requests

1. **Post-Herpetic Neuralgia**
   - Must have a documented pharmacy claim history of prior therapy with at least ONE of the following:
     - Acyclovir
     - Valacyclovir
     - Famciclovir
   - For members without a documented claim history with acyclovir, valacyclovir, or famciclovir, a medical necessity review is completed, and the following criteria must be met:
     - Must have chart documentation which shows the member has tried and failed or has an intolerance to acyclovir, valacyclovir, OR famciclovir

2. **Diabetic Peripheral Neuropathy**
   - Must have a documented pharmacy claim history of prior therapy with BOTH of the following:
     - A diabetic medication
     - Gabapentin at a dose of 1,200mg daily
   - For members without a documented claim history with a diabetic medication and gabapentin at a dose of 1,200mg daily, a medical necessity review is completed,

and the following criteria must be met:
- Must have chart documentation which shows the member has a diagnosis of diabetes, a medical/lab claim for diabetes, or has been treated with a diabetic medication AND has tried and failed gabapentin 1,200mg daily unless there is a contraindication

3. **Neuropathic Cancer Pain**
   - Must be used as an adjuvant analgesic in combination with an opioid, antidepressant, or an anticonvulsant

4. **For lidocaine ointment 5%, lidocaine solution 4%, and lidocaine-prilocaine cream 2.5-2.5% requests**
   - Must be using for a FDA approved or compendia supported indication
   - If being used as part of a compounded product, all active ingredients in the compounded product must be FDA approved for topical use

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Lidocaine 5% patch	90 patches per 30 days
Lidocaine 5% ointment	50 grams per 30 days
Lidocaine 4% solution	50 ml per 30 days
Lidocaine-prilocaine 2.5-2.5% cream	30 grams per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Lidoderm [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Inc; January 2015.
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3. Galer B, Gammaitoni A, Oleka N, et al. Use of the lidocaine patch 5% in reducing intensity of various pain qualities reported by patients with low-back pain. Curr Med Res Opin. 2004; 20 (Suppl 2) S5-12.
4. Gimbel J, Linn R, Hale M, Nicholson B. Lidocaine Patch Treatment in Patients with Low Back Pain: Results of an Open-Label Nonrandomized Pilot Study. American Journal of Therapeutics. 2005; 12: 311-319.
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6. Kivitz A, Fairfax M, Sheldon E, et al. Comparison of the Effectiveness and Tolerability of Lidocaine Patch 5% Versus Celecoxib for Osteoarthritis-Related Knee Pain: Post Hoc Analysis of a 12-week, Prospective, Randomized, Active-Controlled, Open-Label, Parallel-Group Trial in Adults. Clinical Therapeutics. 2008; 30: 2366-2377.
7. Diabetic Peripheral Neuropathic Pain – Consensus Guidelines for Treatment. The Journal of Family Practice. 2006;6 (Supplement) S1-19.
8. National Comprehensive Cancer Network. Adult Cancer Pain (Version 1.2018) – January 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf Accessed September 14, 2018
9. Lidocaine 5% Ointment [prescribing information]. Pulaski, TN: AvKare Inc; September 2015.
10. Lidocaine Hydrochloride Topical Solution 4% [prescribing information]. Eatontown, NJ: West-Ward Pharmaceuticals Corp; July 2016
11. EMLA (lidocaine and prilocaine) [prescribing information]. Parsippany, NJ: Actavis Pharma; December 2014.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy- Added lidocaine 5% ointment, lidocaine 4% solution, and lidocaine-prilocaine 2.5-2.5% cream to policy, revised criteria	*9/18*